An Roinn Sláinte
Department of Health

Stop Smoking

National Clinical Guideline No. 28

SUMMARY January 2022

National Patient Safety Office
Oifig Náisiúnta um Shábháilteacht Othar

NATIONAL CLINICAL EFFECTIVENESS COMMITTEE

TFI Programme

This National Clinical Guideline has been developed by the Stop Smoking Guideline Development Group (GDG), within the Tobacco Free Ireland Programme, Strategy & Research, Healthcare Strategy*, Health Service Executive (HSE).

*Note: During the development of this guideline, some organisational changes occurred within the HSE. In 2017, at the beginning of this guideline development, the HSE Tobacco Free Ireland Programme was situated within the Strategic Planning & Transformation Division of the HSE. However, since June 2021, the HSE Tobacco Free Ireland Programme now sits within Strategy & Research, Healthcare Strategy within the HSE.

Using this summary National Clinical Guideline

This summary should be read in conjunction with the full version NCEC National Clinical Guideline. The full version is available at: https://www.gov.ie/en/collection/c9fa9a-national-clinical-guidelines/

The complete list of appendices can be found in the full version. Only the relevant appendices are in this summary and the same numbering has been retained in both versions.

This National Clinical Guideline applies to the general adult population (aged 18+ years) in Ireland in contact with health services who are current smokers, paying particular attention to pregnant women (all ages), and persons with severe and enduring mental health problems (aged 18+ years) who access secondary care services. This National Clinical Guideline is relevant to all healthcare professionals working in primary care settings, secondary care settings, and community care settings in Ireland.

Disclaimer

NCEC National Clinical Guidelines do not replace professional judgment on particular cases, whereby the clinician or health professional decides that individual guideline recommendations are not appropriate in the circumstances presented by an individual patient, or whereby an individual patient declines a recommendation as a course of action in their care or treatment plan. In these circumstances the decision not to follow a recommendation should be appropriately recorded in the patient's healthcare record.

Users of NCEC National Clinical Guidelines must ensure they have the current version by checking the relevant section in the National Patient Safety Office on the Department of Health website: https://www.gov.ie/en/collection/c9fa9a-national-clinical-guidelines/

Whilst every care has been taken to ensure that all the information contained in this publication is correct, the Department of Health cannot accept responsibility for any errors or omissions which may have occurred.

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Block 1,
Miesian Plaza,
50 - 58 Lower Baggot Street,
Dublin,
D02 XW14

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Membership of the Guideline Development Group (GDG)

The GDG was chaired by Dr Paul Kavanagh, Consultant in Public Health Medicine, Health Service Executive (HSE). This National Clinical Guideline is supported by the HSE Tobacco Free Ireland Programme, Strategy & Research, Healthcare Strategy, HSE.

Membership nominations were sought from a variety of clinical and non-clinical backgrounds so as to be representative of all key stakeholders. A number of national patient advocacy groups were contacted regarding patient representative membership as well as the HSE Quality Improvement Division panel of patient & family representatives. GDG members included those involved in clinical practice, administration, smoking cessation services, pharmacy, research methodology, as well as patient representatives. See Appendix 1 for Terms of Reference for GDG.

Table 1: Members of the Guideline Development Group

Name	Job title and affiliation
Dr Paul Kavanagh (Chair)	Consultant in Public Health Medicine, Health Intelligence, HSE
Martina Blake	National Lead, Tobacco Free Ireland Programme, HSE
Dr Ciaran Browne	Acute Operations, HSE
Elaine Buckley	National Tobacco Cessation Coordinator, HP&I, HSE
Annette Cuddy	Director, Centre of Nurse & Midwifery Education, HSE
Carmel Doherty	Smoking Cessation Nurse Specialist, St James's Hospital
Dr Frank Doyle	Senior Lecturer in Psychology, RCSI
Catherine Halloran	Assistant Director of Midwifery & Nursing, Rotunda Hospital
Dr David Hanlon	National Clinical Advisor and Group Lead for Primary Care, HSE
Áine Lyng	Cancer Prevention Officer, National Cancer Control Programme
Clare MacGabhann	Director of Nursing and Midwifery (Nurse and Midwife Prescribing) Office of the Nursing and Midwifery Services Director, HSE
Stephen McMahon	Patient Representative, Irish Patients Association
Dr Deirdre Mulholland	Director of Public Health, HSE-East
Edward Murphy	Project Manager, Tobacco Free Ireland Programme, HSE
Damien Nee	Patient Representative
Dr Siobhan Ni Bhriain	National Clinical Advisor and Group Lead for Mental Health, HSE
Dr Brian Osborne	Assistant Medical Director, ICGP
Roisin Cunniffe	PSI-The Pharmacy Regulator
Joan O'Sullivan	Smoking Cessation Officer, Health Promotion & Improvement, HSE South
Dr Naomi Petty-Saphon	Specialist Registrar in Public Health Medicine, HSE
Trevor Phillips	Assistant Director of Nursing, Laois/Offaly Mental Health Services, CHO8 Midlands Louth Meath

Dr Keith Ian Quintyne	Consultant in Public Health Medicine, HSE-North East
Aishling Sheridan	Evidence & Information Officer, Tobacco Free Ireland Programme
Prof Michael Turner	Director UCD Centre for Human Reproduction at the Coombe Women and Infants University Hospital.

* Ger Cully & Kate Cassidy previously represented Health Promotion & Improvement on this group.
** Conor O'Leary & Mary Mockler previously represented PSI-The Pharmacy Regulator on this group.
***Barry Hurley, Patient Representative, Irish Advocacy Network participated to Dec 2018.

Credits

The role of the NCEC is to prioritise, quality assure and recommend clinical guidelines to the Chief Medical Officer for endorsement by the Minister for Health. It is intended through ministerial endorsement that full implementation of the guideline will occur through the relevant service plans.

The NCEC and the Department of Health acknowledge and recognises the Chair and members of the Guideline Development Group (GDG) for development of the guideline. The NCEC and Department of Health wish to express thanks and sincere gratitude to all persons contributing to this National Clinical Guideline; especially those that give their time on a voluntary basis.

Acknowledgments

The Chair of the GDG, Dr Paul Kavanagh wishes to acknowledge the following as contributors to the development of NCG:

- HIQA shared its HTA of smoking cessation interventions and Dr Pat Moran and Dr Conor Teljeur provided further advice on this HTA to inform and support guideline development;
- Dr Keith Ian Quintyne, Consultant in Public Health Medicine, HSE, conducted the search and selection of candidate clinical guidelines for adaption;
- Candidate guideline appraisal using the AGREE Instrument was conducted by a task-end subgroup of the CPG comprising the following Dr Paul Kavanagh, Dr Keith Ian Quintyne, Ms Aishling Sheridan, Mr Edward Murphy, Dr Frank Doyle, Mr Barry Hurley, and Ms Aine Lyng and the following Specialist Registrars in Public Health Medicine: Dr. Aoife McKeating, Dr Sarah O'Brien, Dr Louise Marron, Dr Laura Heavey, Dr Eimear Burke, Dr Breda Cosgrave, and Dr Christopher Carroll.
- International guidelines which contributed to the evidence base for guideline development were shared with agreement by the following:
    - Ministry of Health, New Zealand,
    - US Preventative Services Task Force (USPSTF) and Agency for Healthcare Research and Quality (AHRQ), United States,
    - The Canadian Action Network for the Advancement, Dissemination and Adoption of Practice-informed Tobacco Treatment (CAN-ADAPPT), Canada,
    - World Health Organization, Geneva, Switzerland.
- Dr Keith Ian Quintyne and Dr Greg Martin, Consultants in Public Health Medicine, HSE, conducted a supplementary literature review on Carbon Monoxide Breath Testing in pregnancy;

- Dr Anne McCarthy, Ms Joan Quigley, Dr Doireann O'Brien, Dr Helen Kennelly, Ms Caitriona Lee, and Dr Jean Long, Health Research Board, presented draft findings of three literature reviews on e-cigarettes conducted for the Department of Health.
- The work of the GDG was significantly informed by key studies of smoking and quitting behaviour in Ireland:
    - Annette Burns, PhD, shared information on her 3 studies on smoking and mental health difficulties in Ireland exploring (1) Smoking prevalence and disease in people with mental health difficulties in Ireland (2) Smoking cessation care in a psychiatric setting in Ireland and (3) Implementation of a quit smoking programme in community mental health service in Ireland;
    - Ciara Reynolds, PhD candidate, University College Dublin, shared information on her studies of stop smoking services for pregnant women in Ireland;
    - Dr Naomi Petty-Saphon, Consultant in Public Health Medicine, HSE, shared information on her study of smoking and quitting behavior as measured by the Healthy Ireland surveys.
- Dr Helen McAvoy, Institute of Public Health in Ireland, provided advice regarding stop smoking services and health inequalities;
- The work of the GDG was also significantly informed by updates on key developments relevant to stop smoking services in Ireland:
    - Ms Bedelia Collins, HSE, provided advice on alignment of guideline implementation with HSE ICT project QuitManager to support stop smoking services;
    - Dr Maria O'Brien, HSE, provided further advice on alignment of guideline implementation with the Making Every Contact Count programme;
- Centre for Effective Services, in particular Ms Aisling Sheehan and Ms Riona Morris, provided training, advice and support on implementation science to support implementation planning;
- Dr Mark O'Loughlin and Dr Paul Mullane provided advice and support on designing monitoring and evaluation arrangements for the recommendations set out in the guideline.
- HRB-CICER provided training on Guideline Development using GRADE and, Ms Michelle O'Neill and Ms Susan Ahern at HRB-CICER conducted the Budget Impact Assessment;
- HSE Library Services through Ms Jean Harrison and Ms Dympna Lynch, supported with literature searching, including search updates in 2020;
- Dr Fenton Howell and Ms Claire Gordon, Tobacco and Alcohol Control Unit, Department of Health provided advice and support in relation to policy aspects of tobacco control in Ireland.
- Ms Pauline Dempsey, Dr Niamh O'Rourke & Ms Claudine Hughes, National Patient Safety Office, Department of Health, provided advice and support in relation to guideline development and National Clinical Effectiveness Committee procedures;
- Dr Eve O'Toole and Ms Helena Gibbons, National Cancer Control Programme (NCCP) provided advice and NCCP experience with guideline development; in addition, the Prostate Cancer Guideline Development Group, who kindly allowed members to sit-in on their meeting and observe proceedings;
- HSE Communications, in particular Ms Fidelma Browne and Ms Rachel Wright, provided advice and support regarding guideline consultation;
- Ms Sinead Skerry, Mr Gerard Cooke and Ms Ger Conway provided administrative support;

Dr Paul Kavanagh submitted the guideline proposal to the NCEC and successfully submitted the proposal/ guideline for NCEC prioritisation. Support throughout the development of the NCG was provided by Ms Aishling Sheridan, Evidence and Information Officer HSE Tobacco Free Ireland Programme and Mr Edward Murphy, Project Manager HSE Tobacco Free Ireland Programme. All authors approved the final guideline.

The external review carried out by Prof Ken Ward, Director of the Division of Social and Behavioral Sciences at University of Memphis and Prof Charlotta Pisinger, Professor in Tobacco Control, University of Copenhagen and the Danish Heart Foundation is acknowledged. We would like in addition to thank Ms Tina Neylon for her editorial support during preparation for publication.

A full list of members of the Guideline Development Group is available in the previous page/s.

Signed by the Chair(s)_____ Date: 8th of November 2021

National Clinical Guidelines

Providing standardised clinical care to patients in healthcare is challenging. This is due to a number of factors, among them diversity in environments of care and complex patient presentations. It is self-evident that safe, effective care and treatment are important in ensuring that patients get the best outcomes from their care.

The Department of Health is of the view that supporting evidence-based practice, through the clinical effectiveness framework, is a critical element of the health service to deliver safe and high-quality care. The National Clinical Effectiveness Committee (NCEC) is a Ministerial committee set up in 2010 as a key recommendation of the report of the Commission on Patient Safety and Quality Assurance (2008). The establishment of the Commission was prompted by an increasing awareness of patient safety issues in general and high-profile health service system failures at home and abroad.

The NCEC on behalf of the Department of Health has embarked on a quality assured National Clinical Guideline development process linked to service delivery priorities. Furthermore, implementing National Clinical Guidelines sets a standard nationally, to enable healthcare professionals to deliver safe and effective care and treatment while monitoring their individual, team and organisation's performance.

The aim of these National Clinical Guidelines is to reduce unnecessary variations in practice and provide an evidence base for the most appropriate healthcare in particular circumstances. As a consequence of Ministerial mandate, it is expected that NCEC National Clinical Guidelines are implemented across all relevant services in Irish healthcare.

The NCEC is a partnership between key stakeholders in patient safety. NCEC's mission is to provide a framework for national endorsement of clinical guidelines and clinical audit to optimise patient and service user care. The NCEC has a remit to establish and implement processes for the prioritisation and quality assurance of clinical guidelines and clinical audit so as to recommend them to the Minister for Health to become part of a suite of National Clinical Guidelines and National Clinical Audit. The aim of the suite of National Clinical Guidelines is to provide guidance and standards for improving the quality, safety and cost-effectiveness of healthcare in Ireland. The implementation of these National Clinical Guidelines will support the provision of evidence-based and consistent care across Irish healthcare services.

NCEC Terms of Reference

1. Provide strategic leadership for the national clinical effectiveness agenda.
2. Contribute to national patient safety and quality improvement agendas.
3. Publish standards for clinical practice guidance.
4. Publish guidance for National Clinical Guidelines and National Clinical Audit.
5. Prioritise and quality assure National Clinical Guidelines and National Clinical Audit.
6. Commission National Clinical Guidelines and National Clinical Audit.
7. Align National Clinical Guidelines and National Clinical Audit with implementation levers.
8. Report periodically on the implementation and impact of National Clinical Guidelines and the performance of National Clinical Audit.
9. Establish sub-committees for NCEC workstreams.
10. Publish an annual report.

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Glossary of abbreviations

The following abbreviations are used in this document

BA	Brief Advice
BCO	Breath carbon monoxide
BI	Brief Intervention
CES	Centre for Effective Services
CJF	Considered Judgement Form
DoH	Department of Health
EBI	Extended Brief Intervention
ENDS	Electronic Nicotine Delivery System
GDG	Guideline Development Group
GPP	Good Practice Point
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HI	Healthy Ireland
HIQA	Health Information Quality Authority
HRB	Health Research Board
HRB-CICER	Health Research Board – Collaboration in Ireland for Clinical Effectiveness Reviews
HSE	Health Service Executive
HTA	Health Technology Assessment
ICER	Incremental Cost-Effectiveness Ratios
MHC	Mental Health Commission
NCCP	National Cancer Control Programme
NCEC	National Clinical Effectiveness Committee
NRT	Nicotine Replacement Therapy
OECD	Organisation for Economic Co-operation and Development
RR	Risk Ratio
SCHEER	EU Scientific Committee on Health, Environment and Emerging Risks
SHS	Second-hand smoke
TFI	Tobacco Free Ireland
TFIP	Tobacco Free Ireland Programme
TPD	Tobacco Products Directive
WHO	World Health Organization
WHO FCTC	World Health Organization Framework Convention on Tobacco Control

1 National Clinical Guideline recommendations

1.1 Summary of recommendations

General Adult Population (aged 18+ years)

Recommendation 1:
All healthcare professionals should ask about and document individuals' smoking behaviour*,** Ensure this is updated regularly. ***

* See tools on taking a smoking behaviour history.
** Use local implementation process to identify and revise as needed recording tools and link with E-Chart.
*** Use implementation process and development of local PPG to define frequency which fits with local Service.

Quality/Level of Evidence: High **Strength of Recommendation: Strong**

Recommendation 2:
2.1 All healthcare professionals should advise all people who currently smoke about the harms of smoking for themselves and others and the benefits of quitting. Advise that help can be provided or arranged to support a quit attempt. Document the discussion and outcome.

2.2 Where someone is interested in quitting, discuss their treatment needs and preferences. Healthcare professionals should advise that making an unsupported quit attempt is less effective than using recommended supports. Record the outcome and provide or arrange treatment.

Quality/Level of Evidence: High **Strength of Recommendation: Strong**

Good practice points:

Healthcare professionals should consider the following:

- Relapse is a high risk for those who have quit. Evidence on supports to prevent relapse is mixed.
- Extending varenicline treatment for people who have quit using this medicine helps in preventing relapse but extending treatment with other medicines is of uncertain benefit.
- HSE stop smoking services can accept referrals for people who have quit and would like some support to remain smoke-free.
- Where someone is not currently interested in quitting, record this outcome. Consider discussing treatment at the next available opportunity, taking account of their needs and preferences.
- If someone who is not currently interested in quitting raises e-cigarettes, refer to GPPs for Recommendation 3 for points to use in discussion.

Policymakers, health service planners and health service managers should consider the following to support healthcare professionals to implement these recommendations:

- The continued implementation of comprehensive evidence- based tobacco control policy is required to increase the prevalence of positive intention to quit, the incidence of quit attempts and the incidence of supported quit attempts among smokers.
- Training and continuing professional development should be available to all healthcare professionals in settings specified in this guideline to build capacity and capability for implementation of these recommendations.

- Implementation of Tobacco Free Campus Policy and the Making Every Contact Count Framework in settings specified in this guideline will support the identification and treatment of tobacco addiction.
- Patient Administration Systems should be adapted and developed to facilitate the recording of smoking behaviour of service users and care processes provided in line with this guideline.

Recommendation 3:

3.1 For people, who are currently interested in quitting, all healthcare professionals should recommend that behavioural support, either alone or in combination with pharmacological supports, increases the chances of successful quitting. Behavioural support options are:

- Brief intervention (High, Strong);
- Individual or Group Counselling (High, Strong);
- Telephone support (High, Strong);
- Text messaging support (High, Strong) and
- Internet-based support (Moderate-Low, Conditional).

3.2 For people currently interested in quitting all healthcare professionals should recommend varenicline (alone or in combination with nicotine replacement therapy (NRT)) as first-line treatment in the absence of a contra-indication for those wishing to use pharmacological support.*

3.2.1 If varenicline is not suitable, combination NRT treatment should be recommended.*

3.2.2 NRT monotherapy, or bupropion (alone or in combination with NRT) or nortriptyline can also be recommended, but not as first-line.*

Quality/Level of Evidence: High **Strength of Recommendation: Strong**

* See prescribing tools and refer to Summary of Product Characteristics for further information.

Good practice points:

<u>Healthcare professionals should consider the following:</u>

Where someone is interested in quitting but does not wish to use recommended supports, record this outcome, and consider the following:

- Explain that supports are recommended on the basis of effectiveness, safety and accessibility through the health services. Encourage them in their quit attempt and remind them that support is accessible through the health services to increase their chances of success.
- Some people may choose to use other supports, not funded, or provided by the HSE, in their quit attempt and may raise these with a healthcare professional. The following points can be used in discussion:
  - There is no evidence that Acupuncture or Hypnotherapy are effective in helping people quit.
  - Evidence on the effectiveness of the Allen Carr Method is mixed but it does not appear to be more effective than intensive support offered free of charge by specialist stop smoking services.

- Some people may choose to use an e-cigarette to support them in their quit attempt or may consider switching from smoking to using an e-cigarette. The following points can be used in discussion of this choice:
  - E-cigarettes are consumer products. There is some regulation in place to protect consumers of e-cigarettes but not the same quality and safety system as would be in place for a licensed drug or medical device.
  - People who do not smoke or use e-cigarettes should not start.
  - For people who smoke and want to quit, advise them that there are a range of recommended and accessible support options with well-established effectiveness and safety profiles.
  - Smoking tobacco is extremely dangerous and, compared to this, e-cigarettes are likely to be less harmful. They are not harm-free and there is some uncertainty at the moment regarding their health impact.
  - Evidence regarding the effectiveness and safety profile of e-cigarettes as a stop smoking support is evolving.
  - To reduce the harm from smoking, dual use of tobacco and e-cigarettes should be avoided.
  - HSE stop smoking services can provide support to those who wish to use an e-cigarette to make an attempt to quit smoking.

Subgroup considerations – young people (under 18 years)

Smoking is a health risk for young people and may also indicate wider health and wellbeing needs.

- The evidence for effective support to young people to help them quit is limited.
- Behavioural and pharmacological supports recommended for the adult population may be considered for younger people with careful reference to product indications, licensing and side-effects.

Pregnant Women (all ages)

Recommendation 4:

4.1 Routinely offer pregnant women carbon monoxide breath testing at the first antenatal visit and at further visits if required. Provide information about the sources of carbon monoxide, the purpose of the test and opting-out, ensuring respect for women's preferences.

Quality/Level of Evidence: Moderate **Strength of Recommendation: Strong**

4.2 All Healthcare professionals should ask about and document the smoking behaviour* of pregnant women.** Ensure this is updated regularly as pregnancy progresses, on discharge and post-partum***.

Quality/Level of Evidence: High **Strength of Recommendation: Strong**

* See tools on taking a smoking behaviour history
** Use local implementation process to identify and revise as needed recording tools and link with E-Chart.
*** Use implementation process and development of local PPG to define frequency which fits with local service.

Good practice points:

<u>Healthcare professionals should consider the following:</u>

Relapse is a high risk for those who have quit. Pregnancy and the post-partum period may be a particular risk for women who have quit. Refer to GPPs for Recommendation 2 for points that may be helpful, paying regard to Prescribing Tools and the Summary of Product Characteristics in any decision regarding prescribing, especially in pregnancy.

Pregnant Women (all ages) (continued)

Recommendation 5:

5.1 All healthcare professionals should advise pregnant women who currently smoke about the harms of smoking for themselves, their babies and others and the benefits of quitting. Advise that help can be provided or arranged to support a quit attempt. Document the discussion and outcome. Routinely arrange referral to stop smoking services, while providing information about the purpose of the referral and opting-out, ensuring respect for women's preferences.

5.2 Where a woman is interested in quitting, discuss her treatment needs and preferences. Advise that making an unsupported quit attempt is less effective than using recommended supports. Record the outcome and provide or arrange treatment.

Quality/level of evidence: High **Strength of recommendation: Strong**

Good practice points:

Healthcare professionals should consider the following:

Where a woman is not currently interested in quitting, record this outcome. Discuss treatment at the next available opportunity, taking account of her needs and preferences.

Where a woman is not interested in quitting at the moment, there is increased risk of a poorer outcome for her pregnancy. Ensure the monitoring and management of her pregnancy is discussed and planned with her to take account of this risk.

Recommendation 6:

All healthcare professionals should provide women while pregnant and post-partum with information about the risks of second-hand smoke (SHS) exposure to pregnant women and babies, and how to reduce SHS in the home.

Quality/Level of Evidence: Low **Strength of Recommendation: Strong**

Recommendation 7:

7.1 All healthcare professionals should recommend to women currently interested in quitting that behavioural support increases the chances of successful quitting.

Quality/Level of Evidence: High **Strength of Recommendation: Strong**

7.2 All healthcare professionals should recommend that NRT be used during pregnancy and breastfeeding following a discussion of the potential benefits and risks.* Support the woman to make an informed choice regarding her stop smoking plan, ensuring respect for her preferences.

Quality/Level of Evidence: Low **Strength of Recommendation: Conditional**

* See prescribing tools and refer to Summary of Product Characteristics for further information.

Persons using Secondary Mental Health Settings

Recommendation 8:

Healthcare professionals in secondary mental health services should ask about and document individuals' smoking behaviour*, **. Ensure this is updated regularly. ***

Quality/Level of Evidence: High **Strength of Recommendation: Strong**

* See tools on taking a smoking behaviour history
** Use local implementation process to identify and revise as needed recording tools and link with E-Chart
***Use implementation process and development of local PPG to define frequency which fits with local service

Good practice points:

Healthcare professionals should consider the following:

Relapse is a high risk for those who have quit. Admission to an acute secondary mental health service may be a period of particular risk and the care plan can be drafted to reflect this. Refer to GPPs for Recommendation 2 for points that may be helpful, paying regard to Prescribing Tools and the Summary of Product Characteristics in any decision regarding prescribing.

Recommendation 9:

9.1 All healthcare professionals in secondary mental health services should advise those who currently smoke about the harms of smoking for themselves and others and the benefits of quitting. Advise that help can be provided or arranged to support a quit attempt. Specifically discuss the impacts of smoking and the benefits of quitting for mental health. Document the discussion and outcome.

9.2 Where someone is interested in quitting, discuss their treatment needs and preferences. Advise that making an unsupported quit attempt is less effective than using recommended supports. Record the outcome and provide or arrange treatment.

Quality/Level of Evidence: High **Strength of Recommendation: Strong**

Good practice points:

Healthcare professionals should consider the following:

Where someone is not currently interested in quitting, record this outcome. Consider discussing treatment at the next available opportunity, taking account of their needs and preferences.

Recommendation 10:

10.1 All healthcare professionals in secondary mental health services should, for people who are interested in quitting, recommend high intensity interventions combining behavioural and pharmacotherapy support following assessment and full therapeutic review. Behavioural support options are:

- Brief intervention;
- Individual or Group Counselling;
- Phone support;
- Text messaging support; and
- Internet-based support.

10.2 All healthcare professionals in secondary mental health services should recommend varenicline (alone or in combination with NRT) as first-line treatment in the absence of a contra-indication for those wishing to use pharmacological support;*

10.2.1 If varenicline is not suitable, combination NRT treatment should be recommended,*

10.2.2 NRT monotherapy, or bupropion (alone or in combination with NRT) or nortriptyline can also be recommended, but not as first-line.*

Quality/Level of Evidence: Moderate **Strength of Recommendation: Strong**

* See prescribing tools and refer to Summary of Product Characteristics for further information.

10.3 Monitor the person's mental health and pharmacotherapy carefully during the quit attempt and consider the need to adjust other medication dosages as appropriate.

Quality/Level of Evidence: High **Strength of Recommendation: Strong**

* Please refer to Section 3 for further information on these recommendations.

** Table 7 and Table 8 provide further details on the Quality/Level of Evidence used for these recommendations and the rationale for the strength of the recommendations used in this guideline.

2 Development of the National Clinical Guideline

2.1 Background

Tobacco use is the leading cause of preventable death, disease and disability worldwide, with the World Health Organization (WHO) describing it as one of the biggest public health threats the world has ever faced. More than 8 million people worldwide die each year as a direct result of tobacco use or from exposure to SHS, (*WHO, 2020a.*)

Recognition of the scale and global nature of the challenge led the WHO to successfully negotiate the first international treaty under its auspices, the WHO Framework Convention on Tobacco Control (WHO FCTC), (*WHO, 2003*). It was adopted by the World Health Assembly on 21 May 2003, came into force on 27 February 2005, and subsequently has been a landmark development in global cooperation for health. The WHO FCTC is a global tobacco control instrument, with legally binding obligations for its parties organised around the **MPOWER** framework of six evidence-based tobacco control measures: (*WHO, 2008*)

- **M**onitor tobacco use and prevention policies;
- **P**rotect people from tobacco smoke;
- **O**ffer help to quit tobacco use;
- **W**arn about the dangers of tobacco;
- **E**nforce bans on tobacco advertising, promotion and sponsorship;
- **R**aise taxes on tobacco.

Ireland ratified the treaty in 2005. Article 14 of the WHO FCTC addresses demand reduction measures concerning tobacco dependence and cessation and it requires that *"each party shall **develop and disseminate appropriate, comprehensive and integrated guidelines based on scientific evidence and best practices**, taking into account national circumstances and priorities, and shall take effective measures to promote cessation of tobacco use and adequate treatment for tobacco dependence."*

Ireland has a strong track record in tobacco control, which is recognised internationally, (*Joosens, 2020*). *Tobacco Free Ireland* is current government policy, and the second dedicated to tobacco control; it sets a bold target for Ireland to be tobacco-free (smoking prevalence <5%) by 2025, *(Department of Health, 2013). Tobacco Free Ireland* is also a key component of the government's current policy framework for public health, *Healthy Ireland, (Government of Ireland, 2013)*. The Health Service Executive (HSE) takes forward its responsibilities under *Tobacco Free Ireland* through the HSE Tobacco Free Ireland Programme (HSE TFIP), and its priorities and actions are set out in a Programme Plan 2018-2021, as summarised in Figure 1 (*HSE, 2018a*).

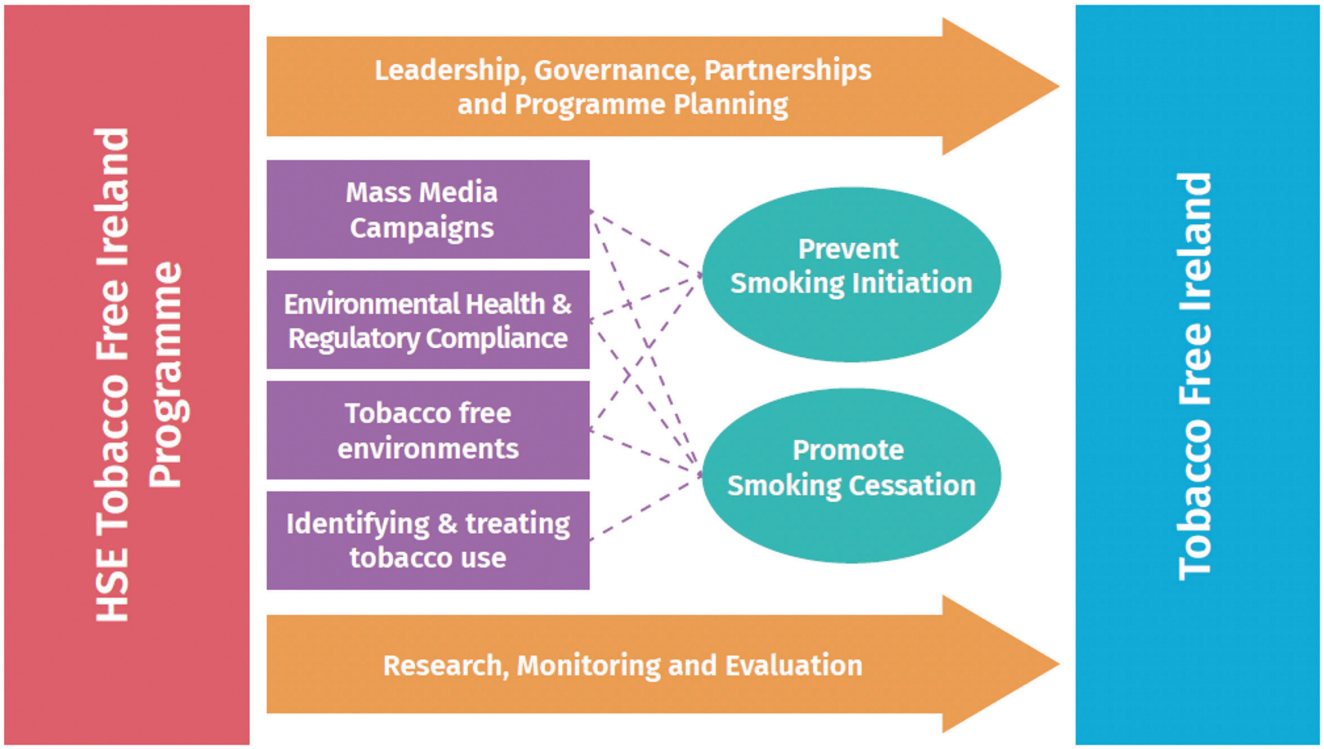


Figure 1: Overview of HSE Tobacco Free Ireland Programme

Stop smoking services are a key element of a comprehensive approach to tobacco control and their importance was highlighted by the WHO in its most recent report on the global tobacco epidemic, *(WHO, 2019)*. While initiation prevention is fundamental to tobacco control, Ireland's goal of becoming tobacco free by 2025 is critically dependent on accelerating progress with smoking cessation, *(Li, 2018)*. The benefit of stopping smoking to the individual and the public's health of quitting is unambiguous, *(US Department of Human Health Sciences, 2020)*. Quitting is beneficial at any age, improves health, the risk of premature death and can add as much as a decade to life expectancy. It reduces costs faced by the individual, by health services and by wider society. Critically, given that smoking is a driver of socio-economic differences in health, quitting is a key way of reducing health inequalities.

In Ireland most people who smoke want to quit: each year approximately 500,000 attempt stopping and 150,000 are successful, *(HSE, 2018c)*. The HSE provides and promotes a wide range of stop smoking services, ranging from online and social media supports, a National Smokers' phoneline, HSE quit clinics and courses, primary care supports provided by GPs, pharmacists and dentists, and tobacco dependence treatments. Across its services, in an average working day, the HSE supports over 1,500 people who are trying to stop smoking, *(HSE, 2018b)*.

A number of initiatives were undertaken by the HSE in recent years to develop and quality assure its stop smoking services, including the establishment of a Tobacco Free Campus Policy, a national standard for its stop smoking support programme and a range of associated tools and resources, *(HSE, 2012) (HSE, 2013a)*.

However, there was no National Stop Smoking Clinical Guideline to support the public, patients, healthcare professionals and health services to strengthen and scale-up quitting in Ireland.

Reflecting commitments in Tobacco Free Ireland and responsibilities under Article 14, WHO FCTC, to build on its work, the HSE TFIP prioritised the development of this National Stop Smoking Clinical Guideline. It provides evidence-based recommendations required for healthcare professionals across a range of settings, regarding the management of smoking cessation among the general adult population, adults in secondary mental health settings, and among pregnant women.

The remainder of this section details current smoking prevalence and trends in Ireland, demographic factors associated with smoking, international comparisons, as well as quitting intentions and quitting behaviours among those who have attempted to stop smoking recently. Refer to the HSE *State of Tobacco Control Report 2018* for more comprehensive and detailed overview, (*HSE, 2018b*).

2.1.1 Tobacco Use in Ireland

The Healthy Ireland Survey 2019 reported that 17% of Irish adults (aged 15+ years) currently smoke; 14% smoke daily and 3% smoke occasionally (*IPSOS MRBI, 2019*). In terms of numbers, this translates to approximately 665,000 adult smokers in Ireland in 2019 and compares with approximately 1,096,000 former smokers, meaning that there are now more quitters than smokers in Ireland. Men in Ireland are more likely to smoke than women; 19% of men compared to 16% of women. Smoking rates are highest among those aged 25-34 years (26%), see Figure 2 for further details.

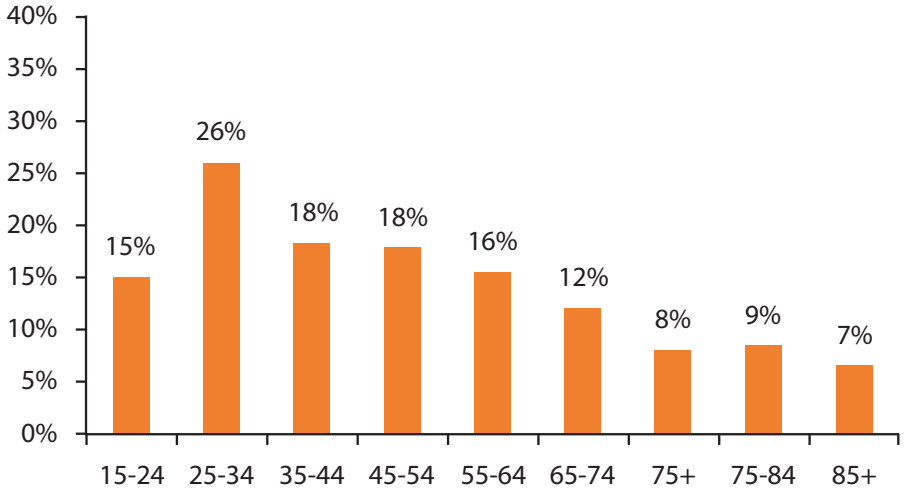


Figure 2: Current smoking prevalence by age, 2019

Source: Healthy Ireland Survey, 2019

Smoking is more common among people living in disadvantaged areas than among people living in more affluent areas (24% versus 14%), (*IPSOS MRBI, 2019*).

Internationally, Ireland ranks mid-range with daily smoking prevalence of 17% (2017), see Figure 3, (*OECD, 2020*).

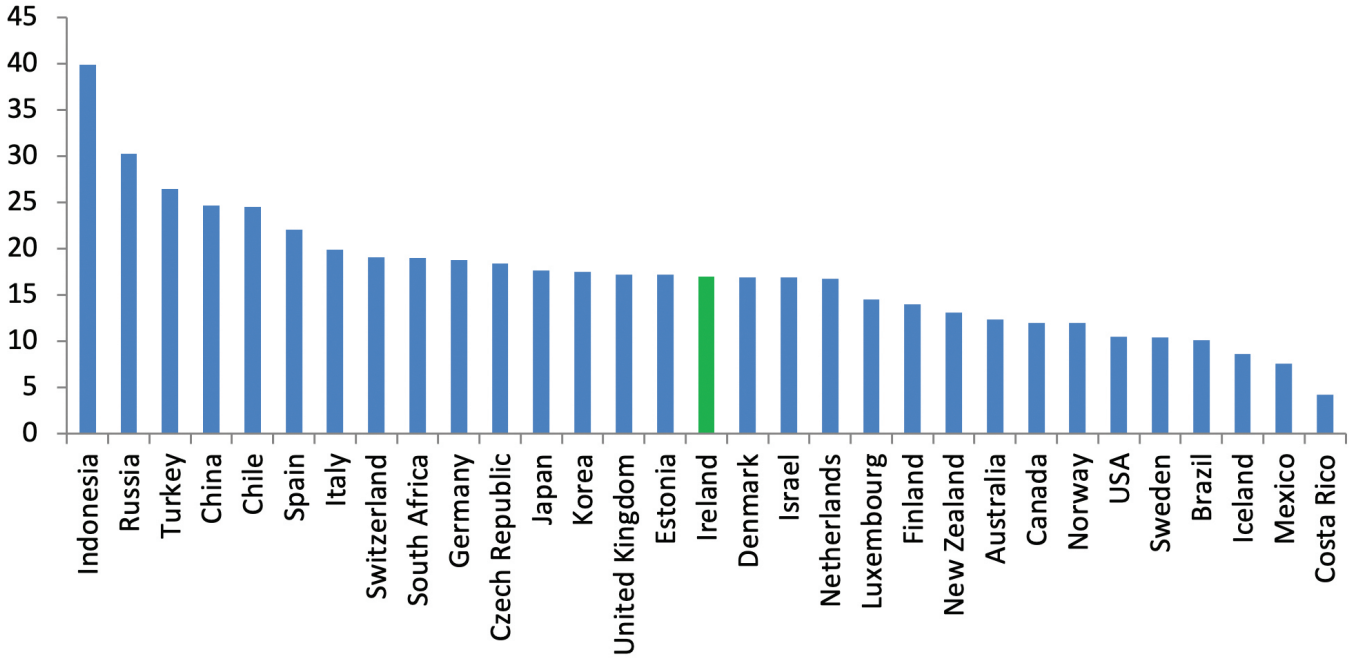


Figure 3: Prevalence of daily smoking among adults, International comparison, 2017*

Source: OECD Health Statistics 2020

* Note: 2017(or nearest year)

In recent years the proportion of adults who reported currently smoking reduced from 23% in 2015 to 17% in 2019, see Figure 4.

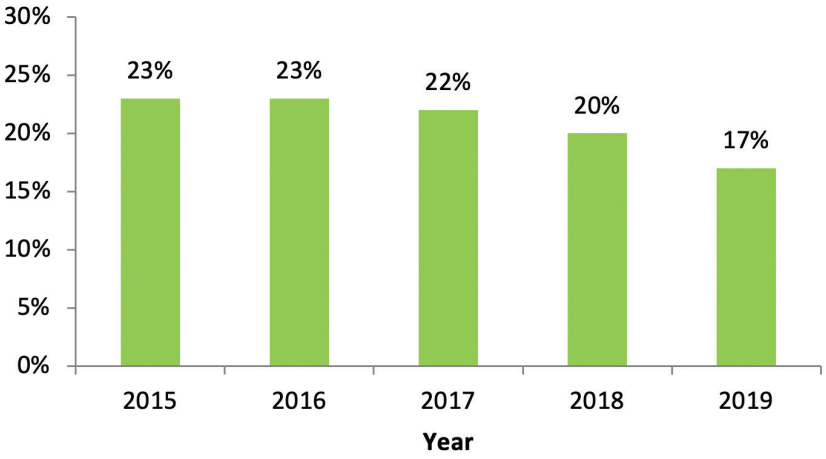


Figure 4: Trend in smoking prevalence 2015 – 2019

Source: Healthy Ireland Survey, 2015, 2016, 2017, 2018 & 2019

The HSE *State of Tobacco Control* report has previously detailed trends across population groups and shown that the pace of progress is uneven: the prevalence of smoking has reduced more quickly among women, younger people and those in higher social classes, (*HSE, 2018b*).

2.1.2 Quitting Intention and Behaviours

In 2019, 40% of current smokers had tried to quit during the past year, and 28% were either trying to quit or actively planning to do so *(IPSOS MRBI, 2019)*. Previous detailed analyses of Healthy Ireland Survey data by the HSE TFIP have shown that males and females were equally likely to make a quit attempt, however quit attempts were more likely among younger age-groups and among those in higher occupational classes, see Figure 5, *(HSE, 2018b)*.

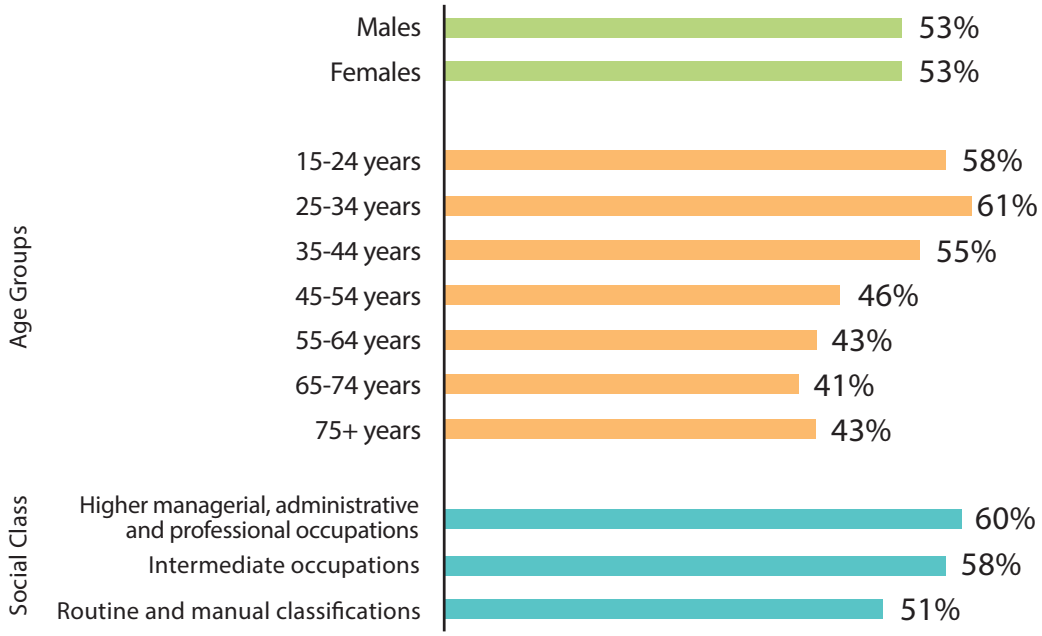


Figure 5: Profile of people who made a quit attempt in the 12 months prior to survey

Source: The State of Tobacco Control in Ireland, 2018

While most of those who made a quit attempt did so due to concerns about their own health (67% in 2019), low proportions of smokers who recently met with a health professional reported that they discussed quitting smoking with that health professional, as detailed in Figure 6 (*IPSOS MRBI, 2018*).

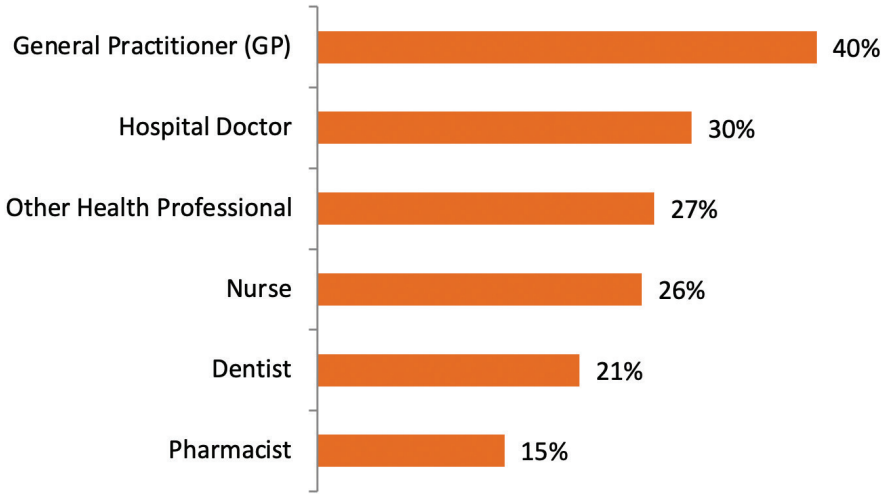


Figure 6: Proportion of smokers who have discussed quitting with a Health Professional, 2018

Source: Healthy Ireland Survey 2018

Just over half (52%) of those who quit smoking recently did so through willpower alone, (*IPSOS MRBI, 2019*). Few quitters are using evidence-based prescribed medications, nicotine replacement products and HSE stop smoking services (including phone support and other channels). Figure 7 displays recent trends in the prescription of medication-based smoking cessation support to medical card holders; over this period, the dispensing of bupropion and varenicline remained low and dispensing of nicotine replacement products has declined.

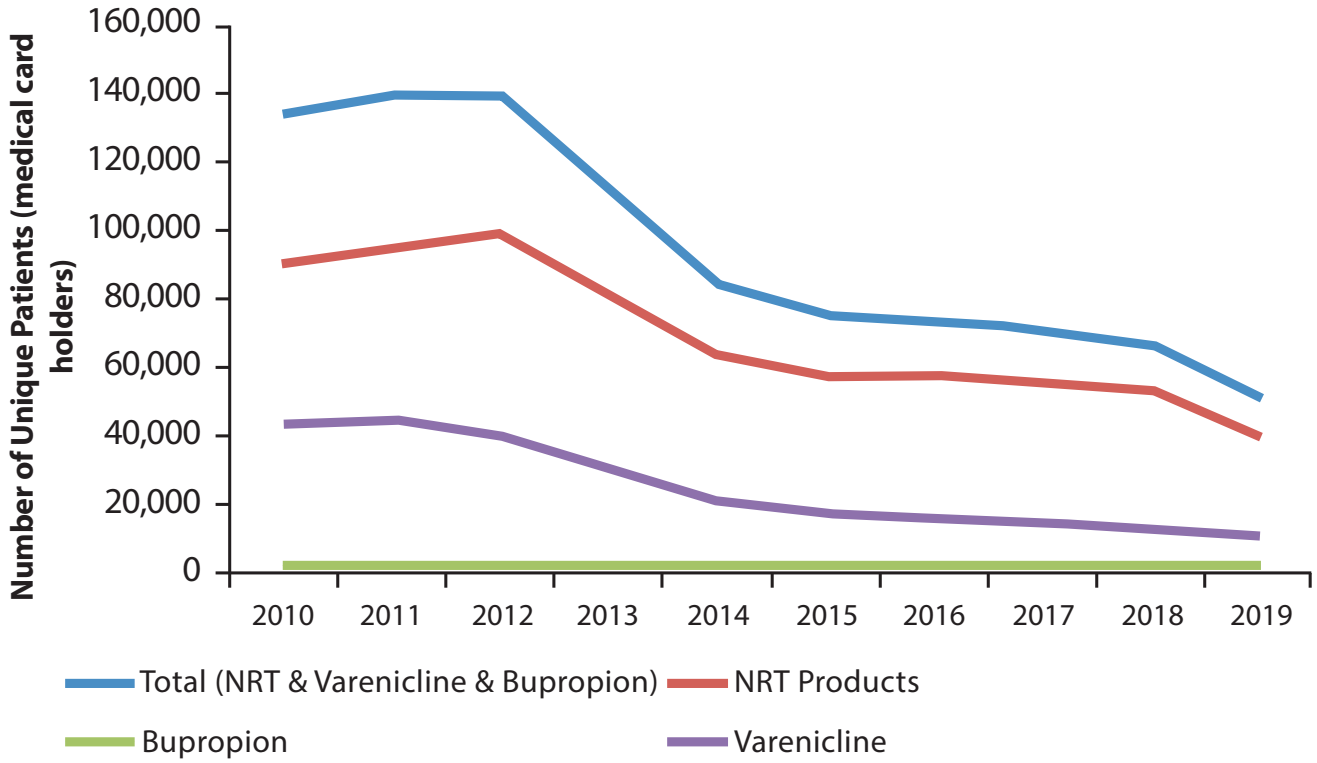


Figure 7: Trends in number of unique patients (medical card holders only) availing of NRT and other stop smoking medications, 2010 to 2019

Source: Primary Care Reimbursement Service (PCRS), April 2018 & July 2020 by request

E-cigarettes, also known as electronic nicotine delivery systems (ENDS), are electronic devices that heat a liquid (that can contain nicotine) to produce an aerosol which is then inhaled by the user. In Ireland, e-cigarettes are generally sold over the counter in retail premises; no product currently has a licensed indication for smoking cessation. The numbers of people attempting to quit smoking who choose to use e-cigarettes as an aid are increasing (HI 2015 – 29%, HI 2019 – 38%).

These findings underscore the need to scale up and strengthen efforts by healthcare professionals to identify people who smoke and offer evidence-based support.

Table 2 sets out a number of myths & facts about smoking among adults. This table was prepared by the GDG from anecdotal experience, and includes myths & facts about:

- The dangers & risks of smoking from the smokers' perspective,
- Quitting and attitudes to quitting from the smokers' perspective,
- Healthcare professionals' attitudes towards smoking and quitting among their patients, and
- The use of supports to quit smoking.

Table 2: Smoking among Adults – Myths & Facts

Myth	Fact
The risk of harm from smoking is low and everyone knows there are lots of smokers who don't experience any health problems from their smoking	• 1-in-2 smokers die from smoking attributable disease and smokers can expect to lose 10 years of life from their habit. • Each week, over 100 people die and over 1,000 people are hospitalised in Ireland from smoking attributable diseases.
Quitting doesn't change your odds because the damage is done from smoking	• Quitting reduces and can reverse the risk of smoking attributable disease, reduce the impact smoking on health and improve quality of life.
Smokers are happy with their habit and don't want to quit	• Out of 665,000 smokers in Ireland, approximately 450,000 say they are interested in quitting and approximately 300,000 have made at least one quit attempt in the last 12 months.
Smokers don't want to be bothered by health professionals about their smoking	• Most smokers expect their smoking to be raised with them by a healthcare professional and are surprised when it's not mentioned.
Asking someone about their smoking is a waste of valuable health professional time	• A healthcare professional asking about smoking and offering advice and help increases the chance of someone quitting and staying quit for good.
Nothing works to help you quit and you're best to go cold turkey	• There are a wide range of safe and accessible supports that can be tailored to choose from and these increase the odds of quitting for good by two to threefold versus going it alone.

Source: Stop Smoking guideline development group, 2020

2.1.3 Socio-economic Inequalities in Smoking

Smoking behaviour is a significant contributor to poorer health and premature mortality experienced by the poorest groups in Ireland.

The GDG requested advice and support from the Institute of Public Health in Ireland to ensure that the development and implementation planning of these guidelines took account of the socio-economic inequalities in smoking and there follows a brief summary of advice provided to the GDG by the Director of Policy at the Institute of Public Health.

Socio-economic Inequalities in Smoking – considerations for the Stop Smoking Clinical Guideline Development Group

Dr Helen McAvoy, Director of Policy, Institute of Public Health

Smoking causes the greatest damage to the most socially disadvantaged communities.

The Institute of Public Health presented perspectives to the GDG in July 2019 on opportunities and challenges in building an equity focus into tobacco control and stop smoking services in Ireland.

Problem definition

- Socio-economic patterning of tobacco-related harms exists across the life course. While a population gradient exists, some groups report a very high (over one third) prevalence of smoking. These include those in poverty, homeless, prisoners, people leaving care, Traveller populations, people with drug and alcohol dependency and those with mental illness.
- Longer duration and higher intensity exposures to tobacco and second-hand smoke are characteristic of more socially disadvantaged communities, resulting in higher nicotine dependence.
- Disadvantaged smokers report the same willingness/intention to quit as more advantaged smokers. In general, they are just as likely to receive quitting advice from the health service. However, disadvantaged smokers are far less likely to make progress on their quit journey, and early relapse is common.
- E-cigarette use is also more likely among users in socially disadvantaged communities, but the overall effect of e-cigarette use on inequalities in tobacco related harms is not yet known.

Equity impact of tobacco control measures

- There are no specific targets in Ireland to reduce inequalities in smoking, smoking in pregnancy or within socially vulnerable subgroups, within tobacco control, maternity or mental health policies.
- Review level evidence on the differential equity effects of broad population level tobacco control policies including taxation, mass media campaigns and regulatory measures (like workplace smoking bans) is mixed. There is no clear conclusion of the overall equity impact of tobacco control policies.

- An equity impact assessment of NHS stop smoking services provides important insights. As most stop smoking interventions had neutral or negative equity impacts (are less likely to succeed in disadvantaged populations), the recommendation is to invest in increasing the reach to, and engagement of, disadvantaged communities in order to achieve comparable impact.
- Tailoring services that are highly accessible, affordable, and engaging is also recommended. More intensive engagement aiming for adherence and retention may be required for disadvantaged communities.

Implications for the development of Clinical Practice Guidelines in Ireland

- Ensure effective implementation of the CPG guidelines on smoking in pregnancy and within mental health services. These will reinforce the reduction of inequalities in smoking.
- Secure the inclusion of measures of socio-economic status as a routine component of health information systems within stop smoking services and across the health service, in combination with robust and validated assessments of smoking status.
- Commit to an independent equity impact assessment of stop smoking services aligned to cycles of periodic review and refreshing of the stop smoking service.
- Develop mechanisms to support the participation of marginalised groups in service design and evaluation, taking into account issues of diversity and intersectionality.
- In line with the pending Health Research Board evidence review on e-cigarette use, build referral and support pathways that take into account inequality issues.
- Seek to remove access issues relating to NRT and other pharmacological supports. For high dependence smokers, many of whom will be socially disadvantaged, the extended use of varenicline may help prevent relapse.
- Consider adaptations to the behavioural support components of stop smoking services that address lower literacy and social context, with enhanced roll out of financial incentives.
- Within workplace approaches, target resources to implement and evaluate stop smoking support for manual or low-paid workers.
- In line with NICE guidance, ensure policies support effective stop smoking interventions in 'closed institutions' including prisons, military establishments, long-stay facilities and mental health services.
- Foster accountability and leadership for reducing inequalities in tobacco-related harm across the health and social care system – growing and supporting champions in key health service settings.
- Integrate peer support and community-based approaches such as the We Can Quit programme, with a view to enhancing the reach and engagement of disadvantaged communities.

**References available.

Institute of Public Health

2.1.4 Smoking and Prioritised Groups

In addition to addressing the needs of people who smoke in the general adult population, and ensuring a focus on socio-economic inequalities in health, this guideline supports targeted approaches for specific groups in line with *Tobacco Free Ireland* and the HSE TFI Programme Plan, *(Department of Health, 2013), (HSE, 2018a)*.

Smoking in pregnancy

Smoking in pregnancy is one of the most important preventable factors associated with adverse pregnancy outcome, *(Macfarlane, 2018)*. There is currently no national system for the recording of maternal smoking in Ireland, and there are difficulties comparing rates internationally due to differing methodological issues. However, according to the Growing Up in Ireland Study, smoking in pregnancy has reduced from 28% of mothers of children born in 1997/1998 to 18% for mothers of children born in 2007/2008; a 35.7% relative decrease in smoking rates in that decade, *(Layte, 2014)*. More recently, the Coombe Women and Infants Hospital reported that between 2011 and 2015 the prevalence of maternal smoking decreased from 14% to 11%, a 21.4% relative reduction, *(Reynolds, 2017a)*.

There are particular features to the challenge of smoking in pregnancy. Pregnant women who smoke in Ireland are generally young, experience socioeconomic deprivation, and often have other physical and mental health needs, including other risky health behaviours *(Reynolds, 2017a)*. Responding effectively to the needs of pregnant women who smoke requires that smoking is identified during antenatal care however, similar to international studies, research in Ireland has shown that up to 40% of women who smoke may not be identified at the time of their antenatal appointment *(Reynolds, 2017a)*. Research and international experience show that the best outcomes for women and their babies can be achieved when smoking is identified early in the pregnancy and effective support is provided to stop smoking *(McArdle, 2018, Fitzpatrick, 2016, Cooper, 2017, Lieberman, 1994)*.

A national audit of smoking cessation services in Irish maternity units reported major gaps, weaknesses and variation in the provision of smoking cessation support across maternity units in Ireland *(Reynolds, 2017b)*. The National Maternity Strategy 2016-2026 identified a need to develop and strengthen the pathway of care for women who smoke in pregnancy, *(Department of Health, 2016)*. In addition, an objective of *First 5: A Whole of Government Strategy for Babies*, Young Children and their Families is that parents, families and communities will be supported to engage in and promote positive health behaviours among babies and young children, starting from the pre-conception period, and the promotion and support of positive health behaviours among pregnant women is a strategic action, *(Government of Ireland, 2019)*. Furthermore, stop smoking advice and support is also identified as a requirement for services in *HIQA's National Standards for Safer Better Maternity Services*, specifically standard 1.4, 2.3 and 4.1 *(HIQA, 2016)*.

Table 3 sets out a number of myths & facts about smoking in pregnancy. This table was prepared by the GDG from anecdotal experience, and includes myths & facts about:

- The dangers & risks of smoking in pregnancy from the smokers' perspective,
- Quitting and attitudes to quitting in pregnancy from the smokers' perspective,
- Healthcare professionals' attitudes towards smoking and quitting among their patients in pregnancy, and
- The use of supports to quit smoking in pregnancy.

Table 3: Smoking in Pregnancy – Myths & Facts

Myth	Fact
The risk of harm from smoking in pregnancy is low and everyone knows women who smoked who didn't run into any problems with their pregnancy	• Smoking prevents babies from having the best start in life and remains a major cause of new-born deaths, early births and babies born with low birth weight.
Quitting doesn't change your odds because the damage is done from smoking	• Stopping smoking is preferable at the earliest opportunity but quitting at any stage in pregnancy - and staying stopped - improves the outcome for women and their babies.
Pregnant women who smoke don't want to be bothered by health professionals about their smoking	• Every woman wants the best possible outcome from her pregnancy; they expect their smoking to be raised with them by a healthcare professional and are surprised when it's not mentioned.
Asking a women who is pregnant about their smoking is a waste of valuable health professional time	• A healthcare professional asking about smoking and offering advice and help increases the chance of someone quitting and staying quit for good.
Nothing works to help you quit and you're best to go cold turkey	• There are a wide range of safe and accessible supports that can be tailored to choose from and these increase the odds of quitting during pregnancy.

Source: Stop Smoking guideline development group, 2020

Smoking among people with lived experience of mental health challenges

People with lived experience of mental health challenges are recognised as a high-prevalence smoking population, which grows with the increasing severity of the mental disorder, *(Royal College Psychiatrists, 2013)*. A recent Irish study in a psychiatric inpatient setting reported a smoking prevalence of 34% *(Burns, 2018a)*. A survey of mental health service in-patients conducted by the Mental Health Commission (MHC) in 2018 found that 38% of people were current smokers *(Finnerty, 2018)*. This is consistent with research published by the HSE TFIP using population-based data, which reported that smoking prevalence among people reporting symptoms indicating a probable mental health problem was 35%, 1.6 times greater than those without symptoms, *(HSE, 2018c)*.

The Inspector of Mental Health Services at the MHC in Ireland has identified that the physical health needs of people with lived experience of mental health problems are significant – their life expectancy is 15 to 20 years less than someone without a mental illness – and they suffer unnecessarily with undiagnosed and poorly managed medical conditions, *(Finnerty, 2018), (Government of Ireland, 2020)*. To date, smoking cessation among those with lived experience of mental health problems has been limited – they have been left behind, raising significant parity of esteem questions. Mental health facilities were exempted from 2004 smoke-free regulations, and 'myths' are regularly reported about poor ability among those with mental health problems to quit, *(Burns, 2018b, MHI, 2019)*. However, people with mental health

problems who smoke are no less likely to want to quit than other persons who smoke, but they do make less attempts at stopping due to perceived difficulties with quitting smoking *(Royal College Psychiatrists, 2013)*. There is good evidence that those with mental health problems or difficulties are capable of quitting smoking *(Prochaska, 2011)* and that treating their tobacco dependence does not seem to harm their mental health recovery *(Morozova, 2015)*. In fact it may even enhance it *Taylor (2014)*. Burns et al report that three-quarters of those in an Irish psychiatric hospital wanted to quit smoking, and almost half would like to get that advice during their inpatient stay; motivation to quit, acceptability of advice and quit rates were in fact similar to nearby general inpatient samples *(Burns, 2018a)*.

Table 4 sets out a number of myths & facts about smoking among persons with mental health challenges. This table was prepared by the GDG from anecdotal experience, and includes myths & facts about:

- The dangers & risks of smoking among persons with mental health challenges,
- Quitting and attitudes to quitting among persons with mental health challenges,
- Healthcare professionals' attitudes towards smoking and quitting among their patients with mental health challenges, and
- The use of supports to quit smoking by persons with mental health challenges.

Table 4: Smoking among persons with mental health challenges – Myths & Facts

Myth	Fact
The risk of harm from smoking for people with mental health difficulties is low and we should be more concerned about helping them with their mental health	• People with mental health difficulties do not experience parity of esteem when it comes to care for their physical health needs. • Smoking is more common and is the main factor in the poorer physical health and reduced life expectancy among people with mental health problems.
Quitting doesn't change your odds because the damage is done from smoking	• Quitting reduces and can reverse the risk of smoking attributable disease, reduce the impact smoking on health and improve quality of life
People with mental health difficulties who smoke are happy with their habit and don't want to quit	• People with mental health difficulties have the same interest in quitting as everyone else and deserve to be treated with parity of esteem.
Asking people with mental health problems about their smoking is a waste of valuable health professional time	• A healthcare professional asking about smoking and offering advice and help increases the chance of someone quitting and staying quit for good. People with mental health problems deserve parity of esteem.

Nothing works to help you quit and you're best to go cold turkey	• There are a wide range of safe and accessible supports that can be tailored to the needs of people with mental health problems and these increase the odds of quitting.
Stopping smoking can make mental health problems worse and medications are dangerous	• Supports, including medicines, can be used safely and effectively for people with mental health difficulties and helping them quit supports and improves their mental and physical health

Source: Stop Smoking guideline development group, 2020

2.2 Clinical and financial impacts of Tobacco Use

2.2.1 Clinical Impacts of Tobacco Use

Internationally the WHO reports that more than 8 million people die each year as a result of tobacco use; more than 7 million of these deaths are as a direct result of smoking, with approximately 1.2 million deaths among non-smokers as a result of exposure to SHS, *(WHO, 2020a)*.

Smoking causes death and disability on a large scale and it is well documented that cigarette smoking has been causally linked to diseases of nearly every organ of the body, to diminished health status and to foetal harm (See Figure 8), *(US Department of Health & Human Services, 2014)*.

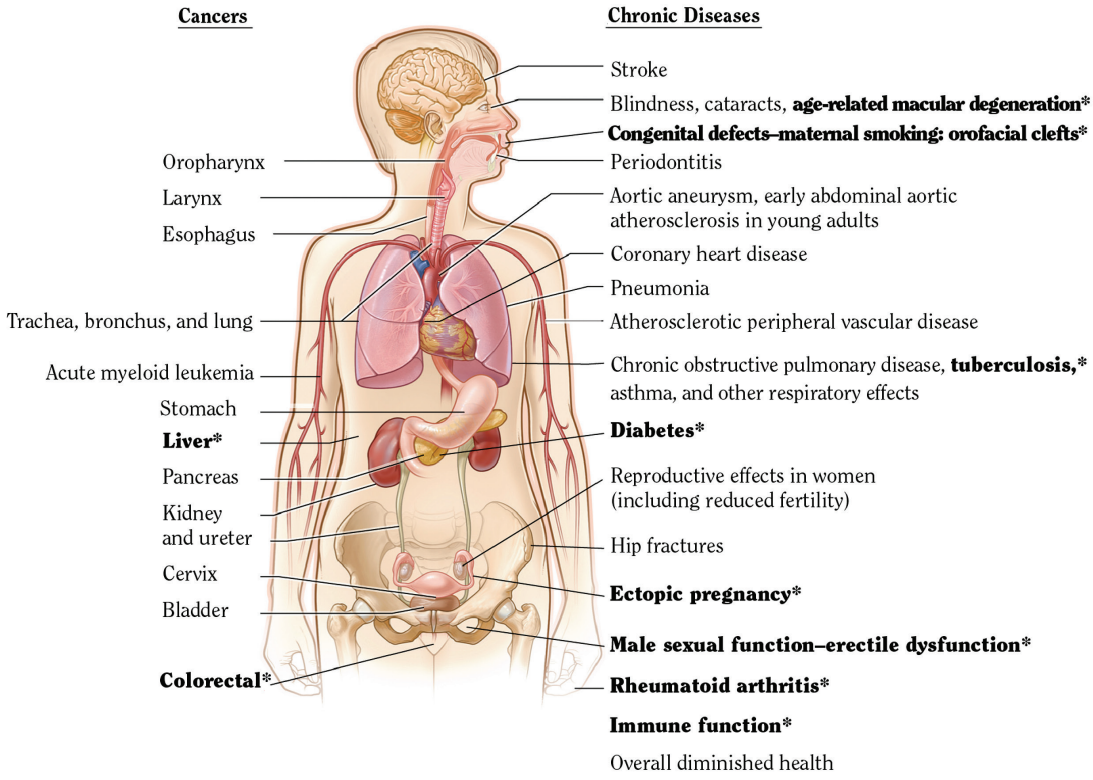


Figure 8: The health consequences causally linked to smoking

Source: US Department of Health & Human Services, 2014

Note: Each condition presented in bold text and followed by an asterisk (*) is a new disease that has been causally linked to smoking in the 2014 US Surgeon General Report.

Tobacco use is also well-recognised for its interaction with a number of medical treatments and with increasing the likelihood of adverse events. For example: smoking is associated with an increased symptom burden following treatments for cancer; smoking increases the dose of medication required for treating mental health conditions, therefore increasing the risk of toxicity; smoking is associated with increased risk of postoperative complications, including wound complications, general infections, pulmonary complications, neurological complications, and admission to intensive care units, *(Luke, 2011, HSE, 2016a & GrØnkjaer, 2014)*.

Finally, in the context of the emergence of SARS-CoV-2, it is also important to recognise the WHO finding that smoking is associated with increased severity of disease and death in hospitalised COVID-19 patients. (WHO, 2020b)

Impacts in our priority groups:
Smoking in pregnancy is one of the most important preventable causes of adverse pregnancy outcome including ectopic pregnancy, miscarriage and stillbirth, *(Macfarlane, 2018)*. In addition, maternal smoking during pregnancy impairs normal foetal growth and development and is associated with low birth weight, foetal growth restriction, stillbirth, preterm birth, and some congenital anomalies. Increasing evidence suggests it also has lifelong consequences for the child, with elevated risks of childhood obesity, neuro-behavioural and cognitive deficits, and impaired lung function, including wheezing and asthma, *(Macfarlane, 2018)*.

Smoking is more common among people with lived experience of mental health problems than among people without that experience. Research by the HSE TFI Programme found, using population data from the *Healthy Ireland Survey*, that smoking was 1.6 times more common among people with probable mental health problems, *(HSE, 2018c)*. This is consistent with international studies which confirm a higher incidence of smoking among people with mental health problems, *(Royal College of Psychiatrists, 2013)*. As a consequence, smoking contributes significantly to the majority of excess mortality among individuals with serious mental illness. Life expectancy among people with severe mental illness is 10 to 25 years less than among the general population, *(Walker, 2015), (Lawrence, 2013), (Chang, 2011), (Chesney, 2014)*. A recent study of older Irish adults reported that those with mental health difficulties were more likely to smoke, and more likely to report smoking-related diseases than those without mental health difficulties, *(Burns et al 2017)*. Smoking also complicates the treatment of those with mental health problems, as it increases the dose of medication required for treating mental health conditions, therefore increasing the risk of toxicity, *(HIQA, 2017)*. Besides their physical health, smoking contributes to the impoverishment commonly experienced by people with lived experience of mental health problems and contributes to stigmatisation and social exclusion, *(ASH, 2016)*. The relationship between smoking and mental health is complex. Many of the factors that lead to poor mental health are also factors that lead people to smoking; in addition, poor mental health can lead people to smoke, sometimes through a false belief that it will help alleviate symptoms. However, there is also evidence, especially for mental health problems that affect mood, like anxiety and depression and dementia, that smoking contributes to the onset of these problems, *(Royal College of Psychiatrists, 2013)*.

Mortality and Morbidity associated with Tobacco Use in Ireland
It is estimated that 6,000 deaths in Ireland were attributed to smoking (1-in-5 of all deaths) in recent years (HSE, 2018b) - see Figure 9. By disease grouping, 40% of all deaths from respiratory diseases and 32% of all deaths from malignant cancers in Ireland were estimated to be caused by smoking.

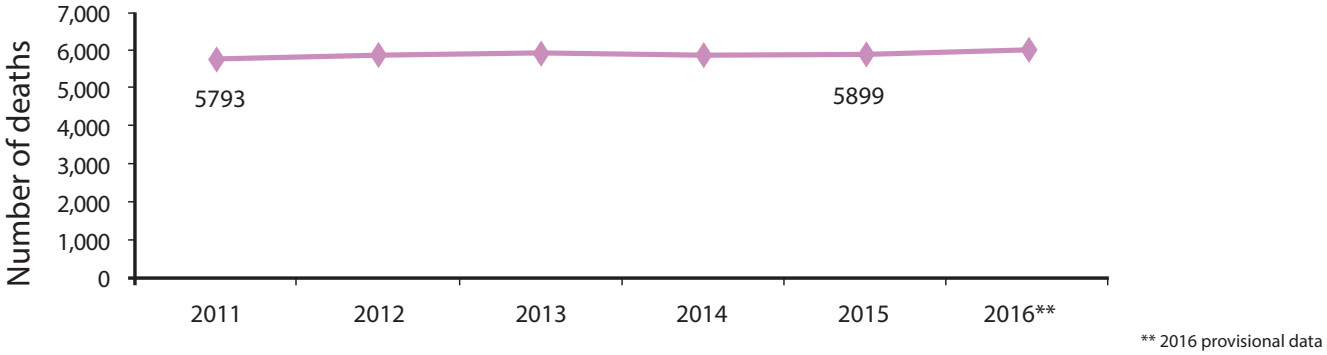


Figure 9: Trend in crude number of deaths estimated to be attributable to smoking and exposure to SHS, 2011-2016*

Source: State of Tobacco Control in Ireland, HSE, 2018

In 2016 there were an estimated 55,000 hospital episodes (day case & inpatient) in publicly-funded hospitals attributable to smoking and exposure to SHS, see Figure 10 *(HSE, 2018b)*. By disease grouping, approximately one-in-five inpatient admissions for respiratory diseases, circulatory diseases or cancers, were estimated to be caused by smoking.

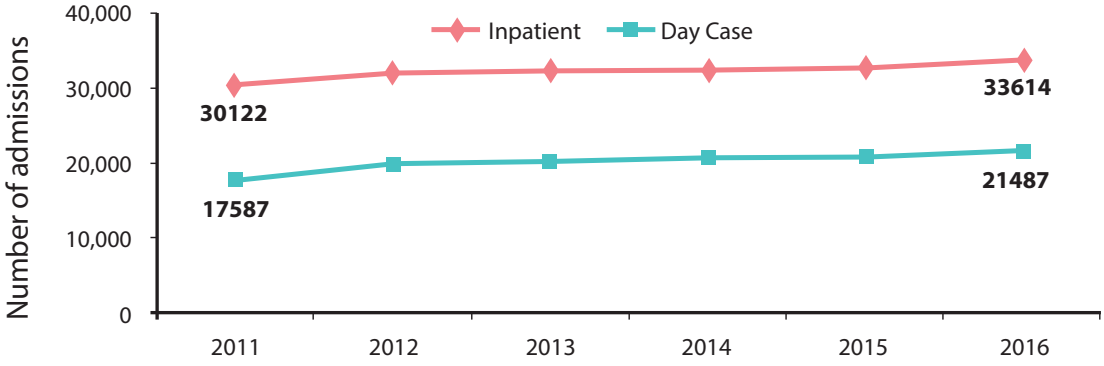


Figure 10: Trend in crude number of hospital admissions (inpatient and day case) estimated to be attributable to smoking and exposure to SHS, 2011-2016

Source: State of Tobacco Control in Ireland, HSE, 2018

2.2.2 Financial Impact of Tobacco Use

Tobacco use is estimated to cost the world's economies more than US$ 1 trillion annually in healthcare expenditure and lost productivity, *(WHO, 2018)*. Globally the burden of tobacco-related disease and costs are borne by low and middle income countries but, even in higher income countries like Ireland, the costs of tobacco use are significant and lifetime healthcare costs are greater for people who smoke than for people who do not, even accounting for the shorter lives of people who smoke.

The Department of Health-commissioned report *An Assessment of the Economic Cost of Smoking in Ireland*, published in 2016, estimated the annual cost to the health service as €460 million, and the total annual costs as €10.7 billion. Detailed breakdowns of these costs are in Table 5 *(ICF International, 2016)*.

Table 5: Impact of smoking in Ireland and costs, 2013

Impact	Number	Cost (€ million)
Deaths attributable to smoking and second-hand smoke	5,950	-
Hospital inpatient admissions	31,500	171
Hospital day case appointments	19,300	13
Hospital outpatient appointments	116,300	15
Hospital emergency department attendances	38,000	10
Primary care	-	256
Hospital transportation	12,700	1
Domiciliary care	-	40
Loss of productivity - smoking breaks	-	136
Loss of productivity - smokers' absense	-	224
Lost productivity - premature death	-	711
Fires	380	4
Fatalities from fires	1	2
Litter	-	69

Source: ICF International, Department of Health Dublin.

2.2.3 Benefits of stopping smoking

In his 2020 report, the US Surgeon General reviewed and summarised the evidence on the benefits from stopping smoking (see Table 6). He also outlined the specific benefits of stopping smoking in pregnancy (see Table 6), *(US Department of Health & Human Services, 2020)*.

Table 6: Summary of evidence on benefits of stopping smoking

In general, the evidence is sufficient to infer that:	
- Smoking cessation improves well-being, including higher quality of life and improved health status	
- Smoking cessation reduces mortality and increases the lifespan	
- Smoking cessation reduces the risk of the following cancers:	
• lung cancer	• laryngeal cancer
• cancers of the oral cavity and pharynx	• oesophageal cancer
• pancreatic cancer	• bladder cancer
• stomach cancer	• colorectal cancer
• liver cancer	• cervical cancer
• kidney cancer	• acute myeloid leukaemia

- Smoking cessation reduces levels of markers of inflammation and hypercoagulability and leads to rapid improvement in the level of high-density lipoprotein cholesterol
- Smoking cessation reduces the development of subclinical atherosclerosis, and that progression slows as time since cessation lengthens
- Smoking cessation reduces the risk of cardiovascular morbidity and mortality and the burden of disease from cardiovascular disease
- Smoking cessation reduces the risk of stroke morbidity and mortality
- The relative risk of coronary heart disease among former smokers compared with never smokers falls rapidly after cessation
- In patients who are current smokers when diagnosed with coronary heart disease, the evidence is sufficient to infer a causal relationship between: • smoking cessation and a reduction in all-cause mortality • smoking cessation and reductions in deaths due to cardiac causes and sudden death and • smoking cessation and reduced risk of new and recurrent cardiac events.
- Smoking cessation remains the only established intervention to reduce loss of lung function over time among persons with chronic obstructive pulmonary disease and to reduce the risk of developing chronic obstructive pulmonary disease in cigarette smokers.
In pregnancy, the evidence is sufficient to infer that:
- Smoking cessation by pregnant women benefits their health and that of their foetuses and new-borns.
- Smoking cessation during pregnancy reduces the effects of smoking on foetal growth and quitting smoking early in pregnancy eliminates the adverse effects of smoking on foetal growth.
- Smoking cessation before or during early pregnancy reduces the risk for a small-for-gestational-age birth compared with continued smoking.

Stopping smoking is also beneficial for people with lived experience of mental health problems. Besides improvements to physical health, in common with the general population, people with mental health problems who stop smoking often require lower doses of medication, *(NCSCT, 2014)*. This is because tobacco smoke speeds up the breakdown of some antipsychotic medications, as well as some antidepressants and benzodiazepines, by speeding up the activity of liver enzymes responsible for drug metabolism. When people with lived experience of mental health problems stop smoking, the breakdown of these medications returns to normal and doses can be lowered, thus helping to minimise some of the negative impacts of these medications. Furthermore, there is comprehensive evidence that smoking cessation is associated with reduced depression, anxiety and stress and improved positive mood as large

for those with mental health problems as those without, and the effect is equal or greater than those of antidepressant treatment for mood and anxiety disorders, *(Taylor, 2014)*.

2.3 Rationale for this National Clinical Guideline

Globally, owing to its significance as a leading cause of preventable death, disease and disability, the WHO identified the need to strengthen national and international tobacco control action through its Framework Convention on Tobacco Control (FCTC), to which Ireland is a party, *(WHO, 2003)*. Article 14 of that convention requires parties to *"develop and disseminate appropriate, comprehensive and integrated guidelines based on scientific evidence and best practices, taking into account national circumstances and priorities, and shall take effective measures to promote cessation of tobacco use and adequate treatment for tobacco dependence."*

A recent survey of 77 countries, signatories to the WHO FCTC, found that 61 (80%) had guidelines, and in general these guidelines recommended brief advice (BA) (100%), recording tobacco use in medical notes (82%), smoking cessation medications (98%), telephone support (61%), and intensive specialist support (87%), *(Nilan, 2018)*.

Tobacco Free Ireland states that the national public health policy objective in relation to tobacco control is to promote and subsequently move towards a tobacco free society, where the population prevalence of smoking is less than 5% *(DoH, 2013)*. It sets out a range of supply, demand and harm reduction strategies that aim to improve the health of the population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke.

While Ireland is recognised internationally as having in place strong tobacco control measures across a wide range of areas, *(Joosens, 2020)*, it currently has no national stop smoking clinical guidelines and *Tobacco Free Ireland* makes the specific recommendation that comprehensive national smoking cessation guidelines should be developed. The development of these guidelines is a priority action in the HSE TFIP Programme Plan 2018-2021 *(HSE, 2018a)*.

These smoking cessation guidelines will strengthen the identification and treatment of tobacco addiction by health professionals across service settings. Section 2.1.2 has highlighted the care gap in Ireland which means that, despite high levels of interest in quitting, many people who smoke find that they are not offered support by health professionals. This situation is not unique to Ireland and in 2020 the US Surgeon General used his report to specifically call out the *"tremendous positive impact that healthcare professionals can have on the health and quality of life of their patients and on the public health of our nation—just by helping smokers to quit." (US Department of Health & Human Services, 2020)*. Furthermore, he notes that *"the evidence is sufficient to infer that the development and dissemination of evidence-based clinical practice guidelines increase the delivery of clinical interventions for smoking cessation."* Addressing this care gap is necessary if Ireland is to progress towards its goal of being tobacco free by 2025, since this will only be achieved through significant scaling up of successful quitting among current smokers. In addition, they will support the implementation of the HSE Tobacco Free Campus policy *(HSE, 2012)*, and link with plans to address modifiable health behaviours in clinical practice through *Making Every Contact Count (HSE, 2016b)*. These guidelines will also support the broader Healthy Ireland policy agenda within the health services and nationally, *(Government of Ireland, 2013)*. They will also help ensure health services in Ireland are aligned with HIQA Standards for Safer Better Healthcare Theme 4, specifically Standard 4.1, which states that "the health and wellbeing of service users are promoted, protected and improved." *(HIQA, 2012)*.

A proposal to develop these guidelines was submitted to the NCEC in 2017. The proposal addressed

criteria established by the NCEC on the case for the development of national clinical guidelines and the proposal to develop National Stop Smoking Clinical Guidelines was prioritised and listed on the NCEC schedule of guidelines prioritised in 2017.

Specific Rationale and Supporting Policy for Our Priority Groups:
Tobacco Free Ireland recognises the consequences of smoking in pregnancy, and smoking cessation among pregnant women is prioritised in the HSE Tobacco Free Ireland Programme Plan 2018-2021, *(DoH, 2013, HSE, 2018a*). In addition, the *National Maternity Strategy 2016-2026 - Creating a Better Future Together (DOH, 2016)* recognises pregnancy as a unique opportunity to focus on health & wellbeing and maternity services can offer the appropriate information and supports to enable women to make changes in behaviour, including smoking cessation. Furthermore, *First 5 – A Whole-of-Government Strategy for Babies, Young Children & their Families 2019-2028 (DCYA, 2018)* supports positive health behaviours, starting from the pre-conception period, including smoking. Stop smoking advice and support is also identified as a requirement for services in HIQA's National Standards for Safer Better Maternity Services, specifically standard 1.4, 2.3 and 4.1. *(HIQA, 2016)*. The standard addresses care provided both to the pregnant woman and to her partner.

Similarly, *Tobacco Free Ireland* identifies persons with mental health problems as a priority group, as does the HSE Tobacco Free Ireland Programme Plan 2018-2021 *(DoH, 2013, HSE, 2018a)*. *Sharing the Vision – a mental health policy for everyone* also identifies the need to better respond to the particular physical needs of people with mental health problems, *(Government of Ireland, 2020)*. The MHC Judgement Support Framework includes regulations relating to the physical health of persons with mental health problems, and also to the premises where they live/are treated, thereby helping to bring a focus on addressing smoking in this group, *(MHC, 2020)*.

2.4 Aim and objectives

The primary aim of this project was to develop comprehensive national stop smoking clinical guidelines for Ireland. As already stated, it is a response to the requirement by government policy, *Tobacco Free Ireland*, and by Article 14 of the WHO FCTC, to which Ireland is a party. It is a key priority for the HSE TFIP Programme Plan 2018-2021. It will help strengthen and scale up efforts across the health services in Ireland to help people who smoke to stop successfully, thereby enabling progress towards a Tobacco Free Ireland and reducing the morbidity and mortality caused by smoking.

The specific objectives of these national stop smoking clinical guidelines are to:

- Define best practice for care of people who smoke in the general adult population, as well as providing a special focus on helping women who are pregnant and users of secondary mental health services,
- Provide systematically developed statements setting out the recommended behavioural and pharmacological supports that can be arranged to help people who smoke quit, using both international and local evidence.

This guideline aims to achieve the following specific outcomes following implementation:

- The identification and treatment of smoking embedded as a key element of healthcare culture in Ireland;
- Routine identification of smokers and delivery of stop smoking support in health services, with guidance fidelity and equity across population groups;
- Increased numbers accessing and completing stop smoking supports, and improved client satisfaction with stop smoking services and supports;
- More effective treatment for patients who smoke with smoking-related illnesses;
- Reduced visibility of smoking and improved environments in all HSE sites and services;
- Increased quitting and increased effectiveness of quit attempts;
- Reduced smoking-related morbidity and mortality resulting in reductions in smoking-related hospital admissions and bed days, and reductions in post-operative complications;
- Improved health & wellbeing, and quality of life for clients, and
- Improved birth weights and other pregnancy outcomes.

2.5 Guideline scope

2.5.1 Population to whom the guideline applies

This guideline applies to the general adult population (aged 18+ years) in Ireland in contact with health services who are current smokers, with particular attention paid to pregnant women (all ages), and persons with severe and enduring mental health problems (aged 18+ years) who access secondary care services.

Exclusions:
This guideline does not apply to those persons (of all ages) in contact with health services who do not use tobacco products with the exception of pregnant women attending 1st antenatal hospital visit. The guideline also does not apply to population-based tobacco control measures to prevent smoking initiation and/or promote quitting (e.g. legislation, taxation, mass media campaigns etc.).

2.5.2 Intended users of the guideline

This National Clinical Guideline is prepared primarily for all healthcare professionals working in HSE operated and funded health and social care settings, including primary care settings, secondary care settings, and community care settings in Ireland. The guideline is also relevant to healthcare planners and managers. The guideline may also be used by healthcare professionals in other settings and by members of the public.

2.5.3 What does this mean in practice?

This document is a clinical guideline. Clinical guidelines are *"systematically developed statements, based on a thorough evaluation of the evidence, to assist practitioner and service users' decisions about appropriate healthcare for specific clinical circumstances across the entire clinical system" (Department of Health, 2019a)*. This guideline intends to support healthcare professionals and patients make decisions about care on an individual case-by-case basis. As such, it is an intervention intended to improve clinical care.

These guidelines will complement and support population-level tobacco control in Ireland. However, it is important to clarify the distinction. The guideline is not intended to assist policy-makers in making decisions about population-level tobacco control interventions such as legislation, taxation, mass media campaigns etc. Neither is it intended to assist health service planners and managers in the design and delivery of health services relevant to tobacco control. As set out in supporting GPPs for the guideline recommendations, the role of policy-makers and health service planners and managers is important in creating an environment which supports healthcare professionals and patients make decisions aligned with guideline recommendations: for example taxation policy can motivate people who smoke to stop and can also remove barriers to accessing stop smoking medications; stop smoking services can be planned and resourced so they are easily accessible and healthcare professionals can be released to attend training to build knowledge and skills for practice in line with these guidelines.

Implementation of these guidelines in specific services will include tailoring to specific context and population by local implementation teams, while ensuring fidelity to the recommendations, *(Baker, 2015)*. Implementation will also be supported by measures to engage and involve specific populations of people who smoke so as to motivate them to use services and ensure that services are accessible. There are tools and resources available through the HSE and expert capability to support implementation of disease prevention and health improvement initiatives is available within the HSE through local public health departments and local health promotion and improvement services. The intent of these guidelines is to define statement of recommended practices to support healthcare professionals and patients make decisions about care and it is not intended to prescribe detailed service or population specific implementation.

2.6 Conflict of interest statement

The guideline development process followed the conflict of interest policy set out by NCEC. All members of the GDG were required to complete a Conflict of Interest (COI) Declaration on appointment to the group, and on an annual basis, which were managed by the Chair. There were no conflicts of interest stated.

2.7 Sources of funding

No external funding was received for the development of this guideline. The Budget Impact Analysis conducted by Health Research Board–Collaboration in Ireland for Clinical Effectiveness Reviews (HRB–CICER), and the Implementation Science workshops and support provided by the Centre for Effective Services (CES) were funded by the Department of Health.

2.8 Protection from Tobacco Industry Interference

The WHO notes:

"The tobacco industry has historically employed a multitude of tactics to shape and influence tobacco control policy. The tobacco industry has used its economic power, lobbying and marketing machinery, and manipulation of the media to discredit scientific research and influence governments in order to propagate the sale and distribution of its deadly product. Furthermore, the tobacco industry continues to inject large philanthropic contributions into social programs worldwide to create a positive public image under the guise of corporate social responsibility." (WHO, 2009a)

Article 5.3 of the WHO FCTC states that *"in setting and implementing their public health policies with respect to tobacco control, parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law."(WHO, 2003)* Guidelines have been agreed between parties to support implementation of this article, *(WHO, 2009b)*.

Since they will become integral to the policies Ireland has in place with respect to tobacco control, the Chair of the GDG sought to ensure protection of the guideline development process from commercial and other vested interests of the tobacco industry through measures described in Section 2.7 and 2.8. Measures were also taken in respect to the consultation on the guideline and the completion of this guideline development process.

2.9 Guideline methodology

The methodology used in the development of this guideline was a blend of the adaptation of existing international guidelines using the ADAPTE tool (ADAPTE Collaboration, 2009) and de novo guideline development process following the process recommended by NCEC (DOH, 2019).

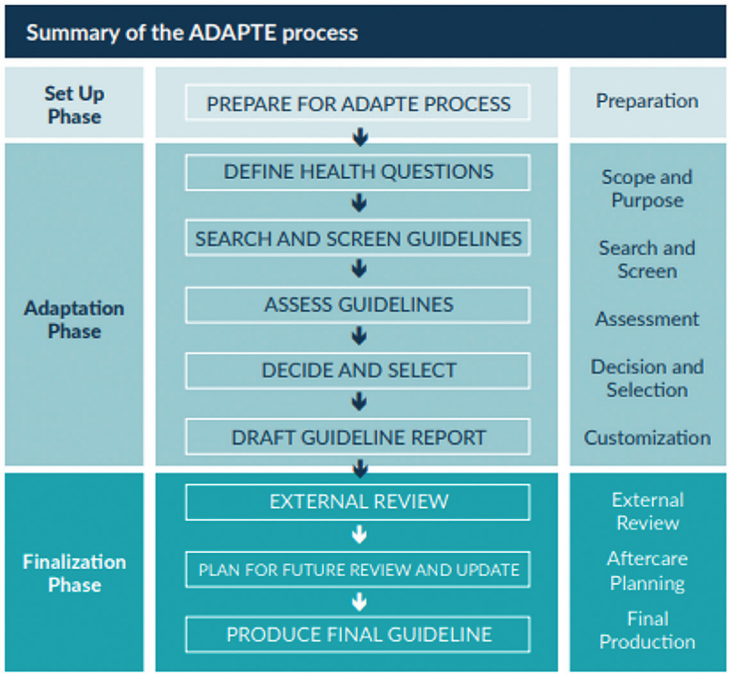


Figure 11: Summary of the ADAPTE process

Step 1: Formulate the key questions

The key questions to be addressed by this guideline were identified through consultation with the GDG. While the primary population of interest was the general adult population, pregnant women and those with mental health problems were also of particular interest as these groups are priority groups for the HSE TFIP as identified in the HSE TFIP Programme Plan 2018-2021 *(HSE,2018)*. The key questions for this guideline are outlined in "PIPOH" format (Patient, Intervention, Professional, Outcome and Healthcare Setting format) in Appendix 2.

Step 2: Search methodology
Initially, a search for international guidelines on smoking cessation was conducted in June 2017 to identify recommendations which could be adapted for use in Ireland, *(Quintyne, 2019)*.

The search strategy included a search of the following search engines:

- Pubmed/PubMed Central (Available URL: www.ncbi.nlm.nih.gov/pmc/);
- National Guideline Clearinghouse (Available URL: www.guideline.gov);
- NICE: National Institute for Health and Care Excellence (Available URL: www.nice.org.uk);
- Canadian CPG Infobase: Clinical Practice Guidelines Database (Available URL: www.cma.ca/En/Pages/Clinical-practice-guidelines.aspx);
- SIGN: Scottish Intercollegiate Guidelines Network (Available URL: www.sign.ac.uk);
- Australian Clinical Practice Guidelines (Available URL: www.clinicalguidelines.gov.au);
- Guidelines International Network (Available URL: www.g-i-n.net/);
- Cochrane Library (Available URL: www.cochranelibrary.com);
- FDA: Food & Drug Administration (Available URL: www.fda.gov/regulatoryinformation/guidances/);
- World Health Organization (Available URL: www.who.int).

The following keywords were used in the search:

- 'smoking/nicotine-addiction/tobacco-use cessation,'
- 'smoking/nicotine-addiction/tobacco-use interventions,' and
- 'treatment of smoking/nicotine-addiction/tobacco-use.'

The search strategy was limited to January 2006 onwards and not earlier as the latest pharmaceutical agent for smoking cessation, varenicline (trade name Chantix® and Champix®) was licensed and introduced into clinical practice from September 2006.

Secondly, the 2017 Health Technology Assessment (HTA) of smoking cessation interventions in Ireland, published by the Health Information and Quality Authority (HIQA), also provided evidence to underpin this national clinical guideline on smoking cessation interventions. This HTA, requested by the National Tobacco Control Advisor (Department of Health), details the clinical and cost-effectiveness of both pharmaceutical & non-pharmaceutical smoking cessation products and services available in Ireland, *(HIQA, 2017)*. It was designed to inform and be used in the development of these guidelines. In general, it was used to cross check and validate the currency of recommendations from international guidelines.

Thirdly, one literature review was undertaken at the request of the GDG to address a gap in the selected international guidelines in relation to the identification of smoking among pregnant women using BCO testing. A structured literature review was undertaken to address the following questions:

- What is the performance of BCO as a tool to identify smokers in pregnancy?
- What is the efficacy of BCO testing in terms of improved referral to smoking cessation programmes and quitting smoking among pregnant women?
- What is the feasibility and acceptability of routine BCO testing during antenatal care?
- What is the optimum cut off to detect smokers using BCO during antenatal care?

The search strategy for this literature review is included in Appendix 3.

Finally, a key challenge to the development of these guidelines was the fast-moving emerging evidence base regarding e-cigarettes and heated tobacco products. In the course of the guideline development project, and having settled provisional recommendations in this area based on the evidence set out above, the Chair of the GDG was informed that the Department of Health had commissioned the Health Research Board (HRB) to conduct an evidence review examining 3 areas:

- What are the public health benefits and harms of e-cigarettes and heat-not-burn products?
- Examine the efficacy of e-cigarettes and heat-not-burn in helping people who smoke to achieve abstinence (smoking cessation).
- Does e-cigarette use by adolescents who are cigarette naive at baseline lead to subsequent cigarette smoking?

There was liaison between the Chair of the GDG, the Department of Health (Tobacco and Alcohol Control Unit) and the National Patient Safety Office (which provides executive support to the NCEC) and the Health Research Board to determine how best to ensure that the value of this significant evidence review could be leveraged in the guideline development process, taking account of the fact that it addressed a fast-moving area. As a consequence, in January 2020, the GDG was briefed by the HRB on its evidence review and key findings so that the GDG could determine any amendments to its proposed recommendation in these draft guidelines prior to publication of the HRB evidence review.

Step 3: Screen and appraise the evidence

International Guidelines:

Identified international guidelines underwent an initial screening process: those that did not focus on the management of smoking cessation were excluded, as were documents that were not guidelines, such as position papers and reviews.

Each candidate guideline was then reviewed by two to four assessors using the AGREE II instrument, see Appendix 4. At least one assessor for each guideline had experience in developing and evaluating guidelines, and all assessors were asked to complete the online training recommended by the AGREE II collaboration before conducting the appraisals (https://www.agreetrust.org/). Assessors independently evaluated the assigned guidelines using the AGREE II instrument; this involved scoring the guideline on 23 items across 6 domains, namely; 'Scope & purpose,' 'Stakeholder Involvement,' 'Rigour of Development,' 'Clarity of Presentation,' 'Applicability' and 'Editorial Independence.'

The appraisers' scores were then totalled per item; this considered the natural discrepancies between appraisers evaluating each candidate guideline. The AGREE II instrument does not set minimum domain scores or patterns of scores across domains to differentiate between high and poor quality guidelines; these decisions should be made by the users. This guideline group considered a value >60% as a sufficient quality score, and a value of >80% as a good quality score. Following elimination of some guidelines (see Appendix 4) the international guideline owners were contacted to seek permission for this guideline group to adapt their guidelines for use in Ireland, and to assess currency of their guideline. Copies of permissions are available on request. The result of the appraisal process and request for permission to adapt for the candidate guidelines are summarised in Appendix 4.

HIQA HTA:
The HIQA HTA was evaluated by four appraisers using the Critical Appraisal Skills Programme (CASP) Checklist for Systematic Reviews (www.casp-uk.net). The ten questions consider three broad issues: (1) Are the results of the study valid? (2) What are the results? and (3) Will the results help locally? The result of the appraisal is summarised in Appendix 4 (b).

Structured Literature Review on smoking in pregnancy and breath carbon monoxide testing:
The search strategy used is detailed in Appendix 3, with a report for this literature review included in Appendix 5.

Health Research Board Evidence Review:
The Health Research Board Evidence Review has been subject to a peer review process to assure quality under the governance of its board.

Step 4: Develop and grade the recommendations
The Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach was used by this GDG to assess the quality of the body of evidence, and to develop and report recommendations, *(Alonso-Coello, 2016)*. Table 7 outlines how the quality of evidence was categorised using GRADE.

Table 7: Quality of Evidence in GRADE

Level of Evidence	Definition	Type of Evidence
High ⨁⨁⨁⨁	The GDG is very confident that the true effect lies close to that of the estimate of the effect.	Consistent evidence from several high-quality studies with consistent results or, in special cases, one large, high-quality and multi-centre trial.
Moderate ⨁⨁⨁	The GDG is moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.	Evidence from one high-quality study or very strong evidence of some other research design with some limitations.
Low ⨁⨁	THE GDG confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.	Evidence from observational studies, case studies, or from randomised, controlled trials with severe limitations.
Very Low ⨁	The GDG has very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of the effect.	Evidence from the opinion of experts, no direct research evidence or one/more studies with very severe limitations.

The levels of evidence associated with each of the international guidelines selected for adaptation was sourced, and were re-classified to the GRADE levels of evidence, where appropriate, in a recommendation matrix (See Appendix 6). The HTA included a network meta-analysis and thus provided direct and indirect measures of effectiveness, the latter being comparisons made between interventions in the absence of head-to-head randomised studies, and were handled in line with NCEC guidelines for grading evidence using GRADE, indirectness of evidence lowered quality and confidence levels; however, in general, there was direct evidence reported by HTA and available decision-making by the GDG, so there was no requirement to rely on indirect or network evidence *(DoH, 2019)*.

To formulate recommendations, the GDG used a considered judgement process adapted from the GRADE Evidence to Decision framework, *(Alonso-Coello, 2016)*. Considered judgement forms (CJFs) (see Appendix 7) were populated for each key question by the Evidence Team, with recommendations from the candidate guidelines, evidence from the HIQA HTA and the primary literature. Considered judgement forms also included relevant Irish epidemiology and national policy where available. The GDG formulated recommendations taking into account the available evidence, the balance of benefits and harms, resource use, acceptability, feasibility of implementation, as well as the estimated values and preferences of patients and society.

Strength of recommendations: the strength of a recommendation expresses the degree to which the GDG is confident in the balance between the desirable and undesirable consequences of implementing the recommendation. A two-level grading system was used: strong, and conditional/weak, see Table 8.

Table 8: Rationale for the strength of a recommendation

Strength of recommendation	Rationale
Strong	The potential positive outcome is highly valued. The benefits will outweigh the harms or the cost.
Conditional/Weak	The potential benefit of the recommendations is uncertain, or the balance between benefit and harm, or cost, is finely balanced, or dependent on other factors. The feasibility of implementations is uncertain or likely to be difficult.

GRADE also provides for GDGs to make no recommendation where confidence in the effect estimates is so low that the panels feel a recommendation is too speculative, or where the trade-offs are closely balanced, and the values and preferences and resource implications not known or too variable. Furthermore, no recommendation may be made where management options have very different undesirable consequences, and individual patients' reactions to these consequences are likely to be so different that it makes little sense to think about typical values and preferences.

Scoping recent evidence to assure currency of guideline recommendations

The development of these guidelines commenced in 2017 on foot of the HIQA HTA and successful prioritisation by the NCEC.

In general, evidence on the effectiveness of stop smoking interventions is robust and stable; there is a considerable body of studies over a large number of years across different settings which enable us to be confident in relation to conclusions about what works and further research studies are very unlikely to significantly impact these conclusions. This point was clear from the HIQA HTA. In other words, these guidelines aim to address a gap in implementation of well-established knowledge.

However, some areas are evolving. Recognising this, the guideline development process timeline was amended to ensure that it could respond to new evidence in the area of e-cigarettes commissioned from the Health Research Board by the Department of Health.

The consultation was used as an opportunity for key stakeholders to identify any new evidence relevant to the guidelines and this was considered post-consultation and prior to submission of the guideline to the NCEC. While the consultation was ongoing, the GDG also updated the search of clinical guidelines and a targeted update of HIQA HTA searches was conducted to identify any significant developments in the field which might impact recommendations prior to finalisation of the guidelines.

A statement in this section of the final guideline document is provided in Appendix 8.

2.10 Consultation summary

The consultation process for the review of the draft clinical guideline took place from 13th October 2020 until 6th November 2020 and had three main elements:

1. Engagement with stakeholders relevant to the guideline
2. Public Consultation
3. International Peer Review (See Section 2.11 for details)

Engagement with stakeholders relevant to the guideline
Individuals or organisations identified as stakeholders in the areas relevant to this guideline in Ireland were invited to review this draft guideline and provide feedback (see Appendix 9 for stakeholder lists). In addition, a broadcast email was distributed to all HSE staff including links to the draft guideline and online submission form.

Public Consultation
A public consultation on the draft guideline was advertised on HSE social media platforms. In addition, a press release was prepared and published on the HSE website. The guideline was available online and feedback submitted via an online form. The format was based on that recommended by NCEC (see Appendix 9). The consultation period ran between 13th October and 6th November 2020. In line with the WHO FCTC, of which Ireland is a Party, measures were taken in the consultation process to protect against tobacco industry interference.

Results & Analysis
During the consultation period, there were 1,151 views of the temporary webpage with draft guideline and online consultation form. The average time a person spent on the page was 5.06 minutes and the bounce rate (the proportion of people who visited the site and viewed one page only) was 55%.

In total, 33 submissions were received. Three contributors outlined that they had a conflict of interest (COI). The majority of replies (n=29) were from Ireland (HSE=17, other=12), 2 from the United Kingdom, 1 from Czech Republic and 1 from Canada.

All feedback received was initially reviewed by a subgroup (PK, AS, MB) of the GDG. The feedback was categorised under a number of headings:

1. Typos, edits, corrections & layout of document,
2. Background chapter,
3. Key Question 1 – General population,
4. Key Question 2 – Smoking in pregnancy,
5. Key Question 3 – Users of secondary mental health settings,
6. Implementation,
7. Further evidence for the attention of the GDG,
8. Other comments (not mentioned above)

The GDG held an online meeting, where the feedback was reviewed by the group and the GDG decided

whether/not the guideline should be amended as a result of the presented feedback. Changes were made to the following guideline recommendations:

- Recommendation 2 GPPs,
- Recommendation 3 GPPs,
- Recommendation 7.2

A small number of changes were also made to the accompanying implementation plan, as suggested by stakeholders, and accepted by the GDG.

A consultation report provides further details of the consultation process for this guideline as well as the feedback received and the decisions regarding edits. The report is available from the TFI programme, and at the following link https://www.hse.ie/eng/about/who/tobaccocontrol/national-clinical-guidelines/

2.11 External review

External reviewers were identified through consultation with members of the GDG. Individuals with national and international reputations in tobacco control were sought who had experience and expertise in relation to stop smoking care. Given that the guideline recommendations relate to behavioural and pharmacological support, reviewer expertise across these domains was considered. Given the relevance of the European Tobacco Products Directive to tobacco control in Ireland, expertise was sought from one reviewer within the European Union. Finally, gender balance was also considered.

International external review of the guideline was undertaken by two experts in the area of tobacco control:

- Reviewer 1 – ***Prof Kenneth D. Ward***, Director of the Division of Social and Behavioral Sciences at University of Memphis, United States of America .
- Reviewer 2 – ***Prof Charlotta Pisinger***, Professor in Tobacco Control, University of Copenhagen and the Danish Heart Foundation, Denmark.

Kenneth D. Ward, PhD is Professor and Director of the Division of Social and Behavioral Sciences in the School of Public Health at The University of Memphis. He also serves as Adjunct Professor of Preventive Medicine at the University of Tennessee College of Medicine. Dr. Ward received a BA in psychology from Brown University, MS and PhD in clinical psychology from The University of Memphis, and completed a clinical psychology residency specializing in behavioral medicine at the University of Mississippi Medical Center. His research focuses on community-, healthcare system-, and population-level approaches to reduce the burden of tobacco use. He is especially interested in improving methods to help smokers quit and is a Certified Tobacco Treatment Specialist and holds a National Certificate in Tobacco Treatment Practice. He is co-founder and Intervention Director of the NIH-supported Syrian Center for Tobacco Studies, which has been a leader in tobacco control efforts for the past 20 years in the Eastern Mediterranean Region. Dr. Ward is a Research Laureate and Fellow of the American Academy of Health Behavior and a fellow of the Society of Behavioral Medicine. He has been a Fulbright Scholar at the Royal College of Surgeons in Ireland, and at the University of Memphis is the recipient of the Faudree Professorship and the Willard R. Sparks Eminent Faculty Award. Dr. Ward is a senior editor of Addiction and Associate Editor of *Journal of Smoking Cessation and Tobacco Regulatory Science*.

Charlotta Pisinger is a medical doctor, has a Ph.D. and a Master of Public Health and is Denmark's first professor in tobacco prevention. She is professor at the University of Copenhagen and adjunct professor at the University of Southern Denmark. She is used as a national tobacco expert, has written the national smoking cessation guidelines, published many tobacco-related reports and presented scientific evidence in the EU Parliament. She has written a background paper on e-cigarettes and health for WHO and has been investigator in several large intervention trials. She has until recently been head of the tobacco committee in the European Respiratory Society and on the board of Danish Society of Public Health. She is former president of the Danish Society of Tobacco Research and former vice-president of the Danish Society of Epidemiology.

Reviewers were asked to consider the guideline in accordance with the questions recommended by the National Quality Assurance Criteria for Clinical Guidelines Version 2 (HIQA/NCEC, 2015, p.14), (See Appendix 9). External reviewers were also asked to provide any additional feedback they felt was relevant.

The GDG held an online meeting, where the feedback was reviewed by the group and the GDG decided whether/not the guideline should be amended as a result of the presented feedback. Further details of the external reviews for this guideline are available in the consultation report, which is available from the TFI programme https://www.hse.ie/eng/about/who/tobaccocontrol/national-clinical-guidelines/

2.12 Implementation

A comprehensive plan for implementation of this guideline is outlined in Appendix 10. This builds on the work that is already being undertaken by a range of HSE services, health care professionals and others involved in the care of people quitting smoking.

Policymakers, health service planners and health service managers should consider that this guideline will inform specific actions in annual operational plans in specified settings, including monitoring of Key Performance Indicators and targets. Particular attention should be paid in planning and monitoring services to smoking-related inequalities in health.

Local procedures and protocols should be developed in services specified in this guideline to support implementation, tailored to the specific context and integrated with local systems for care planning and delivery. Specifically, procedures and protocols should be developed to communicate the policy on tobacco and approach to identifying and treating tobacco addiction for all scheduled and unscheduled admissions to their specific setting.

Funding for guideline implementation is subject to the service planning and estimates process.

Barriers and facilitators

A number of systematic reviews have examined barriers and facilitators to delivery of stop smoking support by health care professionals to the general population *(Sharpe, 2018)* and to the priority groups identified in this guideline, pregnant women *(Flemming, 2015)* and users of secondary mental health services, *(Sheals, 2016)*.

Barriers and facilitators can be considered with reference to the COM-B model of behaviour, reflecting 'Capability', 'Motivation' and 'Opportunity' (Michie, 2011), and include (Sharpe , 2018):

- 'Capability'
  - Lack of knowledge, skills and need for additional training
  - Absence of smoke-free hospital campus
- 'Opportunity'
  - Lack of time and competing demands from overwhelming workload
  - Lack of support (e.g. from colleagues/hospital admin/primary care)
- 'Motivation'
  - Lack of patient motivation (i.e. reluctant to quit, lack of compliance)
  - Personal discomfort (e.g. healthcare worker unwilling to upset patient, risk damage to doctor–patient relationship)
  - Cessation intervention not viewed as priority
  - Healthcare worker sceptical of interventions' effectiveness
  - Lack of incentive (e.g. recognition/reward)
  - Healthcare worker smoking history
  - Negative past intervention experience
  - Smoking viewed as coping mechanism for patients

Among these factors, lack of knowledge, skills and need for additional training as well as lack of time occurred most commonly.

For healthcare professionals working with pregnant women who smoke, building capability of professionals through education while recognising the centrality of the professional-client/patient relationship is key to overcoming barriers to offering stop smoking support; supportive organisational context including factors such as policies and resources are also important, *(Flemming, 2015)*. In addition, the association between maternal smoking and social disadvantage is a particular challenge in this context.

For healthcare professionals working with users of secondary mental health services who smoke, while similar barriers in relation to capability and time are identified, commonly held beliefs were that patients are not interested in quitting and that quitting smoking is too much for patients to take on are particular barriers linked to a culture of smoking as 'the norm' in this service setting and a perception of cigarettes as a useful tool for patients and staff, *(Sheals et al, 2016)*.

Reflecting on this evidence, some of the potential enablers and barriers to the implementation of the recommendations considered by the GDG are listed in Table 9.

Table 9: Potential enablers and barriers to the implementation of recommendations

Enablers	Barriers
All recommendations	
- Monitoring and evaluation - Audit and feedback - Sustainability planning	
Recommendation Numbers: 1,2,4,5,6,8,9	
- Awareness of the guideline and associated tools - Making Every Contact Count (MECC) Framework, associated tools, resources and training. - Recording tools (paper & electronic) - Tobacco Free Campus Policy & local procedures to build culture and support staff practices - Rollout of QUITManager (patient management system for the stop smoking service) to facilitate quick and easy referral to stop smoking services - Budget impact assessment, national service planning	- Myths & negative attitudes towards smoking cessation - Potential resource requirements - Requirement to release staff for training in MECC
Recommendations: 3, 7 &10	
- Prescribing tools - Enhanced nurse & midwife medicinal product prescribing, across all settings	- Medicine availability and current rules re GMS (General Medical Services) and DPS (Drug Payment Scheme) re stop smoking medicines as identified in HIQA Health Technology Assessment - Gaps in QUIT service delivery nationally - Potential resource requirement
Recommendations 4&5 (Maternity settings)	
- Making Every Contact Count (MECC) - Policies & procedures to support staff practices	- Myths & negative attitudes towards smoking cessation - Concerns around raising smoking in pregnancy and routinely using BCO testing - Requirement to release staff for training in MECC
Recommendations: 8 & 9 (Secondary mental-health settings)	
- Support & collaboration with service user advocacy groups - Local champions among service users and staff on the ground - Staff groups and right to smoke-free work environment - Increasing focus on physical health of service users - High intensity intervention combining behavioural support and pharmacotherapy support	- Myths & negative attitudes towards smoking cessation are a particular challenge in mental health settings - Requirement to release staff for training in MECC - Reluctance of healthcare professionals to prescribe adequate and tailored stop smoking medications

2.13 Monitoring and audit

A monitoring and audit plan will assess both the implementation and the effectiveness of the guideline. Monitoring and audit are closely aligned with the implementation plan and overall objectives of the clinical guideline.

Monitoring involves the regular assessment of the compliance of clinical practitioners with the guidelines, and audit means benchmarking compliance compared to specific standards. The process of collating routine information over time will track progress. It can be used to determine Key Performance Indicators – specific and measurable elements of practice that can be used to assess quality of care. The audit criteria can be delineated into process and outcome measures, with additional Key Performance Indicators as appropriate. Process measures track how implementation (of the guideline) is progressing. Outcome measures gauge how successful guideline implementation has been and assess the effectiveness of the recommendations in achieving their stated objectives.

A detailed monitoring and evaluation plan for this guideline is included in Appendix 12. It details the criteria for evaluation, who is responsible for the evaluation/audit, the data sources for each criteria and the frequency with which evaluation/audit of the named criteria should occur. Monitoring and evaluation for this guideline will be managed by the HSE TFI programme, building on and in line with current programme governance.

2.14 Legislation & other related policies

On occasion in clinical practice, prescriptions are written for licensed drugs given for unlicensed indications, and/or via an unlicensed route. Often it is simply a matter of the route or dose being different from those in the manufacturer's SmPC (Summary of Product Characteristics). It is of note that the licensing process for drugs regulates the marketing activities of pharmaceutical companies, and not prescribing practice. Unlicensed use of drugs by prescribers is often appropriate and guided by clinical judgment. This practice is safeguarded in legislation in accordance with Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I 540/2007) as amended. Therapeutic options should be considered on a case-by-case basis as necessary, including consideration of the possibility of a drug interaction.

2.15 Plan to update this National Clinical Guideline

The guideline will be reviewed and updated as appropriate by the HSE Tobacco Free Ireland Programme three years from publication as per the process recommended by NCEC *(DOH, 2019)*. If there is a major change in evidence prior to this, a rapid update may be conducted as per NCEC procedures. Any updates to the guideline in the interim period or as a result of the three-year review will be subject to approval by the NCEC. If the same GDG is unavailable, persons with the equivalent expertise will be recruited to participate in the review process.

3 Appendices

Only appendices 2, 10, 11 and 12 are presented here as they are key to interpreting the recommendations in this summary guideline.

Refer to the full guideline report for the remaining appendices:

Appendix 1: Guideline Development Group Terms of Reference

Appendix 3: Search Strategy

Appendix 4: (a) Quality Scores of Included and Excluded Guidelines
(b) Quality Appraisal of HIQA HTA using CASP Checklist

Appendix 5: A review of the evidence to inform the implementation of carbon monoxide testing during pregnancy

Appendix 6: Recommendation Matrix

Appendix 7: Considered Judgement Form Template

Appendix 8: Report on evidence scoping to assure currency of National Stop Smoking Guideline recommendations

Appendix 9: Consultation Process

Appendix 13: Treatment Effects Based on Direct Evidence, HIQA HTA (2017)

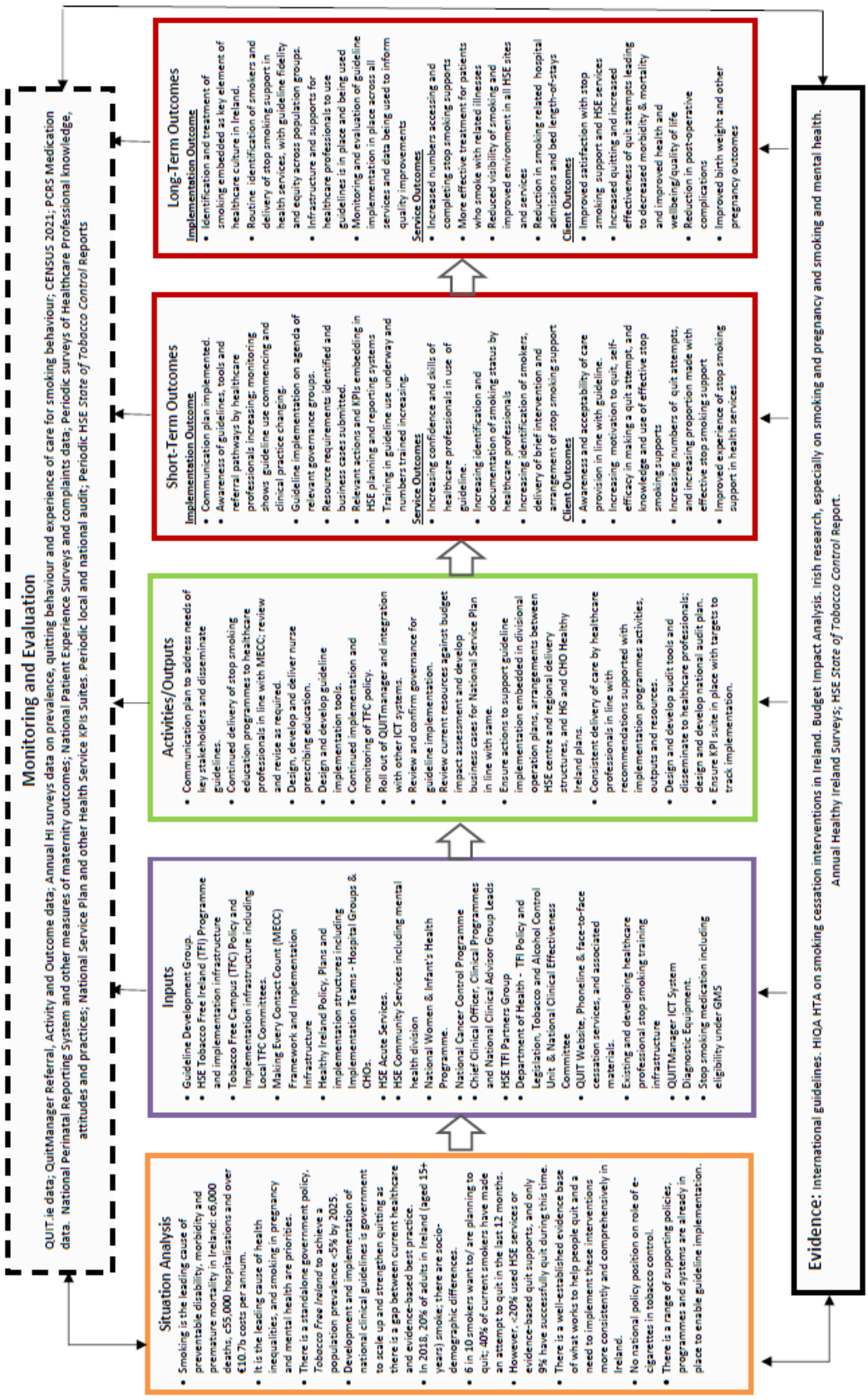
Appendix 2: Key Questions in PIPOH Format

Key question 1	What interventions should be offered by healthcare professionals to people using health services to identify people who smoke and help them stop?
Population	General adult population (aged 18+ years)
Intervention	Identifying smokers in routine clinical care and offering them support (behavioural & pharmacological) to quit smoking
Professional	All healthcare professionals
Outcome	Long-term smoking cessation (≥ 6 months)
Healthcare Settings	Primary care settings, Secondary care settings, Community care settings and mental health services

Key question 2	What interventions should be offered by healthcare professionals to pregnant women using health services to identify those who smoke and to help them stop?
Population	Pregnant women (all ages) from the first antenatal care contact to the postpartum period (3 months)
Intervention	Identifying smokers in routine clinical care and offering them support (behavioural & pharmacological) to quit smoking
Professional	All healthcare professionals
Outcome	Smoking cessation during and after pregnancy; maternal and foetal outcomes where available
Healthcare Settings	Primary care settings, Secondary care settings and Community care settings

Key question 3	What interventions should be offered by healthcare professionals to people using secondary mental health services to identify those who smoke and to help them stop?
Population	Persons with mental health problems (aged 18+ years) requiring secondary mental health services
Intervention	Identifying smokers in routine clinical care and offering them support (behavioural & pharmacological) to quit smoking
Professional	All healthcare professionals
Outcome	Long-term smoking cessation (≥ 6 months)
Healthcare Settings	Secondary care settings

Appendix 10: Logic Model & Implementation plan



All Recommendations						
Implementation enablers/barriers/gaps	**Action / intervention / task to implement recommendation**	**Lead responsibility for delivery of the action**	**Timeframe for completion**			**Expected outcome and verification**
			Yr 1	**Yr 2**	**Yr 3**	
Enablers: - Leadership, Governance, Programme Planning	- Review HSE TFI programme governance to ensure that implementation of these guidelines is a key focus. - Review HSE TFI partners group to ensure collaboration and leadership in place to drive and guide guideline implementation including establishment of a Stop Smoking Clinical Leadership Forum to engage and mobilise health professionals and a Stop Smoking Spearhead Forum to ensure focus on heath inequalities and priority groups - Recognise and regularise specialist in public health medicine leadership for the HSE TFI Programme as a key national public health programme in line with recommendation of Prof Scally in his scoping review on CervicalCheck (https://assets.gov.ie/9785/9134120f5b2c441c81eeed06808351c7.pdf	HSE TFI Programme (Lead)	☑			Outcomes: - National level leadership, governance and programme planning in place to drive implementation of guidelines across a multi-annual programme plan Verification: - Terms of reference - minutes - plans
Enablers: - Monitoring and evaluation - Audit and feedback	- Develop and roll out a plan for audit, monitoring and evaluation	- HSE TFI Programme (Lead) with all relevant stakeholders		☑		Outcomes: - Better use of data to inform implementation of the guideline Verification: - Audit, monitoring and evaluation plan finalised
- Sustainability planning	- Develop sustainability plan for ongoing implementation of the guideline beyond year 3	- HSE TFI Programme (Lead) with all relevant stakeholders			☑	Outcomes: - Guideline more likely to be sustained Verification: - Sustainability plan finalised

Recommendation Numbers: 1,2,4,5,7,8,9						
Implementation enablers/barriers/gaps	**Action / intervention / task to implement recommendation**	**Lead responsibility for delivery of the action**	**Timeframe for completion**			**Expected outcome and verification**
			Yr 1	**Yr 2**	**Yr 3**	
Enabler: - Awareness of the guideline and associated tools	- Development of communication plan to widely communicate guideline across the health service - Raise public awareness/expectations around identification & treatment of smoking as key element of healthcare. - Incorporating of guideline into existing hospital letters/correspondence in advance of appointments/admission etc.	- **HSE Communications** - Guideline Development Group - HSE TFI Programme - HSE Mental Health (strategy & operations) - HSE National Women & Infant's Health Programme - TFI Partner Organisations - HSE Clinical Programmes - Colleges - Recovery Colleges	☑			Outcomes: - Awareness of smoking cessation among healthcare professionals - Changes in knowledge, attitudes and practice by HCPs - Increased uptake of recording tools by HCPs - Increased numbers referred to stop smoking services from various settings - ↑ numbers asked about their smoking behaviour - ↑ numbers accessing stop smoking services - ↑ numbers successfully quitting smoking Verification: - Communication Plan complete - Implementation report completed - Public awareness campaigns completed - Monitoring of guideline implementation - KPI data, HI survey
Enabler: - Making Every Contact Count (MECC)	- Continued rollout of MECC training (online via www.makingeverycontactcount.ie and face-to-face) to healthcare professionals. - Inclusion of MECC training on undergraduate programmes. - Develop strategies for increasing access to and participation in MECC training	- **MECC Team (National)** - Hospital Groups - Community Healthcare Organisations - Regional Integrated Care Organisations (RICOs)		☑		Outcomes: - Changes in knowledge, attitudes and practice by HCPs - Increased uptake of recording tools by HCPs - Increased numbers referred to stop smoking services from various settings - ↑ numbers asked about their smoking behaviour - ↑ numbers accessing stop smoking services - ↑ numbers successfully quitting smoking Verification: - Monitoring of guideline implementation - KPI data, HI survey

Recommendation Numbers: 1,2,4,5,6,8,9						
Implementation enablers/barriers/gaps	**Action / intervention / task to implement recommendation**	**Lead responsibility for delivery of the action**	**Timeframe for completion**			**Expected outcome and verification**
			Yr 1	**Yr 2**	**Yr 3**	
Enabler: - Recording Tools (paper & electronic)	- Inclusion of MECC recording tools (smoking behaviour) across settings. - Roll out electronic record including smoking behaviour recording.	- **MECC Team (National)** - HSE TFI Programme - Mental Health (strategy & operations) - National Women & Infants' Health Programme - Office of the Chief Information Officer - ICGP		☑		Outcomes: - Increased uptake of recording tools by HCPs - Increased numbers referred to stop smoking services from various settings - ↑ numbers asked about their smoking behaviour - ↑ numbers accessing stop smoking services - ↑ numbers successfully quitting smoking Verification: - Monitoring of guideline implementation - KPI data, HI survey
Enabler: - Policies & procedures to support staff practices	- Support & full implementation of Tobacco Free Campus Policy - Development of referral pathways from various settings to stop smoking services	- **Hospital Groups** - **Community Healthcare Organisations** - **HSE TFI Programme** - Quality & Risk, Health & Safety - **HSE TFI Programme**	☑ ☑			Outcomes: - Increased numbers referred to stop smoking services from various settings - ↑ numbers accessing stop smoking services - ↑ numbers successfully quitting smoking Verification: - Monitoring of guideline implementation - KPI data, HI survey

Recommendations: 1,2,4,5,6,8,9						
Implementation enablers/barriers/gaps	**Action / intervention / task to implement recommendation**	**Lead responsibility for delivery of the action**	**Timeframe for completion**			**Expected outcome and verification**
			Yr 1	**Yr 2**	**Yr 3**	
Enabler: - Rollout of QUITManager	- Full implementation across all hospitals. - Link with GP IT systems (healthlink) - Training and access to referral module for staff in other settings including secondary mental health care settings. - Integration of Quitmanager with maternity information system.	- **HSE TFI Programme** - Office of the Chief Information Officer, HSE - Hospital Groups - HSE Mental Health (strategy & operations)			☑	Outcomes: - Increased numbers referred to stop smoking services from various settings - ↑ numbers accessing stop smoking services - ↑ numbers successfully quitting smoking Verification: - Monitoring of guideline implementation - KPI data, HI survey
Barrier: - Potential resource requirements (*as identified in Budget Impact Assessment*)	- Inclusion of financial resource requirement as part of annual estimates process and service planning	- Hospital Groups (regional & local level) - CHOs (regional & local level) - HSE TFI Programme - National Women & Infants' Health Programme - HSE Mental Health (strategy & operations)			☑	Outcomes: - Evidence-based requests for additional funding Verification: - Inclusion in annual estimate/bids and service plans at both national, regional and local area

Recommendations: 8 & 9 (Secondary mental-health settings)						
Implementation enablers/barriers/gaps	**Action / intervention / task to implement recommendation**	**Lead responsibility for delivery of the action**	**Timeframe for completion**			**Expected outcome and verification**
			Yr 1	**Yr 2**	**Yr 3**	
Enabler: - Mental Health Advocacy Groups - Local Champions on the ground - Staff groups and right to smoke-free work environment - Increasing focus on physical health of mental health service users	- Tobacco Free Campus policy implementation - Co-production of best practice guidance documents with Mental Health Ireland and others - Raising public awareness/expectations around identification and treatment of smoking as core element of healthcare in secondary care mental health settings - Inclusion of smoking cessation in care plans in mental health settings	- **HSE TFI Programme** - **Mental Health (Strategy & Operations)** - Mental Health Commission - TFI Partners Group including Mental Health Ireland	☑			Outcomes: - Changes in attitudes by secondary mental healthcare users towards smoking and smoking cessation. - Changes in knowledge, attitudes and practice by HCPs. - Increased numbers referred to stop smoking services from secondary mental health care settings. Verification: - Monitoring of guideline implementation - KPI data, HI survey data, TFC implementation survey data
Barrier: - Myths & negative attitudes towards smoking cessation in mental health settings - Requirement to release staff for training in MECC	- Staff awareness campaign around guideline and associated tools, specific to this setting. - Incentivisation initiatives e.g. TFC bursary initiative	- **HSE TFI Programme** - **Mental Health (Strategy & Operations)** - HSE Communications Unit - Mental Health Commission - TFI Partner groups	☑			Outcomes: - Changes in attitudes by secondary mental healthcare HCPs towards smoking and smoking cessation. - Changes in knowledge, attitudes and practice by HCPs. - Increased numbers referred to stop smoking services from secondary mental health care settings. Verification: - Monitoring of guideline implementation KPI data, HI survey data, TFC implementation survey data

Recommendations: 3, 7 &10						
Implementation enablers/barriers/gaps	**Action / intervention / task to implement recommendation**	**Lead responsibility for delivery of the action**	**Timeframe for completion**			**Expected outcome and verification**
			Yr 1	**Yr 2**	**Yr 3**	
Enabler: - Prescribing tools	- Development of prescribing tools detailing recommended stop smoking medications for various populations. - Education of HCP - Development or update of Patient Information Leaflets	- **HSE TFI Programme** - Pharmacy Partners	☑			Outcomes: - ↑ prescribed recommended pharmacotherapy supports Verification: - Prescribing tools published - Uptake of stop smoking medications as per PCRS data
Enabler: - Enhanced nurse & midwife medicinal product prescribing, across all settings	- Communications campaign specific to nurses and midwives to encourage inclusion of stop smoking medications in their scope of practice	- **HSE Communications Unit** - **HSE TFI Programme** - **Nursing & Midwifery Board of Ireland**		☑		Outcomes: - Increased number of nurses and midwives including stop smoking medications in their scope of practice - ↑ prescribed recommended pharmacotherapy supports Verification: - Uptake of stop smoking medications as per PCRS data

Recommendations: 3, 7 & 10						
Implementation enablers/barriers/gaps	**Action / intervention / task to implement recommendation**	**Lead responsibility for delivery of the action**	**Timeframe for completion**			**Expected outcome and verification**
			Yr 1	**Yr 2**	**Yr 3**	
Barriers: - Medicine availability current rules regarding support for access to stop smoking medicines via the General Medical Services and the Drug Payments Scheme. Advice re same previously provided to Minister for Health to examine this barrier through the HIQA HTA so as to increase uptake of safe, effective stop smoking medicines	- Engagement with Department of Health re options to better support access to stop smoking medicines so as to increase use. .	- **HSE TFI Programme** - Department of Health - HSE PCERS	☑			Outcomes: - Potential removal of barriers (cost) to recommended treatment - Increased numbers using evidence-based pharmacological supports Verification: - Changes in eligibility criteria for free stop smoking medications - Uptake of stop smoking medications as per PCERS
Barriers: - Gaps in QUIT service delivery nationally	- Quit service delivery review, (standards & QA, and needs of service users/model) needs assessment and development plan - Development of on-site intensive cessation services	- **HSE TFI Programme** - Hospital Groups - CHOs - RICOs	☑			Outcomes: - 'Picture' of current QUIT service Verification: - Needs assessment/review conducted - KPI data
Barriers: - Potential resource requirement	- Inclusion of financial resource requirements as part of annual estimates and service planning process	- Hospital Groups (regional & local level) - CHOs (regional & local level) - HSE TFI Programme - National Women & Infants' Health Programme - HSE Mental Health (strategy & operations)			☑	Outcomes: - Evidence-based requests for additional funding Verification: - Inclusion in annual estimate/bids and service plans at both national, regional and local area

Recommendation 10 (Secondary mental-health settings)						
Implementation enablers/barriers/gaps	**Action / intervention / task to implement recommendation**	**Lead responsibility for delivery of the action**	**Timeframe for completion**			**Expected outcome and verification**
			Yr 1	**Yr 2**	**Yr 3**	
Enabler: - High intensity intervention combining behavioural support and pharmacotherapy support	- Design and develop 'high intensity support' - Train staff in delivery of support. - Develop mechanism to feedback data to mental health services on drug use	- **HSE TFI Programme** - **Mental Health (Strategy & Operations)** - **Mental Health Ireland** - Mental Health Commission - Hospital Groups			☑	Outcomes: - Recommended support for users of secondary mental health care settings, who want to quit smoking - ↑ numbers accessing stop smoking services - ↑ numbers successfully quitting smoking Verification: - Monitoring of guideline implementation - KPI data,
Barrier: - Reluctance of healthcare professionals to prescribe adequate and tailored stop smoking medications	- Staff awareness campaign regarding guideline and associated tools, including prescribing tool	- **HSE TFI Programme** - **Mental Health (Strategy & Operations)** - **HSE Communications Unit**	☑			Outcomes: - Increased number of secondary mental health service users attempting to quit smoking, and successfully quitting smoking - Increased number of secondary mental health service users using stop smoking medications Verification: - Monitoring of guideline implementation - KPI data - Uptake of stop smoking medications as per PCERS

Recommendations 4&5 (maternity-specific)						
Implementation enablers/barriers/gaps	**Action / intervention / task to implement recommendation**	**Lead responsibility for delivery of the action**	**Timeframe for completion**			**Expected outcome and verification**
			Yr 1	**Yr 2**	**Yr 3**	
Enabler: - Making Every Contact Count (MECC)	- Maternity-specific resource for face-to-face training of HCPs - Training of midwives in the use of Carbon monoxide monitors as part of face-to-face training. - Continued integration of MECC with roll-out of new maternity information system (MN-CMS)	- **MECC Team (National)**	☑ ☑		☑	Outcomes: - Changes in knowledge, attitudes and practice by HCPs - Increased uptake of recording tools by HCPs - Increased numbers referred to stop smoking services from various settings - ↑ numbers asked about their smoking behaviour - ↑ numbers accessing stop smoking services - ↑ numbers successfully quitting smoking Verification: - Monitoring of guideline implementation - KPI data, HI survey
- Policies & procedures to support staff practices	- Phased implementation of rollout of COBT in all maternity units - Develop opt-out referral pathways from maternity units to stop smoking services	- **National Women & Infant's Health Programme** - HSE TFI Programme			☑	

Appendix 11: Supporting tools

Public website with information and interactive tool
QUIT.ie www.quit.ie https://www2.hse.ie/quit-smoking/ links to social media including Facebook and Twitter
Public Information Leaflets:
Quit Guide – A guide to quitting smoking* https://www.healthpromotion.ie/hp-files/docs/HQS00346.pdf *Also available in Polish, Spanish, French, Portugese, Romanian, Lithuanian & Irish
30 second stop smoking advice https://www.hse.ie/eng/about/who/tobaccocontrol/campus/30-second-stop-smoking-guide.pdf
Give your Baby a Breather – Pregnancy & Smoking https://www.healthpromotion.ie/hp-files/docs/HQS01013.pdf
Growing up smoke free leaflet https://www.healthpromotion.ie/hp-files/docs/HPM00725.pdf
Why we offer carbon monoxide breath testing at your first hospital visit - Information Leaflet for Pregnant Women (Currently in development)
Carbon monoxide breath testing for pregnant women - An improved care pathway with advice for healthcare professionals (Currently in development)
Tools to support Staff
Making Every Contact Count: Making Every Contact Count Training Programme https://www.hse.ie/eng/about/who/healthwellbeing/making-every-contact-count/training-programme/ Making Every Contact Count in Maternity Services (Currently in development) MECC Client Record: https://www.hse.ie/eng/about/who/healthwellbeing/making-every-contact-count/order-resources/making-every-contact-count-client-record.pdf MECC Resources https://www.hse.ie/eng/about/who/tobaccocontrol/resources/
National Standard for Tobacco Cessation Support Programme https://www.hse.ie/eng/about/who/tobaccocontrol/cessation/tobaccocessationnationalstandard.pdf
Tobacco Cessation Support Programme https://www.hse.ie/eng/about/who/tobaccocontrol/cessation/tobacco-cessation-support-programme.pdf
HSE Stop Smoking Referral Form https://www.hse.ie/eng/about/who/tobaccocontrol/resources/tfi-f-1-rev-2-hse-stop-smoking-referral-form1.pdf
Smoking Cessation & Mental Health – A briefing for frontline Staff https://www.hse.ie/eng/about/who/tobaccocontrol/campus/mental-health-briefing-document.pdf
Mental Health Services – Referral Pathway to Assist Service Users to Quit Tobacco https://www.hse.ie/eng/services/list/4/mental-health-services/physical-health-supports-for-mental-health-services/referral-pathway-to-assist-service-user-to-quit-tobacco.pdf
Quit Pharmacy Booklet https://www.healthpromotion.ie/hp-files/docs/HNC00867.pdf

Tobacco Free Campus: National Tobacco Free Campus Policy https://www.hse.ie/eng/staff/resources/hrppg/national-tobacco-free-campus-policy---april-2012.pdf
HSE Tobacco Free Campus Implementation Guidance Document https://www.hse.ie/eng/about/who/tobaccocontrol/campus/tobacco-free-campus-toolkit-guidance-document-oct-16.pdf

Appendix 12: Monitoring and audit

A monitoring and audit plan is required for assessing both the implementation and the effectiveness of a guideline. Monitoring and audit need to closely align with the implementation plan and overall objectives of the clinical guideline.

Monitoring involves the assessment of the compliance of clinical practitioners with the guidelines on a regular basis, and benchmarking compliance compared to specific standards is termed audit. It is a systematic process of collating routine information to track progress over time. It can be used to determine Key Performance Indicators – specific and measurable elements of practice that can be used to assess quality of care.

The audit criteria can be delineated into process and outcome measures, with additional key performance indicators being measured as appropriate. Process measures track how implementation (of the guideline) is progressing. Outcome measures gauge how successful guideline implementation has been and assess how successful recommendations have been in achieving stated objectives (effectiveness).

Targets for specific audit criteria should be attained from pre-existing KPIs in services and from baseline measurements of the below criteria (with a view to quantifying future improvements).

Evaluation of the implementation of guidelines

Criteria	Auditor/Monitor	Data source	Frequency
Process measures			
% of HCWs who have completed MECC training	National and local TFC committees	HSELand / Training records	Annual
Prescribing tools and guidance availability	TFI	HSE	Annual
Number of professional awareness / advertising campaigns	TFI	HSE Communications	Annual
Outcome measures			
Documentation of smoking behaviour as per audit table*	Clinical audit team	Patient chart (physical / electronic)	Quarterly
Number of patients on varenicline therapy ± NRT	TFI	PCERS	Annual
Number of pregnant women offered routine CO monitoring	Clinical audit team	Patient chart (physical / electronic) & MN-CMS	Quarterly

Criteria	Auditor/Monitor	Data source	Frequency
Number of sites that offer routine CO monitoring in maternity services	TFI	Hospital groups clinical directors	Annual
% of nurses/midwives trained to prescribe smoking cessation therapies	Smoking cessation officers	HSELand, Professional training logs, and attendance sheets for face to face training	Annual
% of midwives trained in use of CO monitor	Smoking cessation officers	Professional training logs, attendance sheets for face to face training, scope of practice records	Annual
Number of brief intervention sessions delivered	Clinical audit team	Patient chart (physical / electronic) and smoking cessation officer reports	Quarterly
Number of people engaged in intensive support - phone	TFI	QUITManager	Quarterly
Number of people engaged in intensive support - individual counselling	TFI	QUITManager	Quarterly
Number of people engaged in intensive support - group counselling	TFI	QUITManager	Quarterly
Number of referrals to HSE QUIT	TFI	QUITManager	Quarterly
Proportion of referrals that result in quit attempts supported by HSE QUIT	TFI	QUITManager	Quarterly
Awareness of smoking cessation as part of healthcare among HCWs	TFI / HSE R&E	Staff surveys (CHO and hospital groups)	Periodic

***Clinical audit of documentation – outcome of guideline implementation**

Criteria	Frequency
All services	
% of episodes where HCWs asked and documented smoking behaviour	Annual
% of episodes where HCWs informed smokers of the harm of smoking and benefit of quitting and documented this	Annual
% of episodes where HCWs arranged for interested smokers to avail of smoking cessation services and documented this	Annual
Mental health services	
% of episodes where HCWs asked and documented smoking behaviour	Annual
% of episodes where HCWs informed smokers of the harm of smoking and benefit of quitting and documented this	Annual
% of episodes where HCWs arranged for interested smokers to avail of smoking cessation services and documented this	Annual
Maternity services	
% of episodes where HCWs asked and documented smoking behaviour	Annual
% of episodes where HCWs informed smokers of the harm of smoking and benefit of quitting and documented this	Annual
% of episodes where HCWs arranged for interested smokers to avail of smoking cessation services and documented this	Annual
% of episodes where HCWs asked and documented smoking behaviour on delivery	Annual
% of episodes where HCWs asked and documented smoking behaviour on postpartum discharge	Annual

Evaluation of clinical effectiveness of guidelines

Criteria	Auditor/Monitor	Data source	Frequency
Number of smokers – daily/occasional/ previous	TFI / HSE R&E	Healthy Ireland, Market Research, CSO Census	Annual
Proportion of successful quit attempts supported by HSE QUIT	TFI	QUITManager	Quarterly

KPIs

- % of HCWs who have completed MECC training
- Number of patients on varenicline therapy ± NRT
- Number of people engaged in phone support
- Number of people engaged in individual counselling
- Number of people engaged in group counselling
- Number of smokers – daily/occasional/previous
- Number of quit attempts supported by HSE QUIT
- Number of successful quit attempts supported by HSE QUIT
- Number of referrals to HSE QUIT
- Number of midwives trained in use of CO monitor
- Number of sites that perform CO monitoring to pregnant patients

Evaluation

Formal evaluation of the implementation of the guideline should be undertaken to determine the extent to which the expected outcomes are achieved. This should occur following completion of the implementation period (end year 3). A separate evaluation of the care outcomes should also be undertaken on a continued basis. Most data will be available via the monitoring and audit processes outlined above.

An Roinn Sláinte
Department of Health

Department of Health, Block 1, Miesian Plaza, 50-58 Lower Baggot Street,
Dublin 2, D02 VW90, Ireland

Tel: +353 1 6354000 • Fax: +353 1 6354001 • www.health.gov.ie