(COVER PAGE)

NATIONAL GUIDE TO SMOKING CESSATION TREATMENT
URUGUAY
May 2009

(BACK OF COVER PAGE)

COPY AND REPRODUCTION RIGHTS.

This document is the product of an inter-institutional collaboration coordinated by the National Tobacco Control Program of the Ministry of Public Health of the Eastern Republic of Uruguay.

It may be reproduced in full or in part to be used for charitable or educational purposes, subject to prior authorization. It may not be used for commercial or marketing purposes

The Ministry of Public Health reserves rights of authorship and distribution of this material.

Limit of liability

This Guide is a generic tool designed primarily to help healthcare professionals in treatment of smoking. It is not a substitute for the criteria of professionals. The authors take no responsibility for undue use of this Guide.

For information:
National Tobacco Control Program
18 de Julio 2175 Oficina 503
598 2 4023753
controltobacco@msp.gub.uy

(BACK COVER)

LOGOS

MSP
TOBACCO CONTROL

Sponsored by:
PRONACCAN

NATIONAL GUIDE TO SMOKING CESSATION TREATMENT
URUGUAY
May 2009

This guide is accompanied by a Manual for Smoking Cessation Treatment in First Tier Care and an Algorithm with recommendations to facilitate its application in clinical practice by all members of the healthcare team.

These three publications are complementary and form a set of tools to be used in the various instances of the smoking cessation treatment process at the different levels of healthcare.

Ministry of Public Health
Minister of Public Health
Dr. Maria Julia Munoz

Under-Minister
Dr. Miguel Fernandez Galeano

Director General of Health
Dr. Jorge Basso Garrido

Director of the National Tobacco Control Program
Dr. Winston Abascal

Sponsored by:
National Cancer Control Program
PRONACCAN

AUTHORS

Guide Development Group

Dr. Ana Lorenzo Garcia
Ministry of Public Health.
Directorate General of Health
National Tobacco Control Program

Raquel Baraibar
Ministry of Public Health.
Directorate General of Health
National Tobacco Control Program

Dr. Silvia Melgar Alvarez
Administration of State Healthcare Services
Care Model Reconversion Unit
First Tier Care Network

Dr. Carolina Parodi Debat
University of the Republic
School of Medicine
Hospital de Clinicas
Smoking Cessation Program

Dr. Rosana Gambogi Irigaray
National Resource Fund
Deputy Technical Director

Ana Cenandez Martinez.
National Resource Fund
Smoking Cessation Program

Dr. Elba Esteves Di Carlo.
National Resource Fund
Smoking Cessation Program

Amanda Sica Schimansky.
Honorary Commission for the Fight Against Cancer
Technical – Professional Training Area

Statement on conflicts of interest

None of the members of the Guide Development Group have any conflict of interest to declare.

Contributors

a. Contributions from the different disciplines of First Tier Care

Dr. Ascanio, Selene (First Tier Care Network)
Barrenechea, Cristina (First Tier Care Network)
De Leon, Myriam (School of Nutrition and Dietetics)
Dr. Garcia, Triana (First Tier Care Network)
Dr. Gomez, Elisa (First Tier Care Network)
Dr. Irigoyen, Eliana (First Tier Care Network)
Dr. Melo, Alvaro (First Tier Care Network)
Moratorio, Ximena (First Tier Care Network)
Natero, Virginia (Uruguayan Cardiology Society)
Dr. Nosei, Claudia (First Tier Care Network)
Olivera, Leticia (First Tier Care Network)
Selios, Alexis (First Tier Care Network)
Termezana, Lilian (First Tier Care Network)
Dr. Vizcarra, Patricia (First Tier Care Network)
Zulawski, Maia (First Tier Care Network)

b. Methodological advice

Montevideo Clinical and Epidemiological Research Unit (Spanish acronym UNICEM).
Dr. Giselle Tomasso
Dr. Alicia Aleman
Mercedes Colomar

c. Consensus group:

Professionals involved in smoking cessation programs nationwide and contributed their opinions for use in preparing this guide.
Dr. Acosta, Daniel.
Gremial Medica de Artigas, Bella Union.
Acuna, Alicia.
National Directorate of Civil Aviation and Aeronautical Infrastructure.
Dr. Altier, Gustavo.
Municipal Intendency of Montevideo.
Dr. Albanese, Miguel.
Municipal Intendency of Montevideo.
Dr. Alvarez, Miriam.
San Jose Medical Association.
Dr. Araujo, Lilian.
Maldonado Medical Services Cooperative.
Barreto, Rosario.
Instituto Asistencial Colectivo, Treinta y Tres.
Barros, Mary.
Smoking Cessation Polyclinic, School of Medicine, Hospital de Clinicas.
Dr. Batlle, Maria del Carmen.
Uruguayan Center for Cardiovascular Research; Casa de Galicia.
Dr. Bazano, Alicia.
Municipal Intendency of Montevideo.
Dr. Benavides, Carlos*.
ASSE, Hospital Paso de los Toros, Tacuarembo.
Dr. Bertalmio, Juan.
Municipal Intendency of Montevideo.
Dr. Bianco, Eduardo*.
National Resource Fund.
Blanco, Maria Laura.

Smoking Cessation Polyclinic, School of Medicine, Hospital de Clinicas.
Blanquet, Alicia.
Municipal Intendency of Montevideo.
Dr. Bonilla, Mariela.
Municipal Intendency of Montevideo.
Bosch, Andrea
Durazno Medical Services Cooperative.
Dr. Buroni, Cristina.
ASSE, Hospital Vidal y Fuentes; Lavalleja Medical Services Cooperative.
Dr. Cabezas, Ana Maria
National Resource Fund.
Cafasso, Patricia.
ASSE, Hospital Espanol.
Dr. Camacho, Ema.
Administracion Nacional de Usinas y Transmisiones Electricas.
Dr. Camps, Xavier.
ASSE, Hospital Vidal y Fuentes; Lavalleja Medical Services Cooperative.
Cardona, Alicia.
National Directorate of Civil Aviation and Aeronautical Infrastructure.
Cardozo, Rosario.
State Sanitary Works.
Dr. Casadei, Carol.
Pando Medical Cooperative.
Casco, Maria del Lujan.
Soriano, Cardona, Medical Services Cooperative.
Castillo, Julio.
First Spanish Mutual Aid Association.
Dr. Cecere, Julio.
State Sanitary Works.
Dr. Conde, Diego.
Maldonado Medical Services Cooperative.
Dr. Contrera, Mariela.
ASSE, Hospital Espanol.
Dr. Cordoba, Mario*.
Departmental Intendency of Paysandu; Paysandu Medical Corporation.
Correa, Fernando.
Legislative Palace.
Cosenza, Gonzalo.
Ministry of Economy and Finance
Dr. Chijani, Vilma.
National Directorate of Civil Aviation and Aeronautical Infrastructure.
Dr. Chimiel, Gabriel.
Rocha Medical Cooperative
Crespo, Claudia.
Municipal Intendency of Montevideo.
Dr. Davyt, Osvaldo.
Medical Services Cooperative of Western Colonia.
Dr. Debones, Anabel.
State Sanitary Works
Dr. de Leon, Cirio.
Uruguay Medical Union Medical Services Center.
Destouet, Graciela.
Legislative Palace.
Dr. Deus, Ana L.
Municipal Intendency of Montevideo.
Dr. Diaz, Yisella.
Rocha Medical Cooperative.
Diaz, Alvaro.
Municipal Intendency of Montevideo.
Dr. Diaz, Miriam.
Salto Medical and Surgical Society.
Dominguez, Cristina.
Municipal Intendency of Montevideo, Occupational Health Service.

Dr. Dominguez, Maria Teresa.
Ministry of Economy and Finance
Dr. Dominguez, Gerardo.
Administracion Nacional de Usinas y Transmisiones Electricas.
Dotti, Gabriela.
Dr. Espinosa, Maria.
Canelones Medical Cooperative.
Dr. Eugui, Eva.
Banco de la Republica Oriental del Uruguay.
Failache, Virginia.
Regional Integral Medical Services Cooperative, Las Piedras.
Dr. Fernandez, Ariel.
ASSE, Hospital Colonia de Sacramento, Colonia.
Dr. Fernandez, Cecilia.
Maldonado Medical Services Cooperative.
Fernandez, Silvia.
Administracion Nacional de Usinas y Transmisiones Electricas.
Dr. Filippini, Isaura.
Durazno Medical Services Cooperative.
Dr. Frascheri, Marta.
Lavalleja Medical Services Cooperative.
Dr. Galain, Gustavo.
Municipal Intendency of Montevideo.
Dr. Goja, Beatriz.
Smoking Cessation Polyclinic, School of Medicine, Hospital del Clinicas
Dr. Gonzalez, Alexis.
RAP, Chuy Auxiliary Center
Dr. Gonzalez, Marcela.
Gonzalez, Monica.
Canelones Medical Cooperative.
Dr. Guerrero, Maria Ines*.
Rocha Medical Cooperative.
Gularte, Rosario.
Municipal Intendency of Montevideo.
Dr. Juarez, Maria del Rosario.
PROCARDIAS Association
Lanciano, Graciela.
Municipal Intendency of Montevideo.
Latorre, Estela.
Paso de los Toros Medical Cooperative.
Dr. Lecot, Carlos.
Administracion Nacional de Usinas y Transmisiones Electricas.
Dr. Leites, Maria Angelica.
Hospital de Melo; Cerro Largo Medical Cooperative.
Dr. Licos, Ariel.
Colonia Cooperative Medical Services Organization.
Dr. Lizuain, Maria del Carmen.
ASSE, Rio Negro.
Dr. Longo, Miguelina.
Lopez, Amelia.
Municipal Intendency of Montevideo.
Dr. Lopez, Rodolfo.
Maldonado Medical Services Cooperative.
Luchini, Daniela.
Gremial Medica de Artigas, Bella Union.
Dr. Llambi, Maria Laura.
Smoking Cessation Polyclinic, School of Medicine, Hospital de Clinicas.
Dr. Machado, Lilian.
Claveaux Polyclinic, RAP; PROCARDIAS Association.
Dr. Martinez, Liria.
ASSE, Hospital de Salto; CA Bella Union; Hospital de Florida; Florida Medical Cooperative.
Dr. Martinez, Graciela.

Gremial Medica de Artigas, Bella Union.
Dr. Martinez, Mariana.
Municipal Intendency of Canelones.
Mendez, Nancy.
First Spanish Mutual Aid Association.
Dr. Mendez, Roberto.
Rocha Medical Cooperative.
Dr. Menendez, Adriana*.
ASSE, Hospital Saint Bois.
Dr. Mercadal, Laura.
Pando Medical Cooperative.
Dr. Mesa, Estela.
San Jose Medical Association.
Montelongo, Paula.
RAP, La Cruz de Carrasco Center, Yanicelli Sub-Center.
Dr. Montenegro, Hugo.
Regional Integral Medical Services Cooperative, Las Piedras.
Dr. Mourelle, Sandra*.
Medical Services Cooperative of Western Colonia.
Dr. Navarro, Veronica.
Durazno Medical Services Cooperative.
Dr. Oliveira, Walter*.
ASSE; San Jose Medical Association.
Dr. Pagliotti, Maria Laura.
Departmental Center; Instituto Asistencial Colectivo, Treinta y Tres.
Palacio, Tania.
National Resource Fund; PROCARDIAS Association
Dr. Palacios, Rosa.
Administracion Nacional de Usinas y Transmisiones Electricas.
Dr. Palomino, Miriam.
Uruguay Pneumology Society; School of Medicine CLAEH; Sanatorio SEMM-Mautone, Maldonado
Pallares, Cecilia.
Primary Care Network, La Cruz de Carrasco Center, Montevideo.
Dr. Pamparato, Marcos.
Salto Medical and Surgical Society.
Dr. Parajo, Monica.
Primary Care Network, La Cruz de Carrasco Center, Yanicelli Sub-Center, Montevideo.
Dr. Pelufo, Alicia.
Municipal Intendency of Montevideo.
Dr. Pineyro, Nancy.
San Jose Medical Association
Prego, Rosana.
Municipal Intendency of Canelones.
Dr. Quintan, Ana.
Salto Medical and surgical Society.
Dr. Quartino, Laura.
La Cruz de Carrasco Center, Yanicelli Sub-Center.
Rainieri, Silvana.
Municipal Intendency of Montevideo.
Dr. Ramos, Walter.
Municipal Intendency of Montevideo.
Rebollo, Beatriz.
San Jose Medical Association.
Reyes, Teresita.
ASSE, San Jose.
Rivas, Graciela.
Municipal Intendency of Montevideo.
Dr. Roballo, Laura*.
Central Hospital of the Armed Forces.
Dr. Rodriguez, Adriana*.
Medical Institute for Prevision, Assistance, and Related Services (IMPASA).
Rossi, Cristina.
Primary Care Network, La Cruz de Carrasco Center.

Ruella, Monica.
ASSE, Hospital Colonia de Sacramento, Colonia
Saavedra, Lorena.
ASSE, San Jose
Dr. Salari, Silvia.
ASSE, Colonia Etchepare. San Jose.
Dr. Sangenis, Albar.
Legislative Palace.
Dr. Seres, Silvana.
Maldonado Medical Services Cooperative.
Dr. Sica, Rosario.
Honorary Commission for the Fight Against Cancer Smoking Cessation Service.
Dr. Stankevicius, Antonio.
Municipal Intendency of Montevideo, Occupational Health Service.
Techera, Marisol.
Caja de Auxilio de Socios y Empleados de COETC, Montevideo.
Trinidad, Analia.
Gremial Medica de Artigas, Bella Union.
Dr. Torres, John.
Tacuarembo Medical Cooperative, Paso de los Toros.
Dr. Valentini, Gustavo*.
First Spanish Mutual Aid Association.
Yacosa, Sonia.
Pando Medical Services Center.
Dr. Zeballos, Cristina.
Integral Medical Service.
Dr. Zicari, Lourdes.
Legislative Palace

*Members of the combined pharmacological treatment work group.

d. Consultation on applicability

The following scientific societies lent their support to the National Guide and offered opinions regarding its applicability in their respective fields of specialization.

Uruguayan Society for Internal Medicine
Uruguayan Pneumology Society
Uruguayan Society for Toxicology and Ecotoxicology
Uruguayan Cardiology Society

e. Acknowledgements.

We wish to acknowledge the advice of the following professionals:

Lourdes Galvan and Dr. Cristina Alonso.
Department of Medications Healthcare Products Division. Ministry of Public Health.

Dr. Gustavo Tamosiunas
Professor of Pharmacology. School of Medicine. University of the Republic.

INTRODUCTION

This publication has as its purpose to provide support and reference material for all healthcare personnel, fundamentally in first tier care. It responds to the commitment established in Law Nº 18256, Integral Law on Tobacco Control, Art. 10, which stipulates: "public and private healthcare services will incorporate diagnosis and treatment of tobacco dependence in their national programs, plans, and strategies for primary healthcare ".

Also, the Decree regulating the referenced law, Art. 13, stipulates that:
"healthcare professionals must apply the recommendations established in the **National Guide to Smoking Cessation Treatment** published by the Ministry of Public Health".

Also, this Guide incorporates the measures proposed in Art. 14 of the World Health Organization Framework Convention on Tobacco Control.

This material is the product of the efforts of a group of authors who, week after week, over a long period of time, met to review the scientific evidence available worldwide and discuss comprehensive lines of action based on best practices.

All members of the healthcare teams working on smoking cessation nationwide participated in this process, in order to build a national consensus.

This Guide is integrated with national health plans and strategies in that it seeks to facilitate accessibility to treatments for tobacco dependence, which will be implemented as part of the benefits of the Integrated National Healthcare System for First Tier Care.

Consequently, the National Tobacco Control Program has the satisfaction of presenting this publication which unquestionably represents a fundamental contribution to control the smoking epidemic, while providing tools that will help many of our compatriots overcome this addiction and make the most important decision they can for their health, and quit smoking.

Dr. Winston Abascal
National Tobacco Control Program – MSP

NATIONAL GUIDE TO SMOKING CESSATION TREATMENT
URUGUAY - 2009

Contents

1 Summary

The National Guide to Smoking Cessation Treatment (Uruguay 2009) provides up to date support for the entire healthcare team in the context of the strategy for Primary Health Care (PHC). It focuses, accordingly, on health promotion, prevention, treatment, and rehabilitation.

These guidelines recommend interventions that have proven to be effective in the general population and in special groups, based on a complete national and international bibliographical review of the best available evidence, considering treatments and practices available in Uruguay. The special groups considered are: pregnant and lactating women, children and adolescents, hospitalized patients, and patients en preoperative care, users of mental health services, patients with other addictions, and patients who have relapsed.

This Guide was developed by a group of specialists, and technical specialists on all the groups involved in addressing the issue were consulted.

The recommendations include several important messages:

- **Healthcare teams should implement actions for promotion and prevention of smoking.**
- **All smokers should receive a short advisory message, regardless of their desire to stop smoking.**
- **All smokers who want to stop smoking should receive the necessary support.**
- **Only treatments with proven efficacy should recommended to persons who intend to stop smoking.**

These recommendations are structured with a new nemotechnical method proposed in the 2007 New Zealand Guide, **ABC of Smoking Cessation**, which replaces the "5 As of intervention". This choice was based on its greater simplicity and ease of use for the entire healthcare team.

ABC prompts healthcare workers to:
Ask about smoking status or risk of starting.
Give **B**rief advice to stop smoking.
Give the necessary **Cessation support** for those who wish to stop smoking.

Implicit within this guideline is an assumption that health care workers have the prerequisite knowledge, attitudes and skills to support smokers in the process of cessation from their field of expertise.

2 Fundamentals

Smoking is a chronic addictive disease that evolves with relapses. Nicotine is the substance responsible for the addiction, acting at the level of the central nervous system.

Nicotine is one of the most addictive drugs known, exceeding the addictiveness of cocaine and heroin. For this reason it is important to know that although 70% of smokers want to stop smoking, only 3% of them succeed without help each year.

Smoking is an addiction because it meets the following criteria:

- Compulsive, repetitive behavior
- Continued consumption despite recognizing the damage it causes
- Tolerance: need for progressively greater intake to achieve the same effect.
- Withdrawal syndrome: appearance of symptoms that cause discomfort when intake is reduced or ceases.
- Alteration of aspects of everyday and social life due to the effects of consumption.

As in all addictions biological, psychological, and social factors (genetic predisposition, vulnerable personality, identifying models, peer pressure, etc.) are present.

According the World Health Organization, smoking represented the greatest pandemic of the 20th century, and will remain so in the 21st century if current patterns of tobacco consumption are not modified. At present, an estimated 1.2 billion persons, or 1/3 of the world's population, smoke. In Uruguay, the prevalence of smoking is approximately 32%, based on data from 2006 (1,2). Among doctors the prevalence of smoking is 27% (3), which sends a contradictory message to the population, with the resulting difficulty in offering help for smokers. It is fundamental to recognize the social responsibility and the role model that healthcare personnel represent in the community. A more recent SMU telephone survey of a representative sample of active Uruguayan medical professionals found that 17% of subjects answered affirmatively to the question *"Do you smoke?"*(4); an encouraging figure that will have to be corroborated in new studies.

Tobacco is the only product legal for sale that kills half of its regular consumers when used as recommended by its manufacturer (5). It represents the leading cause of avoidable illness and death (6) worldwide. Of the total deaths in Uruguay (32000 persons / year) around 5,000 are imputable to smoking, and 10 to 15% of them are caused by exposure to second-hand smoke (7).
At the global level this epidemic has spread to developing countries, where it continues to spread, principally affecting women and young people. The WHO predicts that, in the 2020s 80% (6) of deaths from smoking will occur in these countries.

Smoking is more common in persons with lower educational levels and in those living below the poverty line. Most regular smokers start before age 18. Young people are the most vulnerable members of the population and tobacco consumption often represents a gateway to other drugs.

Smoking not only has a high sanitary cost, but also at the economic, social, and environmental levels.

From an economic standpoint, the estimated direct sanitary costs of smokers in Uruguay amount to approximately 150 million dollars a year. This figure could increase by up to 70% due to loss of productivity due to premature death, loss of work days, and other costs, doubling revenues from taxes applied to tobacco products (8).

At the family level, a large part of household income that could be used to purchase food, medicines, or clothing is diverted to buying tobacco. Thus, tobacco consumption contributes to the impoverishment of both families and entire countries.

From a social standpoint, smoking lowers workers' productivity, because smokers get sick more than non-smokers. Half the deaths caused by tobacco consumption occur prematurely between the ages of 35 and 69 years (9). Smoking is also a risk factor in occupational and traffic accidents. This in turn produced an overload on social security systems due to the increase in illnesses responsible for occupational disability or incapacity.

The only effective way to halt this epidemic is by implementing the measures established in the WHO Framework Convention on Tobacco Control[1], among which include health promotion, prevention of starting smoking, and treatment of current smokers are fundamental components.

In Uruguay, tobacco control has changed quali- and quantitatively since March 1, 2006, when a ban on smoking in enclosed public places took effect, accompanied by a firm political commitment to the issue culminating in the approval of Law 18.256 of March 6, 2008 (10).

[1] The Framework Convention on Tobacco Control (FCTC) is the first global public health treaty sponsored by the WHO, signed and ratified by 161 countries when this document went to press (January 2009).
Ratified by Uruguay in September 2004.
http://www.fctc.org/index.php?option=com_content&view=article&id=14&Itemid=11

As regards treatment of the smoking population in Uruguay, there has been a progressive rise in the number of trained professionals and cessation programs, mainly in the last 5 years. However, the intervention of the healthcare team in all smokers who have contact with the healthcare system is far from systematic and universal.

A national guide designed for the entire healthcare team, easy to apply and tailored to the local situation, will be a useful tool to **help all healthcare team members conduct effective intervention in the entire smoking population.**

3 Objectives of this Guide

3.1 General

- Lower the prevalence of smoking and its consequences in the Uruguayan population.

3.2 Specific

- Prevent the start of tobacco consumption.
- Promote cessation among smokers.
- Establish criteria for consensus on smoking cessation treatment, based on the best available evidence.
- Offer simple tools for all members of the healthcare team so that they can intervene effectively in the entire population.
- Promote the creation and maintenance of smoke-free environments, emphasizing their importance in the home.
- Avoid exposing the population to second-hand tobacco smoke.

4 Target audience

This guide is intended for all healthcare team members operating at all levels of care.

All healthcare professionals should be sensitized and committed to the issue, even if they are not members of the healthcare team from a technical- academic standpoint.

5 Development methodology

I – Search and critical analysis of guides based on evidence.
II – Updating of evidence
III – Development of the Uruguayan Guide
IV - Dissemination
V – Assessment of application
VI – Update plan.

I – Search and critical analysis of guides based on evidence.

Among the guides published in the region and in the world, the guide published in New Zealand (11) was chosen because it offers new ideas for smoking cessation treatment, has a friendlier format, and uses updated evidence through the year 2007. Some particular points were taken from the Argentine (12) and United States (13) guides published during the process of developing this guide. The authors were contacted to request the corresponding authorizations.

A critical analysis of the guides considered was conducted by two independent reviewers, using AGREE (Appraisal of Guidelines Research & Evaluation). The conclusion reached was that they are based on the evidence and are of sound methodological quality (14)

II – Update of the evidence

The New Zealand Guide was chosen as the basis for the work, with evidence updated through 2007

a –Bibliographic search

A bibliographic search was conducted in the computer databases most commonly uses for medical literature: Medline, Cochrane Library, Lilacs.

The last search was conducted in May 2008. Broad and inclusive criteria were used.

The key words used for the text search were:
(Smoking OR tobacco) AND cessation

Limits used were:

Methodological filters	Controlled trials
	Reviews
	Meta-analysis
Date of publication filters	2007-2008

It was evaluated whether the Randomized Clinical Investigations (RCIs) found were included or excluded in the systematic reviews of the New Zealand Guide (NZ) or the reviews found. In cases in which they had not been considered in any review, they were subject to critical analysis.

b - Critical analysis of studies

Each of the studies was analyzed to determine its methodological quality, using the McMaster University guides to Analysis of Systematic Reviews and ICAS (15,16)

c - *Classification of the new literature by intervention*.

The studies included were classified based on the interventions addressed and were evaluated by the team members most appropriate for each one.

In all cases in which new studies were included, the coincidence or lack thereof of the direction of the effect of the intervention studied with the prior recommendation was evaluated. If the direction coincided, the recommendation was maintained. If the direction did not coincide, it was proposed to conduct a meta-analysis with all the studies included (the situation never arose). In cases in which the new study did not refer to any of the recommendations made by the NZ Guide, a recommendation was made based on this existing evidence.

d -Classification of evidence and recommendations (17)

Level	Type of de evidence
Ia	Evidence obtained from meta-analysis of controlled and randomized clinical trials
Ib	Evidence obtained from at least one controlled and randomized clinical trial
Iia	Evidence obtained from at least one well designed, non-randomized controlled trial
Iib	Evidence obtained from at least one well designed, quasi-experimental trial
III	Evidence obtained from well designed non-experimental descriptive trials (observational studies) such as comparative studies (cohorts, cases, and controls), of correlation (ecological) or series of cases
IV	Evidence obtained from opinions in reports by experts, or opinions from clinical experiments by recognized authorities.

Degree	Recommendation
A Ia and Ib evidence	Requires at least one randomized controlled clinical trial as part of the body of evidence needed to satisfy the specific requisites of good quality and be consistent with the recommendation.
B IIa, Iib, and III evidence	Requires availability of well designed, but non-randomized clinical trials (quasi-experimental or observational)
C IV evidence	Requires evidence obtained from reports by committees of experts and opinions / clinical experience of recognized authorities. Indicates absence of good quality clinical trials on the subject.
RTG Recommendation of this guide	Recommendations based on clinical experience of the guide development group. Represents local contributions.

III – Development of the Uruguayan Guide

a - Preliminary version

A first draft was prepared based on the New Zealand Guide, with contributions from updates to the evidence.

After being analyzed independently by each member of the guide development group, it was reassessed jointly, reaching a consensus on the text of the **preliminary version.**

b - Consensus version

In June 2008, the preliminary version was distributed to all the groups working on smoking cessation nationwide, with a template to record their opinions on each recommendation proposed in the guide.

After analyzing and summarizing the contributions received, each recommendation was discussed to arrive at a consensus version, in 2 meetings held on June 26 and July 31, 2008. Approximately 80 professionals, mostly representing multidisciplinary groups working on smoking cessation, from all parts of the country, took part in these meetings. All the recommendations were approved by consensus of the attendees.

In the first meeting it was necessary to form a work group to dilucidate a debate on combined pharmacological treatment. This group was made up by representatives of the different opinions. They conducted a review of the evidence and reached an agreement, which was passed on to the second general consensus meeting.

Finally, the consensus version was distributed for final approval.

The National Guide is accompanied by a Manual to apply in First Tier Care and an Algorithm accompanied by practical tools to be distributed in all consulting rooms in public and private healthcare services nationwide.

c - - Evaluation of reviewers.

The consensus version of the guide was subject to an evaluation of applicability nationwide, by the various scientific societies and medical specialists' associations involved in smoking and its consequences.

After collecting the opinions of the different national groups consulted, the guide was sent for evaluation to the international reviewers in Argentina and New Zealand, whose contributions were considered for use in the final document:

Prof Gustavo E Zabert
Professor of Medicine and Surgery, School of Medicine, UNComahue
Former President of the Argentine Association for Respiratory Medicine
Neuquen, Argentina.

Dr Hayden McRobbie MB ChB PhD
Senior Clinical Research Fellow, Queen Mary University of London, Barts & The London School of Medicine and Dentistry
Senior Lecturer, Auckland University of Technology, School of Public Health and Psychosocial Studies
Auckland. New Zealand

IV - Dissemination

The effective dissemination of these materials is essential to ensure the application of the recommendations.

Program for dissemination activities:

a – Informative meeting with Departmental Healthcare Directors.

b – Dissemination plan

- Each Department Manager will select a person responsible trained in smoking for training in application and dissemination of the guide.

- This person responsible will in turn train **representatives** from each public or private healthcare service in the department.

- These representatives will replicate the work methodology for their services healthcare teams.

- The process will be documented in a systematized form.

- The National Guide, the Manual for FTC, and the Algorithm for consulting rooms in all public and private healthcare services nationwide.

V - Evaluation of application

The impact of the guide's application will be evaluated by means of a survey in the smoking population following its implementation. The following indicators were defined:

- number of smokers questioned about their status as smokers x 100 / total smokers surveyed

- number of smokers who received brief advice to stop smoking x100 / number of smokers questioned about their status as smokers.

- number of smokers who received specific orientation to stop smoking x 100 / number of smokers who received brief advice to stop smoking.

VI – Updating plan.

The evidence will be updated every 2 years and whenever necessary. Publication of new versions or updates will be ordered at the discretion of the Ministry of Public Health.

6 General recommendations

First, we present operative definitions and a simplified scheme of the general recommendations presented in this guide:
ABC of smoking cessation.

Then, we examine in depth all the points discussed above.

Operative definitions

Smoker
A person who has smoked at least one cigarette in the last 6 months.
In this group, we can differentiate:

Daily Smoker

A person who has smoked at least one cigarette a day, over the last 6 months.

Occasional Smoker

A person who has smoked less than one cigarette a day; such persons should also considered smokers.

Passive Smoker
A person who does not smoke, but who involuntarily breathes second-hand tobacco smoke or environmental tobacco smoke.

Ex Smoker
A person who, having been a smoker, has maintained abstinence for at least the last 6 months.

Non-Smoker
A person who has never smoked or has smoked less than 100 cigarettes in their life.

ABC for smoking cessation

ASK

1. Ask about and document smoking status for all people. For those who have recently stopped smoking, smoking status should be checked and updated on a regular basis in their clinical history.

BRIEF ADVICE

1. Advise people to stop smoking. For example, you could say: *'Stopping is the best thing that you can do to improve your health. I understand that it can be hard to stop smoking, but if you want to, I can help you.' : 'You may know the risks involved with smoking, but do you realize how harmful it is?'*

2. Personalize the advice. For example, explain how smoking is related to existing health problems and how stopping smoking might help. Highlight the most important benefits of quitting smoking (see Appendix 1).

3. Document that advice was given.
4. Repeat the advice as many times as necessary, bearing in mind that some people make several attempts to quit before stopping for good.

CESSATION SUPPORT

There are two options for providing cessation support.

1. **Provide support:** All health care workers should provide support. Support can include advising the smoker about the advantages of complete abstinence; providing practical strategies to effect behavioral change (see Chapter 6), arranging medication to aid the quit attempt, and arranging for a follow-up consultation in the short term.

2. **Refer:** After consultation, health care workers **without the expertise** or time to help people to stop smoking should refer smokers to specialized smoking cessation services. It is advisable to give the patient a list with information on available smoking cessation services (see Appendix 2)

A – Ask

All people attending any health care service should be asked if they smoke tobacco. Their response should be recorded in their clinical records. The records of anyone who smokes, or has recently quit, should be updated regularly (at least once a year).

Simple systems – such as computer prompts, stickers in the client chart, or including smoking status as a vital sign in the patient's medical record – can remind healthcare workers to ask and document smoking status. (11).

Recommendations

A - Ask about and document smoking status for all patients. This information should be updated on a regular basis.

Recommendation Grading Key

A: The recommendation is supported by GOOD (strong) evidence.
B: The recommendation is supported by FAIR (reasonable) evidence, but there may be minimal inconsistency or uncertainty.
C: The recommendation is supported by EXPERT opinion (published) only.
RTG: Recommendations based on clinical experience of the guide development group.

B – Brief Advice

Brief advice simply means advising people who smoke to stop. It can be done in as short a time as 3 minutes. (18)

Advice should be provided to ***all*** smokers irrespective of whether they want to stop smoking or not.

It is recommended to tailor the advice to the patient's situation. Advice can be strengthened if it can be linked to a smoker's existing medical condition or to the importance of protecting people living with the smoker from exposure to second-hand smoke.

Brief advice appears to work by triggering a quit attempt (19). It also seems to have its greatest effect on less dependent smokers (20).

Evidence

There is evidence from Randomized Clinical Trials (RCTs) that brief advice to stop smoking from a doctor improves abstinence rates measured at 6 months after stopping (20).

Although the evidence is limited, brief advice from nurses, dentists, dental hygienists, pharmacists and all health care workers is likely to have some benefit (21).

There is no evidence that adding self-help written materials to brief advice gives any additional benefit (20), but providing written materials to support the advice that is given may reinforce the importance of quitting and provide information about cessation support.

Recommendations

A - All doctors should provide brief advice to quit smoking at every available opportunity to all patients who smoke.

B - All other health care workers should also provide brief advice to quit smoking at every available opportunity to all patients who smoke.

B - Health care workers should seek appropriate training to enable them to provide brief advice. This training should include providing the health care worker with information on available evidence-based smoking cessation treatments.

C - Record the provision of brief advice in patient records.

Recommendation Grading Key
A: The recommendation is supported by GOOD (strong) evidence.

B: The recommendation is supported by FAIR (reasonable) evidence, but there may be minimal inconsistency or uncertainty.
C: The recommendation is supported by EXPERT opinion (published) only.
RTG: Recommendations based on clinical experience of the guide development group.

C – Cessation Support

Cessation support includes a wide range of intervention levels, from minimal intervention lasting a few minutes in the doctor's office to specialized intervention in a smoking cessation service.

- Minimal intervention consists of generating or increasing the smoker's motivation to quit and offering the patient behavioral management tools (see Chapter 6), with follow up at subsequent doctor visits.
- When the healthcare professional has the necessary skills and time, a more extensive or comprehensive intervention should be implemented, which includes cognitive-behavioral treatment and pharmacological treatment, in patients for whom it is indicated.
- ♦♒♏■ ♦♒♏ patient has severe difficulty quitting or belongs to one of the special groups (see Chapter 8), the doctor should refer the patient to a specialized smoking cessation service.

The components of smoking cessation treatment that have proven to be effective are: **multiple support sessions and pharmacological treatment**.

The effectiveness of treatment depends on the professional's smoking cessation knowledge, skills, and available time.

If the aforementioned interventions cannot be implemented, patients who want to quit should be referred to specialized services. The best referral is that which is accompanied by a brief description of the help the patient is to receive.

Below, we discuss the various forms of support that have proven to be effective to stop smoking long term.

- **Face-to-Face Support**
- **Telephone Support**
- **Pharmacological Treatment**

Face-to-face support

Face-to-face cessation support, either on an individual basis or in a group situation, is fundamental to smoking cessation treatment. It is when alternative approaches to quitting are discussed; on an individual basis or in a group situation, they are proposed in a personalized manner.

While a minimum of 4 sessions is considered sufficient as an initial approach to cessation support, we also know that the outcome of a treatment is directly related to the number of interviews and the variety of approaches taken (multi-component approach: psychological support + written material + physical exercise + relaxation or stress management exercises + pharmacological treatment, etc.)

Aspects that have proven to be effective in treatment are related to:

1. analysis of the patient's ideas and beliefs related to health and smoking as part of treatment; e.g. the patient's beliefs about smoking and health: "smoking calms my nerves"; or the meaning healthy living has for the patient.

2. development of skills to cope with problematic situations; anticipate consequences and develop alternative behaviors.

3. building self esteem, helping the patient perceive self worth.

4. modification of smoking-related behaviors, offering strategies for alternative actions.

5. training in relaxation techniques; reduction of anxiety.

The following table presents some practical smoking cessation coping tools.

Strategies for basic intervention in smokers

LEVEL OF MOTIVATION	SPECIFIC INTERVENTIONS
Unprepared	• Promote a change of attitude toward smoking • Emphasize the relationship between smoking and the patient's present condition. • In relation to the patient's other risk factors, emphasize the added harm smoking represents • Offer help • Perform medium- to long-term follow up (30 days)
Preparable	• Develop a personalized plan • Boost motivation, congratulate patient for the decision and progress made • Reinforce self confidence, convince patient s/he can do it. • Stress the importance of the patient's decision for his/her health • Encourage patient to reduce the number of cigarettes smoked by offering strategies, until s/he stops • Inform patient of the possible appearance of withdrawal symptoms, offering strategies to overcome them • Negotiate a deadline for quitting with the patient. • Assess the need for pharmacological support based on medical criteria. • Perform short- to medium-term follow up (15 days)
Prepared	• Agree on a quit date • Inform patient of the possible appearance of withdrawal symptoms, offering strategies to overcome them • Offer pharmacological support to all patients that do not have contraindications • Perform short-term follow up (7 days) • After patient stops smoking, offer strategies to prevent relapse.

HOW TO…	STRATEGIES
reduce number of cigarettes	• Record number, time, and situation in which patient lights each cigarette • Wrap package so it looks unpleasant • Postpone smoking each cigarette as long as possible, for example going for a walk • Change brands • Don't smoke while doing something else. Separate associated behaviors, for example: Telephone and cigarette, mate and cigarette, coffee and cigarette • Put the package out of reach • don't smoke before breakfast and after meals • Eliminate ashtrays • Drink abundant water or unsweetened juices • Substitute cigarettes with sugar free gum or lozenges
overcome withdrawal syndrome	• Encourage recreational activities, walking, physical exercise • Avoid having foods high in fat and/or refined sugar easily available. • Drink abundant unsweetened liquids. • Monitor portion sizes, increase consumption of fruit and vegetables. • Pharmacological support based on medical criteria
prevent relapse	• Boost motivation, valuing the benefits achieved by quitting. • Boost self confidence, emphasizing the progress made • Anticipate situations of vulnerability and define how to respond, for example: ask the patient *"in what situation do you think you could not avoid lighting a cigarette? and how do you think you could manage that situation without a cigarette?"* • Encourage the patient to seek support if s/he needs it

Motivation and change. All smokers go through varying levels of motivation that modify their thoughts and attitudes. The level of motivation ranges from having no intention to stop smoking to that necessary to stop.

We can classify patients based on the following levels of motivation:

• UNPREPARED
Patients who have not yet considered quitting smoking.
• PREPARABLE
Patients who are already thinking of quitting although they still have considerable ambivalence
• PREPARED
Patients who have already decided to stop smoking.

These levels of motivation are correlated with the stages of change in the process described by Prochanska and Di Clemente, through which a patient passes as she progresses toward quitting smoking, although not always in the order indicated. for example, a patient may pass from directly precontemplation to action, following a motivating event.

LEVEL OF MOTIVATION	STAGE OF CHANGE[2]
Unprepared	**Precontemplation**
Preparable	**Contemplation**
Prepared	**Preparation**
Prepared	**Action**
Maintenance	
Relapse	

Relapse is part of this process, and should be taken as learning for new quitting attempts. It is noteworthy that the patient's antecedents of cessation achievements are very important: the more attempts a patient has made, the closer he is to definitive cessation.

The goal of professional intervention is to stimulate progress in the process of change. (See Chapter 6)

Individual support is provided both in the consulting room with the general physician and in specialized services[3], working toward the same goals in both cases.

The motivational talk takes on its true importance in individual treatment. It aims to reinforce the patient's existing motivations and emphasize the importance of the decision she has made, minimizing resistances.

Quitting is presented as the first commitment. The deadline for total abstinence must be flexible and capable of adapting to each individual's particular needs and circumstances.

In both individual and group treatment, face-to-face support is based on cognitive-behavioral techniques, which have shown a high level of efficacy supported by experimental research.

[2] Stage of change. Refers to the transtheoretical model of Prochaska and Di Clemente, which describes the process of behavioral change**.**

[3] The team at an ideal specialized service would include specialists in areas such as: medicine, psychology, nursing, nutrition, social work, physiotherapy, and physical education.

In all cases the patient is seen as a proactive subject, whose behavior should be considered in a context of environmental variables and cultural processes.

Group support is a tool of great importance for treatment of addicts. Group work, from its multi-dimensionality, offers more tools for treating addictions than individual work. The patient, through a process of identification with others, is able to visualize the possibility of changing his behavior with greater advantages.

Group therapy can be conducted intensively or extensively, depending on the frequency and number of face-to-face encounters it involves. An average of eight group sessions are considered necessary.

Intervention groups in this area do not work as psychotherapy groups but as support groups. They are not self-help groups, because their coordinators should be professionals and not peers (ex smokers).

To implement group treatment, some form of training in group dynamics is a necessity.

Face-to-face support in any of its modes is more effective when provided on a schedule specifically allocated for it and on a paid basis.

Evidence

There is clear and consistent evidence that face-to-face counseling increases smoking cessation rates over that of minimal support (22-24).

Both individual and group-based interventions are effective (22-24).

The effectiveness of intervention is directly tied to the frequency and number of interviews, the variety of treatments implemented (multi-component treatment), and the basic principles of establishing total abstinence as the goal with subsequent follow up. (25)

There is evidence showing that more intensive support in relation to the frequency and duration of interviews with smokers (at least four 20 minute sessions) is associated with higher rates of abstinence (24, 26-28).

There is evidence that when face-to-face support is provided, its effectiveness is independent of the provider (doctor, nurse, psychologist, other), provided s/he has suitable training (28,29)

Recommendations

A - Offer face-to-face support for smoking cessation at both the individual and group levels. Conduct no less than 4 sessions, in the understanding that the greater the number of interventions the better the result.

A – Promote a change of attitude toward smoking. Emphasize the relationship between smoking and the patient's current condition. Emphasize the increase in damage smoking entails when other risk factors are present.

C – Healthcare professionals who provide smoking cessation support should receive suitable training.

C – A specific time should be assigned to provide support in smoking cessation treatments.

RTG – Record the strategies offered and agreements reached. Perform periodic follow up.

Recommendation Grading Key
A: The recommendation is supported by GOOD (strong) evidence.
B: The recommendation is supported by FAIR (reasonable) evidence, but there may be minimal inconsistency or uncertainty.
C: The recommendation is supported by EXPERT opinion (published) only.
RTG: Recommendations based on clinical experience of the guide development group.

Telephone Support

Telephone support is an effective method for encouraging smoking cessation. It can be reactive (where the smoker calls a helpline for information and advice) or proactive (where the smoker receives calls from a telephone counselor at set times). The strongest evidence for efficacy exists for the proactive form of telephone support.

The idea is to establish a prearranged contact with the patient, at prearranged times and days, and provide cessation support over the telephone.

The type of support and strategies are the same as in the other types of treatment.

These services have been developed intensely in different countries because they are cost-effective and have a very wide reach (that is, they can be delivered to many people over a large geographical area).

Evidence

Proactive telephone support for smoking cessation increases long-term abstinence rates (30).

There is evidence that adding telephone support to medication increases short- and long-term abstinence rates over that of medication alone (30-34)

The optimum number of calls is not set, but at least 3 calls are considered necessary (32)

When the intensity of face-to-face counseling is low, such as providing a single counseling session for hospital in-patients, additional follow-up with telephone counseling has been shown to have greater efficacy (35).

As yet, there is no evidence that telephone follow-up after intensive support reduces relapse rates (36)

Recommendations

A – If a telephone counseling system is offered to stop smoking, it should be proactive.

RTG – Use telephone follow-up to help recover patients in case of relapse or loss of motivation.

Recommendation Grading Key

A: The recommendation is supported by GOOD (strong) evidence.
B: The recommendation is supported by FAIR (reasonable) evidence, but there may be minimal inconsistency or uncertainty.
C: The recommendation is supported by EXPERT opinion (published) only.

RTG: Recommendations based on clinical experience of the guide development group.

Pharmacological treatment

Pharmacological smoking cessation treatment is cost effective, compared with treatment of other chronic diseases such as high blood pressure or dyslipemia.

It focuses mainly on alleviating nicotine withdrawal syndrome, which includes irritability, depression, anxiety, lack of concentration, restlessness, increased appetite, constipation, and sleep disorders. Most of the symptoms disappear after 4 weeks' abstinence.

The urge to smoke remains for several months, and can be as strong as in the early stages of cessation, but occurs increasingly less often as the period of abstinence lengthens. Appearance of the urge to smoke is typically related to triggering situations and can be controlled with specific strategies (see Chapter 9).

Withdrawal syndrome is one of the manifestations of physical dependence. Patients who suffer more intensely from it can benefit most from pharmacological treatment. One of the most widely used tools to measure the level of nicotine dependence is the Fagerström Test (see Appendix 3). A simple means of approximating the level of physical dependence is to ask only the third question in the test:

When you wake up, how much time passes before you light your first cigarette?

If the person smokes within the first 30 minutes after awakening, s/he has a higher level of nicotine dependence.

Evidence

There are drugs that have been proven effective for smoking cessation treatment, which at least double the probability of quitting smoking compared with untreated patients (13).

To date there is evidence of effectiveness for smoking cessation treatment with the following first-line options: nicotine replacement therapies (chewing gum, patches, lozenges, nasal spray, inhaler, and sublingual tablets), Bupropion SR, and Varenicline Tartrate.
Second line options include: Nortriptyline and Clonidine (the latter without clinical application at present) (37-41).

There is reliable evidence that pharmacological treatment for smoking is cost effective (42-44).

Further evidence is needed to prove the effectiveness of pharmacological treatment in patients who smoke less than 10 cig/day, in smokeless (chewing), tobacco consumers, in pregnant or lactating women, and in adolescents (see Chapter 8)

There is evidence that the effectiveness of cognitive-behavioral and pharmacological intervention combined is greater than the effectiveness of each intervention separately (13).

Recommendations

A – All pharmacological smoking cessation treatment should be indicated by a doctor and must always be associated with face-to-face support, to achieve fundamental behavioral changes that allow the patient to overcome his or her addiction.

A - Pharmacological treatment should be offered to all patients who attempt to stop smoking, except when they present specific contraindications for each drug (see Appendices 4 through 7) or belong to one of the groups for which evidence of effectiveness is insufficient (patients who smoke less than 10 cig/day, in smokeless tobacco consumers, in pregnant or lactating women, and in adolescents).

Recommendation Grading Key
A: The recommendation is supported by GOOD (strong) evidence.
B: The recommendation is supported by FAIR (reasonable) evidence, but there may be minimal inconsistency or uncertainty.
C: The recommendation is supported by EXPERT opinion (published) only.
RTG: Recommendations based on clinical experience of the guide development group.

The evidence and recommendations for use of the different pharmacological treatment options are described below. Appendices 4 through 7 detail pharmaceutical forms, modes, contraindications, and side effects for each one.

Nicotine replacement therapy

Nicotine replacement therapy (NRT) has been shown to help people stop smoking. It is safe and cost effective.

NRT provides the patient with nicotine without the other substances cigarettes contain, which include more than 200 toxic substances and 50 carcinogens. Its main mechanism of action is to reduce the severity of withdrawal symptoms associated with smoking cessation. Although NRT does not completely relieve the withdrawal symptoms, it makes the experience of stopping more tolerable.

The evidence shows that NRT is effective in people who smoke more than 10 cigarettes per day. However, the number of cigarettes smoked does not always coincide with the level of dependence, and we need to consider form of smoking, for example frequency and intensity of puffs. Accordingly, NRT prescription should be determined based on each patient's individual characteristics.

Worldwide there are several pharmaceutical forms of NRTs[4], which release nicotine by different means. In Uruguay we have the transdermal patches and chewing gum, and lozenges with 2 and 4 mg of nicotine will be available soon (see usage mode for each format in Appendix 4).

Evidence

NRT is effective in aiding smoking cessation. It doubles the chances of 6-month sustained abstinence, compared with placebo. (37)

There is evidence that NRT is safe when prescribed to stop smoking, either the first time or in subsequent attempts. (37). It is also safe when using combinations of different forms of administration (patches and gum).

There is no evidence that matching particular products with particular types of people who smoke makes any difference to outcome. Product selection should be guided by patient characteristics (45).

Higher concentration nicotine patches have proven to be more effective than lower concentration preparations for persons who smoke more than 10 cigarettes a day (46).

NRT should be used for 8 to 12 weeks after quitting, but a small number of smokers may need to use it for longer. Although it is a safe treatment, in such patients close control is essential given that there are reports, although infrequent, of addiction to nicotine administered in chewing gum (47).

[4] These are patches, chewing gum, lozenges, pills, sublingual tablets, inhalers, and nasal spray. When this chapter was completed, only the first two were available in Uruguay.

There is a moderate benefit from combining different nicotine replacement products compared with the use of a single product (37).

There is evidence that NRT is effective in helping smokers reduce the number of cigarettes they smoke before achieving abstinence (48).

Recommendations

A - Offer NRT routinely as an effective medication for people who want to quit smoking tobacco.

A – Maintain NRT for at least 8 weeks after the patient stops smoking.

A – Combining two nicotine replacement products (patch and gum) increases the rate of abstinence.

B – The choice of NRT product type should be defined based on individual characteristics.

B - NRT with chewing gum can help lower consumption before stopping, gradually substituting cigarettes with the gum.

C - People who need NRT for longer than 8 weeks (for example, people who are highly dependent) can continue to use it under strict medical control. Such treatment should not exceed 12 months.

Recommendation Grading Key
A: The recommendation is supported by GOOD (strong) evidence.
B: The recommendation is supported by FAIR (reasonable) evidence, but there may be minimal inconsistency or uncertainty.
C: The recommendation is supported by EXPERT opinion (published) only.
RTG: Recommendations based on clinical experience of the guide development group.

Bupropion

Bupropion is an antidepressant medication that doubles the chances of long-term abstinence from smoking compared with placebo. Its action in helping people to stop smoking is independent of its antidepressant effects, as all the clinical trials included patients without a history of depression. Like NRT, it acts to reduce the severity of withdrawal symptoms, but it has other actions that help people stop.

Evidence that bupropion is more or less effective than NRT is limited.

Bupropion is a safe medication but has a number of contraindications and cautions for use (see Appendix 5). Bupropion is only available with a prescription for psychotropic drugs.

Evidence

Bupropion is effective in aiding smoking cessation, doubling the chances of long-term abstinence compared with placebo. (38).

There is some evidence showing that Bupropion may be more effective than NRT for smoking cessation (13).

There is some evidence supporting the association of Bupropion with NRT in patients with a high level of dependence (13,39,49).

There is evidence showing that Bupropion is safe and effective when used by those with stable cardiovascular and respiratory disease (11).

There is insufficient evidence to recommend the use of bupropion by pregnant women or adolescents who smoke.

There is insufficient evidence to recommend its use in preventing smoking relapse (36). In prolonged treatment with Bupropion (1 year) the benefit was maintained, compared with placebo, while pharmacological treatment continued (50-52).

Recommendations

A - Bupropion can be offered as an effective medication for people who want to stop smoking.

RTG – The decision to use bupropion should be guided by the person's preference and contraindications and precautions for use, also considering each person's characteristics.

RTG – Associated use of Bupropion and NRT is recommended in patients with a moderate to severe level of dependence or with prior failed quit attempts[5].

Recommendation Grading Key
A: The recommendation is supported by GOOD (strong) evidence.
B: The recommendation is supported by FAIR (reasonable) evidence, but there may be minimal inconsistency or uncertainty.
C: The recommendation is supported by EXPERT opinion (published) only.
RTG: Recommendations based on clinical experience of the guide development group.

[5] A failed quit attempt is understood as an attempt made under medical supervision without achieving sustained abstinence. Such patients usually need to be referred to a specialized smoking cessation service.

Varenicline

Varenicline is a partial agonist of nicotine receptors of the brain centers linked to reward circuits. This active mechanism can explain the reduction in severity of withdrawal symptoms and simultaneously the reduction of the sensation of reward associated with nicotine.

There is insufficient evidence to recommend use of varenicline by pregnant women or adolescents who smoke.

Further evidence is needed on its safety profile in large populations and in special groups.

There are no known clinically significant pharmacological interactions (see Appendix 6).

At present there is an FDA alert recommending that patients notify their doctor of any antecedent of psychiatric illness and that doctors monitor any change in a patient's mood or behavior after starting treatment with varenicline.

Varenicline is only available on prescription, with a common prescription.

Evidence

Varenicline is effective in aiding smoking cessation (39,53)

There is insufficient evidence to recommend association of varenicline with any other smoking cessation medication.

There is insufficient evidence to recommend use of varenicline by pregnant women or adolescents who smoke. Further evidence is needed on its safety profile in large populations and in special groups (39,53).

There is some evidence suggesting that varenicline is somewhat more effective than bupropion (39) and there is limited evidence suggesting greater effectiveness compared with NRT (39).

Recommendations

A – Varenicline can be routinely offered as an effective medication for those who want to stop smoking.

RTG - The decision to use varenicline should be guided by the person's preference and contraindications and precautions for use, also considering each person's characteristics.

RTG: Considering its recent appearance on the market and the alerts issued by regulatory agencies, strict clinical control and detection and reporting of adverse events is recommended (see report form in Appendix 8)

Recommendation Grading Key
A: The recommendation is supported by GOOD (strong) evidence.
B: The recommendation is supported by FAIR (reasonable) evidence, but there may be minimal inconsistency or uncertainty.
C: The recommendation is supported by EXPERT opinion (published) only.
RTG: Recommendations based on clinical experience of the guide development group.

Nortriptyline

Nortriptyline is a second line medication in smoking cessation treatment. It is a tricyclic antidepressant that has been shown to be at least as effective as NRT and bupropion in aiding smoking cessation. Its action in helping people to stop smoking is independent of its antidepressant effects, and it works in those without a history of depression.

There is insufficient evidence to recommend the combination of nortriptyline with any other smoking cessation medications.

There is insufficient evidence to recommend use of nortriptyline by pregnant women or adolescents who smoke.

Its main advantages are its low cost and the ability to monitor therapeutic blood levels. Its main disadvantage is the risk of adverse cardiovascular effects. There are a number of contraindications and precautions with its use (see Appendix 7).

Nortriptyline has the potential for more serious side effects than bupropion.

Nortriptyline is only available with a prescription for psychotropic drugs.

Evidence

Nortriptyline is effective in aiding smoking cessation, doubling the chances of long-term abstinence compared with placebo. (40).

There is insufficient evidence to recommend the combination of nortriptyline with any other smoking cessation medications.

There is insufficient evidence to recommend its use by pregnant women or adolescents who smoke.

Nortriptyline has the potential for more serious side effects than bupropion.

Recommendations

A - Nortriptyline can be offered as an effective medication for people who want to stop smoking.

RTG – The use of Nortriptyline should be considered when it proves impossible to use first line drugs.

RTG - The decision to use nortriptyline should be agreed on between doctor and patient, considering the drug's effectiveness and adverse effects.

Recommendation Grading Key
A: The recommendation is supported by GOOD (strong) evidence.
B: The recommendation is supported by FAIR (reasonable) evidence, but there may be minimal inconsistency or uncertainty.
C: The recommendation is supported by EXPERT opinion (published) only.
RTG: Recommendations based on clinical experience of the guide development group.

7 Contributions from the different disciplines of First Tier Care.

In First Tier Care, based on the strategy of Primary Health Care (PHC), smoking cessation treatment requires the participation of all members of the healthcare team. Each one, from their respective discipline, has the opportunity to perform specific interventions to control tobacco addiction at the individual and community level.

The creation of a multidisciplinary team complements and enriches the work of each specialization at all levels of care.

The intervention proposed below is based on the same method described in **ABC** (Ask, Brief advice, and Cessation support), with the help of the specific approaches to smoking of professionals in the areas of Nursing, Dentistry, Nutrition, and Physiotherapy.

Nursing

Nursing personnel receive the user when s/he reaches first tier care. The confidence that usually develops in the nurse/patient relationship represents a strength when implementing interventions focused on fomenting healthy lifestyles and providing appropriate education on the subject of smoking, preventing the start of smoking, and stopping.

Nursing Intervention

Conduct individual and comprehensive nursing consultation, applying the Nursing Care Process (NCP, including the following in relation to smoking:

1. **Promote** education opportunities in waiting rooms on smoking and on the community by distributing leaflets.
2. **Know** the user's status in relation to smoking, especially in the case of children and pregnant women **(Ask)**. For all users, ask about their relationship with tobacco. E.g.: "*Do you smoke? Have you ever been a smoker? Do you spend part of your time with people who smoke in your presence?"*
3. **Record** in the patient's clinical history her status as an active or passive smoker, as well as the type of intervention performed and follow-up actions taken.
4. **If patient is a smoker**: *"how much do you smoke? how long have you smoked?"*
5. **Brief advice and support for smoking cessation**

***If the patient is not thinking of quitting smoking*:**

- Give brief advice (3 minutes are enough) informing the patient of the risks smoking represents for her health and the benefits to be obtained by quitting smoking.
- Ask about the social and family support available to the patient.
- Give patient support material.
- Discuss the subject at another appointment.

***If the patient is thinking of quitting smoking*:**

- Recommend cessation, pointing out the importance of making the decision.
- Reinforce motivation to stop smoking, emphasizing the positive aspects.
- Give patient support material.
- Refer to a treating physician or smoking cessation service, as the situation warrants.

If the patient has stopped smoking it is important to ask: *"how long has it been since you stopped smoking?*". Support patient and take follow up actions.

6. **Work** in smoking cessation groups with other multidisciplinary team members.

Nutrition

Quitting smoking can cause weight gain through different mechanisms:

- The almost immediate recovery of taste and smell produces a greater urge to eat and less ability to control the quantity of food consumed.
- The persistence of the gesture of putting something in your mouth. This time it will not be a cigarette, but food; patients usually prefer sweet and high calorie foods.
- Quitting smoking causes the baseline metabolic rate to drop, which means that patients burn 200 to 300 calories less than when they were smoking (54).

Patients can be expected to gain between 3 and 6 Kg; however, around 10% of patients present greater gains (57-58). On the other hand, we need to be aware that there is a percentage of smokers who, on starting a nutritional treatment to lose weight, increase their tobacco consumption. It is important to identify this kind of behavior and evaluate the situation.

There is evidence (59) that excessive weight gain lowers the benefits of quitting smoking by up to 38% in men and up to 17% in women. For this reason, it is recommended that smoking cessation be accompanied by strategies to control weight gain. This is why a dietician's intervention is important to guide the patient through the smoking cessation process. Proper nutrition and increasing physical activity are key factors in controlling body weight in the two years after quitting smoking.

Dietitian's Intervention

Individual treatment:

Should be provided by all dieticians as part of their usual attention.

1. **Detect** each smoking patient and record his or her status as a smoker in his or her clinical records **(Ask)**
2. **Give Brief advice** on smoking cessation.
3. **Refer** any patient who expresses a desire to stop smoking to a smoking cessation service **(Cessation support).**
4. **Conduct** a consultation with a dietician in all cases, especially when the patient finishes pharmacological treatment.

Group treatment:

Refers to the dietician's intervention as part of the multidisciplinary smoking cessation treatment team.

The intervention is intended to complement the smoking cessation process and provide a space for discussion. It will be implemented gradually when the group is formed.

Guidelines for treatment (individual or group) of patients who are in the process of quitting.

Short term (start of smoking cessation):

1. **Monitor** body weight, agreeing with the patient that the goal is not to prevent weight gain but to keep it within the expected ranges.
2. **Remember** that weight loss is a secondary objective until the smoker reaches 6 months of abstinence, emphasizing that the percentage of patients who undergo excessive weight gains is small.
3. **Offer** nutritional indications that are not excessively restrictive to facilitate adhesion and avoid failure in smoking cessation.
4. **Emphasize** the following aspects:
- increase intake of liquids.
- eat at least 4 meals and the necessary snacks, avoiding a disorderly diet.
- encourage low calorie snacks.

5. **Identify** patients who need individualized nutritional intervention based on the following risk criteria:
- Patients with associated comorbidity (metabolopathies)
- Patients who are obese or have antecedents of obesity.
- Patients who gain more than 5% of their initial body weight during the smoking cessation process.

Medium term:
When the patient **finishes pharmacological treatment** s/he is more vulnerable to excessive weight gain; for this reason it is important to **arrange** a consultation with a dietician.
1. **Agree on** healthy dietary habits.
2. **Address** associated risk factors.
3. **Encourage** physical activity.

Long term:
For ex smokers (6 months' cessation):
1. **Maintain** nutritional consultation to address factors of risk and comorbidity detected.
2. **Define** weight loss goals suited to each individual, in case of weight gain. Promote losses of 5 to 10% of the patient's initial weight.

Dentistry

At the oral level, smoking causes alterations of dental structures and/or restorations, as well as alterations in other sectors. One of the most common reasons for dental consultation is the change of color of restorations and teeth.

Smoking is a decisive factor in the appearance of one of the most common infectious oral pathologies, paradentopathy, commonly known as "pyorrhea," which affects tooth support structures. It starts with mild swelling of the gums (Gingivitis), with bleeding during brushing which, if left untreated, can lead to the loss of teeth. Due to its infectious origin, it can aggravate conditions such as diabetes and cardiovascular disease. During pregnancy mouth infections are considered risk factors that are heightened in smoking mothers.

Smokers should be monitored for the appearance of lesions of the oral mucus membranes, ranging from ulcers to chronic white lesions, considered premalignant (see Appendix 9).

Any healthcare team member who detects any of these oral alterations should refer the patient to dentistry for evaluation and diagnosis.

Dentist's Intervention

Individual treatment:
Should be performed by all dentists as part of customary attention.

1. **Detect** patients who smoke and record their status as smokers in their clinical records **(Ask)**
2. **Promote** oral hygiene,
3. **Inform** the patient about smoking as a risk factor for oral health
4. **Identify** any lesion associated with smoking.
5. **Firmly advise** the patient to stop smoking **(Brief advice)**.
6. **Refer** any patient who expresses a desire to stop smoking to a smoking cessation service **(Cessation support)**.
7. **Refer** the patient to the appropriate service when it is not possible to resolve the pathology detected.

Group treatment*:*
Refers to the dentist's participation in the smoking cessation service.
Intervention will be determined by the group coordinator, by prior arrangement with the institutional dentist of oral hygienist.

Topics will be included such as:

- Promotion of healthy habits.

- Education, motivation, and importance of seeing a dentist to assess oral health status.
- Education for early identification of disorders caused by smoking.

Physiotherapy

The physical therapist's working methodology determines that s/he spends considerable amounts of time with patients, which in turn facilitates his/her assuming a role in which s/he can provide advice and orientation on smoking cessation.

Physical Therapist's Intervention:

1. **Detect** smokers during kinesic evaluation before defining treatments **(Ask)**.
2. **Form** the team that will work on smoking cessation with training in exercises for relaxation, breathing, and general mobility, as part of group treatment
3. **Use** physical activity as a behavioral substitute for smoking.
4. **Promote** physical activity as part of a healthy lifestyle

Teach respiratory exercise by means of techniques to stimulate proper mechanics stressing the use of diaphragmatic, lower costal, and pectoral patterns, controlled inhalation and exhalation, assisted exhalation, and focused ventilation.

5. **Orient** patients in techniques of bronchial hygiene: importance of increasing fluid intake, techniques of forced exhalation and resisted exhalation, huffing, calisthenics interspersed with respiration, and muscular relaxation techniques (Schultz, Jacobson).
6. **Provide**, for patients in rehabilitation, ongoing education on healthy lifestyles and promotion of smoke free environments **(Brief advice).**
7. **Refer** patients who want help to stop smoking to a smoking cessation service **(Cessation support).**

8 Smoking cessation interventions in special groups

Among the smoking population, certain groups have been identified that require different support for various reasons: groups with particularly high smoking prevalence rates, comorbidity that conditions greater difficulty in stopping (mental health disorders), situations in which the benefit of cessation is much greater than in the general population in the short term (pregnant women), situations in which the determining factors of consumption and motivation for cessation are different from the general population (adolescents).

In general, interventions that have been proven to be effective in the general population are also likely to be effective for these population groups. However, the manner in which these interventions are delivered may need to be adapted for each group in order to be acceptable, accessible and appropriate as possible.

Smoking cessation interventions for pregnant and breastfeeding women

Smoking during pregnancy entails risks to the mother (premature delivery, spontaneous abortion, placenta praevia, placental abruption), for the newborn baby (low birth weight), and for the infant (sudden infant death syndrome (SIDS), otitis media, learning difficulties). (60,61).

Second-hand tobacco smoke also has known harmful health effects on pregnant women, newborns, and infants.

Stopping smoking during pregnancy provides benefits for mother and child, and therefore all smoking in women of childbearing age should be recommended to stop smoking and offered help. Help should be offered as early as possible during pregnancy, and during puerperium and breastfeeding (62).

There is limited evidence of the effectiveness and safety of NRT in pregnancy, for both mother and child. However, it is recognized that the main benefit of using NRT is the removal of all other toxins contained in tobacco smoke. Furthermore, NRT used at the recommended doses typically provides less nicotine than tobacco smoke.

For these reasons, today some experts support NRT during pregnancy and recognize it as safe, in the understanding that patients should receive suitable advice on the risks and benefits of nicotine use in both forms (63,64)

Intermittent-use NRT products, such as gum, should be used in preference to patches, because the former release a smaller daily quantity of nicotine.

A similar approach is suggested during breastfeeding, recognizing that the most important thing is for the mother to abstain from smoking. Although nicotine freely passes in and out of breast milk. Due to the relatively low oral availability of nicotine, it is unlikely that this very low level of exposure is harmful to the infant.

In summary, an analysis of the risks and benefits of smoking versus using NRT overwhelmingly supports the use of NRT.

Evidence

There is evidence that multi-session support interventions to help pregnant women stop smoking improve abstinence rates during pregnancy. (65)

There is some evidence that motivational telephone intervention is cost effective to achieve cessation during pregnancy. (66)

There is limited evidence for the effectiveness and safety of NRT during pregnancy. (60,67)

Intermittent-use NRT products, such as gum, lozenges, sublingual tablets and inhalers, should be used in preference to patches. However, if a patch is judged to be the most appropriate product, then it should be used during waking hours only and removed overnight. (63).

Recommendations

A - All health care workers should briefly advise pregnant and breastfeeding women who smoke to stop smoking.

A - Offer all pregnant and breastfeeding women who smoke multi-session cognitive-behavioral smoking cessation interventions from a specialist/dedicated cessation service.

C - NRT can be used in pregnancy and during breastfeeding following a risk-benefit assessment. The decision will be made jointly with the attending obstetrician. If NRT is used, oral NRT products (gum) are preferable to nicotine patches.

RTG – All healthcare professionals should give brief advice to all smoking women who are planning a pregnancy.

RTG – Inform all family members of the risk of second-hand tobacco smoke for pregnant women and newborn babies.

Recommendation Grading Key
A: The recommendation is supported by GOOD (strong) evidence.
B: The recommendation is supported by FAIR (reasonable) evidence, but there may be minimal inconsistency or uncertainty.
C: The recommendation is supported by EXPERT opinion (published) only.
RTG: Recommendations based on clinical experience of the guide development group.

Smoking cessation interventions in children and adolescents

Uruguayan young people have a high overall smoking prevalence rate of 22%, with a predominance of smoking among women (68,69). Nationwide data show that 60% of children of smoking parents are smokers, and 40% when one parent smokes (70).

Adolescence is a special time in life, when the individual starts to build her own identity, and starts to make decisions on her own, setting herself apart from the adult world. Intervention in this age group should be different, given that a young person differs from an adult, in forms and attitudes toward both smoking in general, and cessation in particular.

The WHO –PHO recommend development of Life Skills for prevention and treatment of addictions, which includes:

- Acquire coping strategies and social skills
- Recognize strengths, weaknesses, and opportunities for change
- Stimulate critical awareness
- Build self esteem

Theories of social learning that insist on the central role of imitation at these ages have contributed in the field of health education: they recommend approaching the adolescent through other adolescents.

The healthcare team should be aware of the risk second-hand tobacco smoke poses to children and adolescents exposed in their homes. Smoking family members should be offered brief advice and help to stop smoking.

Evidence

There is evidence for the effectiveness of medical support for smoking cessation in adolescents (13). There is limited evidence to recommend a particular treatment method for this group.

There is evidence showing the effectiveness of intervention by trained peers (71,72).

There is insufficient evidence for the effectiveness of NRT or BPN in adolescents who want to stop smoking (73,74). However, because it is less harmful than smoking, the expert opinion is that NRT may be considered for use in nicotine dependent adolescents who want to stop smoking (75).

Recommendations

B – Always offer adolescents support to stop smoking.

B – Promote interventions focused on smoking prevention and cessation in adolescents through trained peers.

C - NRT may be used in nicotine dependent adolescents if the attending healthcare professional thinks it may represent an aid to a quit attempt (its use in occasional smokers is not recommended).

RTG – it is recommended to develop specific programs for adolescents.

RTG – Based on current recommendations, treatments for adolescents should focus on:

- The concept of addiction and its consequences at the individual, family, and social levels. Identify pressure situations.
- The concept of manipulation by the tobacco industry.
- Developing coping strategies and life skills.
- Implement treatment in informal, non-sanitary spaces.

Recommendation Grading Key

A: The recommendation is supported by GOOD (strong) evidence.
B: The recommendation is supported by FAIR (reasonable) evidence, but there may be minimal inconsistency or uncertainty.
C: The recommendation is supported by EXPERT opinion (published) only.
RTG: Recommendations based on clinical experience of the guide development group.

Smoking cessation interventions for hospitalized and preoperative patients.

Hospitalization is an important opportunity to motivate people to stop smoking, because the patient is particularly receptive to advice from the healthcare team. This includes not only patients who are smokers but also their companions, especially parents and other family members of hospitalized children.

Patients with smoking-related illnesses benefit particularly from smoking cessation, even after many years of heavy smoking.

Smoking increases the risk of complications related to surgery, which can be avoided by not smoking for 6 weeks prior to surgery. A shorter period of abstinence lessens this benefit.

There is growing recognition of the importance of establishing systematic and specific approaches to identify, advise, and support smokers so that they stop smoking during their hospital stay.

The hospital environment also offers healthcare professionals the opportunity to speak with the parents of hospitalized children about the risks of second-hand tobacco smoke for children and adolescents exposed in their homes.

Studies show a good safety profile to start specific pharmacological smoking cessation treatment in hospitalized patients.

Evidence

There is evidence that nicotine is not a significant risk factor in patients with acute cardiac events (76).

There is evidence of greater effectiveness using NRT when treatment is started during hospitalization (35).

There is evidence of safety in the use of NRT in patients with stable cardiovascular disease (37) and Bupropion in patients with cardiovascular and respiratory pathology (11). There is insufficient evidence of the safety of varenicline in patients with cardiovascular pathology.

There is evidence of the effectiveness of support interventions of at least 1 month’s duration following release from hospital, in hospitalized patients (77).

There is evidence of the short-term effectiveness of smoking cessation interventions in the preoperative period. (78)

Smoking cessation in preoperative patients lessens the risks of infection of the surgical wound, delayed healing, and respiratory and cardiac complications in postoperative patients (79).

Recommendations

A – Offer brief systematic advice to stop smoking to all hospitalized patients who are smokers.

A – Offer intensive support with multiple sessions, medication, and follow up for at least 1 month after release for all hospitalized patients who are smokers.

A – Advise smokers in the preoperative period to stop smoking at least 6 weeks before their surgery and offer intensive support and pharmacological treatment if necessary.

A – Bupropion can be used in patients with stable cardiovascular pathology.

B –NRT can be given to patients with cardiovascular disease. However, for those who have suffered an acute vascular event (e.g. IAM or stroke) in the last 2 weeks or who have an inadequately controlled disease, treatment should be discussed with the attending physician. In such cases, oral nicotine replacement products are recommended as the first choice among NRTs.

B – All hospitals should have programs to help their patients stop smoking. This includes offering advice on smoking cessation systematically, and providing the opportunity to access a specialized smoking cessation service in the hospital itself or at an external service.

RTG – To the extent possible, refer all patients who are smokers and who are scheduled for surgery to a specialized service.

RTG – Offer brief advice and intensive support for smoking family members of hospitalized patients.

Recommendation Grading Key
A: The recommendation is supported by GOOD (strong) evidence.
B: The recommendation is supported by FAIR (reasonable) evidence, but there may be minimal inconsistency or uncertainty.
C: The recommendation is supported by EXPERT opinion (published) only.
RTG: Recommendations based on clinical experience of the guide development group.

Smoking cessation interventions for people who use mental health services.

People with mental health disorders have particularly high smoking rates. They typically present greater dependence and greater difficulty quitting smoking (80-83).

People with mental health disorders often do not receive advice on cessation, despite the significant benefits it would entail for their condition.

Intensive smoking cessation interventions, with multiple sessions and medication, are also beneficial for this group, provided the patient is stable when s/he receives treatment. it is also necessary to consider that some of these patients may have difficulty using NRT in gum form correctly.

Smoking modifies the metabolism of some drugs used to treat mental disorders, and therefore alters their effects. Consequently it may be necessary to adjust the doses of such drugs and monitor their blood levels when patients stop smoking.

It should be remembered that specific drugs to stop smoking interact with psychotropic drugs in general, and therefore prescription decisions should be made jointly with the attending psychiatrist, accompanied by close clinical observation of the patient.

Evidence

There is evidence that interventions that are effective in the general population also are effective in patients in mental health services. (24,84,85)

There is evidence that bupropion is effective and safe in this group of patients (86,87)

Most people with mental disorders do not experience worsening of their condition when they stop smoking (85). However, some patients present a depressive event (88), which requires close observation of the patient's evolution.

Smoking cessation can affect the metabolism of a certain number of drugs (89), which include drugs used to treat mental illnesses, and therefore dosage adjustments may be needed.

Recommendations

A – Provide systematic brief advice to stop smoking to all users of mental health services who are smokers.

A - Persons with mental disorders who stop smoking while receiving psychopharmacotherapy should be monitored to determine the need for adjustments in the doses of their medication.

RTG – Offer smoking cessation interventions with proven effectiveness to smokers with mental disorders who are stable.

RTG – If a smoking cessation intervention is administered to a patient with psychiatric illness outside a mental health service, it is essential to have the approval of the attending psychiatrist.

Recommendation Grading Key
A: The recommendation is supported by GOOD (strong) evidence.
B: The recommendation is supported by FAIR (reasonable) evidence, but there may be minimal inconsistency or uncertainty.
C: The recommendation is supported by EXPERT opinion (published) only.
RTG: Recommendations based on clinical experience of the guide development group.

Smoking cessation interventions for patients with other addictions

Smoking in persons with other addictions is more widespread than in the general population. However, this does not mean that such persons are less likely to stop smoking.

Intensive smoking cessation interventions, with multiple sessions and medication, can also be effective for this group, and can also contribute to treatment of their other addictions.

Evidence

There is evidence of short-term effectiveness of smoking cessation interventions in persons with other addictions. (90,91)

In a minority of patients, stopping smoking can trigger a relapse in another addiction overcome previously (92,93).

Recommendations

A – Provide systematic brief advice on cessation to all smokers with other addictions.

RTG – Incorporate smoking cessation treatment with interventions of proven effectiveness in treatment services for other addictions. Given the possibility of relapse in another addiction overcome previously, strict clinical control and intensive support are recommended in these patients.

Recommendation Grading Key
A: The recommendation is supported by GOOD (strong) evidence.
B: The recommendation is supported by FAIR (reasonable) evidence, but there may be minimal inconsistency or uncertainty.
C: The recommendation is supported by EXPERT opinion (published) only.
RTG: Recommendations based on clinical experience of the guide development group.

9 Treatment interventions for relapsing patients

Relapse is part of the process of overcoming addiction to tobacco; 75% of patients who successfully stop smoking require multiple attempts. There are intervention strategies to prevent relapse.

It is important to differentiate the **backslide**, which is individual, occasional, and isolated indulgence in a puff or a cigarette, from **relapse**, which is a return to daily consumption.

There are risk indicators for relapse:

- High physical dependence
- Intense withdrawal syndrome
- High psychological dependence
- Patient with other addictions
- Psychiatric comorbidity
- Antecedent of depression
- Patients who have not made changes to their lifestyle
- Patient's environment with smokers
- Conflictive situations
- Patients with recent personal losses
- Weight gain
- Frequent episodes of craving
- Backslides (each backslide increases the risk of relapse)
- Fantasies of self control

Prevention of relapse

The number and variety of interviews conducted during treatment may help lower the relapse rate and prolong abstinence.

During treatment and the first stages of abstinence, it is extremely important to identify with each patient situations of vulnerability or high risk, proposing suitable responses to such situations.

The suitable response should focus on modifying the relevant circumstance or learning to change one's behavior in response to it. For example, emphasizing that the act of lighting a cigarette does not change an uncomfortable situation, but merely masks it.

If a situation of vulnerability is related to social pressure, it will be necessary to raise the individual's self esteem, for example by changing his perception of self reliance.

The patient will need to understand the importance of "thought before action" to identify situations of vulnerability.

The longer the patient practices this kind of exercises, the more tools s/he will have to cope after s/he stops smoking.

Evidence

Despite the existence of numerous high quality studies, there is no conclusive evidence to support the efficacy of specific interventions to prevent relapses. (36,50-52,94)

Recommendations

RTG – Implement the greatest possible number and variety of interventions during treatment.

RTG – Identify indicators and risk situations early in all patients.

RTG – Do exercises anticipating relapse situations, asking, for example, *"In what situation do you think you could not stop yourself from lighting a cigarette?"*
When the patient can visualize risk situations, ask *"How do you think you could handle this situation without the cigarette?"*

Recommendation Grading Key
A: The recommendation is supported by GOOD (strong) evidence.
B: The recommendation is supported by FAIR (reasonable) evidence, but there may be minimal inconsistency or uncertainty.
C: The recommendation is supported by EXPERT opinion (published) only.
RTG: Recommendations based on clinical experience of the guide development group.

Management of relapse

The smoker is at permanent risk of relapse in her addiction. We know that most smokers can make multiple attempts before achieving lasting abstinence.

It is extremely important to take relapse as a learning experience and not as a failure. Recovery will focus on reviewing the relapse situation.

The successful resolution of problems that appear in the initial stages of abstinence is indicative of a favorable prognosis.

All relapsing patients should be reassessed and treated. The choice of treatment should be guided by the lessons learned from prior quit attempts and individual preference.

There is no evidence to support the choice of a given pharmacological treatment for relapse from among effective drugs to stop smoking.

Evidence

There is evidence that NRT and Bupropion can be used successfully by persons who have used those drugs before. (95-97)

There is insufficient evidence to recommend a minimum time between quit attempts (98,99).

Recommendations

A – provide brief advice to stop smoking to all patients who suffer a relapse.

A - Offer effective intensive support and pharmacological interventions to all patients who start a new attempt to stop smoking.

RTG – It is recommended to refer all relapsing patients to a specialized program.

RTG - Services should offer support to patients who have relapsed as soon as they request it.

RTG – Support for a new quit attempt should include:

- Explaining to the patient that relapse is part of the learning process, and not a failure as it is commonly perceived.
- Reassess the time the patient remained smoke free.

• Review factors that could have led to the relapse (see relapse risk indicators).

• Strengthen the patient's motivation to stop smoking.

• Encourage a new quit attempt.

RTG – The choice of pharmacological treatment in patients who have already used drugs to stop smoking should first opt for that which was effective in prior attempts.

Recommendation Grading Key
A: The recommendation is supported by GOOD (strong) evidence.
B: The recommendation is supported by FAIR (reasonable) evidence, but there may be minimal inconsistency or uncertainty.
C: The recommendation is supported by EXPERT opinion (published) only.
RTG: Recommendations based on clinical experience of the guide development group.

10 Other treatments and interventions

There are treatments and interventions offered to persons who want to stop smoking such as hypnosis, acupuncture, and homeopathic medicine, among others. However, there is evidence that some of these interventions do not help people to stop smoking, and for other interventions there is insufficient evidence as to their effectiveness.

Some evidence of effectiveness.

The evidence available to date suggests that **cytisine**, a drug still under investigation, may be useful in smoking cessation. However, further research is needed to confirm this.

There is some evidence that **glucose** (in pharmaceutical form) increases abstinence in the short term but not in the long term. The short-term effect appears to be stronger when it is used concomitantly with NRT or Bupropion. (100,101).

Evidence of inefficacy.

There is evidence that ansiolitics as specific treatment are not useful for smoking cessation. (102).

Not recommended

There is evidence that **clonidine** is useful in smoking cessation; however, due to its adverse effects, its use is not recommended. (41).

There is evidence from randomized studies that smoking heavily and rapidly as part of an **aversive treatment** increases rates of abstinence to 6 months. However, its use as a smoking cessation strategy is not recommended.

There is evidence that **hypnosis** does not increase long-term rates of abstinence compared with other interventions of comparable intensity. (103)

There is evidence that **acupuncture, digitopuncture, laser therapy, and electrostimulation** do not increase long-term rates of abstinence compared with placebo. (23,104)

There are no studies on other commercially available treatments.

11 Bibliography

1. Ministry of Public Health. National Survey on Risk Factors. Uruguay. 2007
2. National Counsel on Drugs. National Department of Drugs. Fourth National Survey in Homes on Drug Use. Uruguay. 2007.
3. Medical Union of Uruguay. FACTUM. National Medical Survey. Professional and Occupational Status of Doctors. Nationwide. 2001. Available on line at: http://www.smu.org.uy/sindicales/documentos/Factum/index.html
4. Medical Federation of the Interior. National Medical Survey. 2007. Available on line at: http://www.femi.com.uy/not/n8_08_09.html
5. Peruga A. *El Convenio Marco para el Control del Tabaco: respuesta a la globalizacion de una epidemia comunicada*. Gac Sanit. [online newspaper]. 2004; 18(5):343-345.
Available on line at:
http://scielo.isciii.es/scielo.php?pid=S021391112004000700001&script=sci_arttext&tlng=es
6. World Health Organization. Report on the Global Tobacco Epidemic. The Mpower package. 2008. Available on line at:
http://www.who.int/tobacco/mpower/mpower_report_full_2008.pdf
7. Peruga A. Prologo. Lessons from campaigns in favor of smoke-free environments in California. California Department of Health Services. 2001
8. World Health Organization. Ramos A, Curti D. *Economia del control del tabaco en los paises del Mercosur y estados asociados: Uruguay*. 2006. Washington. Available on line at: http://www.paho.org/Spanish/AD/SDE/RA/Tab_Mercosur_URU.pdf
9. Doll R, Peto R, Boreham J, Sutherland I. Mortality in relation to smoking: 50 years' observations on male British doctors. BMJ. 2004; 328:1519.
10. *Medidas relacionadas con la reduccion y demanda del tabaco. Ley 18256*. March 6, 2008. Uruguay. Available on line at:
http://www.presidencia.gub.uy/_web/leyes/2008/03/S405_19%2010%202007_00001.PDF
11. Uruguayan Ministry of health and Enviroment. *Guia Nacional de treatment de la adiccion al tabaco*. 2005. Available on line at:
http://www.foroaps.org/files/TRATADDICTIONTOBACCO.pdf
12. Ministry of Health. New Zealand Smoking Cessation Guidelines.2007. Available on line at: http://www.moh.gov.nz
13. Fiore M, Jaen C, Baker T et al. Clinical Practice Guideline: Treating Tobacco Use and Dependance. 2008. Available on line at: http://www.surgeongeneral.gov/tobbacco
14. Appraisal of guidelines research and evaluation. The AGREE Collaboration. AGREE Instrument Spanish. 2001. Available on line at: www.agreecollaboration.org
15. Gordon H. Guyatt, David Sackett, Deborah J. Cook, Evidence Based Medicine Working Group based on the users' guides to Evidence-based Medicine How to use an article about therapy or prevention. JAMA. 1993; 270(21):2598-2601.
16. Gordon H. Guyatt, David Sackett, Deborah J. Cook, Evidence Based Medicine Working Group based on the users' guides to Evidence-based Medicine How to use an article about therapy or prevention. JAMA. 1994; 271(1):59-63
17. Agency for Healthcare Research and Quality (AHRQ). EPC Evidence Reports [Internet]. Rockville: AHRQ. Available on line at:
http://www.ahrq.gov/clinic/epcindex.htm#methodology
18. Jackson G, Bobak A, Chorlton I et al. Smoking cessation: a consensus statement with special reference to primary care. ICGP. 2001; 55:385-392.
19. Russell M, Wilson C, Taylor C et al. (Effect of general practitioners' advice against smoking. British Medical Journal. 1979; 2(6184):231-5.
20. Lancaster T, Stead LF. Physician advice for smoking cessation. Cochrane Database of Systematic Reviews. 2006.
21. Hall S, Reid E, Ikoumunne OC. et al. Brief smoking cessation advice from practice nurse during routine cervical smear tests appointments: a cluster randomised controlled trial assessing feasibility, acceptability and potential effectiveness. British Journal of Cancer.
2007; 96:1057-1061.
22. Lancaster T, Stead LF. Individual behavioural counselling for smoking cessation. Cohrane Database of Systematic Reviews. 2006.
23. Stead L, Lancaster T. Group behaviour therapy programmes for smoking cessation. Cochrane Database of Systematic Reviews. 2006.

24. USDHHS. Treating Tobacco Use and Dependence. Rockville MD, United States Department of Health and Human Services. Agency for Healthcare Research Quality. 2000.
25. Sutherland G, Phil M. Evidence for Counseling Effectiveness for Smoking Cessation. J Clin. Psychiatry Monograph, 2003;18 (1): 22-33.
26. Ockene J, Hymowitz N, Lagus J et al. Comparaison of smoking behavior change for SI and UC study groups. MRFIT Research Group. Preventive Medicine. 1991; 20(5):564-573.
27. Hall S, Humfleet G, Reus V et al. Extended nortriptyline and psychological treatment for cigarette smoking. American Journal of Psychiatry. 2004; 161(11):2100-2107.
28. Fiore M, Bailey W, Cohen S et al. Treating tobacco use and dependence. Clinical practice guideline Rockville, MD. US Department of Health and Human Services, Public Health Service. 2000
29. Rice V, Stead L. Nursing interventions for smoking cessation. Cochrane Database of Systematic Reviews. 2006.
30. Stead L, Lancaster T, Perera R. Telephone counselling for smoking cessation. Cochrane Database of Systematic Reviews. 2006.
31. Macleod Z, Charles M, Arnaldi V et al. Telephone counselling as an adjunct to nicotine patches in smoking cessation: A randomised controlled trial. Medical Journal of Australia.
2003; 179 (7):349-352.
32. Stead L, Perera R, Lancaster T. A systematic review of interventions for smokers who contact quit lines. Tob Control 2007; 16:3-8.
33. Rabius V, Pike K, Hunter J et al. Effects of frequency and duration in telephone counselling for smoking cessation. Tob Control 2007; 16:71-74.
34. Hollis J, McAfee T, Fellows J et al. The effectiveness and cost effectiveness of telephone counselling and the nicotine patch in a state tobacco quitline. Tob. Control 2007; 16:53-59.
35. Miller N, Smith P, DeBusk R et al. Smoking cessation in hospitalized patients. Results of a randomized trial. Archives of Internal Medicine, 1997; 157(4):409-15.
36. Hajek P, Stead F, West R et al. Relapse prevention interventions for smoking cessation (Review). Cochrane Database of Systematic Reviews. 2007; (2).
37. Silagy C, Lancaster T, Stead L et al. Nicotine replacement therapy for smoking for cessation. Cochrane Database of Systematic Reviews. 2006; (2).
38. Hughes J, Stead L, Lancaster T. Antidepressants for smoking cessation. Cochrane Database of Systematic Reviews. 2006; (2)
39. Cahill K, Stead L, Lancaster T. Nicotine receptor partial agonists for smoking cessation. Cochrane Database of Systematic Reviews 2008, (3).
40. Hughes J, Stead L, Lancaster T. Nortriptyline for smoking cessation: a review. Nicotine Tob Res 2005; 7:491-9.
41. Gourlay S, Stead L, Benowitz N. Clonidine for smoking cessation. Cochrane Database of Systematic Reviews. 2004;(3).
42. Cromwell J, Bartosch W, Fiore M, et al. Cost-effectiveness of the clinical practice recommendations in the AHCPR guideline for smoking cessation. JAMA 1997; 278:1759-66.
43. Maciosek M, Coffield A, Edwards N et al. Priorities among effective clinical preventive services: results of a systematic review and analysis. Am J Prev Med 2006; 31:52-61.
44. Shearer J, Shanahan M. Cost effectiveness analysis of smoking cessation interventions. Aust N Z J Public Health 2006; 30:428-34.
45. West R, McNeill A, Raw M. Smoking cessation guidelines for health professionals: an update. Halt Education Authority. Thorax. 2000; 55(12):987-999.
46. Daughton D, Fortmann S, Glover E et al. The smoking cessation efficacy of varying doses of nicotine patch delivery systems 4 to 5 years post-quit day. Preventive Medicine. 1999, 28(2):113-118.
47. Hajek P, Mc Robbie H, Gillison F. Dependence potencial of nicotine replacement treatments: Effects of product type, patient characteristics, and cost to user. Prev Med.
2007;44(3):230-4
48. Stead L, Lancaster T. *Intervenciones para reducir los danos causados por el consumo continuo de tabaco*. 2007. Cochrane Library Issue (4)
49. Piper M, Federman E, McCarthy D et al. Efficacy of bupropion alone and in combination with nicotine gum. Nicotine &Tobacco Research, 2007; 9(9):947-54
50. Covey L, Glassman A, Jiang H et al. A randomized trial of bupropion and/or nicotine gum

as maintenance treatment for preventing smoking relapse. Addiction 2007; 102(8):1292-302.
51. Hays T, Hurt R, Rigotti N. Sustained-Release bupropion for Pharmacologic Relapse Prevention after Smoking Cessation: A Randomized, Controlled Trial. Ann. Med. Int. 2001, 135:423-433.
52. Sanderson L, Patten Ch, Niaura R et al. Efficacy of bupropion for relapse prevention in smokers with and without a past history of major depression. J. Gen Intern. Med. 2004; 19:828-834.
53. Wu P, Wilson K, Dinoulas P et al. Effectiveness of smoking cessation therapies: A systematic review and meta-analysis. BMC Public Health. 2006; 6(1):300.
54. Filozof C, Fernandez Pinilla M, Fernandez-Cruz A. Smoking cessation and weight gain. Obes Rev. 2004 May;5(2):95-103
55. Fromm P, Melamed S, Benbassat J. Smoking cessation and weight gain. J Fam Pract. 1998 Jun;46(6):460-4
56. Eisenberg D, Quinn B. Estimating the effect of smoking cessation on weight gain: an instrumental variable approach Health Serv Res. 2006; 41(6):2255-66.
57. Nerin I, Beamonte A, Gargallo P et al. Weight gain and anxiety levels in recent ex-smokers Arch Bronconeumol. 2007; 43(1):9-15
58. Pisinger C, Jorgensen T. Waist circumference and weight following smoking cessation in a general population: the Inter99 study. Prev Med. 2007;44(4):290-5
59. Chinn S, Jarvis D, Melotti R et al. Smoking cessation, lung function, and weight gain: a follow-up study. The Lancet, 2005; 365(9471):1629 – 1635
60. Haustein KO. Cigarette smoking, nicotine and pregnancy. International Journal of Clinical Pharmacology and Therapeutics. 1999; 37(9):417–27.
61. Slotkin TA. Fetal nicotine or cocaine exposure: Which one is worse? Journal of Pharmacology and Experimental Therapeutics. 1998; 285(3):931–45.
62. Ahlsten G, Cnattingius S, Lindmark G. 1993. Cessation of smoking during pregnancy improves foetal growth and reduces infant morbidity in the neonatal period. A population based prospective study. Acta Paediatrica. 82(2):177–81.
63. Benowitz N, Dempsey D. Pharmacotherapy for smoking cessation during pregnancy. Nicotine & Tobacco Research. 2004; 6(2):S189–202.
64. Dempsey DA, Benowitz NL. Risks and benefits of nicotine to aid smoking cessation in pregnancy. Drug Safety. 2001; 24(4):277–322.
65. Lumley J, Oliver S, Chamberlain C, Oakley L. Interventions for promoting smoking cessation during pregnancy. 2006. Cochrane Database of Systematic Reviews (2).
66. Parker D, Windsor R, Roberts M, et al. Feasibility, cost, and cost-effectiveness of a telephone-based motivational intervention for underserved pregnant smokers. Nicotine & Tobacco Research. 2007; 9(10): 1043 – 1051.
67. Pollak K, Oncken Ch, Lipkus I. Nicotine replacement and behavioral therapy for smoking cessation in pregnancy. Am J Prev Med 2007; 33(4):297–305.
68. National Counsel on Drugs, Uruguay. National Department of Drugs. Centers for Disease Control. Pan American Health Organization. World Health Organization. *Tabaquismo. Consumo en el ambito de la Ensenanza Media (GYTS). Informe de Investigacion.* Uruguay 2006.
69. National Counsel on Drugs. Presidency of the Republic. Uruguay. 2nd National survey on drug use among studets in secondary education. 2006. Available on line at:
http://www.infodrogas.gub.uy/html/encuestas/documentos/Encuesta_CDEEM.pdf
70.Becona E., Palomares A., Garcia M. *Tabaco y Salud. Guia de Prevencion y Tratamiento del Tabaquismo*. Ed. Piramide, Madrid 1994
71.Vallerant, J, Les Fondements de la Psychologie Sociale, Gaetan Morin Editeur, Quebec 1994: 888p
72. DiFranza J, Pbert L, Flint A et al. Intervention for adolescents: a randomized, controlled trial effect of a pediatric practice-based smoking prevention and cessation Pediatrics. 2008;121:e738-e747
73. Grimshaw G, Stanton A, Lancaster T. Tobacco cessation interventions for young people. 2006. Cochrane Database of Systematic Reviews (2).

74. Muramoto M, Leischow S, Sherrill D. Randomized, double-blind, placebo-controlled trial of 2 dosages of sustained-release bupropion for adolescent smoking cessation. Arch Pediatr Adolesc Med. 2007; 161(11):1068-1074
75. MHRA. 2005. Report of the committee on safety of medicines working group on nicotine replacement therapy: medicines and healthcare products regulatory agency, committee on safety of medicines.
76. McRobbie H, Hajek P. 2001. Nicotine replacement therapy in patients with cardiovascular disease: guidelines for health professionals. Addiction. 96(11):1547–51.
77. Rigotti N, Munafo M, Stead L. *Intervenciones para el abandono del habito de fumar en pacientes hospitalizados* (Cochrane Revision translated). In: La Biblioteca Cochrane Plus, 2007 Numero 4.
78. Moller A, Villebro N. Interventions for preoperative smoking cessation. 2006. Cochrane Database of Systematic Reviews (2).
79. Moller A, Tonnesen H. Risk reduction: Perioperative smoking intervention. Baillieres best Practice & Research in Clinical Anaesthesiology. 2006; 20(2):237–248.
80. McNeill A. 2002. Smoking and Mental Health. London: ASH.
81. Breslau N, Kilbey M, Andreski P. Nicotine dependence, major depression, and anxiety in young adults. Archives of General Psychiatry. 1991; 48(12):1069–74.
82. Haug N, Hall S, Prochaska J et al. Acceptance of nicotine dependence treatment among currently depressed smokers. Nicotine & Tobacco Research. 2005; 7(2):217–24.
83. De Leon J, Diaz FJ. A meta-analysis of worldwide studies demonstrates an association between schizophrenia and tobacco smoking behaviours. Schizophrenia Research. 2005; 76(2–3):135-57.
84. Ranney L, Melvin C, Lux L et al. Systematic review: smoking cessation intervention strategies for adults and adults in special populations. Annals of Internal Medicine. 2006; 145(11):845–56.
85. Bradshaw T, Lovell K, Harris N. Healthy living interventions and schizophrenia: a systematic review. Journal of Advanced Nursing. 2005; 49(6):634–54.
86. George T, Vessicchio J, Termine A et al. A placebo controlled trial of bupropion for smoking cessation in schizophrenia. Biological Psychiatry. 2002; 52(1):53–61.
87. Evins A, Cather C, Deckersbach T et al. A double-blind placebo-controlled trial of bupropion sustained-release for smoking cessation in schizophrenia. Journal of Clinical Psychopharmacology. 2005; 25(3):218–25.
88. Glassman A, Covey L, Dalack G et al. Smoking cessation, clonidine, and vulnerability to nicotine among dependent smokers. Clinical Pharmacology and Therapeutics. 1993; 54(6):670–9.
89. Zevin S, Benowitz N. Drug interactions with tobacco smoking. Clinical Pharmacokinetics. 1999; 36:425–438.
90. Sussman S.. Smoking cessation among persons in recovery. Substance Use & Misuse. 2002; 37(8–10):1275–98.
91. Prochaska J, Delucchi K, Hall S. A meta-analysis of smoking cessation interventions with individuals in substance abuse treatment or recovery. Journal of Consulting and Clinical Psychology. 2004;72(6):1144–1156.
92. Joseph A, Willenbring M, Nugent S, Nelson D. A randomized trial of concurrent versus delayed smoking intervention for patients in alcohol dependence treatment. Journal of Studies on Alcohol. 2004; 65(6):681–91.
93. Joseph A, Nichol K, Anderson H. Effect of treatment for nicotine dependence on alcohol and drug treatment outcomes. Addictive Behaviours. 1993; 18(6):635–44.
94. Croghan IT, Hurt R, Dakhil S et al. Randomized comparison of a nicotine inhaler and bupropion for smoking cessation and relapse prevention. Mayo Clin Proc. 2007; 82(2):186-95
95. Shiffman S, Dresler C, Rohay J. Successful treatment with a nicotine lozenge of smokers with prior failure in pharmacological therapy. Addiction. 2004; 99(1):83–92.
96. Gonzales D, Nides M, Ferry L et al. Bupropion SR as an aid to smoking cessation in smokers treated previously with bupropion: a randomized placebo-controlled study. Clinical Pharmacology and Therapeutics. 2001; 69(6):438–44.
97. Durcan M, White J, Jorenby D et al. Impact of prior nicotine replacement therapy on smoking cessation efficacy. American Journal of Health Behavior. 2002; 26(3):213–20

98. Hughes J, Carpenter M. Stopping smoking: carpe diem? Tobacco Control. 2006; 15(5):415–6.
99. National Institute for Clinical Excellence. Guidance on the use of Nicotine Replacement Therapy (NRT) and Bupropion for smoking cessation. 2002. London: National Institute for Clinical Excellence.
100. West R, Willis N. Double-blind placebo controlled trial of dextrose tablets and nicotine patch in smoking cessation. Psychopharmacology. 1998; 136(2):201–4.
101. West R, May S, McEwen A, McRobbie H, Hajek P. A randomised trial of glucose tablets to aid smoking cessation. Unpublished [a].
102. Hughes JR, Stead LF, Lancaster T. Anxiolytics and antidepressants for smoking cessation. Cochrane Database Syst Rev 2000
103. Abbot N, Stead L, White A, Barnes J. Hypnotherapy for smoking cessation. 2006. Cochrane Database of Systematic Reviews(2).
104. White A, Rampes H, Campbell J. Acupuncture and related interventions for smoking cessation. 2006. Cochrane Database of Systematic Reviews (2).

12 Appendices

1. Benefits of stopping smoking
2. Support services to stop smoking
3. Assessing nicotine dependence
4. Prescribing information for Nicotine Replacement Therapy
5. Prescribing information for Bupropion
6. Prescribing information for Varenicline
7. Prescribing information for Nortriptyline
8. Adverse event report form
9. Tobacco and dental pathology

Appendix 1: Benefits of stopping smoking

See what you gain as the days or months go by without smoking:

1 day

- Your blood pressure and heart rate drop
- Your blood oxygen levels normalize
- Most of the carbon monoxide and nicotine are eliminated

3 days

- You start to regain your sense of taste and smell
- Your bronchial tubes recover their cleaning mechanisms

1 to 3 months

- You breath more easily
- You stop coughing
- Your capacity for physical exercise increases
- The appearance of your skin improves
- You feel you have more energy

1 year

- The risk of heart attack is reduced by 50%

5 years

- The risk of cancer of the mouth, esophagus, and bladder is reduced by 50%

10 years

- The risk of lung cancer is reduced by 50%

15 years

- The risk of death is comparable to someone who has never smoked.

In addition, quitting smoking:

- Improves your family's health
- Raises your self esteem and self confidence
- Sets a good example for your children
- Helps you save money
- Improves your domestic hygiene

Appendix 2 – Support services to stop smoking.

http://www.msp.gub.uy

http://fnr.gub.uy

http://urucan.org.uy

MSP information helpline –0800-4444

Appendix 3 – Assessing nicotine dependence

FAGERSTRÖM TEST *These questions are designed to assess nicotine dependence*		
1- How many cigarettes a day do you smoke?	**> 30**	**3**
	21 to 30	**2**
	11 to 20	**1**
	< 11	**0**
2- Do you smoke more in the first three hours after	**YES**	**1**
You get up than in the rest of the day?	**NO**	**0**
3- How long after you wake up do you smoke your	**< 5 minutes**	**3**
first cigarette?	**6 to 30 min**	**2**
	31 to 60 min	**1**
	> 60 minutes	**0**
4- Which cigarette is hardest for you to skip?	**The first**	**1**
	Another	**0**
5- Is it hard for you not to smoke in places where it's	**YES**	**1**
prohibited?	**NO**	**0**
6- Do you smoke if you're so sick you have stayed in	**YES**	**1**
bed most of the day?	**NO**	**0**

INTERPRETATION OF SCORE (total)
0 - 3 MILD DEPENDENCE
4 - 6 MODERATE DEPENDENCE
7 - 10 HEAVY DEPENDENCE

Appendix 4 – Prescription information for Nicotine Replacement Therapy

All NRTs	**Contraindications:** Acute vascular events in the last 2 weeks: IAM, stroke, severe symptomatic chronic obstructive arteriopathy of LL. Hypersensitivity to nicotine Acute gastro-duodenal ulcer For gum: oropharyngeal lesions, temporal maxillar arthritis **Precautions:** Pregnancy and breastfeeding (see special groups) Adolescents (see special groups) Uncontrolled arterial hypertension Hyperthyroidism
Transdermal patches	- **Pharmaceutical form in Uruguay**: 24-hour patches, in 3 concentrations: 7, 14, and 21 mg. Sale on prescription. - **Usage mode:** Treatment should not be started with patient smoking. Use one patch per day, on a non-pilose area of the skin, rotating placement site. Use for at least 8 weeks. The initial dose is chosen based on level of dependence. In patients who smoke more than 20 cig/day it is recommended to start with 21 mg patches for 1 month and use progressively smaller doses in the next 2 months. - **Advantages**: easy to use. Maintains a constant level of nicotine in blood. - **Side effect:** the most common is skin irritation.
Chewing gum	- **Pharmaceutical form in Uruguay:** 2 and 4 mg gum. Over the counter sale. - **Usage mode:** treatment can be started with patient smoking. Patients may use up to 15, 2 mg pieces of gum per day administered regularly and/or in place of cigarettes, anticipating the urge to smoke. Treatment with chewing gum should be maintained for at least 8 weeks. - Use of 4 mg gum is proposed in patients with high level of dependence. - Each piece should be chewed slowly and "parked" in the cheek at regular intervals, for 40 minutes. Incorrect use of these products can cause side effects. Concomitant intake of food or beverages is to be avoided. - **Advantages:** can be used on demand at times of greatest need**.** - **Side effects:** oropharyngeal and gastric irritation, nausea, hiccup.
Combined treatment	The combination of patches and gum increases the rate of abstinence in patients with severe dependence. Thus, users receive a constant nicotine supplement from the patch and can get a rapid burst of nicotine from the chewing gum.

Appendix 5 – Prescribing information for Bupropion

Pharmaceutical form in Uruguay

Pharmaceutical Form in Uruguay	Bupropion HCL SR 150 mg tablets.
Contraindications	- Epilepsy or antecedent of seizures of any etiology. - Predisposition to seizures: history of severe ECT, CNS tumor, abrupt interruption of alcohol or benzodiazepines. - Bulimia / anorexia nervosa (current or prior). - Bipolar disorder - Use of IMAO within 14 days prior. - Diabetes or decompensated HBP. - Concomitant use of preparations containing Bupropion. - Pregnancy and breastfeeding. - persons under age 18 years.
Precautions	- History of psychiatric illness - Liver or kidney failure. - Diabetes. - Alcohol abuse. - Elderly persons (see below).
Pharmacological Interactions	- Drugs that lower the convulsive threshold (including antipsychotics, antidepressants, antimalarics, tramadol, theophylin, systemic steroids, quinolones, antihistaminics with sedative effect). - Drugs that affect CYP2B6 (including orfenadrine, cyclophosphamide, isofamide, ticlopidine, clopidogrel). - Substrates of CYP2D6 (including antidepressants, antipsychotics, beta blockers, type 1C antiarrhythmics, stimulants). - Anorexigenic drugs. - Citalopram. - Carbamazepine. - Phenobarbitol. - Phenytoin. - Levodopa. - Amantadine. - Ritonavir.
Usage mode	- Days 1 through 5: one tablet (150 mg) per day; from day 6: one tablet twice daily, separating each dose by at least 8 hours. It is recommended not to ingest at night as it can cause difficulty sleeping. - Medication should be started 14 days before the planned quitting date. - It is recommended continue treatment for 2-3 months. - Elderly persons: a 150 mg dose once daily is recommended. - Kidney / liver failure: 150mg once daily is recommended. - Diabetes: if patient uses insulin or oral hypoglucemiants close control of glycemia is required due to the risk of seizures due to hypoglycemia
Adverse effects	- Common (occur in less than 1:100): dry mouth, insomnia, nausea, headache. - Infrequent (occur in between 1: 10000 and 1:1000): seizures, severe hypersensitivity.

Appendix 6: Prescribing information for Varenicline

Pharmaceutical Form in Uruguay	- 0.5 and 1 mg pills. Starter and maintenance set.
Contraindications	- Persons under age 18 years. - Pregnancy and breastfeeding.
Precautions	- Kidney failure, requires dose adjustment. - Patients with history of psychiatric illness, particularly depression. - There is no experience with use of varenicline in epileptic patients. - There is an FDA alert on its use.
Pharmacological Interactions	- There are not sufficient studios at the time of publication of this guide. Publication of evidence is expected.
Usage mode	- Start with varenicline for at least one week before the planned quitting date. - Days 1-3: 0.5 mg once daily; days 4-7: 0.5 mg twice daily; day 8 through end of treatment (12 weeks): 1 mg twice daily.
Dose adjustment	- Persons who do not tolerate the adverse effects may lower the dose temporarily or permanently to 0.5 mg twice daily. - It is not necessary to adjust the dose in persons with mild (estimated creatinine clearance > 50ml/min and ≤80ml/min) to moderate (estimated creatinine clearance ≥30ml/min and ≤50ml/min) kidney failure - In patients with severe kidney failure (estimated creatinine clearance <30ml/min) the recommended dose is 1mg once daily. - Use of varenicline is not recommended in patients with end stage kidney disease.
Adverse effects	- The most common adverse effect is nausea (experienced by 30% of patients). In most cases, nausea appears at the start of treatment, is mild to moderate, and is rarely cause for discontinuation of treatment. - Sleep disorders (vivid dreams) - Constipation. - Most of the symptoms were reported as mild and disappeared in a few weeks.

Appendix 7: Prescribing information for Nortriptyline

Contraindications	- Hypersensitivity to other tricyclic antidepressants - Discontinuation of IMAO (within the previous 14 days) - Recovery phase after an AMI - Pregnancy and breastfeeding - Children <12 years
Precautions	- Pre-treatment ECG, monitor BP - Suicidal thoughts - Bipolar disorder; patients with agitation, hyperactive - Cardiovascular disease - Hyperthyroidism - Glaucoma - History of urinary retention, - Traumatism of skull, seizures - Diabetes - Alcoholism - Recent surgery - Elderly persons - Women of sexually active age - Children < 18 years
Pharmacological Interactions	- Alcohol - Sedatives, cimetidine, reserpine, anticolinergics, antihistaminics sedatives, simpaticomimetics, stimulants, anorexigenic drugs, guanetidine, CYP2D6 substrates, inhibitors, for example other antidepressants, phenothiazines, carbamazepine, class 1C antiarrhythmics, quinidine; drugs that lower the convulsive threshold, for example antipsychotics, tramadol, theophylin, steroids, quinolones; insulin, oral hypoglucemiants; thyroidal hormones.
Dosage	- Adults: Start with 25 mg/day, start 10 to 28 days before the quitting date; gradually increase to 75-100 mg/day over 10- 35 days; continue for 12 weeks. - The dose should be lowered gradually at the end of the treatment to avoid symptoms that may appear if treatment is discontinued abruptly.
Dose adjustment	- Elderly persons: reduce dosage frequency.
Adverse effects	- Drowsiness, gastrointestinal disorders, medullar depression, anticolinergic effects, confusion, hallucinations, restlessness, anxiety, lack of coordination, seizures, extrapyramidal symptoms, allergic reactions, changes in glycemia, hypo/hypertension; IAM; arrhythmias; stroke; hepatitis; serotoninergic syndrome

Appendix 8: Adverse event report form

See instructions and electronic version of the form at
http://www.msp.gub.uy/categoria_108_1_1.html

Appendix 9: Tobacco and dental pathology.

Chronic White Lesions associated with and/or aggravated by smoking.

Frictional keratosis: Whitish lesion, usually located on the lower lip, caused by mechanical aggression, (added to thermal and chemical aggression), produced by holding the cigarette in the same place.

Solar keratosis Is fairly common in Uruguay, and is observed as an alteration of color and consistency of the labial mucosa (lips lighter in color, cracked, hardened), manifesting more commonly in Caucasian men and women, with light skin and eyes, due to prolonged exposure to the sun.

Leukoplakia: A premalignant lesion, with risk of malignization between 4 and 17%. Appears as a painless, white spot, commonly located on the tongue, more frequently in males and in tobacco consumers.
In Uruguay in the year 2005, Beovide found a 5% prevalence of Leucoplakia in men between 40 and 60 years of age.
Stopping smoking for a year can cause the lesion or lesions to disappear up to 60%.

Nicotinic Stomatitis: Manifests as a change in color and consistency of the
Mucus membranes, usually of the palate (appearance of swollen and/or reddened gums), which is usually caused by pipe smoked tobacco, as the smoke goes directly to the palate. It can also be seen in other forms of tobacco consumption.

Lichen Planus: Manifests as a white lesion, with a web-like appearance, located on the mucus membrane of the cheeks. Tobacco can aggravate, but not cause, the lesion.