An Roinn Sláinte
Department of Health

Stop Smoking

National Clinical Guideline No. 28

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 National Clinical Guideline

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/

Published by:

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Miesian Plaza,
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Tel: +353 (1) 6354000

www.health.gov.ie

ISSN 2009-6259.

Citation text

Department of Health (2022). Stop Smoking (NCEC National Clinical Guideline No. 28). Available at:
https://www.gov.ie/en/collection/c9fa9a-national-clinical-guidelines/

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:
    - o 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.
    - o People who do not smoke or use e-cigarettes should not start.
    - o 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.
    - o 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.
    - o Evidence regarding the effectiveness and safety profile of e-cigarettes as a stop smoking support is evolving.
    - o To reduce the harm from smoking, dual use of tobacco and e-cigarettes should be avoided.
    - o 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*).

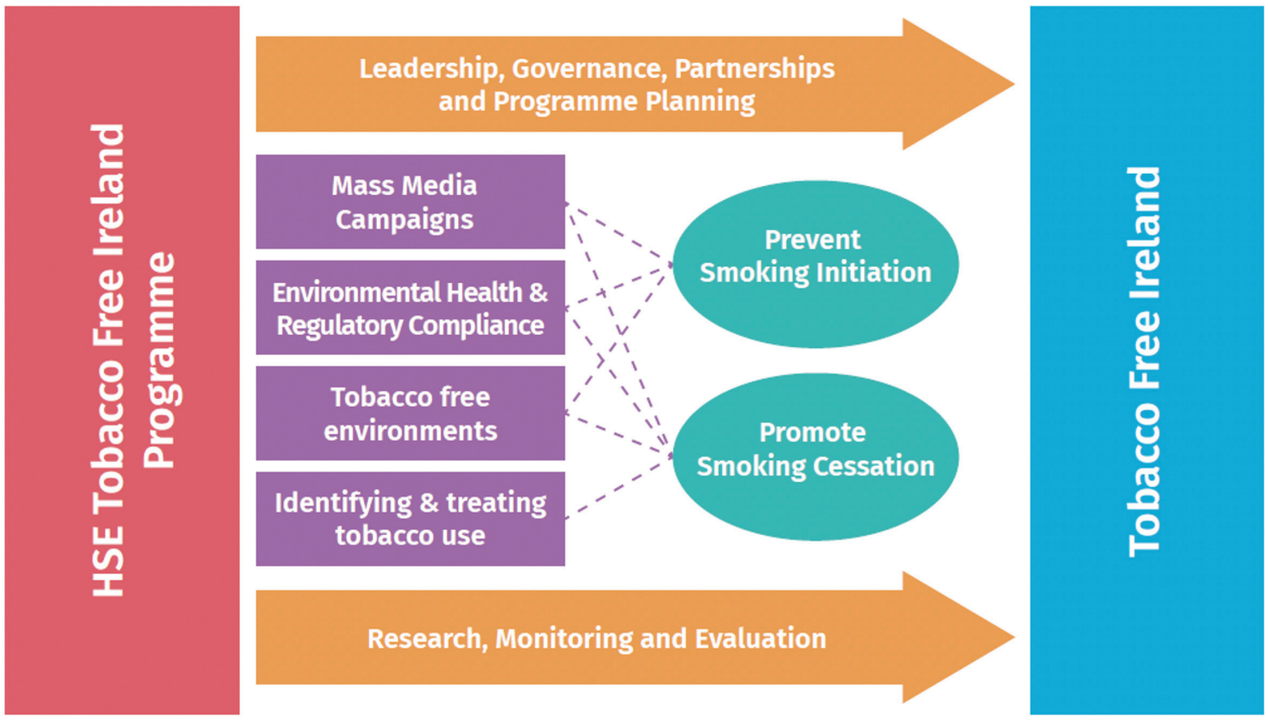


Figure 1: Overview of HSE Tobacco Free Ireland Programme

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.

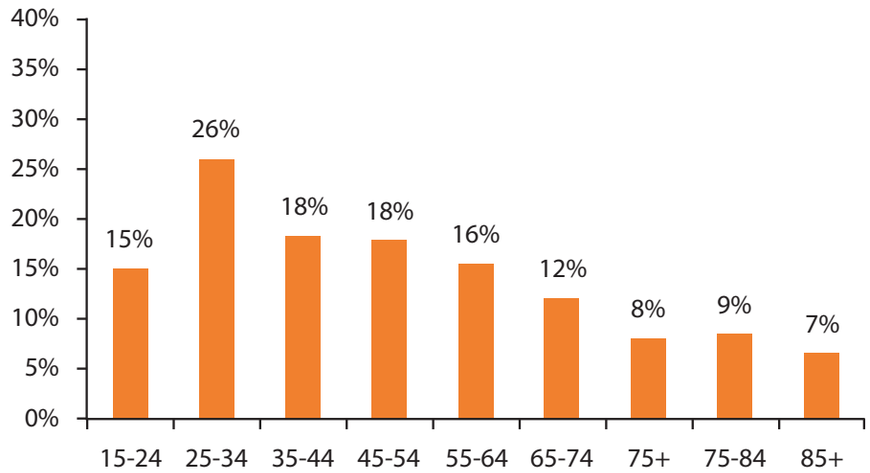


Figure 2: Current smoking prevalence by age, 2019

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*).

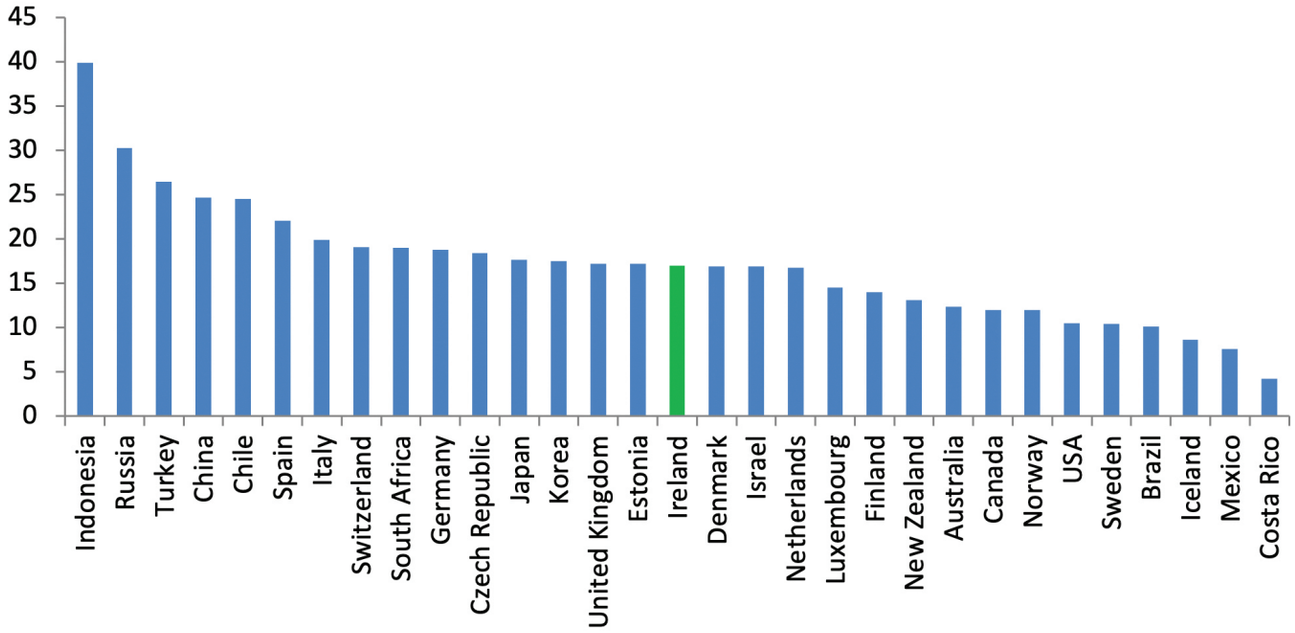


Figure 3: Prevalence of daily smoking among adults, International comparison, 2017*

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.

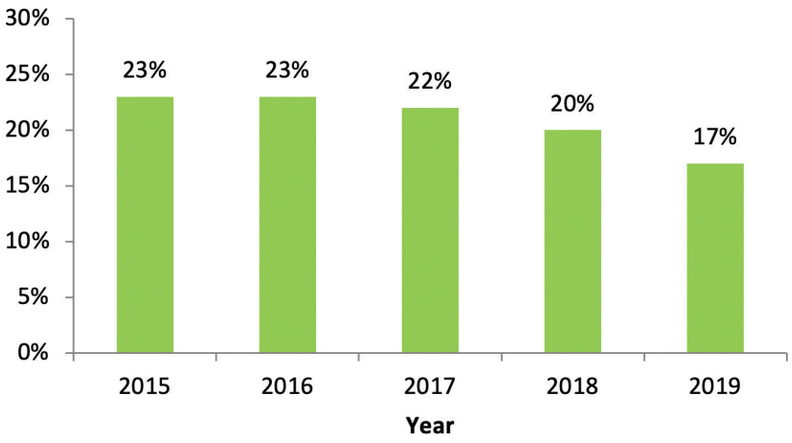


Figure 4: Trend in smoking prevalence 2015 – 2019

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)*.

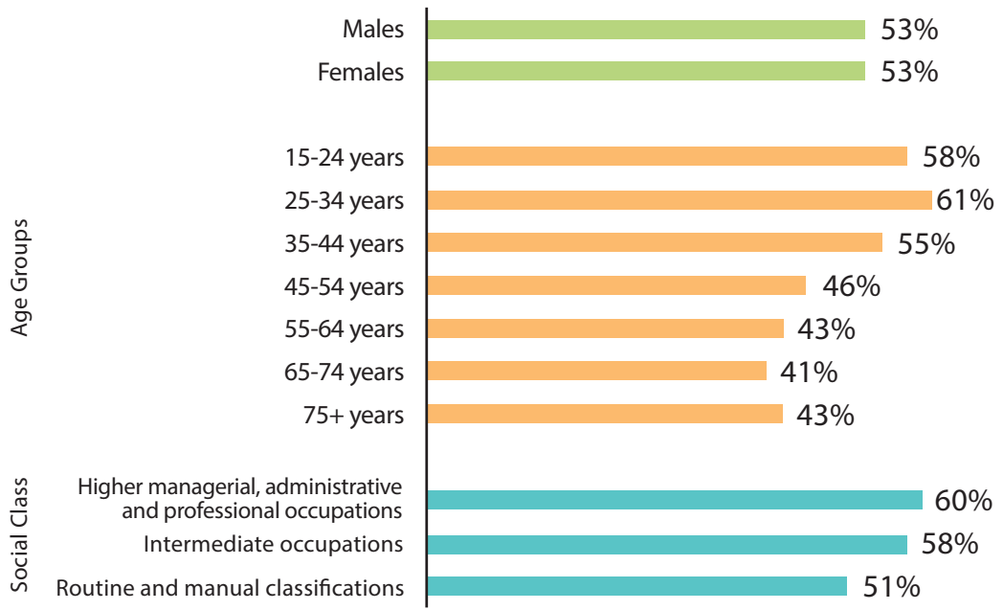


Figure 5: Profile of people who made a quit attempt in the 12 months prior to survey

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*).

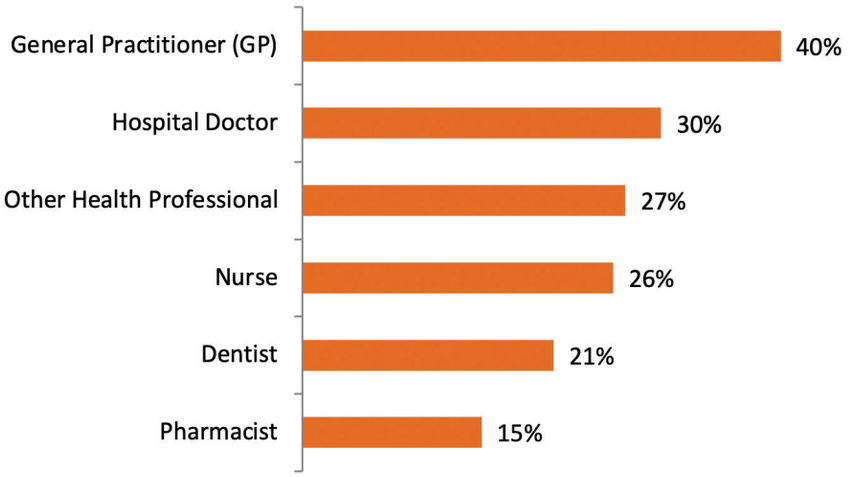


Figure 6: Proportion of smokers who have discussed quitting with a Health Professional, 2018

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.

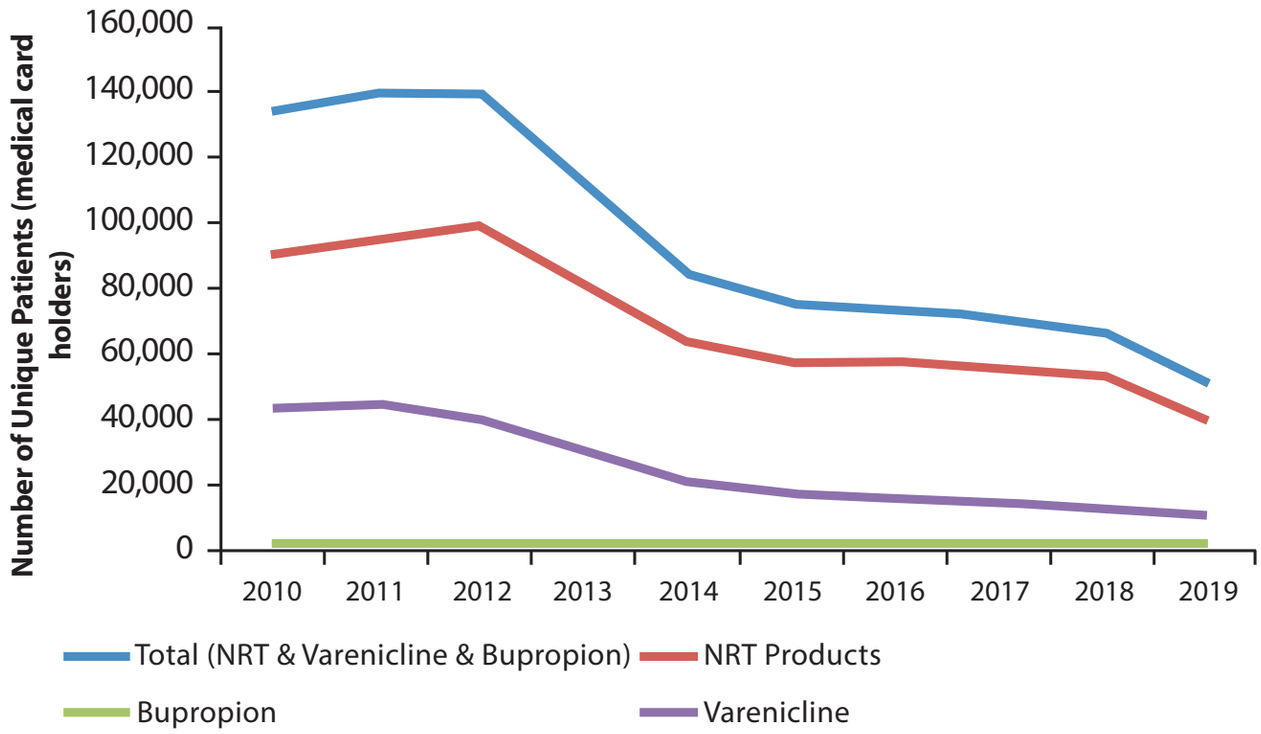


Figure 7: Trends in number of unique patients (medical card holders only) availing of NRT and other stop smoking medications, 2010 to 2019

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.

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)*.

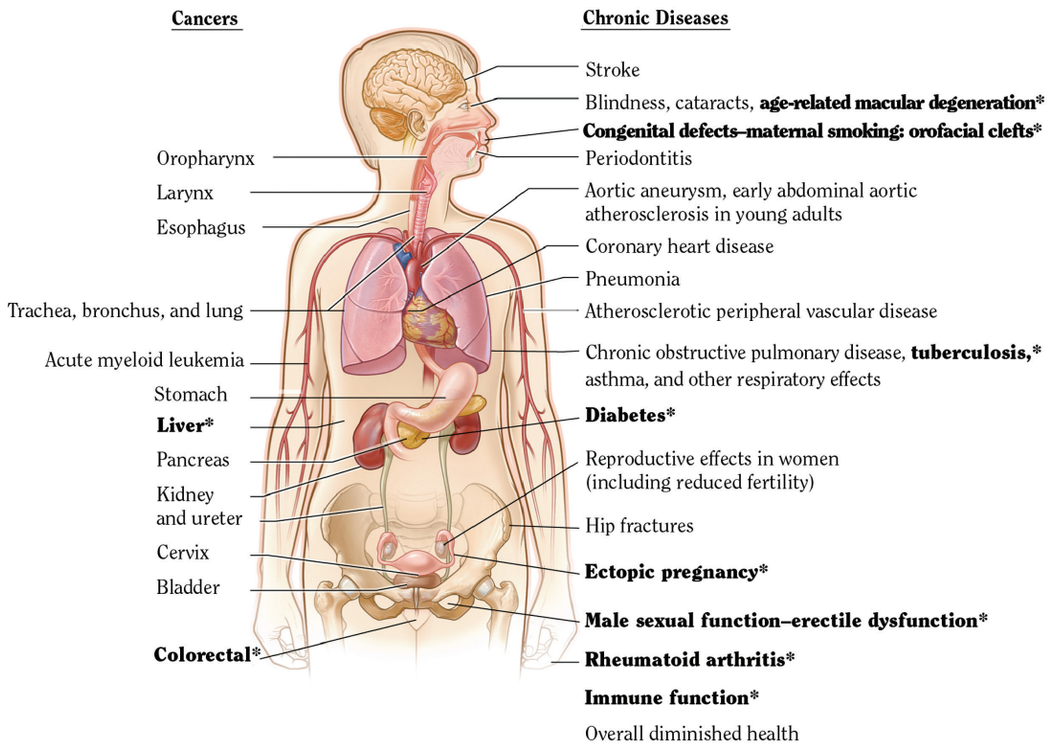


Figure 8: The health consequences causally linked to smoking

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.

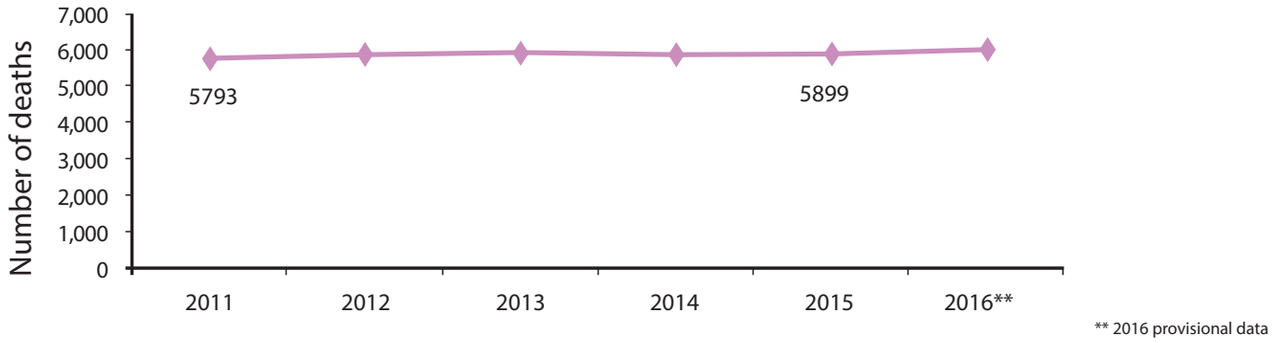


Figure 9: Trend in crude number of deaths estimated to be attributable to smoking and exposure to SHS, 2011-2016*

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.

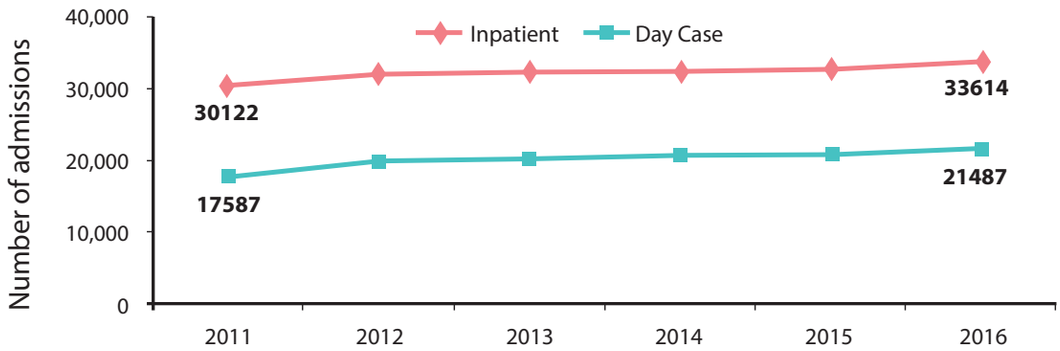


Figure 10: Trend in crude number of hospital admissions (inpatient and day case) estimated to be attributable to smoking and exposure to SHS, 2011-2016

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).

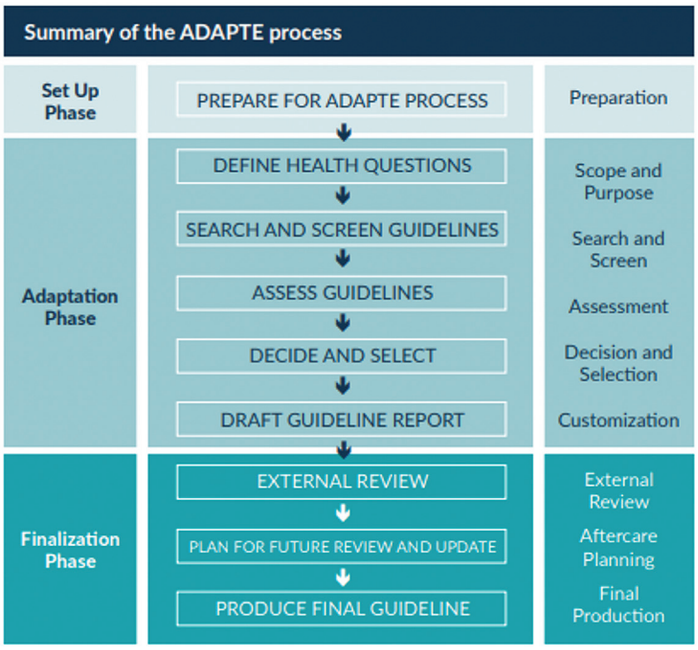


Figure 11: Summary of the ADAPTE process

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 National Clinical Guideline

3.1 Key questions and evidence statements

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 during routine clinical care contacts and offering them support (behavioural & pharmacological) to stop 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

Evidence statement:
Sources of evidence for Key question 1 were international guidelines from New Zealand *(MOH, NZ & NIHI, 2014)*, the United States *(USPSTF, 2015)* and Canada *(CAN-ADAPTT, 2012)*, as well as the HIQA HTA on smoking cessation interventions in Ireland *(HIQA, 2017)*. In addition, the recent HRB Evidence Reviews were considered in relation to e-cigarettes *(HRB, 2020a)*. The recent publication of a preliminary opinion from the European Commission's Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) on e-cigarettes is noted; however, that work is preliminary and is still to be finalised so it was not used by the GDG in decision-making, *(SCHEER, 2020a,b)*. Also included in these evidence statements are national and HSE policy and some evidence from local research. Finally, additional supporting evidence identified through the consultation on draft guideline and the process to scope evidence to assure the currency of guideline recommendations described at Section 2.9 is referenced.

The evidence is discussed under the following sub-headings:

- Asking About Smoking Behaviour and Offering Advice to Quit
- Behavioural & Pharmacological Supports

<u>Asking About Smoking Behaviour and Offering Advice to Quit:</u>
Asking about smoking behaviour and offering advice to quit are elements of health behaviour change interventions that can be used by health professionals in day to day practices in the health services in Ireland, and have been categorised as follows: *(HSE, 2016b)*

- *Brief Advice (BA):* A short opportunistic intervention that directs people where to go for further help using the 3 As model – *(1)* Ask about behaviour; *(2)* Advise on the need for behaviour change; *(3)* Act to refer or signpost people to additional support.
- *Brief Intervention (BI):* An intervention that aims to equip people with tools to change attitudes and explore underlying problems. It involves discussion, negotiation and encouragement with or without follow-up using the 5As model - *(1)* Ask about the behaviour; *(2)* Advise on the need for behaviour change; *(3)* Assess readiness to change; *(4)* Assist with exploration of the barriers and benefits of behaviour change, with identifying options for change, and with goal setting; *(5)* Arrange referral to more intensive support if appropriate.

- *Extended Brief Intervention (EBI):* An EBI is similar in content to a BI but usually lasts longer and consists of an individually focused discussion and follow-up.
- *Specialist Services:* A high intensity intervention delivered by specifically trained health professionals to support a patient through a behaviour change.

This section of the guideline is, therefore, concerned with the "Ask," "Advise" and "Act/Arrange" steps of BA and BI. The next section concerns more extensive and intensive health behaviour interventions delivered by specialist services.

All three guidelines recommend that all healthcare professionals should ask about and document every person's smoking behaviour, and this should be updated regularly. The New Zealand guideline provides some guidance as to how regularly smoking behaviour should be asked about and documented; they suggest at every hospital admission and at least annually in primary care settings. In addition, all three guidelines recommend that all healthcare professionals should offer advice to their patients to quit smoking at every opportunity, irrespective of the individual patient's desire to stop smoking at that time.

The HIQA HTA on smoking cessation interventions identifies BA as the standard of care in the Irish health services. In general it was treated as an active control or a baseline service delivery against which the effectiveness of other interventions are compared, and not specifically assessed in the HTA for its effectiveness. It also distinguishes BA from more extensive and intensive interventions to change health behaviour, which are discussed in the next section. However, BA was noted by HIQA to be one and a half times more likely to result in a successful quit attempt than quitting with no form of support.

In addition to established effectiveness of BI, recent Cochrane systematic reviews and meta-analyses have confirmed the effectiveness of the intervention when led by nursing and community pharmacy professionals, *(Rice, 2017, Carson, 2019)*.

The GDG considered that providing support to prevent relapse is a common challenge faced by healthcare professionals working with people who smoke and want to stop. While this was outside the scope of the guideline, the GDG noted the results of a recent Cochrane systematic review and meta-analysis which reported that behavioural interventions that teach people to recognise situations that are high risk for relapse along with strategies to cope with them provided no worthwhile benefit in preventing relapse in assisted abstainers, *(Livingstone-Banks, 2019)*. Furthermore, in people who have successfully quit smoking using pharmacotherapy, there were mixed results regarding extending pharmacotherapy for longer than is standard: extended treatment with varenicline helped to prevent relapse (evidence for the effect estimate was of moderate certainty, limited by unexplained statistical heterogeneity) but evidence was lacking for extending other pharmacotherapies. More research is needed in this area. The GDG considered that offering healthcare professionals some GPPs in this area would be useful.

In addition to the evidence base for this guideline, a recent survey of the content of stop smoking guidelines from 61 countries found that all guidelines recommended BA and 82% recommended routine recording of smoking behaviour *(Nilan, 2018)*.

Recent findings from the Healthy Ireland Survey indicate that the majority of smokers have not discussed quitting with a health professional during a recent consultation: 60% (General Practitioners), 70% (hospital doctors); 73% (other healthcare professionals); 74% (nurse); 79% (dentist) and 85% (pharmacists), *(IPSOSMRBI, 2018)*. This evidence points to a significant care gap to be addressed through the implementation of these guidelines. Similar care gaps have been described in other countries, *(US Department of Health & Human Services, 2020), (RCP, 2018)*.

Current HSE policy, Making Every Contact Count *(HSE, 2016b)*, which is now being implemented across the health service, aims to ensure that all patients who engage with services, both in hospital and in the community, will be routinely asked about their main lifestyle risk factors for chronic diseases, including smoking. These risk factors will be recorded on patient data systems as well as the intervention carried out by the health professional. The evidence supporting these behaviour change interventions concluded that they are effective both for individual lifestyle behaviours and collectively for all behaviours, including smoking. Together with the HSE Tobacco Free Campus policy *(HSE, 2012)* which requires healthcare staff to treat tobacco addiction as a healthcare issue, full implementation of these HSE policies will create a culture within the health services which will promote disease prevention and health improvement, along with treatment services. This is 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)*.

Benefits and harms:
The harms of smoking and benefits of quitting have been described, with supporting evidence, in the preliminary sections.

Smoking causes death and disability on a large scale and it is well documented that tobacco smoking has been causally linked to diseases of nearly every organ of the body, to diminish health status and to foetal harm, *(U.S. Department of Health and Human Services, 2014)*. The burden of hospitalisation and death attributable to smoking that could be avoided through elimination of this risk factor has been quantified in Ireland: 55,000 hospitalisations and 5,900 deaths *(HSE, 2018b)*.

Stopping smoking results in immediate health benefits and can help avoid most of the excess mortality caused by continuing to smoke, *(Pirie, 2013 & Jha, 2013, US Department of Health & Human Services, 2020)*. Mental health and quality of life benefits are also associated with smoking cessation compared to continued smoking *(Taylor, 2014)*.

Intervention from health professionals has been shown repeatedly, in randomised controlled trials, to increase the percentage of smokers who stop and remain abstinent for six months or more, *(West et al, 2000)*.

In terms of patient reaction to being asked about their smoking behaviour and offered advice, initial findings on the acceptability of MECC among patients and clients is that this approach is well received, and that there is an expectation among patients and clients that they will be asked about their lifestyle and making behaviour changes, such as smoking cessation, *(HSE, 2019)*.

Quality of Evidence:
High quality evidence across all 3 international guidelines.

Values & preferences:
Ireland has ratified the WHO FCTC *(WHO, 2003*) and has the policy goal of becoming tobacco free by 2025, indicating a high value and strong preference for tackling smoking, *(DoH, 2013)*. In particular, national policy on tobacco control states that *"the protection of children must be prioritised in all of the initiatives outlined in the policy" and "denormalisation must be a complementary underpinning theme for all of the initiatives within the policy."*

Healthy Ireland Survey findings from 2015-2019 indicate that the majority of smokers want to quit, valuing the outcome of smoking cessation. Results show a high percentage of smokers are trying to, are planning to, or are considering quitting: 63% (2015), 59% (2016), 57% (2017 and 2018) and 68% (2019), *(IPSOS MRBI, 2015, 2016, 2017, 2018, 2019)*.

In-depth analysis of the Healthy Ireland Survey 2015 identified that smokers are more likely to report poorer health (both physical and mental) compared to people who do not smoke, independent of age, gender and social class. Ex-smokers report better health than current smokers and report similar levels of mental ill-health as never smokers *(HSE, 2018c)*. This is consistent with the body of evidence on the health harms of smoking and the benefits of quitting.

Good health is a state highly valued by patients and by healthcare professionals and, since implementation of recommendations in this area support good health, it is aligned with values and preferences. Healthcare professionals will respect the preference of patients who refuse to discuss their smoking behaviour or who decline advice to stop smoking.

Smoking is a significant driver of health inequalities and the poorer health and premature mortality experienced by our poorest and more excluded groups, *(Petty-Saphon, 2019)*. These guidelines offer the potential to address socio-economic inequalities in health, which is aligned with the goals of *Healthy Ireland (Government of Ireland, 2013)*, the current national policy framework for health and wellbeing in Ireland.

Resource use:
The WHO cites tobacco control as a "best-buy" for public health and has identified population-wide support (including BA) for tobacco cessation to all those who want to quit as an effective intervention with favourable cost-effectiveness for tackling non-communicable disease, *(WHO, 2013a)*.

HIQA conducted a review of cost effectiveness studies of smoking cessation interventions. It concluded that *"the existing literature in this area has consistently found that practically all smoking cessation interventions are associated with very low ICERs (Incremental Cost-Effectiveness Ratios), which would make them appear extremely cost-effective using conventional willingness-to-pay thresholds in Ireland and elsewhere," (HIQA, 2017).* Because BA was considered a standard of care by HIQA in its HTA, the cost-effectiveness and budget impact were not specifically modelled. The HSE is already committed to the implementation of MECC, which supports the guideline recommendation in this area, so no additional resource use implications arise, *(HSE, 2016b)*.

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.

The following are responsible for implementation of recommendations 1 and 2

- All healthcare professionals to ask and advise about smoking.
- Services should support healthcare professionals with their responsibilities through local Tobacco Free Campus Committees or equivalent structures to ensure that appropriate environment, culture, resources and supports are in place.
- HSE Tobacco Free Ireland programme will support HSE operated and funded services through national projects and programmes and set out in its Programme Plan and the implementation plan for this guideline.

Behavioural & Pharmacological Supports:
There are a range of behavioural and pharmacological supports available which, in combination or alone, are proven to be effective in assisting those who want to quit smoking. All international guidelines in our evidence-base and the HIQA HTA support this statement, with the HIQA HTA reporting that the effectiveness of pharmacological interventions is improved by an average of 18% by providing any type of adjunct behavioural therapy, *(HIQA HTA, 2017)*.

Behavioural Supports
All three international guidelines in our evidence base provide recommendations for the provision of behavioural supports to those who want to quit smoking, namely, the New Zealand guideline *(MOH, NZ & NIHI, 2014)*, the US guideline *(USPSTF, 2015)* and the Canadian guideline *(CAN-ADAPTT, 2011)*. In addition, the HIQA HTA provides evidence on the clinical effectiveness of these interventions and recommended that *"providing behavioural support, either alone or in combination with pharmacological interventions, increases the chances of long-term smoking cessation and should continue to be provided to all smokers who would like to avail of this option to help them quit," (HIQA, 2017)*.

Brief Advice
Albeit BA is already addressed above in relation to "Ask," "Advise" and "Act/Arrange," it is noted here that all three guidelines in the evidence-base for this guideline recommend the provision of BI by all healthcare professionals; the Canadian guideline indicates that a BI of 1-3 minutes can be provided, and that there is a dose-response relationship with regard to effect.

Intensive Specialist Support Services - Individual or Group Counselling
All three guidelines in the evidence base for this guideline recommend the provision of intensive specialist support services through counselling, either at individual or group level, as effective. Both the New Zealand and Canadian guidelines recommend a minimum of four sessions should be provided to the individual. Individual and Group Counselling were also found to be effective compared with control based on direct evidence reported by HIQA in its HTA (See Appendix 13).

The effectiveness of intensive specialist support services delivering individual or group counselling to help people stop smoking was also confirmed by recent Cochrane systematic reviews and meta-analyses, *(Lancaster, 2017, Stead, 2017)*.

HSE-operated and funded intensive specialist services provide individual and group counselling in line with a HSE National Standard *(HSE, 2013a)* and comprises at a minimum a pre-quit support contact, 4 support consultation/contacts on a weekly basis in the first month post quit date, follow up at 3 months to review quit status, and follow up at 12 months to review quit status. The HSE also provides a detailed

Tobacco Cessation Support Programme with 7 sessions that can be adapted to meet individual client needs, pace and readiness to change and can be facilitated on an individual or group basis, *(HSE, 2013b)*.

Telephone Support

All three guidelines in the evidence base recommend that the provision of behavioural support by phone to those attempting to quit smoking is effective. Similarly, telephone support was also found to be effective compared with control based on direct evidence reported by HIQA in its HTA *(See Appendix 13)*. This is consistent with a recent Cochrane systematic review and meta-analysis, *(Matkin, 2019)*.

Telephone support operated or funded by the HSE as an intensive specialist stop smoking support service is also delivered in line with the HSE National Standard and its Tobacco Cessation Support Programme, *(HSE, 2013a & HSE, 2013b)*.

Internet and text-based support

HIQA reported that internet-based interventions were more effective than control *(See Appendix 13)*. It defined internet-based interventions as interactive, personalised and non-interactive interventions, focused on standard approaches to information delivery though the internet. The New Zealand guideline notes internet-based support can be offered but identifies the evidence as weak, and so refers to this as good practice, rather than a recommendation. A recent Cochrane systematic review and meta-analysis found that the evidence from trials in adults suggests that interactive and tailored internet-based interventions with or without additional behavioural support are moderately more effective than non-active controls at six months or longer, (Taylor, 2017).

The New Zealand guideline provided 'moderate' evidence of the effectiveness of text message support to those attempting to quit. Mobile phone interventions were distinct from telephone support and defined as any type of mobile phone-based intervention for smoking cessation based around delivery via mobile phone, using any functions or applications that could be used or sent via a mobile phone. Mobile phone-based interventions were reported by HIQA to have similar effectiveness to control, (See Appendix 13). However, a more recent Cochrane systematic review and meta-analysis found that there was moderate-certainty evidence, limited by inconsistency, that automated text messaging interventions were more effective than minimal smoking cessation support (RR 1.54, 95% CI 1.19 to 2.00) it also found that there was also moderate-certainty evidence, limited by imprecision, that text messaging added to other smoking cessation interventions was more effective than the other smoking cessation interventions alone (RR 1.59, 95% CI 1.09 to 2.33), *(Whittaker, 2019)*.

The HSE offers a plan via its QUIT.ie website with personalised daily support via email and text message and a personalised web page to track progress. Content of QUIT.ie and the QUIT plan is in line with the HSE National Standard and its Tobacco Cessation Support Programme, *(HSE, 2013a & HSE, 2013b)*.

Other behavioural or non-pharmacological supports

No recommendations were made in relation to other behavioural supports by international guidelines in our evidence base.

The GDG considered that people interesting in quitting may raise other non-pharmacological supports with healthcare professionals. HIQA found that acupuncture was no more effective than control in helping people to stop smoking and was not recommended; a recent Cochrane systematic review and meta-analysis found that there was insufficient evidence to determine whether hypnotherapy is more effective for smoking cessation than other forms of behavioural support or unassisted quitting, *(Barnes, 2019).*

HIQA also examined the Allen Carr Method as non-pharmacological supports to help people stop smoking. This is a commercial non-pharmacological support which can be delivered as a book or through attending a group workshop. It identified no studies evaluating the efficacy and safety of the Allen Carr Method for smoking cessation that were eligible for inclusion in its HTA. Since then some more studies have reported results in relation to the Allen Car Method delivered free of charge to people who want to stop smoking as either a book or group workshop, *(Foshee, 2017, Keogan, 2019, Frings, 2020)*. Results of these studies were mixed, and while some studies reported positive results when the Allen Carr Method was delivered as a group workshop, it was offered free of charge and it is difficult to draw inferences about the intervention when it is recommended but where the person who wants to stop faces a charge. The studies reporting positive result did not find the Allen Carr Method delivered as a group workshop was any more effective than intensive specialist support delivered as group counselling.

The GDG considered that offering healthcare professionals some good practice points to deal with queries raised by people who smoke interested in stopping with other non-pharmacological supports no recommended in the guidelines would be helpful.

In addition to the evidence base for this guideline, a recent survey of the content of stop smoking guidelines from 61 countries found that all guidelines (100%) recommended BA, 87% recommended intensive specialist support services, 61% recommended telephone support or "quitlines," and 31% recommended text support. *(Nilan, 2018)*

Pharmacological Supports

The following section details the evidence for the pharmacological supports licensed and available in Ireland, specifically varenicline, nicotine replacement therapy (NRT) and bupropion. Just two international guidelines in our evidence base provide recommendations for pharmacological support, namely the New Zealand guideline *(MoH, NZ & NIHI, 2014)* and the US guideline *(USPSTF, 2015)*. In addition, the HIQA HTA provides evidence on the clinical effectiveness of these products *(HIQA, 2017)*.

In Ireland, the Health Products Regulatory Agency regards e-cigarettes as medicinal products subject to medicines legislation where they are used in or assist in smoking cessation, *(HPRA, 2017)*. Therefore, e-cigarettes require authorisation before being placed on the market in Ireland for smoking cessation. Currently no e-cigarettes are authorised for use in or to assist in smoking cessation in Ireland; however, given the use of e-cigarettes as a stop smoking support by those attempting to quit smoking (as described in the previous section), the GDG considered it appropriate that e-cigarettes be examined and they are discussed in this section.

Nicotine Replacement Therapy (NRT)

NRT was first licensed for use in Ireland in 1995 and the current forms of NRT available in Ireland are: transdermal patch; gum; lozenge; inhaler, spray and oro-dispersable film. From the evidence-base for this guideline, both the New Zealand and US guidelines recommend NRT as an effective medication for those who want to quit smoking; the New Zealand guideline recommends that NRT is offered 'routinely' to those who want to quit, and in addition they state this should be for a minimum of 8 weeks. Both of these guidelines recommend combining two NRT products for increased abstinence rates. This is consistent with a recent Cochrane systematic review and meta-analysis which confirmed the effectiveness of NRT *(Hartmann-Boyce, 2019)*, and a further Cochrane review which found that combination NRT is superior to NRT monotherapy, *(Lindson, 2019)*.

Varenicline

Varenicline was first licensed for use in Ireland in 2006. From the evidence base for this guideline, both the New Zealand and US guidelines recommend it as an effective medication for those who want to stop smoking. This is consistent with a recent Cochrane systematic review and meta-analysis which found that varenicline at standard dose increased the chances of successful long-term smoking cessation between two- and three-fold compared with pharmacologically unassisted quit attempts, *(Cahill, 2016*).

Bupropion

Bupropion was first licensed for use in Ireland in 2000. From the evidence base for this guideline, both the New Zealand and US guidelines recommend it as an effective medication for those who want to stop smoking.

The HIQA HTA *(HIQA, 2017)* provided direct comparisons of the clinical effectiveness of these interventions, compared to control/comparator (BA/written materials). They concluded that all interventions had a treatment effect, *(See Appendix 13)*. Varenicline was the most effective single therapy on the direct analysis of evidence (risk ratio (RR) = 2.66) compared to control; NRT and bupropion are similarly effective (RRs close to 1.60). Varenicline and combination NRT showed a statistically significant treatment benefit when compared with NRT monotherapy. Relative to bupropion, varenicline was shown to have a statistically significant treatment effect. On the basis of a fixed effect estimate, combination NRT was also shown to have a statistically significant treatment effect relative to bupropion. Varenicline was the most effective monotherapy and had a small, but not statistically significant, treatment benefit compared to combination NRT. Overall, HIQA advised that *"smoking cessation services should, in the first instance, seek to increase the uptake of varenicline (alone or in combination with NRT) among smokers wishing to use some type of pharmacological support in their attempt to quit" and "should seek to promote the uptake of combination NRT treatment among those for whom varenicline is not suitable," (HIQA, 2017).*

Nortriptyline

Due to the fact that it was not available at the time in Ireland, nortriptyline was not included among the treatments examined by HIQA in its HTA. Since then, it has become available in Ireland and is authorised by the Health Products Regulatory Agency; its therapeutic indication is for relief of depression. It is recommended as an effective medication for those who want to stop smoking in the New Zealand guideline, but is not recommended by the US guideline. A recent Cochrane systematic review and meta-analysis confirmed the effectiveness of nortriptyline monotherapy as a pharmacological support to help people stop smoking, *(Howes, 2020)*.

Combination with behavioural support

HIQA noted that the effectiveness of pharmacological interventions is improved by an average of 18% by providing any type of adjunct behavioural therapy products *(HIQA, 2017)*. This is supported by recent Cochrane reviews which found that behavioural support increases adherence to pharmacological supports and lead to better outcomes, *(Hollands, 2019, Hartmann-Boyce, 2019, Stead, 2016)*.

E-Cigarettes

Neither the New Zealand guideline *(MoH, NZ & NIHI, 2014)* nor the US guideline *(USPSTF, 2015)* recommend e-cigarettes as a support to help people stop smoking.

In relation to e-cigarettes, the HIQA HTA noted that *"although the currently available results for e-cigarettes are promising, there is insufficient evidence at present to reliably demonstrate their effectiveness as an aid to smoking cessation."*

More recently, the HRB conducted a systematic review and meta-analysis of trials of the role of e-cigarettes as a stop smoking support. It reported with low certainty that e-cigarettes and NRT are associated with similar incidence of smoking cessation at 24/26 weeks follow-up and very low level of certainty about smoking cessation outcomes at 52 weeks. Compared to other pharmacological supports, the body of evidence relating to e-cigarettes is small, evolving and not yet fully conclusive, so confidence in the reliable demonstration of their effect size will require further well-conducted trials, *(HRB, 2020a)*. Following publication of the HRB evidence reviews, and while consultation on the draft version of these guidelines was ongoing, the Department of Health identified a recent Cochrane systematic review and meta-analysis to the Chair of the GDG and asked that the GDG consider it, *(Hartmann-Boyce, 2020)*. That review found that there is moderate-certainty evidence that e-cigarettes with nicotine increase quit rates compared to e-cigarettes without nicotine and compared to NRT. Evidence comparing nicotine e-cigarettes with usual care/no treatment also suggests benefit, but is less certain. The Cochrane review reported different conclusions regarding the effectiveness of e-cigarettes than the HRB. There were important differences between the reviews which may contribute to the different conclusions: the HRB were independent of the primary studies in the systematic review; the HRB used a more up-to-date risk of bias tool; the HRB included a greater number of studies in meta-analysis; the HRB used network meta-analysis, an evidence synthesis tool that mobilises a greater body of evidence than that used by the Cochrane Group; the HRB disaggregated study outcomes by endpoint and did not collapse study outcomes; the HRB conducted evidence-driven sensitivity analyses to explore the robustness of its conclusions to various methodological decisions. Overall, the view of the GDG was that the area of agreement between the reviews was more significant to its consideration than areas of disagreement: both studies conclude that there are significant limitations in the evidence base due to the small number of RCTs, often with low event rates and various sources of bias, leading to imprecision in overall estimates of effect size and direction in systematic review and meta-analysis. The GDG reviewed its content in relation to e-cigarettes and confirmed that this reflected its considered judgement on the issues taking account of the available evidence at this point in time and other relevant factors set out in the Considered Judgement Frameworks used to guide its deliberations.

In addition to the evidence base for this guideline, a recent survey of the content of stop smoking guidelines from 61 countries found that 98% recommended NRT, 84% recommended bupropion, and 82% recommended varenicline, *(Nilan, 2018)*. A scoping review of position statements in published and grey literature collected 81 statements from international health organizations and found that comments on e-cigarettes were diverse and level of confidence in evidence was a commonly cited issue, *(Brady, 2019)*.

Recent findings from the Healthy Ireland Survey (2019) indicate that the majority of smokers quit without any support (52%), while 38% of those who made an attempt to quit smoking used e-cigarettes, *(IPSOS MRBI, 2019)*.

Benefits and harms:
The harms of smoking and benefits of quitting have been described, with supporting evidence, in previous sections.

The HIQA HTA reports that no substantive adverse effects were identified following review of the efficacy literature associated with the recommended behavioural interventions outlined here, *(HIQA, 2017)*. It noted some conflicting studies regarding the incidence of major adverse cardiovascular events in users of varenicline and pointed to the then ongoing CATS study as potential to resolve this conflict. The results of that study were published after HIQA completed its HTA and it reported that there was no

evidence that the use of smoking cessation pharmacotherapies, including varenicline, increased the risk of serious cardiovascular adverse events during or after treatment was observed and that smoking cessation medications do not increase the risk of serious cardiovascular events in the general population of smokers, *(Benowitz, 2018)*. HIQA concluded that pharmacological interventions for smoking cessation are largely safe and well-tolerated in the general adult population and in the absence of contraindications, these agents are undoubtedly safer than the continuation of smoking, *(HIQA, 2017)*. All pharmacological interventions referenced in these guidelines and available in Ireland are licensed and regulated by the HPRA.

Unlike pharmacological supports considered in this guideline, e-cigarettes used in or to assist in smoking cessation are subject to medicines legislation and require marketing authorisation for this purpose, no e-cigarette products are licensed with the HPRA in Ireland. So they are currently available in Ireland as consumer products and are subject to provisions set out in the Tobacco Products Directive (TPD) as transposed into Irish law. *(Official Journal of the European Union, 2014 & Government of Ireland, 2018)*. While this sets out some measures for the regulation of e-cigarettes and refill containers, it is not equivalent to the system for regulation of the quality, safety and effectiveness of medicines and it does not provide the person using the product or the healthcare professional recommending it the same assurance in terms of safeguards which apply to other pharmacological stop smoking supports.

The recent HRB evidence mapping *(HRB, 2020b)* identified that e-cigarettes are a highly heterogeneous range of products which means that, unlike other pharmacological supports discussed in this guideline, the person using the product and the healthcare professional recommending it cannot be certain in relation to the exact exposure to nicotine and other constituents of e-cigarettes. A range of harms were associated with e-cigarettes, most due to respiratory diseases, oral diseases, injuries, poisonings, signs and symptoms, or bio-markers for disease. Cohort studies and trials comparing conventional cigarettes to e-cigarettes show lower levels of risk markers in e-cigarette users than in conventional tobacco, which could translate into a reduction in risk of long-term health harms for e-cigarette users versus conventional tobacco users. However, it noted that long term follow-up studies would be required to quantify outcome-specific differences between conventional cigarette users, e-cigarettes users, dual users, and non-users of any type of cigarette. E-cigarettes were associated with the increased likelihood of young people initiating conventional tobacco cigarette smoking, which is a potential public health harm that could undermine progress made in tackling smoking in Ireland.

Quality of Evidence:
High quality evidence across international guidelines and from HIQA HTA on Smoking Cessation Intervention in Ireland (2017).

Values & preferences:
Ireland has ratified the WHO Framework Convention on Tobacco Control (WHO FCTC), *(WHO, 2003)* and has the policy goal of becoming tobacco free by 2025, indicating a high value and strong preference for tackling smoking. In particular, national policy on tobacco control states that *"the protection of children must be prioritised in all of the initiatives outlined in the policy" and "de-normalisation must be a complementary underpinning theme for all of the initiatives within the policy," (DoH, 2013)*.

Smoking is a significant driver of health inequalities and the poorer health and premature mortality experienced by our poorest and more excluded groups, *(Petty-Saphon, 2019)*. This guideline offers the potential to address socio-economic inequalities in health, which is aligned with the goals of *Healthy Ireland (Government of Ireland, 2013)*.

Healthy Ireland Survey findings from 2015-2019 indicate that the majority of smokers want to quit, valuing the outcome of smoking cessation. Results show a high percentage of smokers are trying to, are planning to, or are considering quitting: 63% (2015), 59% (2016), 57% (2017 and 2018) and 68% (2019). *(IPSOS MRBI, 2015, 2016, 2017, 2018, 2019)*

In depth analysis of the Healthy Ireland survey 2015 identified that over 40% of smokers are more likely to report poorer health (both physical and mental) compared to people who do not smoke, independent of age, gender and social class. Ex-smokers report better health than current smokers and report similar levels of mental ill-health as never smokers, *(HSE, 2018c)*. This is consistent with the body of evidence on the health harms of smoking and the benefits of quitting. Good health is a state highly valued by patients and by healthcare professionals and, since implementation of recommendations in this area support good health it is aligned with values and preferences. Healthcare professionals should respect the preference of patients who refuse to discuss their smoking behaviour or who decline advice to stop smoking.

Healthy Ireland Survey data reports few Irish smokers making a supported quit attempt using behavioural supports; in 2019, while 500,000 smokers attempted to quit smoking, only approximately 9,500 smokers received intensive cessation support provided by the HSE. *(HSE, 2020 and HSE, 2018b)*. In addition, of those who reported using stop smoking medications, far fewer smokers making a supported quit attempt used varenicline compared with NRT (<4% versus 24%). It is unclear what effect any prospective policy change designed to increase varenicline use would have on these figures. While this data raises questions in relation to preferences for behavioural and pharmacological support to stop smoking, as previously highlighted, many smokers using health services do not benefit from BI for their smoking behaviour. This care gap is addressed through these guidelines.

In relation to e-cigarettes, the GDG noted that 5% of the population use e-cigarettes (10% of current smokers use e-cigarettes, with 13% of ex-smokers using them) and 38% of those who made an attempt to quit smoking used e-cigarettes, *(IPSOS MRBI, 2019)*. There are trade-offs, potentially undesirable consequences and uncertainties associated with e-cigarette use, with unknowns in terms of values and preferences associated with these in Ireland. In particular, use of a regulated medicine with established quality, safety and an effectiveness profile versus a consumer product without them are very different options for stop smoking support and the individual reactions of people who smoke to these options is likely to vary widely.

The GDG examined the current policy position on tobacco control in Ireland, including e-cigarettes. It noted the strong value and preference expressed in *Tobacco Free Ireland* for the protection of children and de-normalisation in all tobacco control measures. *Tobacco Free Ireland* noted *"a requirement for alternative, less harmful forms of nicotine."* However, *Tobacco Free Ireland* also drew attention to *"a discrepancy in relation to the nicotine containing products available"* in that *"Nicotine Replacement Therapy available currently from pharmacies is well regulated while other products such as Electronic Nicotine Delivery Systems (ENDS), e.g. e-cigarettes, are not regulated for specifically other than under general product safety legislation operated under the European Communities (General Product Safety) Regulations 2004,"* that *"there is growing concern internationally about the quality, safety and 'regulatory gap' of these emerging products, broadly called ENDS"* and that there *"appears to be general consensus that there is a lack of research in relation to the long-term health effects of e-cigarettes and a lack of sufficient evidence that they aid with smoking cessation."*

Tobacco Free Ireland was published in 2013 and is now past the mid-point to its 2025 goal, but it has not yet benefited from review. Since then, the EU Tobacco Products Directive 2014/40/EU has been transposed into Irish law, *(Official Journal of the European Union, 2014 & Government of Ireland, 2018)* and further evidence including the HRB evidence reviews has become available. *(HRB, 2020a,b,c)* In 2019 the EU Scientific Committee on Health, Environment and Emerging Risks (SCHEER) was mandated to assess the most recent scientific and technical information on e-cigarettes to inform the European Commission's review of the Tobacco Product Directive, specifically its provisions on e-cigarettes, *(SCHEER, 2020a,b)*. A preliminary opinion has been recently published, which draws conclusions to the HRB evidence review, *(SCHEER, 2020a,b)*. It confirms evidence of negative health effects from e-cigarettes and notes the need for further long term human health studies; strong evidence for a "gateway effect" from e-cigarettes to combustible tobacco product was identified; and finally weak evidence for the support of electronic cigarettes' effectiveness in helping smokers to quit was reported. Because this report is preliminary, it was not considered in decision-making by the GDG. In addition, HIQA was commissioned to provide advice to the Minister for Health in relation to smoking cessation interventions, including e-cigarettes, and it noted: *"Although the currently available results for e-cigarettes are promising, there is insufficient evidence at present to reliably demonstrate their effectiveness as an aid to smoking cessation. It would be appropriate to await the results of ongoing trials before deciding whether e-cigarettes should be recommended for those for whom varenicline is not suitable. Should additional evidence confirm the effectiveness of e-cigarettes as a smoking cessation aid, a decision to advocate their use should also take into consideration any additional information on the long-term safety of e-cigarettes use, as well as any emerging data in relation to concerns about the social normalisation of e-cigarettes leading to increased uptake among people who have never smoked, or later migration to tobacco cigarettes." (HIQA, 2017)* More recently, the HRB was commissioned to conduct evidence reviews for the Department of Health to inform any review of policy in relation to e-cigarettes. The outcome is awaited.

Resource use:

The WHO has cited tobacco control as a "best-buy" for public health and has identified population-wide support (including BA) for tobacco cessation to all those who want to quit as an effective intervention with favourable cost-effectiveness for tackling non-communicable disease, *(WHO, 2013a)*.

HIQA conducted a review of cost effectiveness studies of smoking cessation interventions. It concluded that *"the existing literature in this area has consistently found that practically all smoking cessation interventions are associated with very low ICERs (Incremental Cost-Effectiveness Ratios), which would make them appear extremely cost-effective using conventional willingness-to-pay thresholds in Ireland and elsewhere"*. It found that increasing the smoking cessation budget to promote the use of varenicline-based regimens (combination NRT therapy for those for whom varenicline is not suitable) would be a cost-effective use of resources. *(HIQA, 2017)*

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 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.

The GDG made no recommendation in relation to e-cigarettes as a stop smoking support. With regard to grading quality of evidence and the strength of recommendations using the GRADE approach, *(GRADE, 2013)* the reasons, considered collectively by the GDG, for this decision were:

- Confidence in effect estimates and stability of findings for e-cigarettes as a stop smoking support were much lower than and compared unfavourably with established pharmacological alternatives, noting as well that the HRB evidence was based on a network meta-analysis and introduces indirectness of evidence; lack of confidence into how effects from published research of specific e-cigarette products studied under specific conditions in specific populations would translate into practice, given that e-cigarettes are a very heterogeneous group of products which are not licensed as medicines. The GDG viewed a recommendation as speculative compared with well-established pharmacological support alternatives.
- Trade-offs at individual level are likely to be associated with a recommendation in relation to e-cigarettes, but there are still substantial uncertainties, in particular regarding the long-term health outcomes of e-cigarettes and broader public health implications, especially when compared with the well-established safety profile and public health impact of other treatment options.
- Recommendation and use of a regulated pharmacological support with established quality, safety and effectiveness profile versus a heterogeneous group of consumer products with unregulated quality, safety and effectiveness profile and with uncertain trade-offs are very different options for stop smoking support. The GDG viewed that individual reactions of people who smoke and healthcare professionals to these different options is likely to vary widely and there is relatively little local research evidence in this specific area.
- Ireland is committed to becoming tobacco-free and both protection of children and de-normalisation of tobacco use are to be prioritised in all tobacco control measures. There is substantial uncertainty regarding potential trade-offs between individual-level and population-

level efforts to tackle smoking associated with a recommendation and the GDG viewed this as speculative rather than precautionary. The GDG carefully examined the current national policy direction on tobacco control. In relation to e-cigarettes, it noted a need to identify, engage with and reconcile values and interests with due regard to scientific evidence, and that this is a role for the policy, based on public and political discourse, to find a position that best expresses a balance of social values and interests. A suite of evidence reviews has been commissioned by the Department of Health from the Health Research Board, and the outcome of its consideration is awaited. Such a position, in turn, could be taken into account by the GDG in its considered judgement of e-cigarettes.

Albeit no recommendation is made, the GDG recognised the need for advice to support people who smoke and healthcare professionals in relation to decision-making on e-cigarettes and proposed GPPs.

The GDG also discussed the issue of smoking in younger people. Albeit outside the scope of this guideline, the GDG noted HIQA's comments regarding the safety of NRT in this group: *"There is little reason to believe that NRT poses a significantly greater risk to adolescent smokers compared to adult smokers. NRT is licensed in individuals over the age of 12 under the recommendation of a healthcare professional"* and proposed GPPs that could be considered in this sub-population.

Good practice points relating to Recommendation 3:

Healthcare professionals should consider the following:

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.
- 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.

The following are responsible for implementation of recommendation 3

- All healthcare professionals to advise about and arrange recommended behavioural and pharmacological supports.
- All healthcare professionals with appropriate training, scope of practice and professional registration to provide recommended behavioural and pharmacological supports.
- Services should support healthcare professionals with their responsibilities through local Tobacco Free Campus Committees or equivalent structures to ensure that appropriate environment, culture, resources and supports are in place.
- HSE Tobacco Free Ireland programme will support HSE operated and funded services through national projects and programmes and set out in its Programme Plan and the implementation plan for this guideline.

Key question 2	What interventions should be offered by healthcare professionals to pregnant women using health services to identify people 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

Evidence statement:
Sources of evidence for Key Question 2 include international guidelines from New Zealand *(MoH, NZ & NIHI, 2014)*, the United States (USPSTF, 2015) and Canada *(CAN-ADAPTT, 2012*), and WHO *(WHO, 2013b)* as well as the HIQA HTA on smoking cessation interventions in Ireland *(HIQA, 2017)*. In addition, the GDG commissioned a review of the evidence to inform the implementation of carbon monoxide breath testing during pregnancy, conducted by Dr Greg Martin and Dr Keith Ian Quintyne, Specialists in Public Health Medicine HSE (see Appendix 5 and full report in supporting documents). Also included in these evidence statements are national and HSE policy and some evidence from local research.

As per the general adult population, the evidence is discussed under the following sub-headings:

- Asking About Smoking Behaviour and Offering Advice to Quit
- Behavioural & Pharmacological Supports

Asking About Smoking Behaviour and Offering Advice to Quit:
Behaviour change intervention categorisation has been set out in Section 3.1 and this section of the guideline is, therefore, concerned with the "Ask," "Advise" and "Act/Arrange" steps of BA and BI as offered by healthcare professionals to pregnant women using health services.

All guidelines recommend that all healthcare professionals should ask about and document every person's smoking behaviour, and this should be updated regularly. Specifically in relation to pregnant women, the US guideline recommends that clinicians ask all pregnant women about tobacco use, advise them to stop using tobacco, and provide support, rating the quality of supporting evidence as high; the New Zealand guideline recommends that all healthcare workers should briefly advise pregnant and breastfeeding women who smoke to stop, rating the quality of the evidence as high; and the Canadian guideline recommends smoking cessation should be encouraged for all pregnant, breastfeeding and postpartum women, rating the quality of evidence as high; the WHO guideline recommends that healthcare providers should ask all pregnant women about their tobacco use (past and present) and exposure to SHS, as early as possible in the pregnancy, and at every antenatal care visit, although the quality of evidence is reported as low, taking account of the broad range of healthcare models and country income levels addressed by the WHO guideline.

The Canadian and WHO guidelines specifically identify that pregnant women's partners and families should also be advised about smoking, including SHS, and offered advice to quit, with the quality of evidence rated as moderate by the Canadian guideline and low by the WHO guideline. In addition, the New Zealand guideline recommends that pregnant women should be advised about the benefits of smoke-free homes and cars, with the quality of evidence rated as moderate. However, a recent Cochrane systematic review and meta-analysis did not find, however, that interventions that aim to enhance partner support appear to have an impact on increasing long-term abstinence from smoking, *(Faseru, 2018)*.

As previously discussed, the HIQA HTA on smoking cessation interventions in Ireland identifies BA as the standard of care in the Irish health services.

National and international evidence has shown that smoking status can be missed in the course of antenatal care, and this means that care cannot be planned and delivered which is responsive to women's needs, addresses risk in pregnancy and averts poor outcomes. *(McArdle, 2018), (Shipton, 2009)*. Smoking is the leading source of elevated carbon monoxide (CO) levels for pregnant women, however there are

other reasons including exposure to faulty domestic appliances and SHS. Exposure to CO in pregnancy can lead to poor outcomes. Antenatal care pathways which include routine BCO testing and referral to stop smoking services provide a way to improved care through minimising missed opportunities to offer help to stop smoking. While these have been consistently implemented in other health systems, *(NHSInform, Scotland, 2020) (Public Health Wales, 2015)*, care in Ireland is fragmented and inconsistent. *(Reynolds, 2017b)*. Evidence was reviewed for the GDG and it was found that using BCO testing during antenatal care, combined with 'opt-out' referral to smoking cessation services, attendance to support services increased twofold and the probability of quitting by delivery, which translated into a clinically important increase in birth weight. Studies have also shown that the implementation of BCO testing with opt-out referral to stop smoking services has not impacted relations between healthcare workers and pregnant women and has been well received, *(Martin, 2019)*. A recent systematic review also identified that, while it does not itself increase the likelihood of a woman making a successful attempt to stop smoking, BCO testing can be a useful in assessing exposure to smoking, *(Grangé, 2020)*.

A recent audit of maternity units in Ireland reported that smoking cessation services were inadequate in the Irish maternity services and there are variations in practices between hospitals, *(Reynolds, 2017b)*. Women's experience of tobacco product use related care during pregnancy will be monitored through the National Maternity Experience Survey. Results from the first National Maternity Experience Survey published in September 2020 found that women rated their receipt of information on smoking and other tobacco related products during antenatal care positively with a score of 8.6, however, the question is framed to focus on perceived need and will need to be developed to provide a comprehensive measure of experience versus need, *(National Care Experience Programme, 2020)*.

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, *(HSE, 2018a)*.

Smoking in pregnancy is a focus in *Creating a Better Future Together: National Maternity Strategy 2016-2026* which specifically calls for maternity hospitals/units to be tobacco-free campuses, have an on-site smoking cessation service available for pregnant women, and that midwives and other frontline health care professionals have formalised and documented training in smoking cessation, *(Department of Health, 2016)*. An objective of *First 5: A Whole of Government Strategy for Babies, Young Children and their Families* is that parents, families and communities 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, *(Department of Children & Youth Affairs, 2018)*.

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. The standard addresses care provided both to the pregnant woman and to her partner, *(HIQA, 2016)*.

As previously identified, current HSE policy, MECC *(HSE, 2016b)*, aims to ensure that all patients who engage with services, both in hospital and in the community, will be routinely asked about their main lifestyle risk factors for chronic diseases, including smoking. Together with the HSE Tobacco Free Campus policy *(HSE, 2012)*, full implementation of these policies will create a culture within the health services which will promote disease prevention and health improvement, along with treatment services.

Benefits and harms:
The harms of smoking and benefits of quitting, including for pregnant women, have been described, with supporting evidence, in previous sections.

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 diminish health status and to foetal harm, *(US Department of Health & Human Services, 2014).*

Smoking in pregnancy is one of the most important preventable causes of adverse outcome including ectopic pregnancy, miscarriage and stillbirth, *(Macfarlane, 2018)*. It 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 exposure to smoking during pregnancy 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)*.

Stopping smoking results in immediate health benefits and stopping smoking can help avoid most of the excess mortality caused by continuing smoking *(Pirie, 2013) (Jha, 2013) (US Department of Health & Human Services, 2020)*. Smoking cessation by pregnant women benefits their health and that of their foetuses and new-borns, reduces or eliminates the effects of smoking on foetal growth and reduces the risk for a small-for-gestational-age birth compared with continued smoking, *(US Department of Health & Human Services, 2020)*. For babies, being smoke free is a good start to life and reduces the risk of chronic disease in later life.

Smoking, and smoking during pregnancy, is socially patterned with the highest prevalence in the poorest and most vulnerable groups, contributing significantly to the adverse quality of life, including poverty, higher occurrence of disease and excess mortality experienced in these groups. Tackling smoking, especially smoking in pregnancy, is a key population-level intervention to reduce health inequalities, *(McAvoy, 2013)*.

In terms of patient reaction to being asked about their smoking behaviour and offered advice, initial findings on the acceptability of MECC among patients and clients is that MECC is well-accepted, and that there is an expectation among patients and clients that they will be asked about their lifestyle and making behaviour changes, such as smoking cessation, *(HSE, 2019)*. As discussed, routine BCO testing and referral to stop smoking services is an effective quality improvement in antenatal care which is generally well received; successful implementation is critically dependent on staff training and good communication with pregnant women.

Quality of Evidence:
High quality evidence across 3 international guidelines for routinely asking pregnant women about their smoking status and offering advice to quit; moderate quality evidence to augment this approach by routinely offering pregnant women BCO testing and making referral to stop smoking services as part of their antenatal pathway of care; moderate to low quality evidence to extend the approach to pregnant women's partners and to include SHS exposure.

Values & preferences:
As previously discussed, policy in Ireland places a high value and strong preference for tackling smoking and, in particular, national policy on tobacco control states that *"the protection of children must be prioritised in all of the initiatives outlined in the policy." (Department of Health, 2013)*. Strategic policy in

relation to maternity services, and newborn and young children, also indicates a high value and strong preference for the best outcomes for pregnant women and their babies and for supporting pregnant women who smoke to quit and for giving children the best start in life. This is also reflected in HIQA standards for maternity services, *(Department of Health, 2016) (HIQA, 2016)*.

Good outcomes for pregnant women and children are highly valued by women and by healthcare professionals and, since implementation of recommendations in this area support good outcomes, it is aligned with values and preferences. Healthcare professionals should respect the preference of women who prefer not to take up routine BCO testing or to discuss smoking behaviour, or who decline advice to stop smoking or referral to a stop smoking service.

Inequalities in smoking in pregnancy are well-established, with prevalence greatest in the poorest socioeconomic groups in Ireland, *(McAvoy, 2013)*. This means that the burden of poor outcomes from smoking in pregnancy is heaviest in this group, which is unfair. Furthermore, evidence now shows that a good start to life, beginning during pregnancy, is foundational to good health in childhood, adulthood and later life. Exposure to smoking during pregnancy sets up health inequalities across the life course, *(WHO, 2014)*. Helping women stop smoking during pregnancy is a powerful way of disrupting and levelling-up health inequalities, *(Marmot, 2010)*.

Resource use:
The WHO has cited tobacco control as a "best-buy" for public health and has identified population-wide support (including BA) for tobacco cessation to all those who want to quit as an effective intervention with favourable cost-effectiveness for tackling non-communicable disease, *(WHO, 2013a)*.

HIQA conducted a review of cost effectiveness studies of smoking cessation interventions. It concluded that *"the existing literature in this area has consistently found that practically all smoking cessation interventions are associated with very low ICERs (Incremental Cost-Effectiveness Ratios), which would make them appear extremely cost-effective using conventional willingness-to-pay thresholds in Ireland and elsewhere." (HIQA, 2017)*. Because BA was considered a standard of care by HIQA in its HTA, the cost-effectiveness and budget impact were not specifically modelled. The HSE is already committed to the implementation of MECC, which supports the guideline recommendation in this area, so no additional resource use implications arise, *(HSE, 2016b)*.

Evaluation of experience with routine BCO testing and referral to stop smoking services found that it has a favourable resource use profile: additional cost per delivery was UK£31 and the incremental cost per additional quit was UK£952; 31 pregnant women needed to be treated for each additional quitter, *(Bell, 2018)*

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.

* 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**

Good practice points:

Healthcare professionals should consider the following:

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.

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:

6.1 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**

The following are responsible for implementation of Recommendation 4, 5 and 6

- All midwives providing care to pregnant women at first antenatal visit to ensure carbon monoxide breath test offered appropriately with information on purpose and opt-out.
- All healthcare professionals providing care to pregnant women to ask and advise about smoking and SHS exposure.
- Maternity services providing first antenatal visit care should support midwives by ensuring appropriate information, resources, and arrangements in place for offering carbon monoxide breath testing.
- Services should support healthcare professionals with their responsibilities through local Tobacco Free Campus Committees or equivalent structures to ensure that appropriate environment, culture, resources and supports are in place.
- HSE Tobacco Free Ireland programme will support HSE operated and funded services through national projects and programmes and set out in its Programme Plan and the implementation plan for this guideline.

Behavioural & Pharmacological Supports:

As discussed, there are a range of behavioural and pharmacological supports available for the general adult population which, in combination or alone, are proven to be effective in assisting those who want to quit smoking. The following section details the evidence of the effect of supports in helping pregnant women who want to quit smoking. Recommended behavioural supports are discussed followed by pharmacological supports.

Behavioural Supports:

All international guidelines in our evidence base provide recommendations for the provision of behavioural supports to pregnant women who want to quit smoking, namely, the New Zealand *(MoH, NZ & NIHI, 2014)*, the United States *(USPSTF, 2015)* and Canada *(CAN-ADAPTT, 2012)*, and WHO *(WHO, 2013b)*. The international guidelines identify the quality of evidence as high, except in the case of the WHO where the quality of evidence is moderate.

In addition, the HIQA HTA provides evidence on the clinical effectiveness of behavioural support intervention, noting that *"pregnant women who smoke should be offered a psychosocial intervention in the first instance"* and that *"the psychosocial intervention with the largest body of evidence to support its effectiveness is counselling."* It reported that health education (RR 1.43, 95%CI: 1.07 – 1.92) and counselling (RR 1.35, 95% CI: 1.17 – 1.57) were effective. This is consistent with a recent Cochrane systematic review and meta-analysis found that psychosocial interventions to support women to stop smoking in pregnancy can increase the proportion of women who stop smoking in late pregnancy and the proportion of infants born low birth weight, *(Chamberlain, 2017)*. A systematic review published after the HIQA HTA also reported similar findings on the effectiveness of behavioural supports, *(Taylor, 2020)*. A further systematic review reported positive findings for the effectiveness of digitally delivered behavioural support in pregnancy and that intervention effectiveness increased with more intensive combinations of behavioural change techniques, *(Griffiths, 2018)*.

HIQA also reported that evidence suggested financial incentives were an effective support (RR 2.28, 95% CI: 1.55 – 3.34). This is consistent with findings reported in recent Cochrane systematic reviews and meta-analyses, *(Notley, 2019)*. However, HIQA noted that the primary studies of financial incentives were

inconsistent and that the overall effect size related to one strongly positive study with a significantly more intensive intervention, so it concluded that further research would be required and that any implementation of financial incentives in Ireland would require prior implementation of routine BCO testing. In addition, it identified that the implementation of financial incentives would require comprehensive budget impact assessment, since the intensive interventions that have demonstrated efficacy in research settings are dependent on ultrasonography. The GDG discussed the issue of incentives to help people who smoke to stop, especially pregnancy women, and its' view was that a programme of local research would be required to make any decision around if and how this approach could be used in Ireland.

Pharmacological Supports:
Pharmacological treatments of any kind for pregnant women carry with them particular considerations regarding safety. This is reflected across all guidelines in relation to pharmacological support for pregnant women to stop smoking.

Although safe, effective and recommended in the general adult population, bupropion and varenicline are not recommended for pregnant women.

In relation to NRT, the US guideline concludes that the current evidence is insufficient to assess the balance of benefits and harms of pharmacotherapy interventions for tobacco cessation in pregnant women. The WHO guideline does not make a recommendation on the use or non-use of NRT in pregnancy. The New Zealand guideline recommends that pregnant women can use NRT in pregnancy and during breastfeeding and that, regarding the risks versus benefits of using NRT during pregnancy, reports the quality of evidence is moderate; and the Canadian guideline recommends that if counselling is found ineffective, intermittent dosing with nicotine replacement therapies (such as lozenges, gum) is preferred over continuous dosing of the patch after a risk-benefit analysis, reporting the quality of evidence as low. Finally, HIQA notes that there is evidence of beneficial effect for NRT as an aid to smoking cessation (RR 1.41; 95% CI 0.99 to 2.0) in pregnancy, although the certainty of this evidence is limited because in many studies the adherence to the NRT is low. It goes on to note: *"NRT should only be offered to women when psychosocial interventions have been unsuccessful" and that "licensed prescribers must use their professional judgment when offering women a prescription for NRT, and it should only be provided following discussion about the potential risks and benefits."* A more recent Cochrane systematic review and meta-analysis found that there was low-certainty evidence that NRT increased the likelihood of smoking abstinence in later pregnancy (RR 1.37, 95% CI 1.08 to 1.74), *(Claire, 2020)*.

Benefits and harms:
The harms of smoking and benefits of quitting have been described, with supporting evidence, in previous sections, and the specific harms and benefits for pregnant women have also been discussed.

Behavioural interventions are safe; however, there are potential harms and benefits associated with using NRT in pregnancy. Studies have found that women often do not use the product as prescribed and either do not start using NRT or stop it early; in addition, healthcare professionals can be hesitant to recommend NRT.

HIQA notes in its review of the safety of pharmacological supports for stopping smoking in pregnancy that *"NRT may be safely administered in pregnancy under the supervision of a medical professional, particularly when behavioural therapies have failed."* Nicotine exposure during pregnancy is associated with neuro-behavioural effects in children and, while these effects are described with nicotine from tobacco product use, it is uncertain whether the same effects are associated with NRT use. A challenge in resolving

these questions is the NRT use in pregnancy generally arises in response to the use of tobacco products which contain nicotine. Studies of NRT use in pregnancy have not identified significant increases in adverse events. In conclusion, HIQA note that *"NRT should only be offered to women when psychosocial interventions have been unsuccessful"* and that *"licensed prescribers must use their professional judgment when offering women a prescription for NRT, and it should only be provided following discussion about the potential risks and benefits."* A recent systematic review concluded there was insufficient evidence as to whether maternal use of NRT during pregnancy is harmful to the foetus, *(Taylor, 2020)*.

Quality of Evidence:
Moderate to low quality evidence across two international guidelines with support from HIQA HTA findings, noting limitations in studies.

Values & preferences:
Health policy in Ireland places a high value and strong preference for tackling smoking and, in particular, national policy on tobacco control states that *"the protection of children must be prioritised in all of the initiatives outlined in the policy." (Department of Health, 2013)*. Strategic policy in relation to maternity services, new-borns and young children, also indicate a high value and strong preference for the best outcomes for pregnant women and their babies and for supporting pregnant women who smoke to quit and giving children the best start in life. This is also reflected in HIQA standards for maternity services.

Good outcomes for pregnant women and children are highly valued by women and by healthcare professionals and, since implementation of recommendations in this area support good outcomes, it is aligned with values and preferences.

Inequalities in smoking in pregnancy are well-established, with prevalence greatest in the poorest socioeconomic groups in Ireland, *(McAvoy, 2013)*. This means that the burden of poor outcomes from smoking in pregnancy is heaviest in this group, which is unfair. Furthermore, evidence now shows that a good start to life, beginning during pregnancy, is foundational to good health in childhood, adulthood and later life. Exposure to smoking during pregnancy sets up health inequalities across the life course, *(WHO, 2014)*. Helping women stop smoking during pregnancy is a powerful way of disrupting and levelling-up health inequalities, *(Marmot, 2010)*.

NRT is licensed for use in pregnancy, but it is clear that the balance of potential harms and benefits will require careful discussion and shared decision-making between the pregnant woman and healthcare professional.

Resource use:
The WHO has cited tobacco control as a "best-buy" for public health and has identified population-wide support (including BA) for tobacco cessation to all those who want to quit as an effective intervention with favourable cost-effectiveness for tackling non-communicable disease, *(WHO, 2013a)*. HIQA conducted a review of cost effectiveness studies of smoking cessation interventions. It concluded that *"the existing literature in this area has consistently found that practically all smoking cessation interventions are associated with very low ICERs (Incremental Cost-Effectiveness Ratios), which would make them appear extremely cost-effective using conventional willingness-to-pay thresholds in Ireland and elsewhere." (HIQA, 2017)*

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.

The GDG made a conditional recommendation in relation to NRT in pregnancy, with reference to the GRADE approach, (GRADE, 2013), for the following reasons:

- Desirable effects of NRT use to support stopping smoking in pregnancy probably outweigh the undesirable effects; there is some uncertainty in the area, but it is low;
- There is a clear need to consider the individual woman's values more carefully than usual and for healthcare professionals to allocate more time than usual to shared decision making, making sure that they clearly and comprehensively explain the potential benefits and harms to the woman.

The following are responsible for implementation of Recommendation 7

- All healthcare professionals providing care to pregnant women to advise about and arrange recommended behavioural and pharmacological supports.
- All healthcare professionals providing care to pregnant women with appropriate training, scope of practice and professional registration to provide recommended behavioural and pharmacological supports.
- Services should support healthcare professionals with their responsibilities through local Tobacco Free Campus Committees or equivalent structures to ensure that appropriate environment, culture, resources and supports are in place.
- HSE Tobacco Free Ireland programme will support HSE operated and funded services through national projects and programmes and set out in its Programme Plan and the implementation plan for this guideline.

Key question 3	What interventions should be offered by healthcare professionals to people using secondary mental health services to identify people 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

Evidence statement:
Sources of evidence for Key Question 3 include international guidelines from New Zealand *(MoH, NZ & NIHI, 2014)* and Canada *(CAN-ADAPTT, 2012)*, as well as the HIQA HTA on smoking cessation interventions in Ireland *(HIQA, 2017)*. Also included in these evidence statements are national and HSE policy and some evidence from local research.

As per the general adult population, the evidence is discussed under the following sub-headings:

- Asking About Smoking Behaviour and Offering Advice to Quit
- Behavioural & Pharmacological Supports

<u>Asking About Smoking Behaviour and Offering Advice to Quit:</u>
Behaviour change intervention categorisation is set out in Section 3.1 and this section of the guideline is, therefore, concerned with the "Ask," "Advise" and "Act/Arrange" steps of BA and BI as offered by healthcare professionals to persons with mental health problems (aged 18+ years) requiring secondary mental health services.

All guidelines recommend that all healthcare professionals should ask about and document every person's smoking behaviour, and this should be updated regularly. Specifically in relation to people using secondary mental health services, the Canadian guideline recommends that *"health care providers should screen persons with mental illness and/or addictions for tobacco use"* and note the quality of evidence as high; the New Zealand guideline recommendation is to *"provide brief advice to stop smoking to all users of mental health services who smoke,"* and also note the quality of evidence as high.

As previously discussed, the HIQA HTA on smoking cessation interventions in Ireland identifies BA as the standard of care in the Irish health services.

Recent findings from the Healthy Ireland Survey (2018) indicate that the majority of smokers have not discussed quitting with a health professional during a recent consultation: 60% (General Practitioners); 70% (hospital doctors); 73% (other healthcare professionals); 74% (nurse); 79% (dentist) and 85% (pharmacists). This evidence points to a significant care gap to be addressed through implementation of these guidelines. Similar care gaps have been described in other countries, *(RCP, 2018), (Department of Health & Human Services, 2020)*.

The issue of the high burden of smoking and poor provision of stop smoking support to mental health service users has been identified internationally, *(Royal College of Psychiatrists, 2013) (ASH, 2016)*. Attitudes, expectations and culture in relation to smoking can be a particular challenge in this service setting, *(Kerr, 2013), (Kulkami, 2014)*. In Ireland, the mental health sector was exempted from smoke-free workplace legislation, *(Jochelson, 2006)*, and this challenge has also been identified with poor delivery of stop smoking support to users of secondary mental health services compared to other service settings, *(Currie, 2010)*. It has been demonstrated that, despite higher smoking prevalence compared to other patients, motivation to quit, acceptability of cessation advice and quit rate similar to other patients, provision of clinical care for tobacco use among users of secondary mental health services were approximately one third that seen in Irish general inpatient samples, (Burns, 2018a). This significant care gap was confirmed by the MHC in the census it conducted in 2018, *(Finnerty, 2018)*.

Sharing the Vision, *A Mental Health Policy for Everyone* highlights the importance of paying attention to the physical needs of people with lived experience of mental health problems, *(Government of Ireland, 2020)*.

The Regulation on General Health (Regulation 19) under the Mental Health Act 2001 requires that *"adequate arrangements are in place for access by residents to general health services and for their referral to other health services as required"* and that *"each resident's general health needs are assessed regularly as indicated by his or her individual care plan and in any event not less than every six months."* The Mental Health Commission's Judgement Support Framework, which assists with compliance and promotes continuous improvement against the regulations, specifically cites assessment and documentation of smoking status on a six-monthly basis, *(MHC, 2018)*.

As previously identified, current HSE policy, MECC *(HSE, 2016b)* aims to ensure that all patients who engage with services, both in hospital and in the community, will be routinely asked about their main lifestyle risk factors for chronic diseases, including smoking. Together with the HSE Tobacco Free Campus policy *(HSE, 2012)*, full implementation of these HSE policies will create a culture within the health services which will promote disease prevention and health improvement, along with treatment services. Specific tools and resources have been produced by the HSE Tobacco Free Ireland Programme for the secondary mental health service sector, *(HSE, 2016a)*.

Benefits and harms:
The harms of smoking and benefits of quitting have been described, with supporting evidence, in previous sections, including people with lived experience of mental health difficulties.

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 diminish health status and to foetal harm, *(US Department of Health & Human Services, 2014)*.

People with lived experience of mental health difficulties experience worse physical health than the general population, dying on average 10-20 years younger, *(Walker, 2015)*, *(Lawrence, 2013), (Chang, 2011), (Chesney, 2014)*. They have a higher prevalence of smoking, *(HSE, 2018c), (RCP, 2013)* tend to smoke more heavily with greater nicotine addiction, *(Prochaska, 2011 & 2017)*, and their smoking behaviour is a significant contributor to poor health and premature mortality in people with lived experience of mental health problems, *(Kelly, 2011), (Callaghan, 2014), (Bandiera, 2015)*.

Stopping smoking results in immediate health benefits and can help avoid most of the excess mortality caused by continuing smoking, *(Pirie, 2013), (Jha, 2013)*. Despite the challenges they face, people with lived experience of mental health problems are equally capable of quitting than those without these problems, *(Prochaska, 2011)*. Irish studies have shown 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; furthermore, their motivation to quit, the acceptability of advice and support and successful quit rate were similar to general inpatient samples, *(Burns, 2018a)*.

Smoking cessation is not associated with any exacerbation of symptoms among those with lived experience of mental health problems, *(Hall, 2009), (Morozova, 2015)*, and mental health and quality of life benefits are also associated with smoking cessation compared to continuing smoking, *(Taylor, 2014)*, with improvements in symptoms reported for people using secondary mental health services who are supported to stop smoking, *(Prochaska, 2013)*. Medications used to treat mental health problems in

secondary mental health services interact with smoking in a way that requires dosages to be increased; quitting can lead to circumstances where medication dosage can be reduced, *(Taylor, 2012)*.

The HIQA HTA specifically examined the benefits of quitting for users of secondary mental health services and reported that it *"has the potential to deliver significant health benefits for smokers and their families, including those with mental health problems"* and specifically *"there are additional advantages, such as reduced length of stay in hospital, lower drug doses, fewer complications, higher survival rates, better wound healing, decreased infections and fewer re-admissions after surgery," (HIQA, 2017)*.

There are wider benefits with quitting for secondary mental health service users. Smoking contributes to the issues of stigma, social exclusion and poverty that affect secondary mental health service users and ensuring they experience equity is key to guaranteeing they enjoy parity of esteem, *(ASH, 2016)*.

Quality of Evidence:
High quality evidence across 2 international guidelines for routinely asking secondary mental health service users about their smoking status and offering advice to quit.

Values & preferences:
Health policy in Ireland places a high value and strong preference for tackling smoking. Strategic policy in relation to mental health and the work of the MHC also indicate a high value and strong preference for prioritising physical health and smoking among people with lived experience of mental health difficulties, *(Government of Ireland, 2020), (Finnerty, 2018), (MHC, 2018)*.

As previously discussed, people with lived experience of mental health problems are also interested in quitting, *(Burns, 2018b), (Prochaska 2011 & 2017)*. The lack of parity of esteem for mental health service users in relation to engaging with their higher burden of smoking and consequent physical health needs is an inequity which has been identified by service users and service providers as an issue that must be addressed, *(Mental Health Ireland, 2019)*.

Resource use:
The WHO cites tobacco control as a "best-buy" for public health and has identified population-wide support (including BA) for tobacco cessation to all those who want to quit as an effective intervention with favourable cost-effectiveness for tackling non-communicable disease, *(WHO, 2013a)*.

HIQA conducted a review of cost effectiveness studies of smoking cessation interventions. It concluded that *"the existing literature in this area has consistently found that practically all smoking cessation interventions are associated with very low ICERs (Incremental Cost-Effectiveness Ratios), which would make them appear extremely cost-effective using conventional willingness-to-pay thresholds in Ireland and elsewhere."* Because BA was considered a standard of care by HIQA in its HTA, the cost-effectiveness and budget impact were not specifically modelled, *(HIQA, 2017)*. The HSE is already committed to the implementation of MECC, which supports the guideline recommendation in this area, so no additional resource use implications arise, *(HSE, 2016b)*.

Recommendation 8:
Healthcare professionals in secondary mental health services 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**

Good practice points:

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:

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.

The following are responsible for implementation of Recommendations 8 and 9

- All healthcare professionals providing care to users of secondary mental health services to ask and advise about smoking.
- Services should support healthcare professionals with their responsibilities through local Tobacco Free Campus Committees or equivalent structures to ensure that appropriate environment, culture, resources and supports are in place.
- HSE Tobacco Free Ireland programme will support HSE operated and funded services through national projects and programmes and set out in its Programme Plan and the implementation plan for this guideline.

<u>Behavioural & Pharmacological Supports:</u>
As discussed, there are a range of behavioural and pharmacological supports available for the general adult population which, in combination or alone, are proven to be effective in assisting those who want to quit smoking. The following section details the evidence of the treatment effect of supports in helping users of secondary mental health services who want to quit smoking.

The New Zealand guidelines make a general recommendation that effective interventions identified for the general population should be used for people with mental health disorders who smoke. The Canadian guidelines recommend that *"health care providers should offer counselling and pharmacotherapy treatment to persons who smoke and have a mental illness and/or addiction to other substances"* and identify the quality of the evidence as high.

The HIQA HTA found that *"high-intensity interventions combining pharmacotherapy and behavioural support have been shown to improve quit outcomes in people attending secondary mental health services."* It defines *"high intensity"* as treatment of 24 sessions (45 minutes each) delivered over 26 weeks. It states the evidence is limited, noting the challenges associated with recruiting and retaining participants in stop smoking studies among secondary mental health service users, with many studies having in place specific exclusion criteria which prevent this population from participating.

One of the largest studies of the effectiveness of stop smoking supports in people with lived experience of mental health difficulties was the EAGLES study. It was excluded from the HIQA HTA because participants in the study were drawn from a wider population than just secondary mental health service users, and the secondary mental health service users were selected with specific inclusion criteria which meant that they may not be fully representative of all people in that population, *(Anthenelli, 2016)*. A subsequent secondary analysis of the EAGLES study was also excluded because it used more proximal quit end points (9-12 weeks continuous abstinence) than was defined for inclusion in the HIQA HTA. This study, however, confirmed the efficacy of varenicline, bupropion, and transdermal nicotine patch (NRT) on those with psychiatric disorders, *(Evins, 2019)*.

Since the HIQA HTA, new systematic reviews examining support to stop smoking for people who use mental health services have been published, *(Siskind, 2020, Kozak, 2020, Peckham, 2017, Schwindt, 2017)*. These provide further support to the role of established behavioural and pharmacotherapy interventions to help secondary mental health service users quit.

Evidence regarding the care gap in relation to supporting secondary mental health service users who smoke to stop has already been discussed. The supporting policy and regulatory framework to this recommendation regarding support to secondary mental health service users who smoke to stop has also been identified above.

Benefits and harms:
The harms of smoking and benefits of quitting have been described, with supporting evidence, in previous sections, and the specific harms and benefits for secondary mental health service users have also been discussed.

Behavioural interventions are safe; however, there are potential harms and benefits associated with pharmacological stop smoking interventions in this population.

The safety of pharmacological stop smoking interventions was carefully and comprehensively assessed by the HIQA HTA.

Bupropion is contraindicated in patients with bipolar affective disorder and should not be used by those taking monoamine oxidase inhibitors (MAOIs).

Case reports and post-marketing surveillance analyses raised potential concerns about the neuropsychiatric safety of varenicline and bupropion. Further observational studies reported inconsistent results. These matters culminated in medicine regulators in Europe and USA adding warnings regarding the use of varenicline in people with pre-existing psychiatric conditions. A definitive study of the safety of stop smoking medicine, including varenicline, was conducted through the EAGLES trial which found no increased incidence of adverse neuropsychiatric effects in patients with or without pre-existing psychiatric disorders who were provided with pharmacological support to stop smoking. As a result, the warnings issued by medicine regulators in Europe and USA were withdrawn.

In summary, in the absence of contra-indications, pharmacological interventions can be offered safely to users of secondary mental health services to help them stop smoking, with careful monitoring. Both international guidelines make recommendations in this area. The Canadian guidelines recommend that *"while reducing smoking or abstaining (quitting), health care providers should monitor the patients'/ clients' psychiatric condition(s) (mental health status and/or other addiction(s)). Medication dosage should be monitored and adjusted as necessary."* The New Zealand guidelines recommend that health professionals should *"carefully monitor people with mental health disorders who stop smoking while still using medication for their mental health disorder, as the dosage of their medication may need to be reduced."* Both rate the quality of supporting evidence as high.

Quality of Evidence:
High-quality evidence from one international guideline (New Zealand) and positive recommendations made in the HIQA HTA, albeit noting specific issues arising for trials in this population and resulting limitations in evidence.

The evidence supporting monitoring of users of secondary mental health services who are being provided with pharmacological support to stop smoking is rated as high quality by two international guidelines.

Values & preferences:
The issues discussed regarding Recommendation 9 apply here and are not repeated. Also there are particular parity of esteem issues for mental health service users in relation to the conduct of robust trials to provide a clear and definitive evidence base for action to address a high burden health need. While it is important that an evidence-based approach underpins clinical guidance, the GDG also considered the specific challenges in relation to building evidence for action in this population.

Resource use:
The WHO cites tobacco control as a "best-buy" for public health and has identified population-wide support (including BA) for tobacco cessation to all those who want to quit as an effective intervention with favourable cost-effectiveness for tackling non-communicable disease, (WHO, 2013a). HIQA conducted a review of cost effectiveness studies of smoking cessation interventions. It concluded that *"the existing literature in this area has consistently found that practically all smoking cessation interventions are associated with very low ICERs (Incremental Cost-Effectiveness Ratios), which would make them appear extremely cost-effective using conventional willingness-to-pay thresholds in Ireland and elsewhere," (HIQA, 2017)*.

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 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**

The following are responsible for implementation of Recommendation 10

- All healthcare professionals providing care to users of secondary mental health services to ask and advise about smoking.
- All healthcare professionals providing care to users of secondary mental health services with appropriate training, scope of practice and professional registration to provide recommended behavioural and pharmacological supports.
- Services should support healthcare professionals with their responsibilities through local Tobacco Free Campus Committees or equivalent structures to ensure that appropriate environment, culture, resources and supports are in place.
- HSE Tobacco Free Ireland programme will support HSE operated and funded services through national projects and programmes and set out in its Programme Plan and the implementation plan for this guideline.

3.2 Summary budget impact analysis

A budget-impact analysis (BIA), addresses the expected changes in the expenditure of a healthcare system after the adoption of a new intervention. *(Mauskopf, 2016)* In the context of guideline development, the purpose of the BIA is to quantify the resource implications of implementing the recommendations. This BIA was developed by Health Research Board-Collaboration in Ireland for Clinical Effectiveness Review (HRB-CICER) to support the work of the Stop Smoking GDG. In line with national guidelines, direct costs and benefits were assessed from the perspective of the publicly-funded health and social care system, the Health Service Executive, over a five year time horizon. *(HIQA, 2018 (a), HIQA, 2018 (b))*

To address the needs of people aged 18 years and over who smoke in the general population in Ireland, those who smoke and use secondary mental health services and those who smoke in pregnancy (of any age), a number of key changes will result from implementing the guideline recommendations. These include the provision of enhanced behavioural support services and increased pharmacological support for those attempting to quit, additional resources for coordinating the National Stop Smoking Programme, the expansion of existing advice services for pregnant women and the introduction of BCO testing for pregnant women. The total incremental cost of implementing the recommendations was estimated at €29.7 million over five years, of which 96.4% (€28.6 million) related to direct costs and 3.6% (€1.1 million) to the opportunity cost of training time and increased consultation time. This estimate included the following over a five year period:

- the recruitment of 68 new stop smoking advisors to enable the provision of enhanced behavioural support services (€23 million) to approximately 65,000 additional smokers who will set a quit date,
- increased pharmacological support (€4.7 million) to aid successful quit attempts for an estimated 24,500 smokers with medical cards ,
- the appointment of two national coordinators for the Stop Smoking Programme (€0.85 million),
- the provision of advice on SHS (€0.76 million) to over 250,000 pregnant women
- the provision of BCO testing at the first outpatient antenatal visit and follow-up advice (€0.41 million) to over 180,000 and 27,000 pregnant women respectively.

The BIA captures the costs and impact of implementing the Stop Smoking guidelines over a five year period. However, beyond the time horizon of the BIA, successful quit attempts will also substantially reduce the risk of disease and the burden of smoking, leading to fewer interactions at primary care level, reduced hospital admissions and fewer smoking related deaths.

A full copy of the BIA document is available for further information at Annex A.

4 Appendices

Appendix 1: Guideline Development Group Terms of Reference

"Diagnosis and Treatment of Nicotine Addiction"[1]

National Clinical Practice Guidance Development Group

Rationale

Tobacco Free Ireland is government policy on tobacco control. To achieve the goal of a smoking prevalence of less than 5% by 2025, there is a need to scale-up and strengthen smoking cessation in Ireland. The HSE *Tobacco Free Ireland* Programme takes forward actions relevant to the health services and in line with government policy and the World Health Organization's MPOWER for tobacco control. To this end it intends to develop National Clinical Practice Guidance, which will be proposed to the National Clinical Effectiveness Committee for quality assurance and thereafter endorsed by the Minister for Health to better support and develop smoking cessation services in Ireland.

Intended Outcome

This National Clinical Practice Guidance Development Group will assist the HSE *Tobacco Free Ireland* Programme to reduce smoking prevalence by strengthening and scaling up smoking cessation services in Ireland through the development of National Clinical Practice Guidance for the Diagnosis and Treatment of Nicotine Addiction and providing advice on the implementation of this guidance.

Authority and Reporting Relationship of the Group

The National Clinical Practice Guidance Development Group will operate as an advisory group and will report through its Chair to the HSE *Tobacco Free Ireland* Programme, Health and Wellbeing Division, HSE.

Purpose and ways of working

1. The National Clinical Practice Guidance Development Group will advise the HSE *Tobacco Free Ireland* Programme on National Clinical Practice Guidance for the Diagnosis and Treatment of Nicotine Addiction for proposal to the National Clinical Effectiveness Committee for quality assurance and onward submission to the Minister for Health for endorsement.

2. The National Clinical Practice Guidance Development Group will develop National Clinical Practice Guidance for the relevant audiences in accordance with the agreed National Clinical Effectiveness Committee standards, processes and methods.

3. National Clinical Practice Guidance Development Group will develop and implement a work plan to address its delegated purpose.

4. The National Clinical Practice Guidance Development Group members will:

- Be collectively responsible for its recommendations, stand by the recommendations of the Group and not speak against them in public;
- Operate with a quorum of 50% of the full membership of the Group and no recommendations should be confirmed unless the meeting is quorate;

- Normally arrive at decisions by a consensus of Group members present. Voting will only be used for decision-making in exceptional circumstances. Before a decision to move to a vote is made, the Chair will, in all cases, consider whether continuing the discussion at a subsequent meeting is likely to lead to consensus. When required, voting will be anonymous, and decisions determined by a simple majority of Committee members present at a quorate meeting. Only Committee members present at the meeting will be eligible to vote. There will be no proxy voting. The Chair of the Committee will be included in the vote and, in the event of there being an equality of votes, the Chair will have a second, casting vote.
- Observe the HSE's Code of Standards and Behaviours;
- Adopt a procedure in line with National Clinical Effectiveness Committee's Conflicts of Interest Policy, sign a declaration of interest form and inform the Chair of any additions or changes to declared interests throughout the development process;
- Sign a confidentiality agreement relating to any information designated confidential, such as academic or commercial-in-confidence material or sensitive personal data. Confidential papers and confidential information disclosed in Group deliberations should not be discussed with colleagues who are not members of the Group, with other organizations, the media, or members of the Group who are excluded from discussions because of a conflict of interest.
- Not submit comments as stakeholders during the consultation on the draft guidance. If a Group member is involved with a registered stakeholder organisation, they should not submit comments during the consultation on behalf of that organisation – someone else in the organisation should draft and submit the comments.

Membership and responsibilities of Chair and members

- National Clinical Practice Guidance Development Group members will be appointed by the Chair, and National Clinical Practice Guidance Development Group membership will reflect both the spread of interests and expertise required for the business designated to the Group through these terms of reference.
- Committee members will be drawn from the HSE, the professional community, the academic community and other areas, as appropriate, and as agreed by the Chair and will include practitioners, managers, people using services, their family members and carers, and advocates.
- External experts may be invited to attend and advise the National Clinical Practice Guidance Development Group on specific topics and can be drawn from a wide range of areas as appropriate.
- The Chair's responsibilities are to:
    - Develop and agree terms of reference with the Group, for ratification by the HSE *Tobacco Free Ireland* Programme;
    - Ensure the guidance is developed in accordance with the agreed National Clinical Effectiveness Committee standards, processes and methods;
    - Set and agree timelines;
    - Set and circulate the agenda of each meeting to members;
    - Encourage broad participation from members in discussion, steer the discussions according to the agenda, keep the group discussion unified and discourage disruption or dominance by any members, encourage constructive debate without forcing agreement and prevent repetitive debate.
    - Identify and assign tasks for members;

  - Agree a process for dealing with conflicts of interest;
  - Identify and oversee the progress of specific subgroups;
  - End each meeting with a summary of decisions and actions.
- The members' responsibilities are to:
  - Review and agree membership of group with the Chair;
  - Convene as required;
  - Review existing policies, guidelines, national and international evidence of best practice, relevant scientific and clinical expert opinion pertaining to the clinical practice guidance area;
  - Determine whether to adapt, adopt or develop a new clinical practice guidance;
  - Draft clinical practice guidance developed in accordance with the agreed National Clinical Effectiveness Committee standards, processes and methods;
  - Draft tools which will support implementation of the clinical practice guidance and make recommendations on implementation;
  - Consult with relevant interested parties and the public;
  - Review and incorporate feedback from consultation process as appropriate;
  - Finalise clinical practice guidance and determine proposal of same to the HSE *Tobacco Free Ireland* programme.
- Additional roles for service users on clinical guideline groups:
  - Ensure that key questions are informed by issues that matter to service users;
  - Identify outcome measures they think are important for each key question;
  - Assist the guideline development group with the collection of service user views e.g. by helping to prepare questions for focus groups;
  - Help the guideline development group with consultation arrangements;
  - Identify areas where service users' preferences and choices may need to be acknowledged in the clinical guideline;
  - Help write the information for the service users' section of the clinical guideline including identifying sources of further information;
  - Help ensure that the clinical guideline is clearly and sensitively worded.

Arrangements for meetings including minutes and attendance

- Meetings of the Group shall be held at such times and places as are deemed necessary to facilitate the conduct of its business.
- Members may also be required to attend a working group or sub-group that may be associated with the Committee and will be expected to contribute to virtual discussions and occasional teleconferences as appropriate.
- An agenda will be set and distributed by the Chair in advance of the meeting and circulated with associated papers.
- Any other business shall be discussed at the discretion of the Chair.
- The draft minutes of the Group meetings shall be drawn up and submitted to the next meeting for approval.

- A record will be kept of Group members' attendance at meetings via the minutes.
- Members of the Group are expected:
    - To attend at least 75% of their Committee's meetings during a 12-month period;
    - Not to miss more than 2 consecutive Committee meetings.

Review of Terms of Reference

- These terms of reference were reviewed and agreed at the first meeting of the Group.
- Any amendments will be referred to the HSE Tobacco Free Ireland Programme.

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 3: Search Strategy

(a): Search strategy for International Guidelines – June 2017

A search for international guidelines was conducted in June 2017 of the following search engines, for the period January 2006 to June 2017;

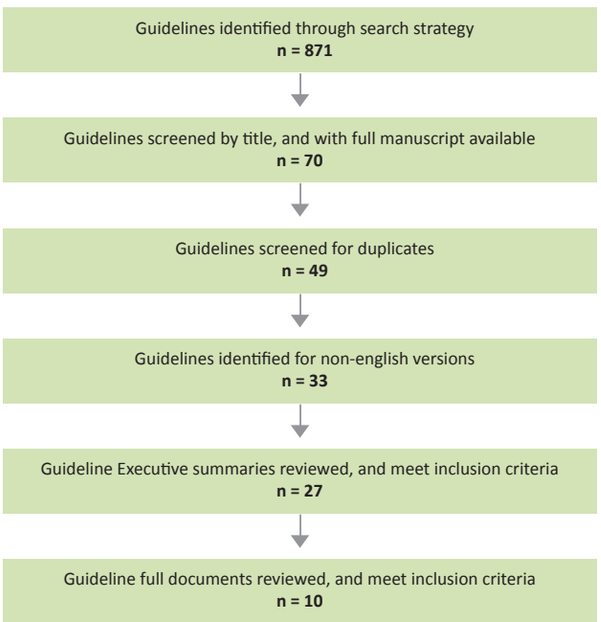
- National Guideline Clearinghouse (NGC) (Available URL: www.guideline.gov),
- National Institute for Health and Care Excellence (NICE) (Available URL: www.nice.org.uk),
- New Zealand Guidelines Group (Available URL: http://www.health.govt.nz/about-ministry-health-websites/new-zealand-guidelines-group
- Canadian Medical Association 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 (G-I-N) (Available URL: www.g-i-n.net/);
- Cochrane Library (Available URL: www.cochranelibrary.com),
- World Health Organization (Available URL: www.who.int).

- Using the following keywords:

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

In addition, members of the GDG were asked to identify potential candidate international guidelines for review.

Figure 1: Flow chart of search & selection of guidelines



(b): Search strategy for literature review – April 2019

A structured literature review was undertaken to address the following questions:

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

PubMed and Google Scholar were searched using the search terms, and inclusion and exclusion criteria below. OpenGrey was searched to identify documents outside of the peer reviewed literature.

Additional peer reviewed papers, studies and reports were found and included by reviewing the bibliographies of identified literature.

The following search terms were used:
("Tobacco"[Mesh] OR "Tobacco Use"[Mesh] OR "Tobacco Use Disorder"[Mesh] OR "Tobacco Smoking"[Mesh] OR "Smokers"[Mesh] OR "smoking"[Title/Abstract] OR "smokers"[Title/Abstract] OR "tobacco"[Title/Abstract]) AND ("Pregnancy"[Mesh] OR "Pregnancy, High-Risk"[Mesh] OR "Pregnancy Outcome"[Mesh] OR "Pregnancy Complications"[Mesh] OR "pregnant"[Title/Abstract] OR "pregnancy"[Title/Abstract]) AND ("Carbon Monoxide"[Mesh] OR "breath carbon monoxide"[Title/Abstract] OR "exhaled air carbon monoxide"[Title/Abstract] OR "expired air carbon monoxide"[Title/Abstract] OR "carbon monoxide screening"[Title/Abstract]).

Inclusion criteria:

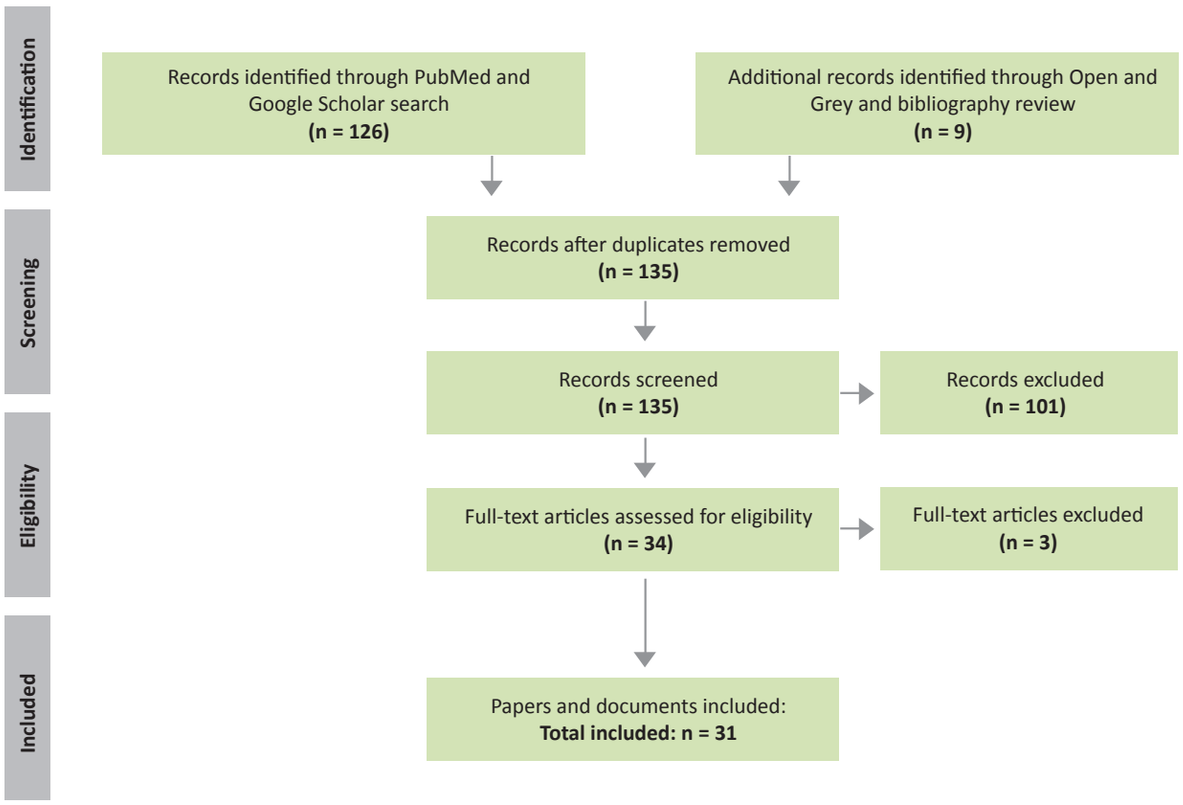
1. Papers were included if they addressed one of the four aims of the review; and

2. Papers were included if the patient population studied were in high-income countries.

Exclusion criteria:

1. Papers were excluded if they were not published in English;
2. Papers were excluded if they did not have humans as their main object of inquiry; and
3. Papers were excluded if the time from publication was longer than 20 years.

Figure 2: Flow chart of search & selection of papers for literature review



Appendix 4 (a): Quality Scores of Included and Excluded Guidelines

Table A: International guidelines selected for adaptation in Ireland, with details of appraisal, permissions and decision to include/exclude

	Publisher/ Organisation	Guideline Name	Country/ Region	Year of Publication	AGREE Rigour of Development Score	AGREE Overall guideline assessment score	Reason for Inclusion/Exclusion
1	NICE	NICE Guideline NG92: Stop Smoking Interventions & Services	UK	2018	87.5%	94.4%	Excluded: Intellectual Property Rights Fee required and decision by GDG not to proceed with this.
2	European Network for Smoking and Tobacco Prevention (ENSP)	ENSP Guidelines for treating tobacco dependence	EU	2016	39.1%	62.5%	Excluded: Unable to obtain permission to adapt following numerous attempts to contact owners.
3	Agency for Healthcare Research and Quality (AHRQ)	Behavioural and pharmacotherapy interventions for tobacco smoking cessation in adults, including pregnant women: U.S. Preventative Services Task Force recommendation statement	USA	2015	76.6%	87.5%	Included: Scored well overall, and in 'rigour of development' domain. Permission obtained to adapt in Ireland.
4	National Institute for Health Innovation [NIHI] & Ministry for Health, New Zealand.	The New Zealand Guidelines for Helping People to Stop Smoking.	New Zealand	2014	63.0%	75.0%	Included: Scored well overall and in 'rigour of development' domain. Permission obtained to adapt in Ireland.
5	South African Thoracic Society	South African tobacco smoking cessation clinical practice guideline.	South Africa	2013	29.9%	38.9%	Excluded: As number of reviewers did not recommend this guideline for use and, in addition, the AGREE 'Overall Guideline Assessment' Score & 'Rigour of Development' score for this guideline scored <60%
6	World Health Organization	WHO Recommendations for the Prevention & Management of Tobacco Use & Second-hand Smoke Exposure in Pregnancy	Global	2013	86.8%	83.3%	Included: Scored well overall, and in 'rigour of development' domain. Permission obtained to adapt in Ireland.
7	Royal Australian College of General Practitioners	Supporting smoking cessation: a guide for health professionals	Australia	2011	33.9%	62.5%	Excluded: As AGREE 'Rigour of Development score' for this guideline scored <60%

	Publisher/ Organisation	Guideline Name	Country/ Region	Year of Publication	AGREE Rigour of Development Score	AGREE Overall guideline assessment score	Reason for Inclusion/Exclusion
8	The Canadian Action Network for the Advancement, Dissemination and Adoption of Practice-informed Tobacco Treatment (CAN-ADAPTT)	Canadian Smoking Cessation Clinical Practice Guideline	Canada	2011	70.1%	83.3%	Included: Reproduction of the CAN-ADAPTT Smoking Cessation Guideline is permitted for educational and non-commercial purposes, in any form, including electronic form, without requiring the consent or permission of the authors and/or the CAN-ADAPTT project, provided that the following is noted on all electronic or print versions: © CAN-ADAPTT/CAMH 2012
9	National Tobacco Control Programme, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India	Tobacco Dependence Treatment Guidelines	India	2011	22.9%	33.3%	Excluded: As number of reviewers did not recommend this guideline for use and in addition, the AGREE 'Overall Guideline Assessment' Score & 'Rigour of Development' score for this guideline scored <60%
10	The Canadian Action Network for the Advancement, Dissemination and Adoption of Practice-informed Tobacco Treatment (CAN-ADAPTT)	Canadian Smoking Cessation Guideline: Specific Populations: Pregnant and Breastfeeding Women.	Canada	2010	68.8%	77.8%	Included: Reproduction of the CAN-ADAPTT Smoking Cessation Guideline is permitted for educational and non-commercial purposes, in any form, including electronic form, without requiring the consent or permission of the authors and/or the CAN-ADAPTT project, provided that the following is noted on all electronic or print versions: © CAN-ADAPTT/CAMH 2012
11	Japanese Circulation Society	Guidelines for Smoking Cessation	Japan	2010	32.8%	50.0%	Excluded: As number of reviewers did not recommend this guideline for use and in addition, the AGREE 'Overall Guideline Assessment' Score & 'Rigour of Development' score for this guideline scored <60%

Structure & Content of AGREE II

The AGREE II consists of 23 key items organised within 6 domains followed by 2 global rating items ("Overall Assessment"). Each domain captures a unique dimension of guideline quality.

Domain 1. Scope and Purpose is concerned with the overall aim of the guideline, the specific health questions, and the target population (items 1 to 3).

Domain 2. Stakeholder Involvement focuses on the extent to which the guideline was developed by the appropriate stakeholders and represents the views of its intended stakeholders (items 4-6).

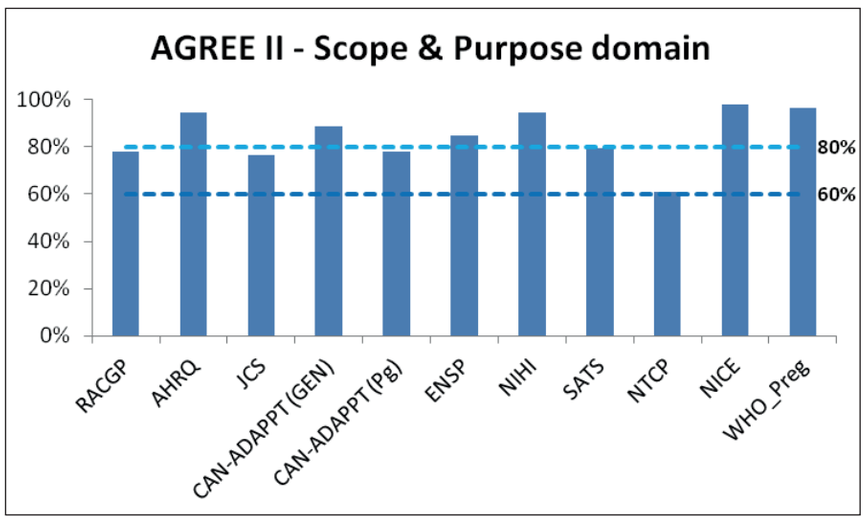
Domain 3. Rigour of Development relates to the process used to gather and synthesize the evidence, the methods to formulate the recommendations, and to update them (items 7-14).

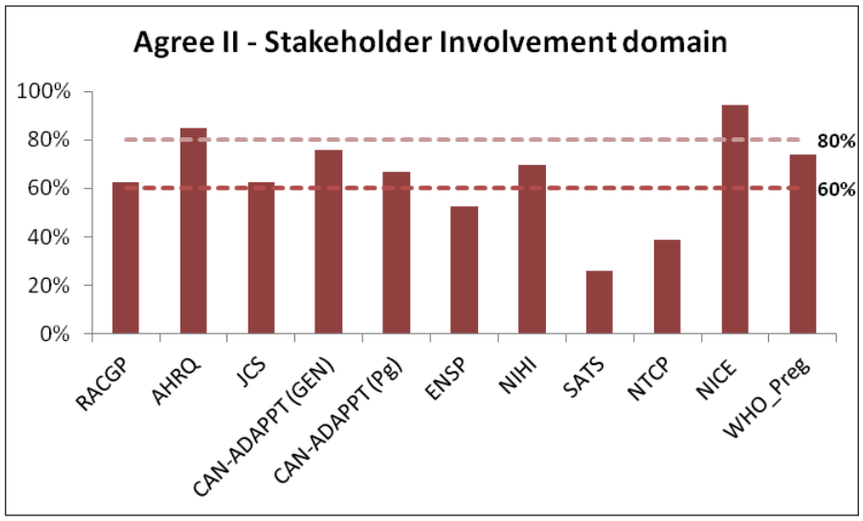
Domain 4. Clarity of Presentation deals with the language, structure, and format of the guideline (items 15-17).

Domain 5. Applicability pertains to the likely barriers and facilitators to implementation strategies to improve uptake, and resource implications of applying the guideline (items 18-21).

Domain 6. Editorial Independence is concerned with the formulation of recommendations not being unduly baised with competing interests (items 22-23).

Overall assessment includes the rating of the overall quality of the guideline and whether the guideline would be recommended for use in practice.

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NICE
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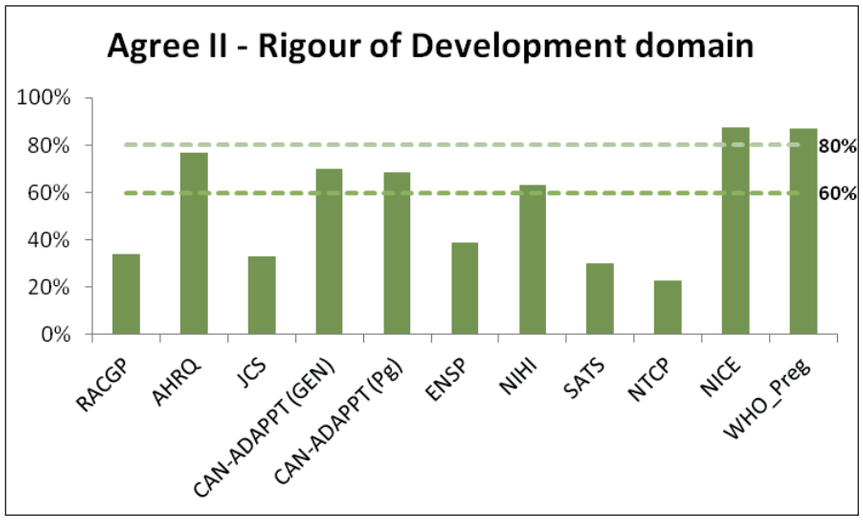
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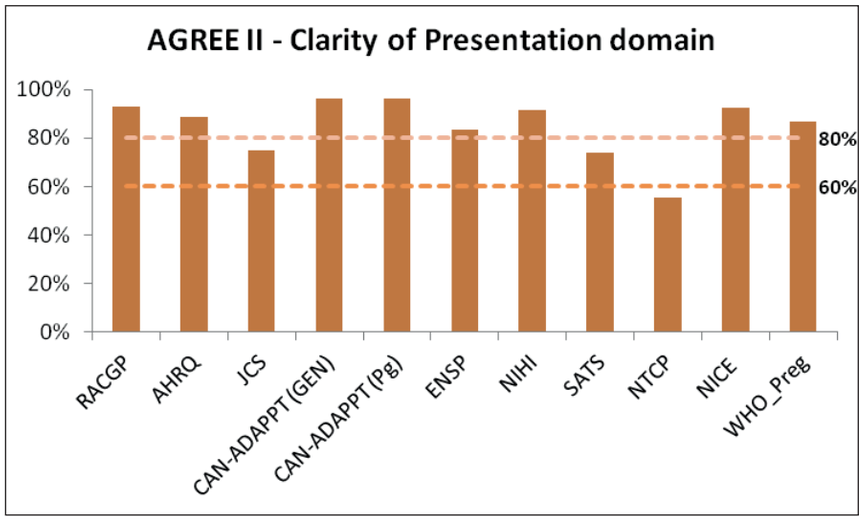
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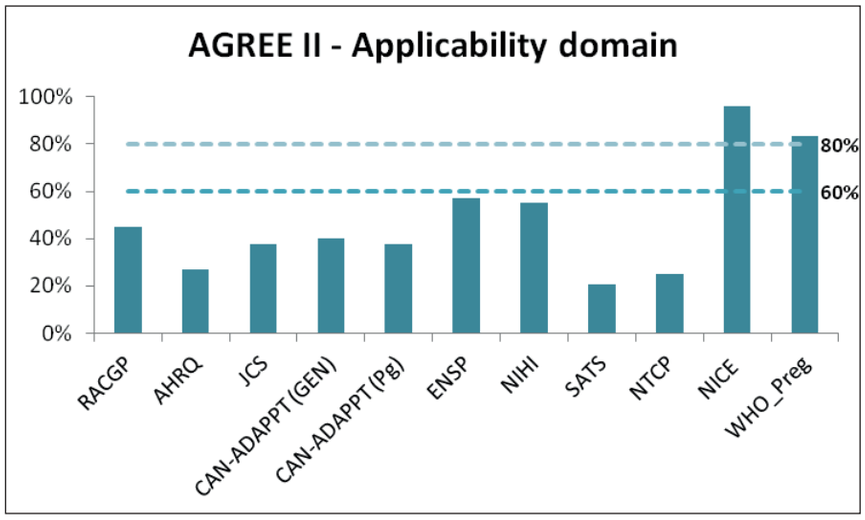
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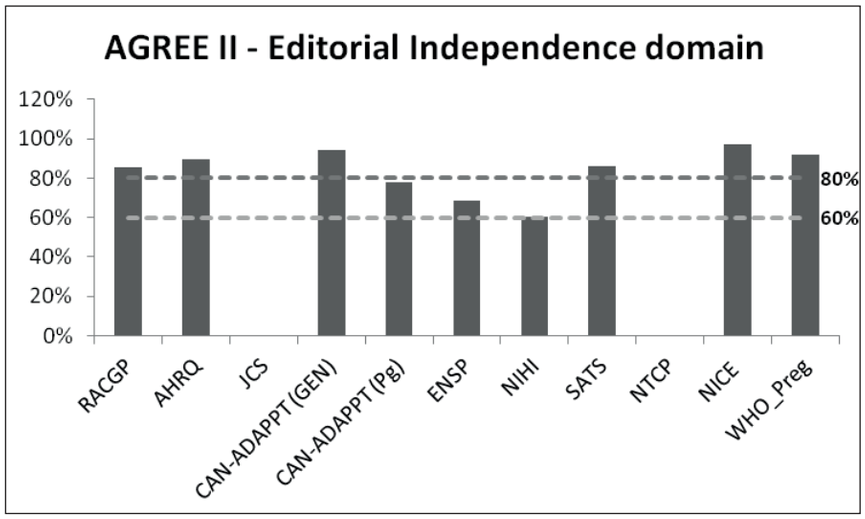
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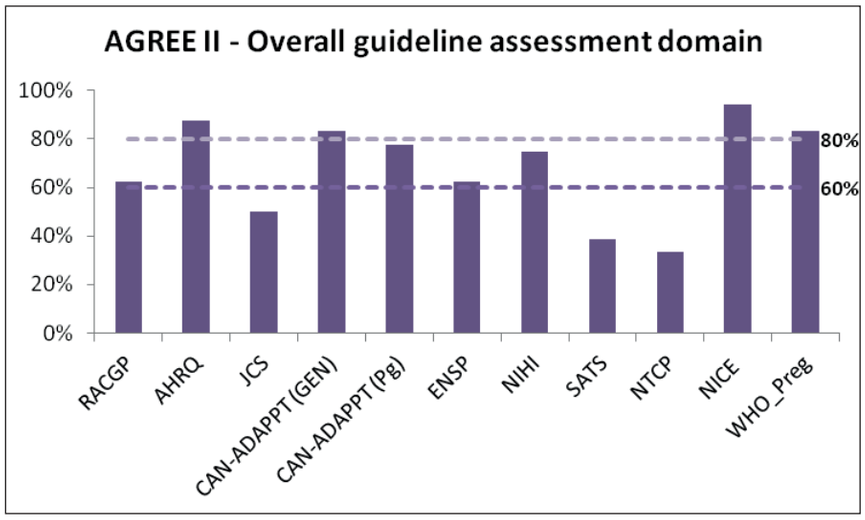
AGREE II - Overall guideline assessment domain
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Appendix 4 (b): Quality Appraisal of HIQA HTA using CASP Checklist

CASP Checklist: 10 questions to help you make sense of a Systematic Review

CASP
Critical Appraisal Skills Programme

www.casp-uk.net
info@casp-uk.net
Summertown Pavilion, Middle Way Oxford OX2 7LG

10 Questions	
1.	Did the review address a clearly focused question?
2.	Did the authors look for the right papers?
3.	Do you think all the important, relevant studies were included?
4.	Did the review's authors do enough to assess the quality of the included studies?
5.	If the results of the review have been combined, was it reasonable to do so?
6.	What are the overall results of the review?
7.	How precise are the results?
8.	Can the results be applied to the local population?
9.	Were all the outcomes considered?
10.	Are the benefits worth the harm and costs?

1. Did the review address a clearly focused question?			
Review 1	**Review 2**	**Review 3**	**Review 4**
Yes	Yes	Yes	Yes
HTA had defined TOR. Three systematic reviews were conducted. Each has clearly defined focus in terms of population, intervention and outcomes - clear PICO tables	An evidence-based analysis of the clinical effectiveness and cost-effectiveness of treatments that help people stop smoking (general adult population, pregnant women, persons attending secondary mental health services).	ICO Page 94-95. Populations: general unselected adults aged 18+ yrs, pregnant women, persons attending secondary mental health settings. Intervention: Pharma and non-pharma Outcomes: Clinical & cost effectiveness of pharma and non-pharma smoking cessation products and services. 6+ months smoking cessation and abstinence in late pregnancy in pregnant women.	
2. Did the authors look for the right papers?			
Yes	Yes	Yes	Yes
The HTA considered RCTs. Rather than begin with primary evidence, it appropriately focused on Cochrane reviews, extracted data meeting requirements, and updated these as required. In the absence of a Cochrane systematic review for a given intervention, Medline and Embase were searched for relevant systematic reviews. Where no previous Cochrane or other high-quality systematic review was available for an intervention, electronic searches were conducted in Medline, Embase and the Cochrane Register of Controlled Trials to identify RCTs comparing that intervention with another eligible intervention or no treatment. Well-reasoned and clear rationale was presented for the approach.	Randomised Controlled Trials	RCTs only. Page 91 - defined populations Page 92 - defined interventions Page 93 - defined outcome measures.	

3. Do you think all the important, relevant studies were included?			
Yes	Yes	Yes	Yes
Given the volume of evidence and the requirements of the HTA, a method for identifying relevant studies was developed, clearly communicated and argued in the report, and implemented. The question of the completeness and stability of the evidence base is addressed by the authors through analysis of results, which included Prediction Intervals which enables an informed view to be formed as to whether any additional evidence is likely to impact on the conclusions from the systematic review.	Cochrane Systematic reviews - existing, and updates if necessary. Medline and Embase were searched for relevant systematic reviews. Electronic searches were conducted in Medline, Embase and the Cochrane Register of Controlled Trials to identify RCTs comparing that intervention with another eligible intervention or no treatment.	Cochrane reviews, HIQA updated Cochrane reviews where required. Medline, Embase, Cochrane Register and Controlled Trials where absence of Cochrane reviews. Inclusion criteria - types of interventions relevant to Irish health system. Exclusion criteria: Those that examined harm reduction or recruitment. Search methods page 93.	A robust systematic review and process is outlined.
4. Did the review's authors do enough to assess the quality of the included studies?			
Yes	Yes	Yes	Yes
In relation to the Cochrane Reviews, this was by proxy. Where the HTA updated a previous systematic review that used the Cochrane risk of bias tool, an assessment of the quality and rigour of that systematic review was carried out to decide if re-assessment was necessary. If the review used a different method of assessing risk of bias, then the risk of bias analysis was carried out again using the Cochrane approach.	De novo quality assessment of the Cochrane reviews was not undertaken, as a quality rating of each of the reviews identified was reported in a 2015 review of reviews of behavioural and pharmacotherapy interventions for tobacco cessation for the US Preventive Services Task Force. These quality assessments, which used a modified version of the Assessing the Methodological Quality of Systematic Reviews (AMSTAR) tool to quality rate the reviews, were accepted for use in this report on the basis that they met best practice.	Data extraction from new studies carried out independently by 2 people, any disagreements involved a 3rd reviewer. For quality assurance purposes, a random sample of one in 10 studies was selected from the systematic reviews and data extraction from the primary studies was carried out. Risk of bias was assessed using the Cochrane risk of bias tool for randomised controlled trials. For all interventions, small study bias was assessed using a funnel plot in combination with multiple tests for asymmetry (including the Harbord and Egger's tests).	Listed in the appendices.

5. If the results of the review have been combined, was it reasonable to do so?			
Yes	Yes	Yes	Yes
Meta-analysis and network meta-analysis approaches were used. Heterogeneity was estimated and considered. Variation was explored with meta-regression. Direct and indirect comparisons were conducted and reported.	Studies pooled into two groups: pharmacotherapy and non-pharmacotherapy. Results clearly displayed, for example page 110.	Page 97-99 Assessment of heterogeneity.	Heterogenous - But appropriate info was collated for extrapolation.
6. What are the overall results of the review?			
Treatment effects based on direct evidence (options vs control), indirect and network reports and effective interventions identified. Most superior intervention also identified.	All active treatments are better than control. That is, the evaluated pharmacological interventions result in higher rates of long-term (six months or longer) smoking cessation than control. NRT monotherapy and bupropion are similarly effective. Used in combination they are more effective than when used as monotherapies, although the improved effect is only statistically significant compared to NRT monotherapy alone. Varenicline, either as monotherapy or combined with NRT monotherapy or bupropion, is more effective than NRT monotherapy or bupropion as monotherapy. Cytisine and e-cigarettes are similarly effective. They are both supported by limited evidence and so the confidence bounds around the average treatment effect are wide.Results expressed as risk ratios with confidence intervals.	Summary chapter - see page 320.Effect size explained as RR of a smoker having abstained from smoking for 6 months +.Also 95% CI.QALYs	Smoking cessation measures (pharmaco & non-phamaco) are cost effective for the Irish system.

7. How precise are the results?			
Confidence intervals, credible interventions and precision intervals reported. Precision of the results discussed and likely impact of new evidence explored.	95% CI provided with results.	Dependent on the population studied.	Relatively precise - but there are some limitations with combing such large disperse amounts of data.
8. Can the results be applied to the local population?			
Yes	Yes	Yes	Yes
	Specific to smoking cessation services provided in Ireland.	Inclusion criteria of types of interventions that are available and applicable to the Irish health system. Page 92.	They have been contextualised for the Irish setting.
9. Were all the outcomes considered?			
Yes	Yes	Yes	Yes
		Clinical effectiveness. Cost effectiveness. Pharma & non-pharma including e-cigarettes. Safety. Budget Impact Analysis. Implications for patient, health services and society. Pages 320-323.	Yes
10. Are the benefits worth the harm and costs?			
Yes	Yes	Yes	Yes
HTA explores safety and cost-effectiveness profile of interventions		Summary page 320-323.	

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

Prepared by:

Dr Greg Martin, Specialist Registrar in Public Health Medicine

Dr Keith Ian Quintyne, Specialist in Public Health Medicine

On behalf of the Smoking Cessation Guideline Development Group

Executive summary

Under-reporting of smoking status is an important problem that contributes to low uptake of support to stop services. While estimates vary (depending on the population being studied), non-disclosure of smoking status during antenatal can be as high as 75% of smokers. A study conducted in Ireland provided evidence that the figure in that study population was closer to 44%. Using breathed carbon monoxide (BCO) tests to identify smokers during antenatal care has been recommended by the National institute for Health and Care Excellence (NICE) together with an 'opt out' referral to smoking cessation services in the UK. No guidelines for BCO testing have been established in Ireland at the time of writing. This literature review set out to identify evidence from the literature to answer four questions.

1. What is the performance of BCO as a tool to identify smokers in pregnancy?
BCO is a valid reliable test to detect carbon monoxide (CO) in exhaled air. Making inference about smoking must take into account the fact that second hand smoke and air pollutants can increase BCO and that BCO in a smoker might not be detectable four hours after their last cigarette. Using BCO to make inference about smoking can therefore have false positives (low specificity) and false negative (low sensitivity). The sensitivity and specificity of the test varies, and is dependent on the level of BCO detected. This value in turn should be at an appropriate level that is considered sufficient to conclude that the individual is a smoker.

2. What is the efficacy of BCO testing in terms of improved referral to smoking cessation programs and quitting smoking?
Studies have shown that by using BCO testing during antenatal care, combined with 'opt-out' referral to smoking cessation services, attendance to support services increased by twofold and the probability of quitting by deliver increased by nearly twofold.

3. What is the feasibility of , and acceptability of routine BCO testing during antenatal care?
BCO testing is safe, quick, non-invasive, inexpensive and yields immediate results at the point of care. Studies have shown that the implementation of BCO testing with opt-out referral to stop smoking services has not translated into impaired relations between healthcare workers and pregnant women (as was feared) but has instead been well received.

4. What is the optimum cut-off to detect smokers using BCO during antenatal care?
Outside of pregnancy, the recommended cut-off for BCO testing to detect smoking in the previous four hour is 10ppm. It is well established that the cut off needs to be lower during pregnancy (due to physiological changes of pregnancy). The manufacturer recommends a cut off of 7ppm. Lowering the cut off increases the sensitivity (making the test more likely to correctly identify women who do smoke) but decreases the specificity (making it more likely to incorrectly suggest that an individual smokes when in fact she does not). Studies have shown that at a cut off of 7ppm the test has a sensitivity of 0.6 and

specificity of 0.99 while at a cut off of 4ppm the test has a sensitivity of 0.9 and specificity of 0.92. The risk and benefits associated with false positive and false negative results should inform the appropriate cut off in a clinical setting in Ireland.

1. Background

Maternal smoking is arguable the most important modifiable risk factor for adverse pregnancy outcomes(1) including impaired foetal growth, increased the risk of foetal death(2), learning difficulties(3), and obesity and diabetes later in life(4). Passive smoking is also linked to adverse outcomes(5). In Ireland, a study conducted in a tertiary maternity hospital between 2011 and 2015 that included 42,509 women, found that the prevalence of smoking decreased from 14.3 to 10.9% ($p<0.001$) over the 5-years period(6). While this represents an substantial improvement, smoking remains an important problem in pregnancy in Ireland and is typically under-reported(7). Under-reporting of smoking status during pregnancy can contribute to low levels of uptake of support to stop smoking(8). Compared to women in advantaged circumstances, women in disadvantaged circumstances are four times more likely to smoke prior to pregnancy and half as likely to quit in pregnancy; disadvantaged women are also more likely to resume smoking after delivery(9).

Smoking cessation either before pregnancy or in the first half of pregnancy can reduce risk and normalise foetal growth(10). A Cochrane Review of smoking cessation interventions pooled results from 72 trails that included 56 randomised controlled trials (over 20,000 pregnant women) and nine cluster-randomised trials (over 5,000 pregnant women) provided data on smoking cessation outcomes. The review concluded that cessation intervention produced a significant reduction in smoking in late pregnancy following interventions (risk ratio (RR) 0.94, 95% CI (confidence interval) 0.93 to 0.96). Smoking cessation interventions reduced low birth weight (RR 0.83, 95% CI 0.73 to 0.95) and preterm birth (RR 0.86, 95% CI 0.74 to 0.98), and there was a 53.91g (95% CI 10.44 g to 95.38 g) increase in mean birth weight(11).

The National Institute for Health and Care Excellence (NICE) guidelines recommend testing for carbon monoxide (CO) at the first antenatal visit. All women with a positive breath carbon monoxide (BCO) test are referred to an 'opt-out' stop smoking service (SSS)(12). No guidelines for BCO tests have been established in Ireland (at the time of writing). In 2017, just one out of all 19 units nationally conducts a BCO test in pregnancy(13). Anecdotal reports suggest that this number has gone up since then.

2. Methods

2.1. Aim

A structured literature review was undertaken to address the following questions:

1. What is the performance of breath carbon monoxide (BCO) as a tool to identify smokers in pregnancy?
2. What is the efficacy of BCO testing in terms of improved referral to smoking cessation programmes and quitting smoking among pregnant women?
3. What is the feasibility and acceptability of routine BCO testing during antenatal care?
4. What is the optimum cut off to detect smokers using BCO during antenatal care?

2.2. Search strategy

PubMed and Google Scholar were searched using the search terms, and inclusion and exclusion criteria below. OpenGrey was searched to identify documents outside of the peer reviewed literature. Additional peer reviewed papers, studies and reports were found and included by reviewing the bibliographies of identified literature.

2.3. Search terms

("Tobacco"[Mesh] OR "Tobacco Use"[Mesh] OR "Tobacco Use Disorder"[Mesh] OR "Tobacco Smoking"[Mesh] OR "Smokers"[Mesh] OR "smoking"[Title/Abstract] OR "smokers"[Title/Abstract] OR "tobacco"[Title/Abstract]) AND ("Pregnancy"[Mesh] OR "Pregnancy, High-Risk"[Mesh] OR "Pregnancy Outcome"[Mesh] OR "Pregnancy Complications"[Mesh] OR "pregnant"[Title/Abstract] OR "pregnancy"[Title/Abstract]) AND ("Carbon Monoxide"[Mesh] OR "breath carbon monoxide"[Title/Abstract] OR "exhaled air carbon monoxide"[Title/Abstract] OR "expired air carbon monoxide"[Title/Abstract] OR "carbon monoxide screening"[Title/Abstract]).

2.4. Inclusion criteria

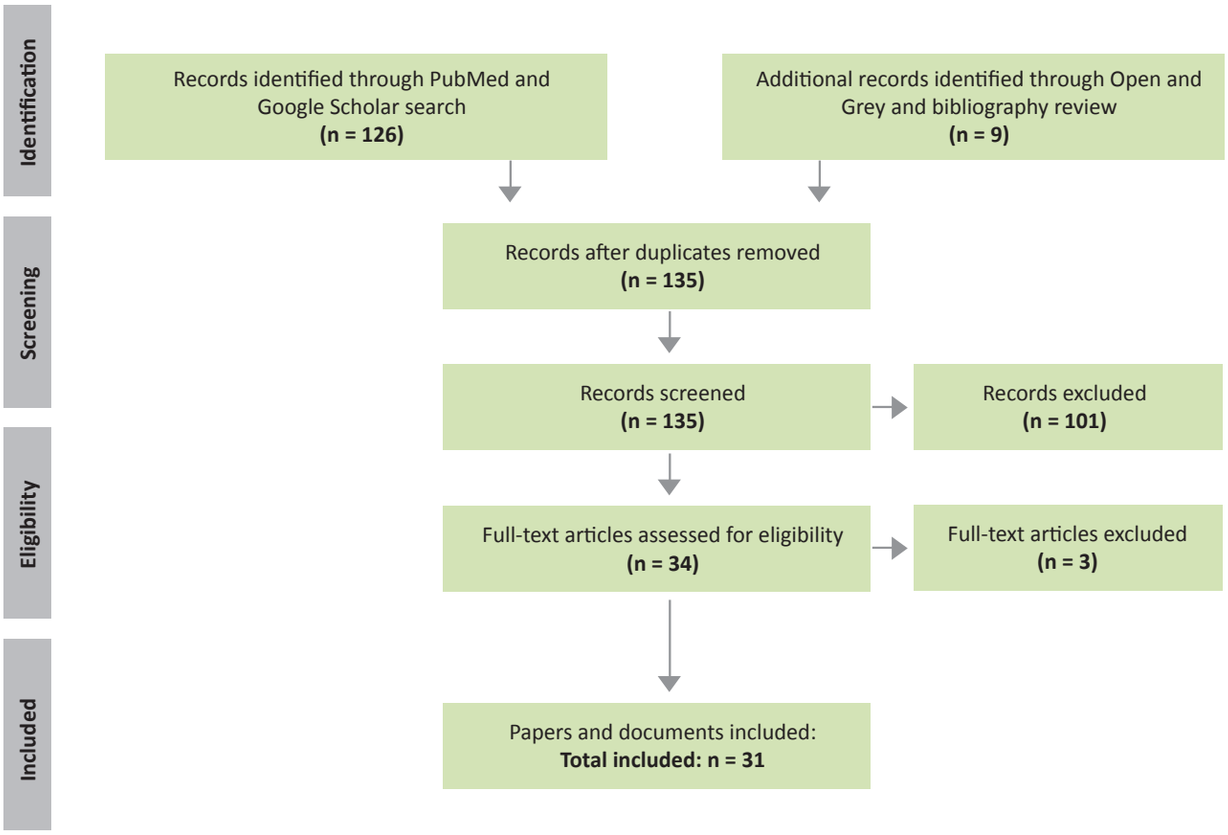
1. Papers were included if they addressed one of the four aims of the review; and
2. Papers were included if the patient population studied were in high-income countries.

2.5. Exclusion criteria

1. Papers were excluded if they were not published in English;
2. Papers were excluded if they did not have humans as their main object of inquiry; and
3. Papers were excluded if the time from publication was longer than 20 years.

2.6. Paper selection

Figure 1. PRISMA flow diagram of electronic and manual citation review



3. Results

Appendix 3A provides a table that summarises the study characteristics and findings of the main studies identified in this review. A summary narrative is provided that addresses the four questions of this review.

3.1. What is the performance of BCO as a tool to identify smokers in pregnancy?

As many as three-quarters of women may not disclose their smoking status when they present to maternity services; however, there are large discrepancies in the literature regarding rates of non-disclosures (14, 15). In a relatively large sample of pregnant women (n=3,475) a retrospective, cross sectional study found that reliance on self-reported smoking status underestimated true smoking by 25% ($p<0.001$)(8). An observational study that considered pregnant women (n=234) in Ireland in 2019 identified that 44% of pregnant women who had a BCO test result of 3ppm or more did not self-report smoking(16). Non-disclosure of smoking leads to inaccurate smoking prevalence rates and missed opportunities to offer advice and support to quite (8, 17).

Biochemical markers can be used to identify people who fail to disclose their smoking behaviour (8, 18). The most commonly used biomarker in research settings is cotinine, a by-product of nicotine that can be found in the urine, saliva or blood(19). The use of cotinine as a biomarker for smoking can be costly as it require laboratory involvement, whereas BCO is comparatively inexpensive(20). The feasibility and acceptability of using BCO testing in an antenatal setting is addressed in section 3.3 below. BCO testing can improve identification of smokers at the first antenatal visit. This testing complements routine history taking but should not replace it as this test may produce a false negative in smokers who have not had a cigarette in the previous four hours (21).

BCO can only detect CO exposure in the previous three to five hours and is therefore not useful to reflect exposure to tobacco smoke over longer periods of time(17). Despite this, BCO correlates well with serum and urine cotinine levels and has shown high sensitivity and specificity for distinguishing between smokers and non-smokers(21). The extent to which BCO testing correctly identifies smokers and non-smokers depends on the cut-off point used to categorise the subjects. At a cut off of 7 parts per million (ppm) (recommended by the NICE guidelines and the BCO test manufactures, when testing pregnant women(12)) BCO testing provides a sensitivity of 0.6 and a specificity of 0.99(12, 22). The literature that considers the optimum cut-off point and the associated sensitivity and specificity of the test is discussed in section 3.4. below.

McArdle et. al. tested postpartum women (n = 119) in an inpatient setting in Ireland using a BCO cut off of 2ppm and found that 44.4% of self-reported smokers were not identified by the test. A low cut-off point of 2ppm was used in this study to increase the sensitivity of the test as the authors anticipated high false negatives. The authors concluded that the use of BCO in an inpatient setting was not appropriate due to constrains on usual smoking behaviour(7).

CO is emitted from cigarette smoke, exhaust fumes, and from malfunctioning or poorly ventilated fossil-fuelled heating and cooking appliances(2). These extrinsic factors as well as partners' smoking habits can affect routine BCO testing results (23, 24).

3.2. What is the efficacy of BCO testing in terms of improved referral to smoking cessation programmes and quitting smoking among pregnant women?

In the UK, Campbell *et. al.* showed that, following the identification of smokers using BCO testing at antenatal ultrasound appointments (n=2,300), using 'opt-out' appointment booking with smoking cessation services instead of 'opt-in', increased engagement with services from 12.7% (95% CI 11.4-14.1%) to 18.4% (95% CI 16.8 – 20%) of women. The percentage of women that set a 'quit date' went up from 2.5% (95% CI 1.9-3.2%) to 5.3% (95% CI 4.4-6.3%) ((25). In contrast to this, a study by Bauld *et. al.* conducted a study at two sites in the UK (n=3,712) found that while introducing an 'opt-out' referral pathway did increased engagement with stop smoking services, it did not increase the number of women who actually quit smoking. The authors speculated that this might have been because automatic referral may include women who are not motivated to stop smoking (22). Following the conflicting findings of Campbell *et. al.* (25) and Bauld *et. al.* (22), Bell *et. al.* conducted an interrupted time series analysis that included pregnant women (n=37,726) across eight acute NHS hospital trusts and 12 local authorities in the UK. Using a BCO cut off of 4ppm, found a twofold increase in referral rate and a significant increase in the probability of quitting by delivery (OR 1.81, 95%CI 1.54 to 2.12). The additional cost per delivery was £31 and the incremental cost per additional quit was £952 (26).

McGowan *et. al.* provide a detailed description of the implementation of a smoking cessation service provided to pregnant women (n=12,000) in three hospitals in Glasgow, Scotland. The authors highlight the variation between the sites in terms of the proportion of women that actually took the BCO test (despite all of them being offered it), with a range from 89% down to 35% (27).

3.3. What is the feasibility and acceptability of routine BCO testing during antenatal care?

BCO testing is safe, quick, non-invasive, inexpensive and yields immediate results at the point of care (28, 29). The National Institute for Health and Care Excellence (NICE) guidelines recommend testing for CO at the first antenatal visit and that all women with a positive BCO test are referred to an 'opt-out' stop smoking service (SSS)(12).

Prior to implementation of the NICE guidelines in the UK, healthcare staff expressed concerns that BCO testing would unjustly accuse women who do not smoke of doing so, and that it would affect their relationship with the women (24). Following the implementation of the guidelines however, they found that it had little effect on their relationship with women and that the SSS staff had a unique opportunity to address second-hand smoke, smoke-free homes and the effect of smoking around children with non-smokers who may be regularly exposed to passive smoke(24). Reynolds *et. al.* suggest that an alternative pathway could be implemented whereby cotinine is sampled and tested only in self-reported non-smokers who have a high BCO level in order to keep the expense on maternity services as low as possible(21).

3.4. What is the optimum cut off to detect smokers using BCO during antenatal care?
Gomez *et. al.* provided a descriptive analysis including pregnant women (n=856) attending an obstetric hospital in France. The authors showed an inverse relationship between the parts per million CO identified though BCO testing in pregnant women and birth weight. Lower birth weights were identified in neonates were the mothers BCO tests provided results between 5 and 10ppm suggesting that a threshold of less than 10ppm (which is used in non-pregnant adults) should be considered for pregnant women(30).

Reynolds *et. al.* used an ROC curve to determine cut-off for BCO testing in pregnancy and found that 3ppm was optimal (16, 21). Bauld *et. al.* established the sensitivity and specificity of BCO testing in pregnant women by comparing the results to identified smokers though either urine cotinine or self-reporting smoking. A sensitivity and specificity of BCO identified were 0.79 and 0.94 respectively (22). ROC analysis suggested that the optimum cut-off is 4ppm. The authors however acknowledge that both the NICE guidelines and the manufacturers' recommendation are that a cut off of 7ppm be used. A cut off of 7ppm would provide a sensitivity of 0.6 and a specificity of 0.99(12, 22).

Bailey compared the sensitivity and specificity of using BCO to detect smoking behaviour in pregnant women (using a validated self-reporting smoking assessment and urine cotinine as the comparison standard) at two cut-off points, 8ppm and 4ppm. At 8ppm, the sensitivity of BCO was 0.56 and the specificity was 0.99 whereas at 4ppm the sensitivity of BCO was 0.9 and the specificity was 0.92. In both cases, where the participants had smoked more than five cigarettes in the previous 24 hours, the sensitivity of the test increased (31).

4. Discussion

The literature provides that there is general consensus that using BCO testing in pregnancy is an acceptable, effective and cost effective intervention to identify pregnant women that smoke as an adjunct to existing antenatal identification of self-reported smoking through history taking. The evidence suggests that by introducing 'opt-out' referral to smoking cessation services for women identified as smoking, both engagement with the services and the proportion of women who quit smoking increases.

BCO testing of non-pregnant people uses at cut-off of 10ppm to identify smokers. The evidence suggests that this threshold should be lower in pregnant women. The NICE guidelines suggest a cut-off of 7ppm that provides a sensitivity of 0.6 and specificity of 0.99 (high false negatives and low false positives). Some authors have argued for an even lower threshold than that and propose 4ppm that provides a sensitivity of 0.9 and specificity of 0.92.

Arguably, the threshold should be set at a level that provides a sensitivity and specificity that balance the risk associated with smokers not being identified (due to a sensitivity that is too low) and the risk associated with incorrectly identifying non-smokers as smokers (due to the specificity being too low). The experience in the UK following the implementation of the NICE guidelines has provided evidence that

when women are incorrectly identified as smokers, that this has not adversely affected their relationship with healthcare workers but instead opened up and opportunity to talk about related issues like second hand smoker and the impact of partners who smoke. The NICE guidelines' threshold was set before this evidence was available. A threshold of less than 7ppm is therefore likely to be optimal.

Table 3A - Study characteristics and findings of the main studies identified in this review.

INDEX	TITLE	FIRST AUTHOR	YEAR OF PUBLICATION	STUDY DESIGN	POPULATION / PARTICIPANTS / SETTING	INTERVENTIONS, CONTROLS AND OUTCOME MEASURES	FINDINGS	CONCLUSION	STRENGTHS AND WEAKNESSES
1	A prospective, observational study investigating the use of carbon monoxide screening to identify maternal smoking in a large university hospital in Ireland	Reynolds, C. et. al.	2018	A prospective observational cohort study	Women (n=250) and their partners (n=54) recruited at their first antenatal visit at a large university hospital in Ireland.	Intervention: Carbon monoxide breath test (BCO). Histories taken in a standardised manner were used to identify 'self-reported smokers'. BCO results in self-reported non-smokers were used to identify "non-disclosers". Verified smoking was defined as having a CO level of >= 3ppm and / or self-reported smoking at the first antenatal visit or research questionnaire.	Based on the receiver-operating characteristic (ROC) curve, a BCO cut-off point of >=3ppm was the optimal level to identify on-going smoking. At booking history, 15% of women reported as current smokers. Based on BCO of women (combined with the research questionnaire), the rate increased to 25%. Non-disclosers had similar characteristics to non-smokers. No extrinsic factors affected maternal BCO levels.	BCO screening can improve identification of smokers at the first antenatal visit. This screening complements routine history taking but should not replace it as this test may produce a false negative in smokers who have not had a cigarette in the previous four hours. Cotinine may need to be used as an adjunct to CO screening in women with high CO levels who report that they are non-smokers to rule out a false positive test.	An important strength of this study is that it distinguished smokers and non-disclosers (unlike previous studies that compared verified smokers with non-smokers). A limitation of the study is that the authors did not collect cotinine samples for verification of smoking status (given that BCO can only detect CO in subjects who have smoked in the previous four hours).

2	Opt-out' referrals after identifying pregnant smokers using exhaled air carbon monoxide: impact on engagement with smoking cessation support	**Campbell et. al.**	2017	A 'before-after' service development evaluation	Self-reported smokers attending 'antenatal' booking appointment (before) and women with CO>=4ppm identified at 12 week ultrasound appointments an NHS Foundation Trust in the UK. Approximately 2,300 women attended antenatal care in each period.	Intervention: 'Opt-out' referral to Stop Smoking Services (SSS) of women identified using CO>=4ppm using BCO. This group was compared to 'Opt-in' referral to SSS of women who self-identified as smokers at antenatal booking. The percentage of women referred to SSS in each group and the proportion that set a quite date with SSS were the major outcomes compared.	Before implementation 23.4% (n=536) women reported smoking at booking and 12.7% (n=290) were referred to SSS. After implementation, 22.9% (n=524) women reported smoking at booking and an additional 6.8% (n=156) were identified via the 'opt-out' referrals. In total, 18.4% (n=421) were referred to SSS in the intervention group. 5.3% (n=121) in the intervention group set a 'quit date' compared with 2.5% (n=57) in the control group.	Adding CO screening with 'opt-out' referrals at ultrasound doubled the number and percentage of women who set a quite date.	The non-randomised study design means that there may be alternative explanations for the study findings. By using a time-matched comparison period, the authors controlled for the potential effect of annual stop smoking campaigns. Generalizability of the findings is a potential issue; referral procedures were introduced into an acute hospital trust serving a disadvantaged neighbourhood where the awareness of SSS is likely to be poor and smoking rates at the time of delivery were higher than the national average.

3	Implementation of routine biochemical validation and an 'opt out' referral pathway for smoking cessation in pregnancy	**Bauld et. al.**	2012	1) A pilot study (before / after comparison) and 2) ROC analysis to determine the optimum cut off for BCO testing	Pregnant women (n=3712) attending antenatal services at two sites in the UK.	1) Intervention: an "opt out" referral pathway for smoking cessation in pregnancy for women identified as smokers. Outcomes measured were: referral to smoking cessation services and number of women who set quit dates. Data were compared with a non-intervention timeframe of the preceding year. 2) Comparison of self-reporting, BCO testing and urinary cotinine-validated smoking status were made	1) The introduction of an 'opt-out' referral pathway between maternity and stop smoking services resulted in more women being referred for support to quit but not higher numbers of quitters. 2) ROC curve analysis provided an optimum cut off for BCO testing at 4ppm that provided a sensitivity of 0.79 and a specificity of 0.94	1) Automatic referral may include women who are not motivated to stop and who may not engage with stop smoking services. 2) Routine BCO testing should involve a cut off of 4ppm to identify smoking in pregnancy.	The new method of identifying and referring smokers was not implemented consistently in both study sites. The authors therefore cannot be entirely confident that those included were representative of all pregnant smokers in the pilot sites at the tie of study.

4	Evaluation of a complex healthcare intervention to increase smoking cessation in pregnant women: interrupted time series analysis with economic evaluation	**Bell et. al.**	2018	Interrupted time series analysis of routine data before and after introduction of intervention; within study economic evaluation	Pregnant women (n = 37,726) with singleton deliveries in eight acuter NHS hospital trusts and 12 local authorities in the UK	Intervention: A package of measure implemented in trusts and smoking cessation services aimed at increasing the proportion of pregnant smokers quitting during pregnancy (including BCO with routine opt-out referral to smoking cessation services at antenatal visits). Outcomes measured included: referral to smoking cessation services; probability of quitting smoking during pregnancy; additional cost to health services; incremental cost per additional women quitting	After introducing the intervention the referral rate increase more than twofold (incidence rate ratio = 2.47, 95% CI 2.16 to 2.81) and the probability of quitting by delivery increased (adjusted OR=1.81 95%CI 1.54 to 2.12). The additional cost per deliver was £31 and the incremental cost per additional quit was £952. 31 pregnant women needed to be treated for each additional quitter.	The implementation of a system wide complex healthcare intervention was associated with significant increase in rates of quitting by delivery.	Strengths: More than 35,000 deliveries across a region which included eight acute hospital trust and smoking cessation services were included. Limitations: The authors used routinely collected data from a number of different sources. Organisations collected different variables or defined variables differently. The study design was non-randomised and observations; thus alternative explanations for theft findings should be considered.

5	Using expired air carbon monoxide to determine smoking status during pregnancy: preliminary identification of an appropriately sensitive and specific cut-point.	**Bailey**	2013	A descriptive analysis of sensitivity and specificity of BCO using various cut-off points to establish smoking status	Pregnant women (n=167) at four medical practices located in semi-urban and rural areas of the southern US entering prenatal care during their first trimester.	Intervention: BCO used to establish smoking status. Control: BCO results were compared to smoking status established using a validated self-reporting smoking assessment and urine cotinine tests. Sensitivity and specificity of BCO was calculated at various cut-off points.	Using 8ppm as the cut off, only 1% of non-smokers were incorrectly categorised as smokers and 56% of all smokers were correctly identified. This increased to 67% of smokers who had smoked more than 5 cigarettes in the previous 24h. However at 4ppm, 8% of non-smokers were misclassified as smokers and 90% of all smokers were identified. This increased to 96% of those who smoked more than 5 cigarettes in the previous 24h.	A cut-off of 4ppm may be needed to identify pregnant smokers using expired air samples.	The study had several strengths including a high percentage of smoker's assessment of two cut off points at both early and late pregnant. However, the sample size, while sufficient to meet all of the analytical assumptions, was still relatively small compared to the population under investigation.

6	Breathe': the stop smoking service for pregnant women in Glasgow	McGowan et. al.	2010	A descriptive analysis of the a stop smoking service provided to pregnant women in Glasgow	Pregnant women (n=12,000) in three maternity units in Glasgow, Scotland	Intervention: an opt-out smoking cessation service provided to women who were identified as smokers through either BCO test (using 7ppm cut off) or self-reporting. Outcome measures included: 1) the number and proportion of women who undertook the BCO test, 2) the number and proportion of women identified as smokers who attended the smoking cessation service, 3) the number and proportion of women who set a quit date and 4, the number of women who quit smoking.	There was substantial variation between sites with regard to the number of women who engaged with the BCO test, from 89% to 35%. Of women identified as smokers, only 20% attended a face-to-face appointment with specialist smoking cessation midwives; 19% set a quite smoking date and 6% had quit four weeks after their quite date.	The authors highlighted the difficulties (in a real world setting) of identifying and engaging pregnant smokers. The authors suggest that further research is needed to "establish the most effective way to identify pregnant smokers, refer them for specialist support, engage them effectively with specialist smoking cessation services, and decide exactly what the support should be and where it should be provided".	The paper provides a detailed description of a service and an honest appraisal of its shortcomings. The paper does not attempt (nor is it designed) to provide any explanation or attribution for the results that are provided.

7	Smoking status in pregnant women. Assessment of self-report against carbon monoxide	**Campbell et. al.**	2001	Descriptive analysis comparing self-reported smoking with BCO testing	Pregnant women (n=7,405) who agreed to complete a breath test and a questionnaire about smoking status in Australia.	The study provided the sensitivity, specificity, positive and negative predictive values of self-reporting using BCO as the standard of comparison.	The sensitivity and specificity of self-reporting against BCO were 87% and93% respectively. The PPV and NPV were 76% and 97% respectively	The authors highlight the difficulties that remain in determining smoking status in pregnant women and the inconsistencies between biochemical and self-reporting measures.	The study examines the validity of self-reporting in a cohort of women who were told that they would also be receiving a BCO test to biochemically determine their smoking status. These results are therefore not generalizable.
8	Expired air carbon monoxide concentration in mother and their spouses above 5ppm is associated with decreased fatal growth	**Gomez et. al.**	2004	Descriptive analysis of observational data	Pregnant women (n=856) who attended an obstetric hospital in France.	BCO was tested in the first trimester and at delivery. The main outcome of interest that was measured was birth weight.	A dose-dependent relationship was identified with decreasing birth weight as BCO ppm results increased. 0-5ppm - 3,406g; 6-10ppm - 3,048g; 11-20ppm - 2,858g; >20ppm - 2,739g.	BCO results are inversely associated with fatal growth in a dose dependant manner.	This was not an interventional study with randomised participants. Alternative explanations should be explored.

9	The identification of maternal smokers postnatal in an Irish maternity hospital	Cradle et. al.	2018	Descriptive analysis of observational data	Women on a postnatal ward (n=119) in an Irish maternity hospital.	BCO tests (using a cut off of 2ppm) and questionnaires were used to establish post-partum smoking status that was compared with self-reported smoking status at first antenatal visit.	BCO testing in an inpatient environment was ineffective in identifying current smokers. Few women quit smoking following the first antenatal visit.	Postnatal smoking cessation interventions should receive greater attention.	Strength of the study was that it was conducted in a large university hospital that accepts women without differentiation across all socioeconomic groups and across the urban-rural divide. Limitations of the study include that BCO is only sensitive to identify cigarette use in the preceding four hours and so is an inappropriate instrument in an in-patient setting.
10	The implications of high carbon monoxide levels in early pregnancy for neonatal outcomes	Reynolds et. al.	2019	Secondary analysis of prospective, observational data	Pregnant women (n=234) attending an antenatal clinic in Ireland	At the first antenatal visit, a research questionnaire was completed and a BCO test performed. Obstetric and neonatal data was collected by midwives at the antenatal visit and after delivery.	22.6% had a BCO >=34 but only 15.4% disclosed smoking to the midwife on routine questioning. 44% of women with a BCO level of more than 3ppm did not report current smoking. An inverse relationship was found between BCO level and birth weight.	An increased BCO level was associated with a lower birth weight at delivery. This strengthens the case for using BCO screening at first antenatal visit.	This was the first study (to the best knowledge of the authors) that investigated pregnancy outcomes using a RCO curve to obtain the appropriate cut-off for smoking verification.

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	New Zealand Guideline	US Guideline	Canada (General) Guideline
Question 1 - General Adults - Behavioural Supports			
	Recommendation (Level of Evidence)	**Recommendation (Level of Evidence)**	**Recommendation (Level of Evidence)**
Identification of smokers	Ask about and document every person's smoking status. For people who smoke or have recently stopped smoking, check and update their smoking status regularly (at every admission to hospital and at least annually in primary care). All health care settings (general practice, medical centres, hospitals, etc) should have systems in place to ensure that smoking status is accurately documented. **[HIGH]**	The USPSTF recommends that clinicians ask all adults about tobacco use, advise them to stop using tobacco, and provide behavioral interventions and U.S. Food and Drug Administration (FDA)–approved pharmacotherapy for cessation to adults who use tobacco**.(HIGH)**	• ASK: Tobacco use status should be updated, for all patients/clients, by all health care providers on a regular basis. **[HIGH]** • ADVISE: Health care providers should clearly advise patients/clients to quit. **[LOW]** • ASSESS: Health care providers should assess the willingness of patients/clients to begin treatment to achieve abstinence (quitting). **[LOW]** • ASSIST: Every tobacco user who expresses the willingness to begin treatment to quit should be offered assistance. **[HIGH]** • Healthcare Professionals are encouraged to refer patients/clients to relevant resources as part of the provision of treatment, where appropriate. **[HIGH]**

	New Zealand Guideline	US Guideline	Canada (General) Guideline
Question 1 - General Adults - Behavioural Supports			
	Recommendation (Level of Evidence)	**Recommendation (Level of Evidence)**	**Recommendation (Level of Evidence)**
Staff/ Training/ Organisations	• Support and encourage health care workers who smoke to stop. **[GPP]** • Give training to all health care workers to assist them in screening for tobacco use, making an offer of treatment and referring people who want help with stopping smoking to a stop-smoking service. Such training should be relevant to trainees and sensitive to their other time commitments. **[GPP]** • For health care workers who provide stop-smoking treatment (ie, stop-smoking practitioners), give the appropriate level of training to enable them to provide evidence-based, stop-smoking interventions (including multi-session behavioural support and advice on using stop-smoking medicines). **[GPP]** • Health care organisations (at all levels) should put in place tools and systems that (1) prompt health care workers to implement the ABC pathway and (2) provide feedback on performance. **[GPP]** • Health care organisations should foster and support clinical leadership in helping people stop smoking. **[GPP]** • All hospitals should have systems for helping patients to stop smoking. These include routinely providing advice to stop smoking, offering cessation support and referring those who want help to a stop-smoking service. **[MODERATE]** • Advise parents and family members of hospitalised children to stop smoking and offer them support to help them quit. **[GPP]**		

	New Zealand Guideline	US Guideline	Canada (General) Guideline
Question 1 - General Adult - Behavioural Supports (continued)			
	Recommendation (Level of Evidence)	**Recommendation (Level of Evidence)**	**Recommendation (Level of Evidence)**
Behavioural Therapy	• All doctors should give brief advice to stop to all of their patients who smoke at every opportunity. **[HIGH]** • All other health care workers should also give brief advice to stop to every person they see who smokes at every opportunity. **[MODERATE]** • In the person's records, note that brief advice was provided. Take care to use the correct clinical codes where applicable. **[MODERATE]** • Health care workers should seek appropriate training so that they can provide brief advice effectively. **[MODERATE]** • Provide brief advice to stop smoking to all hospitalised people who smoke. **[HIGH]** • Advise smokers awaiting surgery to stop smoking and offer them cessation support before surgery. **[HIGH]**		• Minimal interventions, of 1-3 minutes, are effective and should be offered to every tobacco user. However, there is a strong dose-response relationship between the session length and successful treatment, and so intensive interventions should be used whenever possible. **[HIGH]** • Counselling by a variety or combination of delivery formats (self-help, individual, group, helpline, web-based) is effective and should be used to assist patients/clients who express a willingness to quit. **[HIGH]**
Self-help resources	Make self-help materials available, particularly those that are tailored to individuals, but do not make them the main focus of efforts to help people stop smoking. **[GPP]**		

	New Zealand Guideline	US Guideline	Canada (General) Guideline
Question 1 - General Adult - Behavioural Supports (continued)			
	Recommendation (Level of Evidence)	**Recommendation (Level of Evidence)**	**Recommendation (Level of Evidence)**
More intensive smoking cessation therapy	• Providing face-to-face, stop-smoking support either to individual patients or to groups of people who smoke is an effective method of stopping smoking. **[HIGH]** • Aim to see people for at least four support sessions. **[HIGH]** • Health care workers providing evidence-based, stop-smoking support (that is, more than just brief advice) should be competent to do so (see requirements on the previous page). **[MODERATE]** • Health care workers trained as stop-smoking practitioners require dedicated time to provide stop smoking support. **[MODERATE]** • Arrange multi-session intensive support and medication for all hospitalised patients who smoke and want help with stopping, and follow them up for at least one month after discharge. **[HIGH]**		• Because multiple counselling sessions increase the chances of prolonged abstinence, health care providers should provide four or more counselling sessions where possible. **[HIGH]** • Motivational interviewing is encouraged to support patients/clients willingness to engage in treatment now and in the future. **[MODERATE]** • Two types of counselling and behavioural therapies yield significantly higher abstinence rates and should be included in smoking cessation treatment: 1) providing practical counselling on problem solving skills or skill training and 2) providing support as a part of treatment. **[MODERATE]**
Combined counselling and pharmacotherapy			• Combining counselling and smoking cessation medication is more effective than either alone, therefore both should be provided to patients/clients trying to stop smoking where feasible. **[HIGH]**

	New Zealand Guideline	US Guideline	Canada (General) Guideline
Question 1 - General Adults - Behavioural Supports (continued)			
	Recommendation (Level of Evidence)	**Recommendation (Level of Evidence)**	**Recommendation (Level of Evidence)**
Telephone counselling	Offer telephone counselling as an effective method of stopping smoking. **[HIGH]**		
Text message support	Offer text message support as an effective method of stopping smoking. **[MODERATE]**		
Internet-based support	Internet-based support can be offered to people who want help in stopping smoking, although there is currently insufficient evidence to determine what degree of support is required to increase long-term abstinence rates. **[GPP]**		
Relapse Prevention Interventions	There is insufficient evidence to recommend any specific relapse prevention interventions. However, services should offer ongoing support to people who need further help to remain smokefree. **[GPP]**		
Follow-up			Healthcare providers should conduct regular follow-up to assess response, provide support and modify treatment as necessary. **[LOW]**

	New Zealand Guideline	US Guideline	Canada (General) Guideline
Question 1 - General Adults - Pharmacotherapy Supports			
	Recommendation (Level of Evidence)	**Recommendation (Level of Evidence)**	**Recommendation (Level of Evidence)**
Pharmacotherapy Supports		The USPSTF concludes that the current evidence is insufficient to recommend electronic nicotine delivery systems (ENDS) for tobacco cessation in adults, including pregnant women. The USPSTF recommends that clinicians direct patients who smoke tobacco to other cessation interventions with established effectiveness and safety (previously stated). **(LOW).**	

	New Zealand Guideline	US Guideline	Canada (General) Guideline
Question 1 - General Adults - Pharmacotherapy Supports			
	Recommendation (Level of Evidence)	**Recommendation (Level of Evidence)**	**Recommendation (Level of Evidence)**
NRT	• Offer NRT routinely as an effective medication for people who want to stop smoking. **[HIGH]** • Personal preference should guide which NRT product (eg, patches, gum, lozenges, inhalator or spray) a person uses. **[GPP]** • People should use NRT for at least eight weeks. **[HIGH]** • Combining two NRT products (eg, patch and gum are a popular combination) increases abstinence rates**. [HIGH]** • NRT can be used to encourage a person to reduce their smoking before they try to stop. **[MODERATE]** • People who need or want NRT for longer than eight weeks (eg, people who are highly dependent) can continue to use it. **[GPP]** • People with cardiovascular disease can use NRT. **[MODERATE]** • Pregnant women can use NRT after they have been informed of and have weighed up the risks and benefits. If they use patches, they should remove them overnight. **[GPP]** • Young people (12–18 years of age) who are dependent on nicotine can use NRT if the health care worker believes that NRT may help them to stop smoking. **[GPP]** • Provide NRT to hospitalised people who smoke to help manage tobacco withdrawal symptoms. **[GPP]**		
Bupropion	• Bupropion can be offered as an effective medication for people who want to stop smoking. **[HIGH]** • The decision to use bupropion should be guided by the person's preference along with contraindications and precautions for use. **[GPP]** • Monitor people using bupropion for adverse effects. **[GPP]**		

	New Zealand Guideline	US Guideline	Canada (General) Guideline
Question 1 - General Adults - Pharmacotherapy Supports			
	Recommendation (Level of Evidence)	**Recommendation (Level of Evidence)**	**Recommendation (Level of Evidence)**
Varenicline	• Varenicline can be offered as an effective medication for those who want to stop smoking. **[HIGH]** • The decision to use varenicline should be guided by the person's preference, and the criteria of the Special Authority for prescribing, as long as the person has discussed the contraindications and precautions for use with a clinician. **[GPP]** • Monitor people using varenicline for adverse effects. **[GPP]**		
Nortriptyline	Nortriptyline can be offered as an effective medication for people who want to stop smoking. **[HIGH]** The decision to use nortriptyline should be guided by the person's preference as long as they have discussed the risks of use with a health care worker. **[GPP]** Monitor people using nortriptyline for adverse effects. **[GPP]**		

	New Zealand Guideline	US Guideline	Canada Guideline	WHO Guideline
Question 2 - Pregnancy - Behavioural Supports				
	Recommendation (Level of Evidence)	**Recommendation (Level of Evidence)**	**Recommendation (Level of Evidence)**	**Recommendation (Level of Evidence)**
Identification of smokers	All health care workers should briefly advise pregnant and breastfeeding women who smoke to stop. **[HIGH]**	The USPSTF recommends that clinicians ask all pregnant women about tobacco use, advise them to stop using tobacco, and provide behavioral interventions for cessation to pregnant women who use tobacco**. (HIGH).**	Smoking cessation should be encouraged for all pregnant, breastfeeding and postpartum women. **[HIGH]** Partners, friends and family members should also be offered smoking cessation interventions. **[MODERATE]** A smoke-free home environment should be encouraged for pregnant and breastfeeding women to avoid exposure to second-hand smoke. **[MODERATE]**	Health-care providers should ask all pregnant women about their tobacco use (past and present) and exposure to SHS, as early as possible in the pregnancy, and at every antenatal care visit. **[LOW]**

	New Zealand Guideline	US Guideline	Canada Guideline	WHO Guideline
Question 2 - Pregnancy - Behavioural Supports				
	Recommendation (Level of Evidence)	**Recommendation (Level of Evidence)**	**Recommendation (Level of Evidence)**	**Recommendation (Level of Evidence)**
Staff/ Training/ Organisations				All health-care facilities should be smoke-free to protect the health of all staff, patients, and visitors, including pregnant women. **[LOW]** All work and public places should be smoke-free for the protection of everyone, including pregnant women. **[LOW]** Health-care providers should provide pregnant women, their partners and other household members with advice and information about the risks of SHS exposure from all forms of smoked tobacco as well as strategies to reduce SHS in the home. **[LOW]** Health-care providers should, wherever possible, engage directly with partners and other household members to inform them of the risks of SHS exposure to pregnant women from all forms of smoked tobacco, and to promote reduction of exposure and offer smoking cessation support. **[LOW]**

	New Zealand Guideline	US Guideline	Canada Guideline	WHO Guideline
Question 2 - Pregnancy - Behavioural Supports				
	Recommendation (Level of Evidence)	**Recommendation (Level of Evidence)**	**Recommendation (Level of Evidence)**	**Recommendation (Level of Evidence)**
Behavioural Therapy	All health care workers should briefly advise pregnant and breastfeeding women who smoke to stop. **[HIGH]** Offer all pregnant and breastfeeding women who smoke multi-session, behavioural, stop-smoking interventions without delay from a dedicated stop-smoking service. **[HIGH]** Where women have had a smokefree pregnancy, offer them help to remain smokefree after birth. **[GPP]** Advise on the benefits of having smokefree homes and cars. **[MODERATE]**		During pregnancy and breastfeeding, counselling is recommended as first line treatment for smoking cessation. **[HIGH]**	Health-care providers should routinely offer advice and psychosocial interventions for tobacco cessation to all pregnant women, who are either current tobacco users or recent tobacco quitters.* (Recent tobacco quitters may include women who used tobacco before the pregnancy, and who have either spontaneously quit or stopped using tobacco in the pre-conception period or in early pregnancy, before their first antenatal visit) **[MODERATE]**

	New Zealand Guideline	US Guideline	Canada Guideline	WHO Guideline
Question 2 - Pregnancy - Pharmacotherapy Supports				
	Recommendation (Level of Evidence)	**Recommendation (Level of Evidence)**	**Recommendation (Level of Evidence)**	**Recommendation (Level of Evidence)**
Pharmacotherapy Supports		The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of pharmacotherapy interventions for tobacco cessation in pregnant women. **(LOW)**		
NRT	Pregnant women can use NRT in pregnancy and during breastfeeding. Discuss with them the risks versus benefits of using NRT during pregnancy. **[MODERATE]**		If counselling is found ineffective, intermittent dosing nicotine replacement therapies (such as lozenges, gum) are preferred over continuous dosing of the patch after a risk-benefit analysis. **[LOW]**	The panel cannot make a recommendation on use or non-use of nicotine replacement therapy to support cessation of tobacco use in pregnancy. **[MODERATE]**
Bupropion				The panel does not recommend use of bupropion or varenicline to support cessation of tobacco use in pregnancy. **[VERY LOW]**
Varenicline				The panel does not recommend use of bupropion or varenicline to support cessation of tobacco use in pregnancy. **[VERY LOW]**

	New Zealand Guideline	Canada Guideline
	Recommendation (Level of Evidence)	**Recommendation (Level of Evidence)**
Question 3 - Mental Health – General Recommendations re Care		
General Recommendations	Offer effective interventions (such as those identified in the previous sections) to people with mental health disorders who smoke. **[GPP]** Carefully monitor people with mental health disorders who stop smoking while still using medication for their mental health disorder, as the dosage of their medication may need to be reduced. **[HIGH]**	Health care providers should screen persons with mental illness and/or addictions for tobacco use. **[HIGH]** While reducing smoking or abstaining (quitting), health care providers should monitor the patients'/clients' psychiatric condition(s) (mental health status and/or other addiction(s)). Medication dosage should be monitored and adjusted as necessary. **[HIGH]**
Question 3 - Mental Health – Behavioural Support		
Behavioural Therapy	Provide brief advice to stop smoking to all users of mental health services who smoke. **[HIGH]**	
Question 3 - Mental Health – Pharmacological Support		
Combined counselling & pharmacotherapy		Health care providers should offer counselling and pharmacotherapy treatment to persons who smoke and have a mental illness and/or addiction to other substances. **[HIGH]**

Appendix 7: Considered Judgement Form Template

QUESTION	
POPULATION:	
INTERVENTION:	
COMPARISON:	
MAIN OUTCOMES:	
SETTING:	
PERSPECTIVE:	
BACKGROUND:	
CONFLICT OF INTERESTS:	

ASSESSMENT OF CRITERIA

	JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
1.	Problem		
2.	Desirable Effects		
3.	Undesirable Effects		
4.	Certainty of evidence		
5.	Values		
6.	Balance of effects		
7.	Resources required		
8.	Certainty of evidence of required resources		
9.	Cost effectiveness		
10.	Equity		
11.	Acceptability		
12.	Feasibility		

TYPE OF RECOMMENDATION

Strong recommendation against the intervention	Conditional recommendation against the intervention	Conditional recommendation for either the intervention or the comparison	Conditional recommendation for the intervention	Strong recommendation for the intervention
○	○	○	○	○

CONCLUSIONS

Recommendation
Justification
Subgroup considerations
Implementation considerations
Monitoring and evaluation
Research priorities

Completed Considered Judgement Frameworks can be found here:
https://www.hse.ie/eng/about/who/tobaccocontrol/national-clinical-guidelines/

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

Evidence Team: Dr Paul Kavanagh, Ms Aishling Sheridan, Dr Keith Ian Quintyne

1. Introduction

Section 2.9 of the guideline describes the methodology used to formulate recommendations. The Guideline Development Group (GDG) employed a blend of guideline adaptation using the ADAPTE tool and de novo guideline guideline development following processes recommended by the National Clinical Effectiveness Committee (NCEC).

A search of international guidelines for adaptation was conducted in June 2017. Candidate guidelines for adaptation were identified. This was combined with a 2017 Health Technology Assessment (HTA) conducted by the Health Information and Quality Authority (HIQA). A literature review was also conducted to identify evidence in relation to routine Breath Carbon Monoxide Testing (BCOT) as an adjunct to asking women who are pregnant about smoking.

In general, the evidence-based regarding what works in helping people who smoke to stop is well-established and stable, with relatively few significant emerging developments. This is reflected in the findings of the HIQA HTA, specifically the Prediction Intervals it reports for effect size estimates in its meta-analysis (e.g. Table 4.6).

The exception is the area of e-cigarettes.

During the late stages of guideline development in 2019, it emerged that the DoH Tobacco and Alcohol Control Unit had commissioned the Health Research Board (HRB) to conduct a series of evidence reviews in relation to e-cigarettes. A decision was made to bring this evidence into the guideline development process. The GDG were briefed in early 2020 on the HRB work, which was subsequently published prior to commencement of consultation on these draft guidelines in October 2020.

It was identified in the draft guidelines that a process would be undertaken post consultation to scope emerging evidence since the development of the recommendation by the GDG so as to assure currency prior to completion of guideline development for submission to NCEC. It was not feasible, practical or planned to re-commence the guideline development process de novo, but rather to provide reasonable assurance to the GDG and to stakeholders that the recommendations made were sound in the context of current evidence, especially evidence emerging since evidence searches were completed. The External Reviewers also addressed this question, and this process complements the assurance which they have provided.

2. Approach

A number of components to scoping evidence currency was undertaken.

A. Guidelines

The principle approach to development of these guidelines was adaptation of existing guidelines. That process is described in Section 2.9 of the Guideline, with further information in Appendices 3 and 4. That search was repeated in July 2020 and the findings are discussed in Section 3 of this report. The adapted guidelines were reviewed to confirm that they were not updated since they were accessed by the GDG at the start of the guideline development process.

B. HIQA HTA

In general, the HIQA HTA findings were used to corroborate and triangulate with recommendations in adapted guidelines. As discussed, the evidence-based regarding what works in helping people who smoke to stop is well-established and stable.

To assure currency regarding unselected adults, a hierarchy of evidence approach was adopted to this scoping process, focussing on systematic review level evidence that may have emerged since the HIQA HTA, which, in general closed its searched in 2016.

The Cochrane Library was searched from 2016 onwards using the MeSH term "Smoking Cessation"; the search was repeated with the MeSH term "Tobacco Use Cessation" and a specific search of outputs from the Cochrane Tobacco Addiction Group was also conducted to affirm completeness.

The HIQA HTA also examined evidence in relation to the two sub-population considered in these guidelines. In addition to the Cochrane Library search for unselected adults, the search strings used by HIQA was used to repeat searches in PUBMED from 2016 onwards, limited to systematic reviews and meta-analyses (see Appendices 1 and 9, HIQA HTA 2017).

C. BCOT Literature Review

The search conducted in relation to BCOT was repeated in PUBMED from 2019 onwards, picking up from the end date of the original search.

D. E-cigarettes

The HRB evidence review presented robust, comprehensive and up-to-date evidence on e-cigarettes. It was published in October 2020, with updated searches conducted by its authors at the HRB to assurance currency. This was not repeated.

A Cochrane systematic review on e-cigarettes was published following publication of the HRB evidence reviews in October 2020. This was identified to the Chair of the GDG by the National Tobacco Control Advisor at the Tobacco and Alcohol Unit at the DoH with a request that it be considered by the GDG. This systematic review was also identified in the steps at point B above.

E. Consultation and External Review

While various proposed sources of evidence were identified to the GDG through consultation, as discussed in the consultation report, in general, these were not items of research evidence addressing the effect of interventions relevant to the questions considered by the GDG.

Specifically, the issue of emerging evidence in relation to the Allen Carr Method (AC) intervention. This intervention was discussed in the guideline document, as it was identified in the HIQA HTA; however, there was no evidence to support any finding by HIQA concerning its effectiveness. Since then, primary randomised controlled trials were published and these were identified to the GDG through consultation. Because these were primary studies and have not yet been subject to systematic review and meta-analysis, they were not identified in Step B described above. For this reason, for completeness, a search of PUBMED was conducted used the text word "Allen Carr"[tw]; this was conducted from 2016 onwards, taken account of the timelines for the HIQA search.

One source of recommendations on smoking in pregnancy was also identified and is discussed.

Scoping evidence

The searches were conducted by one member of the GDG (PK). Titles and abstracts were collated,

then reviewed with two other members of the evidence team (AS and KIQ) to determine what, if any implication, arose for the currency of the recommendations made by the GDG. This report describes the outcomes, which were brought for discussion to the GDG post consultation on the draft guidelines in December 2020. The final decision of the GDG is also noted.

3. Findings

A. Guidelines

Table 3.1 describes the findings from a PUBMED search of current guidelines.

Table 3.1: Findings from PUBMED search for up-to-date guidelines

Reference	Evidence Team Comment	GDG Decision
Longman, J. M., Adams, C. M., Johnston, J. J., & Passey, M. E. (2018). Improving implementation of the smoking cessation guidelines with pregnant women: How to support clinicians?. *Midwifery, 58*, 137–144. https://doi.org/10.1016/j.midw.2017.12.016	A qualitative exploration of barriers and facilitators to guideline implementation. Not a guideline. No action	No action
Shields P. G. (2015). New NCCN Guidelines: Smoking Cessation for Patients With Cancer. Journal of the National *Comprehensive Cancer Network : JNCCN, 13*(5 Suppl), 643–645. https://doi.org/10.6004/jnccn.2015.0191	The National Comprehensive Cancer Network® (NCCN®) is a not-for-profit alliance of 30 leading cancer centers devoted to patient care, research, and education. The literature review was conducted in 2015 and thus is superseded by the HIQA HTA in terms of currency. The principle recommendations offered to clinicians are similar to those set out in guidelines adapted in this project. No action	No action
Shields, P. G., Herbst, R. S., Arenberg, D., Benowitz, N. L., Bierut, L., Luckart, J. B., Cinciripini, P., Collins, B., David, S., Davis, J., Hitsman, B., Hyland, A., Lang, M., Leischow, S., Park, E. R., Purcell, W. T., Selzle, J., Silber, A., Spencer, S., Tanvetyanon, T., … Scavone, J. (2016). Smoking Cessation, Version 1.2016, NCCN Clinical Practice Guidelines in Oncology. *Journal of the National Comprehensive Cancer Network : JNCCN, 14*(11), 1430–1468. https://doi.org/10.6004/jnccn.2016.0152		
Oliveira, G., Mendes, M., Dutra, Ó. P., Achutti, A., Fernandes, M., Correia, V. A., Ferreira, M., Coelho, A. S., Soares, M., Évora, M., Mariotto, M. G., & Morais, J. (2019). 2019 Recommendations for reducing tobacco consumption in the Portuguese-speaking countries. Recomendações de 2019 para a redução do consumo de tabaco nos países de língua portuguesa. *Revista portuguesa de cardiologia : orgao oficial da Sociedade Portuguesa de Cardiologia = Portuguese journal of cardiology : an official journal of the Portuguese Society of Cardiology, 38*(4), 233–244. https://doi.org/10.1016/j.repc.2019.04.003	Abstract in English but article in Portuguese. No action	No action

Reference	Evidence Team Comment	GDG Decision
Jankowski, P., Kawecka-Jaszcz, K., Kopeć, G., Podolec, J., Pająk, A., Sarnecka, A., Zdrojewski, T., Czarnecka, D., Małecki, M., Nowicka, G., Członkowska, A., Niewada, M., Stańczyk, J., Undas, A., Windak, A., Cedzyńska, M., Zatoński, W., & Podolec, P. (2017). Polish Forum for Prevention Guidelines on Smoking: update 2017. Kardiologia polska, 75(4), 409–411. https://doi.org/10.5603/KP.2017.0066	The document lacked detail on methods for guideline recommendation. The principle recommendations offered to clinicians are similar to those set out in guidelines adapted in this project. No action	No action
McGuire, H., Desai, M., Leng, G., & Richardson, J. (2018). NICE public health guidance update. *Journal of public health (Oxford, England), 40*(4), 900–902. https://doi.org/10.1093/pubmed/fdy132	The article discusses the UK NICE Guidelines. These were identified by the GDG but issues arose with licensing under fee for adaptation. No action	No action
Brady, B. R., De La Rosa, J. S., Nair, U. S., & Leischow, S. J. (2019). Electronic Cigarette Policy Recommendations: A Scoping Review. American journal of health behavior, 43(1), 88–104. https://doi.org/10.5993/AJHB.43.1.8	A scoping review of position statements in published and gray literature to map the range and frequency of e-cigarette use recommendations. Study collected 81 statements from international health organizations, found that comments on e-cigarettes were diverse and level of confidence in evidence was a commonly cited issue. No action, but a useful contextual reference.	No action Add as contextual reference.
Dautzenberg, B., Adler, M., Garelik, D., Loubrieu, J. F., Mathern, G., Peiffer, G., Perriot, J., Rouquet, R. M., Schmitt, A., Underner, M., & Urban, T. (2017). Practical guidelines on e-cigarettes for practitioners and others health professionals. A French 2016 expert's statement. *Revue des maladies respiratoires, 34*(2), 155–164. https://doi.org/10.1016/j.rmr.2017.01.001	French language article. The subject of e-cigarettes was reviewed by HRB with more up to date evidence and the GDG were requested by the Department of Health to consider this review. No action	No action
Nowak, D., Gohlke, H., Hering, T., Herth, F. J., Jany, B., Raupach, T., Welte, T., & Loddenkemper, R. (2015). Positionspapier der Deutschen Gesellschaft für Pneumologie und Beatmungsmedizin e.V. (DGP) zur elektronischen Zigarette (E-Zigarette) [Position paper of the German Respiratory Society (DGP) on electronic cigarettes (E-cigarettes) in cooperation with the following scientific societies and organisations: BVKJ, BdP, DGAUM, DGG, DGIM, DGK, DKG, DGSMP, GPP]. *Pneumologie (Stuttgart, Germany), 69*(3), 131–134. https://doi.org/10.1055/s-0034-1391491	German language article. The subject of e-cigarettes was reviewed by HRB with more up to date evidence and the GDG were requested by the Department of Health to consider this review. No action	No action

Table 3.2 describes the findings from search of guideline clearinghouses.

Table 3.2: Findings from search for up-to-date guidelines at guideline clearinghouses

Clearinghouse	Guideline	Evidence Team Comment	GDG Decision
https://www.ahrq.gov/gam/index.html	In Progress: Tobacco Smoking Cessation in Adults, Including Pregnant Persons: Interventions | United States Preventive Services Taskforce https://uspreventiveservicestaskforce.org/uspstf/draft-update-summary/tobacco-smoking-cessation-in-adults-including-pregnant-women-interventions	This guideline provided evidence based for the GDG recommendations. Update is ongoing and not available for GDG to consider at this point in time. No action	No action
https://www.nice.org.uk/	**Stop smoking interventions and services NICE guideline [NG92] Published date: 28 March 2018** Update planned Tobacco: preventing uptake, promoting quitting and treating dependence (update) In development [GID-NG10086] Expected publication date: 01 September 2021	Issue re adaption under a license with fee already discussed in the guideline document. No action	No action
https://joulecma.ca/cpg/homepage	Nil	No action	No action
https://www.sign.ac.uk/	Nil	No action	No action
https://www.clinicalguidelines.gov.au	**The Royal Australian College of General Practitioners. Supporting smoking cessation: A guide for health professionals. 2nd edn. East Melbourne, Vic: RACGP, 2019.** https://www.racgp.org.au/getattachment/00185c4e-441b-45a6-88d1-8f05c71843cd/Supporting-smoking-cessation-A-guide-for-health-professionals.aspx	In general, the recommendations proposed are very well aligned with those in this guideline. Content in the RACGP guideline regarding e-cigarettes is similar to this guideline, however, a conditional recommendation is made. Raise with GDG for discussion	The GDG considered this matter carefully in line with its Considered Judgement Framework and its view was that the GRADE criteria for making no recommendation were more appropriate than offering a conditional recommendation.
https://g-i-n.net/home	Nil new or additional to above		No action

The currency of the US, New Zealand, Canada and WHO guidelines adapted by the GDG were all affirmed through review of the relevant websites.

B. HIQA HTA

In total, 49 Cochrane reviews were identified. Table 3.3 describes the findings.

Table 3.3: Findings from search of Cochrane Library

Reference	Evidence Team Comment	GDG Decision
Hartmann-Boyce J, McRobbie H, Lindson N, Bullen C, Begh R, Theodoulou A, Notley C, Rigotti NA, Turner T, Butler AR, Hajek P. Electronic cigarettes for smoking cessation. Cochrane Database of Systematic Reviews 2020, Issue 10. Art. No.: CD010216. DOI: 10.1002/14651858. CD010216.pub4.	This study found that there is moderate-certainty evidence that ECs with nicotine increase quit rates compared to ECs without nicotine and compared to NRT. Evidence comparing nicotine EC with usual care/no treatment also suggests benefit, but is less certain. More studies are needed to confirm the degree of effect, particularly when using modern EC products. Confidence intervals were wide for data on AEs, SAEs and other safety markers. Overall incidence of SAEs was low across all study arms. The study did not detect any clear evidence of harm from nicotine EC, but longest follow-up was two years and the overall number of studies was small. This study was published following the publication of the HRB reviews. The Cochrane review reported different conclusions regarding the effectiveness of ECs than the HRB. There were important differences between the reviews which may contribute to the dfferent conclusions: the HRB were independent of the primary studies in the systematic review; the HRB used a more up-to-date risk of bias tool; the HRB included a greater number of studies in meta-analysis; the HRB used network meta-analysis, a more powerful evidence synthesis tool than that used by the Cochrane Group; the HRB disaggregated study outcomes by endpoint and did not collapse study outcomes; the HRB conducted evidence-driven sensitivity analyses to explore the robustness of its conclusions to various methodological decisions. For review with GDG.	Overall, the view of the GDG was that the area of agreement between the reviews was more significant to its consideration than areas of disagreement: both studies conclude that there are significant limitations in the evidence base due to the small number of RCTs, often with low event rates and various sources of bias, leading to imprecision is overall estimates of effect size and direction in systematic review and meta-analysis. The GDG reviewed its content in relation to ECs and confirmed that this reflected its considered judgement on the issues taking account of the available evidence at this point in time and other relevant factors set out in the Considered Judgement Frameworks used to guide its deliberations.
Campbell K, Coleman-Haynes T, Bowker K, Cooper SE, Connelly S, Coleman T. Factors influencing the uptake and use of nicotine replacement therapy and e-cigarettes in pregnant women who smoke: a qualitative evidence synthesis. Cochrane Database of Systematic Reviews 2020, Issue 5. Art. No.: CD013629. DOI: 10.1002/14651858. CD013629.	This study did not address the effectiveness of the interventions under consideration in this guideline, No action	No action

Reference	Evidence Team Comment	GDG Decision
Howes S, Hartmann-Boyce J, Livingstone-Banks J, Hong B, Lindson N. Antidepressants for smoking cessation. Cochrane Database of Systematic Reviews 2020, Issue 4. Art. No.: CD000031. DOI: 10.1002/14651858. CD000031.pub5.	This study confirms the effectiveness of buproprion which is currently referenced in the guideline. It also confirms the effectiveness of nortriptyline compared with placebo (RR 2.03, 95% CI 1.48 to 2.78). This drug was excluded from the HIQA HTA because at the time it was not licensed in Ireland. It is now licensed from 2016. It was identified in the New Zealand Guideline. GDG to discuss and consider adding this drug to the list of recommended pharmacological interventions.	The GDG reviewed and a decision was made to add nortriptyline to the list of recommended pharmacotherpies with reference to the made to this evidence in the relevant section.
Claire R, Chamberlain C, Davey MA, Cooper SE, Berlin I, Leonardi-Bee J, Coleman T. Pharmacological interventions for promoting smoking cessation during pregnancy. Cochrane Database of Systematic Reviews 2020, Issue 3. Art. No.: CD010078. DOI: 10.1002/14651858. CD010078.pub3.	This study found that compared to placebo and non-placebo (behavioural support only) controls, there was low-certainty evidence that NRT increased the likelihood of smoking abstinence in later pregnancy (RR 1.37, 95% CI 1.08 to 1.74). This adds to the evidence base supporting the low certainty conditional recommendation made by the GDG in this area. It may be added to the discussion of evidence in the final guideline.	Add to discussion of evidence at relevant section in guideline.
Whittaker R, McRobbie H, Bullen C, Rodgers A, Gu Y, Dobson R. Mobile phone text messaging and app-based interventions for smoking cessation. Cochrane Database of Systematic Reviews 2019, Issue 10. Art. No.: CD006611. DOI: 10.1002/14651858. CD006611.pub5.	This study found that there was moderate-certainty evidence, limited by inconsistency, that automated text messaging interventions were more effective than minimal smoking cessation support (RR 1.54, 95% CI 1.19 to 2.00). There was also moderate-certainty evidence, limited by imprecision, that text messaging added to other smoking cessation interventions was more effective than the other smoking cessation interventions alone (RR 1.59, 95% CI 1.09 to 2.33). This more up to date systematic review offers stronger and more certain evidence regarding text-based support than the HIQA review. The New Zealand guideline had noted there was “moderate” evidence to support text-based support. The GDG may update the guideline to reflect this more current evidence.	Add to discussion of evidence at relevant section in guideline.
Ussher MH, Faulkner GEJ, Angus K, Hartmann-Boyce J, Taylor AH. Exercise interventions for smoking cessation. Cochrane Database of Systematic Reviews 2019, Issue 10. Art. No.: CD002295. DOI: 10.1002/14651858. CD002295.pub6.	This study found there is no evidence that adding exercise to smoking cessation support improves abstinence compared with support alone. The GDG have made no recommendation in this area and no action is required.	No action

Reference	Evidence Team Comment	GDG Decision
Carson-Chahhoud KV, Livingstone-Banks J, Sharrad KJ, Kopsaftis Z, Brinn MP, To-A-Nan R, Bond CM. Community pharmacy personnel interventions for smoking cessation. Cochrane Database of Systematic Reviews 2019, Issue 10. Art. No.: CD003698. DOI: 10.1002/14651858. CD003698.pub3.	This study found that community pharmacists can provide effective behavioural support to people trying to stop smoking. This is consistent with the existing recommendation made by the GDG in this guideline. The GDG may update the guideline to reflect this more current evidence and may specific reference to this healthcare professional group. It may be added to the discussion of evidence in the final guideline.	Add to discussion of evidence at relevant section in guideline.
Lindson N, Aveyard P, Hughes JR. Reduction versus abrupt cessation in smokers who want to quit. Cochrane Database of Systematic Reviews 2019, Issue 10. Art. No.: CD008033. DOI: 10.1002/14651858. CD008033.pub4.	This Cochrane Review has been withdrawn with agreement from the author team as it is superseded by the new review: Lindson N, Klemperer E, Hong B, Ordóñez-Mena JM, Aveyard P. Smoking reduction interventions for smoking cessation. Cochrane Database of Systematic Reviews 2019, Issue 9. Art. No.: CD013183. DOI: 10.1002/14651858.CD013183. pub2.	No action
Livingstone-Banks J, Norris E, Hartmann-Boyce J, West R, Jarvis M, Chubb E, Hajek P. Relapse prevention interventions for smoking cessation. Cochrane Database of Systematic Reviews 2019, Issue 10. Art. No.: CD003999. DOI: 10.1002/14651858. CD003999.pub6.	This study found that behavioural interventions that teach people to recognise situations that are high risk for relapse along with strategies to cope with them provided no worthwhile benefit in preventing relapse in assisted abstainers. In people who have successfully quit smoking using pharmacotherapy, there were mixed results regarding extending pharmacotherapy for longer than is standard. Extended treatment with varenicline helped to prevent relapse; evidence for the effect estimate was of moderate certainty, limited by unexplained statistical heterogeneity. Moderate-certainty evidence, limited by imprecision, did not detect a benefit from extended treatment with bupropion, though confidence intervals mean we could not rule out a clinically important benefit at this stage. Low-certainty evidence, limited by imprecision, did not show a benefit of extended treatment with nicotine replacement therapy in preventing relapse in assisted abstainers. More research is needed in this area, especially as the evidence for extended nicotine replacement therapy in unassisted abstainers did suggest a benefit. The GDG may wish to consider this and review its good practice point in this area.	GDG reviewed and updated relevant good practice point.

Reference	Evidence Team Comment	GDG Decision
Roelsgaard IK, Esbensen BA, Østergaard M, Rollefstad S, Semb AG, Christensen R, Thomsen T. Smoking cessation intervention for reducing disease activity in chronic autoimmune inflammatory joint diseases. Cochrane Database of Systematic Reviews 2019, Issue 9. Art. No.: CD012958. DOI: 10.1002/14651858. CD012958.pub2.	This study focused on a specific sub-population and is outside the scope of this guideline. No action.	No action.
Lindson N, Klemperer E, Hong B, Ordóñez-Mena JM, Aveyard P. Smoking reduction interventions for smoking cessation. Cochrane Database of Systematic Reviews 2019, Issue 9. Art. No.: CD013183. DOI: 10.1002/14651858. CD013183.pub2.	This study found there was moderate-certainty evidence that neither reduction-to-quit nor abrupt quitting interventions result in superior long-term quit rates when compared with one another. Evidence comparing the efficacy of reduction-to-quit interventions with no treatment was inconclusive and of low certainty. GDG has made no comment on this matter in the guideline and this study confirms that there is no certain basis to providing definitive recommendation to healthcare professionals on this matter.	No action.
Hollands GJ, Naughton F, Farley A, Lindson N, Aveyard P. Interventions to increase adherence to medications for tobacco dependence. Cochrane Database of Systematic Reviews 2019, Issue 8. Art. No.: CD009164. DOI: 10.1002/14651858. CD009164.pub3.	This study found that in people who are stopping smoking and receiving behavioural support, there is moderate-certainty evidence that enhanced behavioural support focusing on adherence to smoking cessation medications can modestly improve adherence. There is only low-certainty evidence that this may slightly improve the likelihood of cessation in the shorter or longer-term. This is consistent with the guideline recommendation that behavioural support should be recommended in conjunction with pharmacotherapy. The GDG may update the guideline to reflect this more current evidence.	Add to discussion of evidence at relevant section in guideline.
Lindson N, Thompson TP, Ferrey A, Lambert JD, Aveyard P. Motivational interviewing for smoking cessation. Cochrane Database of Systematic Reviews 2019, Issue 7. Art. No.: CD006936. DOI: 10.1002/14651858. CD006936.pub4	The study found that there is insufficient evidence to show whether or not motivational interviewing helps people to stop smoking. The guideline does not make recommendations in relation to Motivational Interviewing and so no action is required.	No action.

Reference	Evidence Team Comment	GDG Decision
Notley C, Gentry S, Livingstone-Banks J, Bauld L, Perera R, Hartmann-Boyce J. Incentives for smoking cessation. Cochrane Database of Systematic Reviews 2019, Issue 7. Art. No.: CD004307. DOI: 10.1002/14651858. CD004307.pub6.	This study found that overall there is high-certainty evidence that incentives improve smoking cessation rates at long-term follow-up in mixed population studies. There is also moderate-certainty evidence, limited by some concerns about risks of bias, that incentive schemes conducted among pregnant smokers improve smoking cessation rates, both at the end of pregnancy and post-partum. The GDG has already considered financial incentives. These are not cited in any of the guidelines adapted in this guidelines development process. The findings of the HIQA HTA in this regard were noted. This is a complex area, and health system context is important. Stop smoking services in Ireland already address and remove a number of financial disincentives for people who smoke; some issues reagrding NRT have been identified to be addressed in the implementation plan. The GDG may wish to discuss this matter further.	The view of the GDG was that any recommendation and service development in this area would require local research to confirm effectiveness and inform implementation. Comments on incentives will be added to relevant evidence sections of the final guideline.
Barnes J, McRobbie H, Dong CY, Walker N, Hartmann-Boyce J. Hypnotherapy for smoking cessation. Cochrane Database of Systematic Reviews 2019, Issue 6. Art. No.: CD001008. DOI: 10.1002/14651858. CD001008.pub3.	This study found there is insufficient evidence to determine whether hypnotherapy is more effective for smoking cessation than other forms of behavioural support or unassisted quitting. No recommendation has been made in relation to this intervention in the guideline so no change is required. The GDG may wish to add specific comments in its Good Practice Points to support healthcare professionals with queries that may be raised regarding interventions that are not recommended.	Add to discussion of evidence at relevant section in guideline. Good practice points will be developed to address support to healthcare professionals with queries that may be raised regarding interventions that are not recommended.
Hartmann-Boyce J, Hong B, Livingstone-Banks J, Wheat H, Fanshawe TR. Additional behavioural support as an adjunct to pharmacotherapy for smoking cessation. Cochrane Database of Systematic Reviews 2019, Issue 6. Art. No.: CD009670. DOI: 10.1002/14651858. CD009670.pub4.	This study found that there is high-certainty evidence that providing behavioural support in person or via telephone for people using pharmacotherapy to stop smoking increases quit rates. This is consistent with recommendations made by the GDG in the guideline. It may be added to the discussion of evidence supporting this recommendation in the final guideline.	Add to discussion of evidence at relevant section in guideline.
Zeng L, Yu X, Yu T, Xiao J, Huang Y. Interventions for smoking cessation in people diagnosed with lung cancer. Cochrane Database of Systematic Reviews 2019, Issue 6. Art. No.: CD011751. DOI: 10.1002/14651858. CD011751.pub3.	The guideline is not addressing specific issues in this population. No action.	No action.

Reference	Evidence Team Comment	GDG Decision
Matkin W, Ordóñez-Mena JM, Hartmann-Boyce J. Telephone counselling for smoking cessation. Cochrane Database of Systematic Reviews 2019, Issue 5. Art. No.: CD002850. DOI: 10.1002/14651858. CD002850.pub4.	This study confirms the effectiveness of telephone support. The intervention was already discussion and recommended by the GDG in the guideline. It may be added to the discussion of evidence in the final guideline.	Add to discussion of evidence at relevant section in guideline.
Lindson N, Chepkin SC, Ye W, Fanshawe TR, Bullen C, Hartmann-Boyce J. Different doses, durations and modes of delivery of nicotine replacement therapy for smoking cessation. Cochrane Database of Systematic Reviews 2019, Issue 4. Art. No.: CD013308. DOI: 10.1002/14651858. CD013308.	This study found there is high-certainty evidence that combination NRT works better than a single form of NRT, that higher-dose nicotine gum works better than lower-dose gum, and that there is no difference in effect between different types of NRT (such as gum or lozenge). This is consistent with recommendations made by the GDG in the guideline. It may be added to the discussion of evidence supporting this recommendation in the final guideline.	Add to discussion of evidence at relevant section in guideline
Clair C, Mueller Y, Livingstone-Banks J, Burnand B, Camain JY, Cornuz J, Rège-Walther M, Selby K, Bize R. Biomedical risk assessment as an aid for smoking cessation. Cochrane Database of Systematic Reviews 2019, Issue 3. Art. No.: CD004705. DOI: 10.1002/14651858. CD004705.pub5.	This study found that there is little evidence about the effects of biomedical risk assessment as an aid for smoking cessation. The GDG have made no recommendation in the guideline regarding use of biomedical risk assessment as an aid to stop smoking so there is no action required. For clarity, the recommendation in relation to routine BCO at first antenatal visit is intended to strenghten “Ask” of brief intervention and is not for motivational purposes. No action.	No action.
Fanshawe TR, Hartmann-Boyce J, Perera R, Lindson N. Competitions for smoking cessation. Cochrane Database of Systematic Reviews 2019, Issue 2. Art. No.: CD013272. DOI: 10.1002/14651858. CD013272.	This study found that at present, it is impossible to draw any firm conclusions about the effectiveness, or a lack of it, of smoking cessation competitions. The GDG have made no recommendation in this area in the guideline. No action	No action

Reference	Evidence Team Comment	GDG Decision
Livingstone-Banks J, Ordóñez-Mena JM, Hartmann-Boyce J. Print-based self-help interventions for smoking cessation. Cochrane Database of Systematic Reviews 2019, Issue 1. Art. No.: CD001118. DOI: 10.1002/14651858. CD001118.pub4.	This study found that there was moderate-certainty evidence shows that when no other support is available, written self-help materials help more people to stop smoking than no intervention. When people receive advice from a health professional or are using nicotine replacement therapy, there is no evidence that self-help materials add to their effect. Since brief advice is the basic standard of care recommended in the guideline, there is no marginal benefit based on this evidence for adding written materials. Written material are widely available through HSE QUIT, however. The GDG has made no recommendation in this area and no further action is required.	No action
Wolfenden L, Goldman S, Stacey FG, Grady A, Kingsland M, Williams CM, Wiggers J, Milat A, Rissel C, Bauman A, Farrell MM, Légaré F, Ben Charif A, Zomahoun HTV, Hodder RK, Jones J, Booth D, Parmenter B, Regan T, Yoong SL. Strategies to improve the implementation of workplace-based policies or practices targeting tobacco, alcohol, diet, physical activity and obesity. Cochrane Database of Systematic Reviews 2018, Issue 11. Art. No.: CD012439. DOI: 10.1002/14651858. CD012439.pub2.	This study is not relevant to the scope of the guideline. No action is required.	No action
Medley N, Vogel JP, Care A, Alfirevic Z. Interventions during pregnancy to prevent preterm birth: an overview of Cochrane systematic reviews. Cochrane Database of Systematic Reviews 2018, Issue 11. Art. No.: CD012505. DOI: 10.1002/14651858. CD012505.pub2.	This study was a review of existing Cochranes reviews. It included a review of pharmacological interventions for smoking cessation in pregnancy. It is superseded by Claire R, Chamberlain C, Davey MA, Cooper SE, Berlin I, Leonardi-Bee J, Coleman T. Pharmacological interventions for promoting smoking cessation during pregnancy. Cochrane Database of Systematic Reviews 2020, Issue 3. Art. No.: CD010078. DOI: 10.1002/14651858. CD010078.pub3. Accessed 05 December 2020. No action.	No action.

Reference	Evidence Team Comment	GDG Decision
Faseru B, Richter KP, Scheuermann TS, Park EW. Enhancing partner support to improve smoking cessation. Cochrane Database of Systematic Reviews 2018, Issue 8. Art. No.: CD002928. DOI: 10.1002/14651858. CD002928.pub4.	This study found that interventions that aim to enhance partner support appear to have no impact on increasing long-term abstinence from smoking. However, most interventions that assessed partner support showed no evidence that the interventions actually achieved their aim and increased support from partners for smoking cessation. Some guidelines make comments on this point, but the GDG made no recommendation in this area, nor offered any good practice point and so no action is required.	Add to discussion of evidence at relevant section in guideline.
Hartmann-Boyce J, Chepkin SC, Ye W, Bullen C, Lancaster T. Nicotine replacement therapy versus control for smoking cessation. Cochrane Database of Systematic Reviews 2018, Issue 5. Art. No.: CD000146. DOI: 10.1002/14651858. CD000146.pub5.	This study found that there is high-quality evidence that all of the licensed forms of NRT (gum, transdermal patch, nasal spray, inhalator and sublingual tablets/lozenges) can help people who make a quit attempt to increase their chances of successfully stopping smoking. NRTs increase the rate of quitting by 50% to 60%, regardless of setting, and further research is very unlikely to change our confidence in the estimate of the effect. This is consistent with recommendations made by the GDG in the guideline. It may be added to the discussion of evidence supporting this recommendation in the final guideline.	Add to discussion of evidence at relevant section in guideline.
Behbod B, Sharma M, Baxi R, Roseby R, Webster P. Family and carer smoking control programmes for reducing children's exposure to environmental tobacco smoke. Cochrane Database of Systematic Reviews 2018, Issue 1. Art. No.: CD001746. DOI: 10.1002/14651858. CD001746.pub4.	This study concerned issues outside the scope of the guideline. No action.	No action.
Rice VH, Heath L, Livingstone-Banks J, Hartmann-Boyce J. Nursing interventions for smoking cessation. Cochrane Database of Systematic Reviews 2017, Issue 12. Art. No.: CD001188. DOI: 10.1002/14651858. CD001188.pub5.	This study found that there is moderate quality evidence that behavioural support to motivate and sustain smoking cessation delivered by nurses can lead to a modest increase in the number of people who achieve prolonged abstinence. This is consistent with recommendations made by the GDG in the guideline. It may be added to the discussion of evidence supporting this recommendation in the final guideline.	Add to discussion of evidence at relevant section in guideline.

Reference	Evidence Team Comment	GDG Decision
Bala MM, Strzeszynski L, Topor-Madry R. Mass media interventions for smoking cessation in adults. Cochrane Database of Systematic Reviews 2017, Issue 11. Art. No.: CD004704. DOI: 10.1002/14651858. CD004704.pub4.	This study concerned issues outside the scope of the guideline. There are already mass media campaigns in place in Ireland which motivate and signpost people who smoke to use stop smoking services. No action	No action
Schuit E, Panagiotou OA, Munafò MR, Bennett DA, Bergen AW, David SP. Pharmacotherapy for smoking cessation: effects by subgroup defined by genetically informed biomarkers. Cochrane Database of Systematic Reviews 2017, Issue 9. Art. No.: CD011823. DOI: 10.1002/14651858. CD011823.pub2.	This study concerned issues outside the scope of the guideline No action	No action
Taylor GMJ, Dalili MN, Semwal M, Civljak M, Sheikh A, Car J. Internet-based interventions for smoking cessation. Cochrane Database of Systematic Reviews 2017, Issue 9. Art. No.: CD007078. DOI: 10.1002/14651858. CD007078.pub5.	This study found that the evidence from trials in adults suggests that interactive and tailored Internet-based interventions with or without additional behavioural support are moderately more effective than non-active controls at six months or longer, but there was no evidence that these interventions were better than other active smoking treatments. This is consistent with recommendations made by the GDG in the guideline. It may be added to the discussion of evidence supporting this recommendation in the final guideline.	Add to discussion of evidence at relevant section in guideline.
van den Brand FA, Nagelhout GE, Reda AA, Winkens B, Evers SMAA, Kotz D, van Schayck OCP. Healthcare financing systems for increasing the use of tobacco dependence treatment. Cochrane Database of Systematic Reviews 2017, Issue 9. Art. No.: CD004305. DOI: 10.1002/14651858. CD004305.pub5.	This study found that full financial interventions directed at smokers when compared to no financial interventions increase the proportion of smokers who attempt to quit, use smoking cessation treatments, and succeed in quitting. There was no clear and consistent evidence of an effect on smoking cessation from financial incentives directed at healthcare providers. The GDG considered financial incentives. These are not cited in any of the guidelines adapted in this guidelines development process. The findings of the HIQA HTA in this regard were noted. This is a complex area, and health system context is important. Stop smoking services in Ireland already address and remove a number of financial disincentives for people who smoke; some issues regarding NRT have been identified to be addressed in the implementation plan. The GDG may wish to discuss this matter further.	The view of the GDG was that any recommendation and service development in this area would require local research to confirm effectiveness and inform implementation. Comments on incentives will be added to relevant evidence sections of the final guideline

Reference	Evidence Team Comment	GDG Decision
Lenferink A, Brusse-Keizer M, van der Valk PDLPM, Frith PA, Zwerink M, Monninkhof EM, van der Palen J, Effing TW. Self-management interventions including action plans for exacerbations versus usual care in patients with chronic obstructive pulmonary disease. Cochrane Database of Systematic Reviews 2017, Issue 8. Art. No.: CD011682. DOI: 10.1002/14651858. CD011682.pub2.	This study concerned issues outside the scope of the guideline No action	No action
McCabe C, McCann M, Brady AM. Computer and mobile technology interventions for self-management in chronic obstructive pulmonary disease. Cochrane Database of Systematic Reviews 2017, Issue 5. Art. No.: CD011425. DOI: 10.1002/14651858. CD011425.pub2.	This study concerned issues outside the scope of the guideline No action	No action
Kew KM, Carr R, Crossingham I. Lay-led and peer support interventions for adolescents with asthma. Cochrane Database of Systematic Reviews 2017, Issue 4. Art. No.: CD012331. DOI: 10.1002/14651858. CD012331.pub2.	This study concerned issues outside the scope of the guideline No action	No action
McNeill A, Gravely S, Hitchman SC, Bauld L, Hammond D, Hartmann-Boyce J. Tobacco packaging design for reducing tobacco use. Cochrane Database of Systematic Reviews 2017, Issue 4. Art. No.: CD011244. DOI: 10.1002/14651858. CD011244.pub2.	This study concerned issues outside the scope of the guideline No action	No action

Reference	Evidence Team Comment	GDG Decision
Lancaster T, Stead LF. Individual behavioural counselling for smoking cessation. Cochrane Database of Systematic Reviews 2017, Issue 3. Art. No.: CD001292. DOI: 10.1002/14651858. CD001292.pub3.	This study found that there is high-quality evidence that individually-delivered smoking cessation counselling can assist smokers to quit. There is moderate-quality evidence of a smaller relative benefit when counselling is used in addition to pharmacotherapy, and of more intensive counselling compared to a brief counselling intervention. This is consistent with recommendations made by the GDG in the guideline. It may be added to the discussion of evidence supporting this recommendation in the final guideline.	Add to discussion of evidence at relevant section in guideline.
Stead LF, Carroll AJ, Lancaster T. Group behaviour therapy programmes for smoking cessation. Cochrane Database of Systematic Reviews 2017, Issue 3. Art. No.: CD001007. DOI: 10.1002/14651858. CD001007.pub3.	This study found that group therapy is better for helping people stop smoking than self-help, and other less intensive interventions. This is consistent with recommendations made by the GDG in the guideline. It may be added to the discussion of evidence supporting this recommendation in the final guideline.	Add to discussion of evidence at relevant section in guideline.
Chamberlain C, O'Mara-Eves A, Porter J, Coleman T, Perlen SM, Thomas J, McKenzie JE. Psychosocial interventions for supporting women to stop smoking in pregnancy. Cochrane Database of Systematic Reviews 2017, Issue 2. Art. No.: CD001055. DOI: 10.1002/14651858. CD001055.pub5.	This study found that psychosocial interventions to support women to stop smoking in pregnancy can increase the proportion of women who stop smoking in late pregnancy and the proportion of infants born low birthweight. This is consistent with recommendations made by the GDG in the guideline. It may be added to the discussion of evidence supporting this recommendation in the final guideline.	Add to discussion of evidence at relevant section in guideline.
Mosdøl A, Lidal IB, Straumann GH, Vist GE. Targeted mass media interventions promoting healthy behaviours to reduce risk of non-communicable diseases in adult, ethnic minorities. Cochrane Database of Systematic Reviews 2017, Issue 2. Art. No.: CD011683. DOI: 10.1002/14651858. CD011683.pub2.	This study concerned issues outside the scope of the guideline No action.	No action.
Thomas D, Abramson MJ, Bonevski B, George J. System change interventions for smoking cessation. Cochrane Database of Systematic Reviews 2017, Issue 2. Art. No.: CD010742. DOI: 10.1002/14651858. CD010742.pub2.	This study concerned issues outside the scope of the guideline. No action.	No action.

Reference	Evidence Team Comment	GDG Decision
Apollonio D, Philipps R, Bero L. Interventions for tobacco use cessation in people in treatment for or recovery from substance use disorders. Cochrane Database of Systematic Reviews 2016, Issue 11. Art. No.: CD010274. DOI: 10.1002/14651858. CD010274.pub2.	This study concerned issues outside the scope of the guideline. No action.	No action.
Lindson-Hawley N, Hartmann-Boyce J, Fanshawe TR, Begh R, Farley A, Lancaster T. Interventions to reduce harm from continued tobacco use. Cochrane Database of Systematic Reviews 2016, Issue 10. Art. No.: CD005231. DOI: 10.1002/14651858. CD005231.pub3.	This study concerned issues outside the scope of the guideline. No action.	No action.
van Eerd EAM, van der Meer RM, van Schayck OCP, Kotz D. Smoking cessation for people with chronic obstructive pulmonary disease. Cochrane Database of Systematic Reviews 2016, Issue 8. Art. No.: CD010744. DOI: 10.1002/14651858. CD010744.pub2.	This study concerned issues outside the scope of the guideline. No action.	No action.
Pool ERM, Dogar O, Lindsay RP, Weatherburn P, Siddiqi K. Interventions for tobacco use cessation in people living with HIV and AIDS. Cochrane Database of Systematic Reviews 2016, Issue 6. Art. No.: CD011120. DOI: 10.1002/14651858. CD011120.pub2.	This study concerned issues outside the scope of the guideline. No action.	No action.
Cahill K, Lindson-Hawley N, Thomas KH, Fanshawe TR, Lancaster T. Nicotine receptor partial agonists for smoking cessation. Cochrane Database of Systematic Reviews 2016, Issue 5. Art. No.: CD006103. DOI: 10.1002/14651858. CD006103.pub7.	This study found that cytisine increases the chances of quitting, although absolute quit rates were modest in two recent trials. Varenicline at standard dose increased the chances of successful long-term smoking cessation between two- and three-fold compared with pharmacologically unassisted quit attempts. This is consistent with recommendations made by the GDG in the guideline. It may be added to the discussion of evidence supporting this recommendation in the final guideline.	Add to discussion of evidence at relevant section in guideline.

Reference	Evidence Team Comment	GDG Decision
Stead LF, Koilpillai P, Fanshawe TR, Lancaster T. Combined pharmacotherapy and behavioural interventions for smoking cessation. Cochrane Database of Systematic Reviews 2016, Issue 3. Art. No.: CD008286. DOI: 10.1002/14651858. CD008286.pub3.	This study found that interventions that combine pharmacotherapy and behavioural support increase smoking cessation success compared to a minimal intervention or usual care. This is consistent with recommendations made by the GDG in the guideline. It may be added to the discussion of evidence supporting this recommendation in the final guideline.	Add to discussion of evidence at relevant section in guideline.
Jeyashree K, Kathirvel S, Shewade HD, Kaur H, Goel S. Smoking cessation interventions for pulmonary tuberculosis treatment outcomes. Cochrane Database of Systematic Reviews 2016, Issue 1. Art. No.: CD011125. DOI: 10.1002/14651858. CD011125.pub2.	This study concerned issues outside the scope of the guideline No action.	No action.
Khanna P, Clifton AV, Banks D, Tosh GE. Smoking cessation advice for people with serious mental illness. Cochrane Database of Systematic Reviews 2016, Issue 1. Art. No.: CD009704. DOI: 10.1002/14651858. CD009704.pub2.	This study found that people with serious mental illness are more likely to smoke than the general population. Yet it could not find any high quality evidence to guide the smoking cessation advice healthcare professionals pass onto service users. However, the currency of this evidence review is superseded by the HIQA HTA, which informed GDG recommendations in the current guideline. No action	No action

Table 3.4 describes the findings from the update of the HIQA search on stop smoking interventions in pregnancy. In total, 513 articles were identified from 2016 to date, of which 47 were systematic reviews or meta-analyses. Following article and abstract review, a small number were relevant to the guideline questions.

Table 3.4: Findings from search on smoking in pregnancy

Reference	Evidence Team Comment	GDG Decision
Taylor, L., Claire, R., Campbell, K., Coleman-Haynes, T., Leonardi-Bee, J., Chamberlain, C., Berlin, I., Davey, M. A., Cooper, S., & Coleman, T. (2020). Fetal safety of nicotine replacement therapy in pregnancy: systematic review and meta-analysis. Addiction (Abingdon, England), 10.1111/add.15185. Advance online publication. https://doi.org/10.1111/add.15185	This study found that available evidence from randomized controlled trials and non-randomized comparative studies does not currently provide clear evidence as to whether maternal use of nicotine replacement therapy during pregnancy is harmful to the fetus. This is consistent with recommendations made by the GDG in the guideline. It may be added to the discussion of evidence supporting this recommendation in the final guideline.	Add to discussion of evidence at relevant section in guideline.
Grangé, G., Berlin, I., Bretelle, F., Bertholdt, C., Berveiller, P., Blanc, J., DiGuisto, C., Dochez, V., Garabedian, C., Guerby, P., Koch, A., Le Lous, M., Perdriolle-Galet, E., Peyronnet, V., Rault, E., Torchin, H., & Legendre, G. (2020). Smoking and smoking cessation in pregnancy. Synthesis of a systematic review. Journal of gynecology obstetrics and human reproduction, 49(8), 101847. https://doi.org/10.1016/j.jogoh.2020.101847	This study found that "counselling", including all types of non-pharmacological interventions, has a moderate benefit on smoking cessation, birth weight and prematurity. The systematic use of measuring expired air CO concentration does not influence smoking abstinence, however, it may be useful in assessing smoked tobacco exposure prior to and after quitting. The use of self-help therapies and health education are recommended in helping pregnant smokers quit and should be advised by healthcare professionals. Nicotine replacement therapies (NRT) may be prescribed to pregnant women who have failed to stop smoking after trying non-pharmacological interventions. Different modes of delivery and dosages can be used in optimizing their efficacy. Smoking in the postpartum period is essential to consider. The same treatment options as during pregnancy can be used. This is consistent with recommendations made by the GDG in the guideline. It may be added to the discussion of evidence supporting this recommendation in the final guideline.	Add to discussion of evidence at relevant section in guideline.

Reference	Evidence Team Comment	GDG Decision
Claire, R., Chamberlain, C., Davey, M. A., Cooper, S. E., Berlin, I., Leonardi-Bee, J., & Coleman, T. (2020). Pharmacological interventions for promoting smoking cessation during pregnancy. The Cochrane database of systematic reviews, 3(3), CD010078. https://doi.org/10.1002/14651858.CD010078.pub3	Already identified in Cochrane search No further action	
Turner, E., Jones, M., Vaz, L. R., & Coleman, T. (2019). Systematic Review and Meta-Analysis to Assess the Safety of Bupropion and Varenicline in Pregnancy. Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco, 21(8), 1001–1010. https://doi.org/10.1093/ntr/nty055	This study found there was no strong evidence that either major positive or negative outcomes were associated with gestational use of bupropion or varenicline. The GDG has made no recommendation in this area so no action is proposed.	No action.
Griffiths, S. E., Parsons, J., Naughton, F., Fulton, E. A., Tombor, I., & Brown, K. E. (2018). Are digital interventions for smoking cessation in pregnancy effective? A systematic review and meta-analysis. Health psychology review, 12(4), 333–356. https://doi.org/10.1080/17437199.2018.1488602	This study found that he primary meta-analysis produced a sample-weighted odds ratio (OR) of 1.44 (95% CI 1.04-2.00, p = .03) in favour of digital interventions compared with comparison groups. Computer-based (OR = 3.06, 95% CI 1.28-7.33) and text-message interventions (OR = 1.59, 95% CI 1.07-2.38) were the most effective digital platform. Moderator analyses revealed seven (Behaviour Change Techniques) BCTs associated with smoking cessation: information about antecedents; action planning; problem solving; goal setting (behaviour); review behaviour goals; social support (unspecified); and pros and cons. A meta-regression suggested that interventions using larger numbers of BCTs produced the greatest effects. This paper highlights the potential for digital interventions to improve rates of smoking cessation in pregnancy. This is consistent with recommendations made by the GDG in the guideline. It may be added to the discussion of evidence supporting this recommendation in the final guideline	Add to discussion of evidence at relevant section in guideline.
Hendrick, V., Suri, R., Gitlin, M. J., & Ortiz-Portillo, E. (2017). Bupropion Use During Pregnancy: A Systematic Review. The primary care companion for CNS disorders, 19(5), 17r02160. https://doi.org/10.4088/PCC.17r02160	This study found while more studies are needed, research to date suggests that bupropion may be a reasonable treatment option for depressed pregnant women who require pharmacotherapy, particularly when they also are attempting to reduce nicotine use during pregnancy. The GDG has made no recommendation in this area so no action is proposed.	No action

Reference	Evidence Team Comment	GDG Decision
Chamberlain, C., O'Mara-Eves, A., Porter, J., Coleman, T., Perlen, S. M., Thomas, J., & McKenzie, J. E. (2017). Psychosocial interventions for supporting women to stop smoking in pregnancy. The Cochrane database of systematic reviews, 2(2), CD001055. https://doi.org/10.1002/14651858.CD001055.pub5	Already addressed in Cochrane search above No action	No action

Table 3.5 describes the findings from the updated search on stop smoking interventions in secondary mental health service users. In total, 898 articles were identified from 31/12/2016 to date, of which 168 were systematic reviews or meta-analyses. Following article and abstract review, a small number were relevant to the guideline questions.

Table 3.5: Findings from search on smoking and secondary mental health service users

Reference	Evidence Team Comment	GDG Decision
Siskind, D. J., Wu, B. T., Wong, T. T., Firth, J., & Kisely, S. (2020). Pharmacological interventions for smoking cessation among people with schizophrenia spectrum disorders: a systematic review, meta-analysis, and network meta-analysis. The lancet. Psychiatry, 7(9), 762–774. https://doi.org/10.1016/S2215-0366(20)30261-3	The study found evidence to support use of pharmacological agents for smoking cessation for people with psychosis. Varenicline might be superior to bupropion; however, additional direct testing and combination trials of pharmacological agents for smoking cessation are required to inform clinical decision making for people with psychosis This is consistent with recommendations made by the GDG in the guideline. It may be added to the discussion of evidence supporting this recommendation in the final guideline	Add to discussion of evidence at relevant section in guideline.
Kozak, K., & George, T. P. (2020). Pharmacotherapy for smoking cessation in schizophrenia: a systematic review. Expert opinion on pharmacotherapy, 21(5), 581–590. https://doi.org/10.1080/14656566.2020.1721466	The study findings support the efficacy and safety of first-line pharmacotherapies (including varenicline, sustained-release bupropion, and nicotine replacement therapies (NRT)) for the treatment of tobacco use disorder in smokers with schizophrenia. This is consistent with recommendations made by the GDG in the guideline. It may be added to the discussion of evidence supporting this recommendation in the final guideline	Add to discussion of evidence at relevant section in guideline.
Aldi, G. A., Bertoli, G., Ferraro, F., Pezzuto, A., & Cosci, F. (2018). Effectiveness of pharmacological or psychological interventions for smoking cessation in smokers with major depression or depressive symptoms: A systematic review of the literature. Substance abuse, 39(3), 289–306. https://doi.org/10.1080/08897077.2018.1439802	This study found that more research is needed into effectively addressing smoking in people with concurrent mental disorder. This is superseded by the HIQA HTA and above. No action.	No action

Reference	Evidence Team Comment	GDG Decision
Peckham, E., Brabyn, S., Cook, L., Tew, G., & Gilbody, S. (2017). Smoking cessation in severe mental ill health: what works? an updated systematic review and meta-analysis. BMC psychiatry, 17(1), 252. https://doi.org/10.1186/s12888-017-1419-7	This study found that bupropion and varenicline, which have been shown to be effective in the general population, also work for people with severe mental ill health and their use in patients with stable psychiatric conditions. This is consistent with recommendations made by the GDG in the guideline. It may be added to the discussion of evidence supporting this recommendation in the final guideline	Add to discussion of evidence at relevant section in guideline.
Schwindt, R., Hudmon, K. S., Knisely, M., Davis, L., & Pike, C. (2017). Impact of Tobacco Quitlines on Smoking Cessation in Persons With Mental Illness: A Systematic Review. Journal of drug education, 47(1-2), 68–81. https://doi.org/10.1177/0047237918762104	This study found results revealed an overall positive impact of cessation services delivered via a tobacco quitline. This is consistent with recommendations made by the GDG in the guideline. It may be added to the discussion of evidence supporting this recommendation in the final guideline	Add to discussion of evidence at relevant section in guideline.

C. BCOT Literature Review

Table 3.6 describes the findings from the updated search on BCOT.

Table 3.6: Findings from search on BCOT

Abstract	Evidence Team Comment	GDG Decision
McArdle, C., O'Duill, M., O'Malley, E. G., Reynolds, C., Kennedy, R., & Turner, M. J. (2019). The identification of maternal smokers postnatally in an Irish maternity hospital. Irish journal of medical science, 188(2), 587–589. https://doi.org/10.1007/s11845-018-1849-3	Already identified. No action.	No action
Reynolds, C., Egan, B., Kennedy, R. A., O'Malley, E., Sheehan, S. R., & Turner, M. J. (2019). The implications of high carbon monoxide levels in early pregnancy for neonatal outcomes. European journal of obstetrics, gynecology, and reproductive biology, 233, 6–11. https://doi.org/10.1016/j.ejogrb.2018.11.020	Already identified. No action	No action
Claire, R., Coleman, T., Leonardi-Bee, J., & Berlin, I. (2019). Saliva cotinine concentrations in pregnant women who smoke and use nicotine patches. Addiction (Abingdon, England), 114(9), 1651–1658. https://doi.org/10.1111/add.14662	Not relevant to guideline question. No action	No action

Abstract	Evidence Team Comment	GDG Decision
Hengstler, K., van 't Sant, P., & Jira, P. E. (2019). Carboxyhemoglobin in umbilical cord blood and maternal smoking. Journal of perinatal medicine, 47(7), 780–784. https://doi.org/10.1515/jpm-2019-0004	Not relevant to guideline question. No action.	No action
Van Vliet, E., Kinney, P. L., Owusu-Agyei, S., Schluger, N. W., Ae-Ngibise, K. A., Whyatt, R. M., Jack, D. W., Agyei, O., Chillrud, S. N., Boamah, E. A., Mujtaba, M., & Asante, K. P. (2019). Current respiratory symptoms and risk factors in pregnant women cooking with biomass fuels in rural Ghana. Environment international, 124, 533–540. https://doi.org/10.1016/j.envint.2019.01.046	Not relevant to guideline question. No action.	No action
Bowden C. (2019). Are We Justified in Introducing Carbon Monoxide Testing to Encourage Smoking Cessation in Pregnant Women?. Health care analysis : HCA : journal of health philosophy and policy, 27(2), 128–145. https://doi.org/10.1007/s10728-018-0364-z	A discussion document. Lacked systematic search of evidence and critical appraisal of research studies. Not relevant to guideline question. No action	No action
Grangé, G., Berlin, I., Bretelle, F., Bertholdt, C., Berveiller, P., Blanc, J., DiGuisto, C., Dochez, V., Garabedian, C., Guerby, P., Koch, A., Le Lous, M., Perdriolle-Galet, E., Peyronnet, V., Rault, E., Torchin, H., & Legendre, G. (2020). Rapport d'experts et recommandations CNGOF-SFT sur la prise en charge du tabagisme en cours de grossesse—texte court [CNGOF-SFT Expert Report and Guidelines for Smoking Management during Pregnancy-Short Text]. Gynecologie, obstetrique, fertilite & senologie, 48(7-8), 539–545. https://doi.org/10.1016/j.gofs.2020.04.005	Article in French language. No action	No action
Berveiller, P., Rault, E., & Guerby, P. (2020). Données physiologiques et psychologiques influençant le comportement tabagique de la femme enceinte – Rapport d'experts et recommandations CNGOF-SFT sur la prise en charge du tabagisme en cours de grossesse [Physiological and Psychological Data influencing Pregnant Women Smoking Behavior - CNGOF-SFT Expert Report and Guidelines for Smoking Management during Pregnancy]. Gynecologie, obstetrique, fertilite & senologie, 48(7-8), 551–558. https://doi.org/10.1016/j.gofs.2020.03.023	Article in French language. No action	No action

Abstract	Evidence Team Comment	GDG Decision
Valencia, S., Callinan, L., Shic, F., & Smith, M. (2020). Evaluation of the MoMba Live Long Remote Smoking Detection System During and After Pregnancy: Development and Usability Study. JMIR mHealth and uHealth, 8(11), e18809. https://doi.org/10.2196/18809	Comparison of two technologies to test for exhaled carbon monoxide. Not relevant to guideline question. No action	No action

D. E-cigarettes

The HRB sets out comprehensive and up-to-date evidence, which has been subject to external peer review and quality assurance in line with requirements of its Board. The recent Cochrane review has been considered under point B above.

E. Consultation and External Review

The currency of evidence regarding the Allen Carr Method (AC) was raised in consultation and External Reviewer comments. HIQA in its HTA conducted a de novo search to identify trials evaluating the Allen Carr method on 20 May 2016. However, no studies evaluating the efficacy and safety of the Allen Carr method for smoking cessation that were eligible for inclusion in this HTA were identified.

Table 3.7 describes the findings from the updated search on AC. Four studies were identified, one of which was a protocol for one of the other identified studies, so three studies are listed.

Table 3.7: Findings from search on AC

Abstract	Evidence Team Comment	GDG Decision
Foshee, J. P., Oh, A., Luginbuhl, A., Curry, J., Keane, W., & Cognetti, D. (2017). Prospective, randomized, controlled trial using best-selling smoking-cessation book. Ear, nose, & throat journal, 96(7), 258–262. https://doi.org/10.1177/014556131709600719	A small study which found no effect from intervention of provided Allen Carr book for free, compared with a recommendation to read the book against a background of stop smoking counselling at recruitment. Those who got the book for free were more likely to report reading it, but reporting reading the book did not increase quitting. No action	
Keogan, S., Li, S., & Clancy, L. (2019). Allen Carr's Easyway to Stop Smoking - A randomised clinical trial. Tobacco control, 28(4), 414–419. https://doi.org/10.1136/tobaccocontrol-2018-054243	A small study with high loss to follow up, differential across intervention and higher in the control arm and using a minimally effective comparator found that free attendance at AC face to face workshop was more effective than control.	
Frings D, Albery IP, Moss AC, et al. Comparison of Allen Carr's Easyway programme with a specialist behavioural and pharmacological smoking cessation support service: a randomized controlled trial. Addiction. 2020;115(5):977-985. doi:10.1111/add.14897	A larger study than Keogan et al using a more effective comparator and with better retention. A higher proportion of those assigned to AC actually took the intervention. There was no clear evidence of a difference in the efficacies of the Allen Carr's Easyway (AC) and specialist smoking cessation support involving behavioural support and pharmacotherapy.	

Abstract	Evidence Team Comment	GDG Decision
Overall comments	In summary, the Evidence Team found a small number of studies published since the HIQA search in 2016, of varying design, size and quality that reported conflicting results. While the studies conducted by Keogan et al and Frings et al suggest some benefit from AC, it should be noted that in these studies AC was offered free of charge. AC is not a free service in Ireland; other stop smoking interventions, including specialist services offerin one-to-one or group behavioural support are free of charge. Studies have demonstrated that financial incentives play a significant role in whether or not people interested in stopping smoking access interventions. In the Frings et al study, a higher proportion of participants assigned to AC actually attended the intervention than the comparator. It may be useful to add some comments under the evidence section in the guideline to AC and to pick this up as content under good practice points in relation to interventions that may be raised by people who want to stop smoking but do not wish to use recommended interventions.	The GDG considered this matter. Adapted guidelines make no comment on AC. The state of the evidence is uncertain compared to other stop smoking interventions and there are practical issues in terms of translation to real-world effect such as costs. There is no grounds for a recommendation on AC. However, good practice points will be developed to provide support to healthcare professionals on how to handles enquiries from people who want to stop smoking regarding interventions that are not recommended.

Finally, an expert opinion from the American College of Obstetricians and Gynaecologists was identified through consultation (https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2020/05/tobacco-and-nicotine-cessation-during-pregnancy) but it was consistent with the US guidelines adapted by the GDG.

4. Conclusions and Implications for finalisation of the guideline

In general, the evidence regarding the effectiveness of interventions to help people who smoke to stop is well-established and stable.

The purpose of this report was to describe the process put in place by the GDG to provide assurance that the recommendations it has made are robust in terms of current evidence, especially evidence which has emerged since searches was conducted to build the evidence base for guideline development.

Overall, the outcome of the report should provide assurance to the GDG that its recommendations are robust and sound in terms of current evidence.

The guidelines which it adapted have not been updated. There are no new guidelines which offer recommendations that diverge from those made by the GDG. This is to be expected.

- *The Royal Australian College of General Practitioners 2019 guideline merits discussion by the GDG, but again in general this is well aligned with the recommendations made by the GDG.*

Processes to examine the currency of the HIQA HTA has identified a number of additional systematic reviews and meta-analyses which are well-aligned with the GDG recommendations and which could be cited as additional, up-to-date supporting evidence. There are some specific points which merit discussion by the GDG:

- *Nortriptyline is now available for use in Ireland. It was omitted from the initial HIQA HTA. Its effectiveness is supported by a systematic review and meta-analysis by Cochrane. It could be added to recommendations on pharmacotherapy and the appropriate section of the document could discuss the evidence.*
- *Similarly, text-messaging is used by the HSE QUIT programme. Its effectiveness is supported by a systematic review and meta-analysis by Cochrane. It could be added to recommendations on behavioural support and the appropriate section of the document could discuss the evidence.*
- *Relapse prevention is a common question which arises for healthcare professionals. The guidelines already provide some GPPs. There is now systematic review and meta-analysis evidence by Cochrane to develop these points further. It could be added to GPPs and the appropriate section of the document could discuss the evidence.*
- *The issue of incentives is complex. The GDG could revisit this issue and confirm it is satisfactorily discussed in the guideline with reference to newer evidence.*

There is new evidence in a Cochrane review which supports the recommendations made by the GDG regarding BCOT and this could be cited; otherwise, there is nil new in this area.

The issue of current evidence on e-cigarettes is well-addressed through the HRB evidence reviews. A recent Cochrane review is also identified and key points have been identified.

- The recent Cochrane evidence review should be considered by the GDG along with evidence team comments.

Finally, some new primary studies regarding the Allen Carr Method have been identified.

- The GDG should examine new evidence on AC along with evidence team comments and consider if GPPs for healthcare professionals on how to respond to queries on a range of non-recommended interventions (including e-cigarettes, AC method, hypnotherapy and acupuncture) could be considered.

The GDG should examine this report and determine how to finalise its recommendations post consultation.

ENDS

Dr Paul Kavanagh, 7th of December 2020

Appendix 9: Consultation Process

All Stakeholders were asked to complete the following Declaration of Interest before making a submission:

Declaration of Interest Form:

This must be completed by anyone who wishes to submit feedback on the following document.

As a Party to the World Health Organizations' Framework Convention on Tobacco Control (FCTC), these guidelines which will support implementation of the WHO FCTC in Ireland and are therefore protected from interference by those with commercial and other vested interests of the tobacco industry. Submissions from these groups, or organisations funded by these groups will not be accepted.

Please tick ☑ the statement that relates to you

- I declare that I DO NOT have any conflicts of interest ☐
- I declare that I DO have a conflict of interest ☐*(please detail below)*

- I declare that I DO NOT have any links with and HAVE NEVER received funding from tobacco industry ☐
- I declare that I DO have links with and/or I HAVE received or am receiving funding from tobacco industry ☐*(please detail below)*

Details of conflict/link with and/or funding from tobacco industry:
Name:
Contact email address:
Is this submission made on your own behalf or on behalf of your organisation? **Personal ☐ Organisation ☐**
Organisation:
Date:

Please tick ☑ to confirm

- I wish to have my feedback considered in this consultation ☐

- I understand that my information and feedback may be made available in a public report based on this consultation ☐

- I understand that my information and feedback may be made available in response to a freedom of information request ☐

Table 9A: Identified Stakeholders (Internal to HSE) relevant to this guideline invited to make submissions on draft guideline

Stakeholders (Internal to HSE) invited to make submissions on draft guidelines
HSE Leadership Team
Office of the Chief Clinical Officer
National Director, Quality Assurance & Verification Division
National Director, Quality Improvement Division
National Director, National Cancer Control Programme
National Director, Mental Health
National Director, Obstetrics
National Director, Community Operations
National Director, Primary Care
National Director, National Screening Services
National Director, Acute Operations
National Director, Strategic Planning & Transformation
Integrated Care Programme for Prevention and Management of Chronic Disease
National Clinical Programmes (Clinical Leads/Programme Managers)
Hospital Groups – Chief Executive Officers
Hospital Groups – Group Directors of Nursing
Hospital Groups – Group Clinical Directors
Hospital Groups – Directors of Midwifery
Hospital Groups – Healthy Ireland Executive Leads & Project Managers
Community Health Organisations – Chief Officers
Community Health Organisations – Health & Wellbeing Heads of Service
Mental Health Division – Executive Clinical Directors
Mental Health Division – Clinical Directors
Mental Health Division – Directors of Nursing
Community Health Organisations – Directors of Public Health Nursing
Community Health Organisations – Self Management Support Coordinators
Director, Office of Nursing & Midwifery Services
Assistant National Director, Health Promotion & Improvement
Healthy Ireland Lead
Tobacco Free Ireland Programme Group
Health Promotion & Improvement Managers
Stop Smoking Advisors

Making Every Contact Count Programme
Healthy Eating & Active Living Programme
Alcohol Programme
Healthy Childhood Programme
Sexual Health & Crisis Pregnancy Programme
Assistant National Director, Public Health
Directors of Public Health
National Women & Infants' Programme
National Health & Social Care Professions (HSCP) Office
Primary Care Reimbursement Service (PCRS)
National Office for Suicide Prevention

Table 9B - Identified Stakeholders (External to HSE) relevant to this guideline invited to make submissions on draft guideline

Stakeholders (External to HSE) invited to make submissions on draft guidelines
AIMS Ireland
Barnardos
CORU
Department of Children & Youth Affairs
Dr Des Cox, Royal College of Physicians of Ireland (RCPI)
Dr Fenton Howell, Tobacco & Alcohol Control Unit, Department of Health.
Dr Mairin Ryan, Health Information & Quality Authority
Health Research Board (HRB)
Hospital Pharmacists Association of Ireland
International Guideline Groups:
- New Zealand Guideline Group
- United States Guideline Group
- World Health Organisation
Irish College of General Practitioners
Irish College of Psychiatrists
Irish Dental Association
Irish Maternity Support Network
Irish Patients Association
Irish Practice Nurses Association

Ms Ciara Mellett, Healthy Ireland, Department of Health
Ms Claire Gordan, Tobacco & Alcohol Control Unit, Department of Health.
Ms Laura Magahy, Slaintecare, Department of Health
National Association of General Practitioners
National Clinical Effectiveness Committee
National Patient Forum
Nursing & Midwifery Board of Ireland
Pharmaceutical Society of Ireland
Prof Charlotta Pisinger (External Reviewer)
Prof Ken Ward (External Reviewer),
RCPI – Faculty of Public Health Medicine
RCPI – Institute of Obstetrics & Gynaecology
Royal College of Surgeons of Ireland
Tobacco Free Ireland Partners Group Members (Non-HSE members) - Ash Ireland - Asthma Society of Ireland - COPD Ireland - HSE Environmental Health - Institute of Public Health - Irish Cancer Society - Irish Heart Foundation - Irish Thoracic Society - Mental Health Ireland - National Women's Counsel of Ireland - Spunout - Tobacco Free Research Institute

Table 9C – Questions asked to International Reviewers

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Tobacco Free Ireland Programme, HSE

Peer Review of

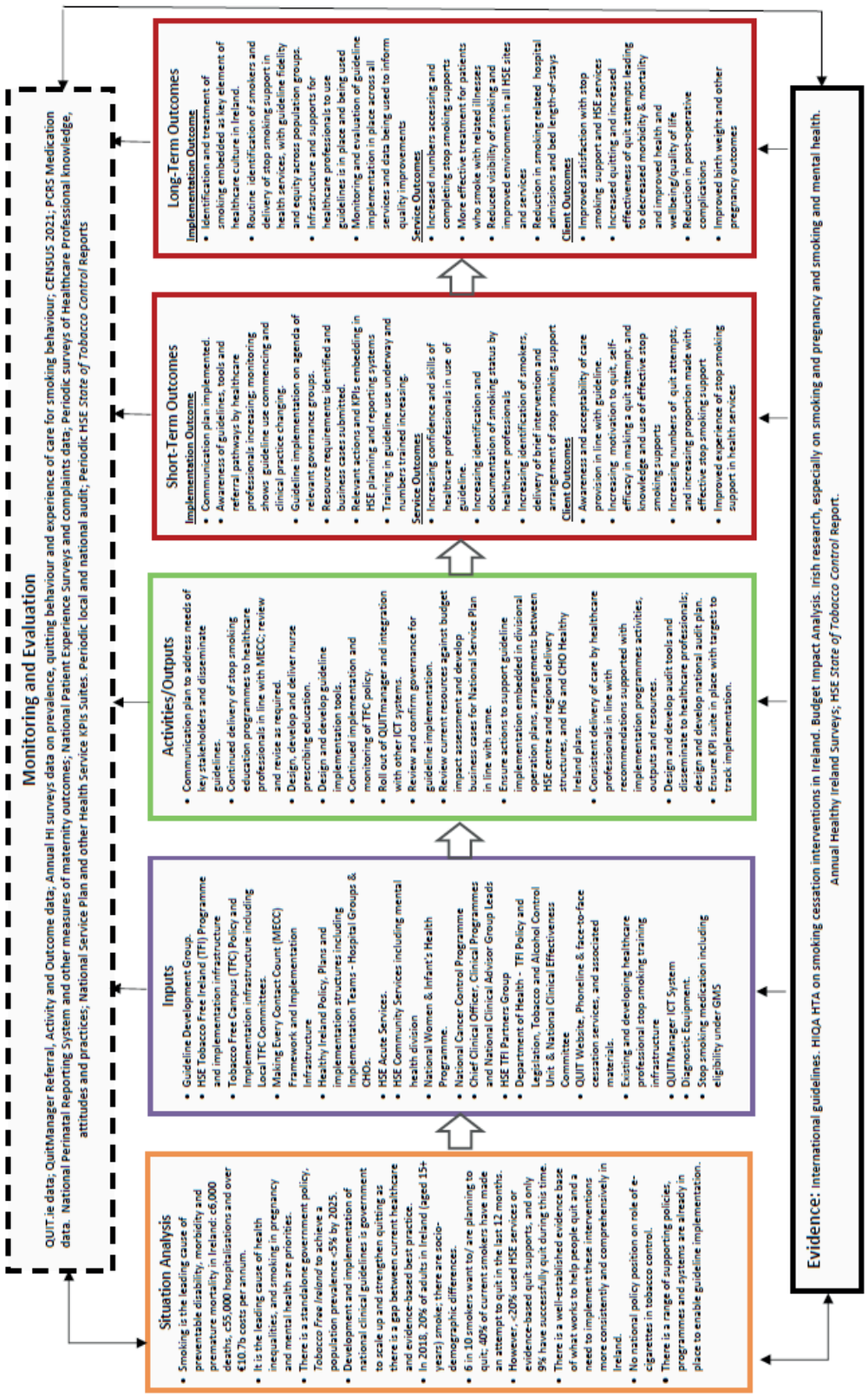
Draft National Stop Smoking Clinical Guidelines for Ireland

Question 1: Has the appropriate evidence been identified and reviewed in line with the scope and clinical questions posed by this guideline?
Question 2: Are there specific links between decisions and the available scientific evidence?
Question 3: Have the risks and potential harms of recommendations been fully considered in the context of clinical practice?
Question 4: Is the guideline clearly written, user friendly and allow for individual clinician decisions?
Question 5: Is the guideline suitable for routine use as intended (in so far as you are able to comment on the Irish situation)?
Question 6: Are there relevant international or well-referenced guidelines (recommendations) on the same topic that these guidelines conflict with, and if yes are the reasons for this justified in the guidelines? (NCEC Framework for Endorsement of National Clinical Guidelines, 2015)
Overall Comments:

Thank you for taking the time to review these draft guidelines.
Please forward your completed document to aishling.sheridan@hse.ie on or before Monday 23rd November, 2020

A copy of the consultation report relating to this guideline is available from the HSE Tobacco Free Ireland Programme by email: tfi@hse.ie

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.

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

Table 1: Treatment effects based on direct evidence: behavioural interventions, HIQA HTA

Comparison	Studies (n)	Participants (n)	Risk Ratio (95% CI)	p-value	95% prediction Interval	I^2 (95% CI)
Individual counselling versus Nothing	1	155	0.85 (0.27 – 0.63)	0.772		
Telephone support versus Nothing	1	1,821	1.11 (0.74 – 1.67)	0.621		
Internet-based versus Nothing	3	3,671	1.46 (1.18 – 1.81)	0.001		0.61 (0.00 – 0.89)
Control versus Nothing	14	9,720	1.67 (1.34 – 2.07)	<0.001	(0.97 – 2.85)	0.31 (0.00 – 0.64)
Intensive advice versus Nothing	9	6,707	1.74 (1.36 – 2.24)	<0.001	(0.96 – 3.15)	0.36 (0.00 – 0.71)
Acupuncture versus Nothing	2	243	2.49 (1.23 – 5.02)	0.011		0.00
Group behaviour therapy versus Nothing	6	846	3.16 (1.26 – 7.90)	0.014	(0.19 – 53.03)	0.69 (0.28 – 0.87)
Acupuncture versus Control	12	2,249	1.03 (0.83 – 1.29)	0.778	(0.76 – 1.40)	0.03 (0.00 – 0.60)
Mobile phone-based versus Control	3	1,112	1.18 (0.88 – 1.60)	0.272		0.51 (0.00 – 0.86)
Intensive advice versus Control	25	16,196	1.19 (1.05 – 1.35)	0.008	(0.84 – 1.67)	0.28 (0.00 – 0.56)
Telephone support versus Control	41	44,218	1.35 (1.21 – 1.51)	<0.001	(0.78 – 2.35)	0.64 (0.49 – 0.74)
Internet-based versus Control	5	5,128	1.43 (1.02 – 2.00)	0.041	(0.45 – 4.51)	0.70 (0.23 – 0.88)
Individual Counselling versus Control	8	3,696	1.48 (1.17 – 1.85)	0.001	(1.11 – 1.96)	0.00 (0.00 – 0.57)
Group behaviour therapy versus Control	18	5,072	1.80 (1.36 – 2.40)	<0.001	(0.66 – 4.92)	0.66 (0.45 – 0.79)
Individual Counselling versus Telephone support	2	1,226	1.02 (0.74 – 1.42)	0.884		0.22
Intensive advice versus Telephone support	3	2,869	1.11 (0.77 – 1.59)	0.572		0.00 (0.00 – 0.88)

Comparison	Studies (n)	Participants (n)	Risk Ratio (95% CI)	p-value	95% prediction Interval	I^2 (95% CI)
Mobile phone-based versus Internet-based	1	755	1.43 (0.88 – 2.31)	0.151		
Group behaviour therapy versus Individual counselling	4	2,854	1.10 (0.87 – 1.40)	0.426		0.42 (0.00 – 0.81)
Intensive advice versus Individual Counselling	2	1,028	1.40	(1.08 – 1.80)	0.426	0.42 (0.00 – 0.81)
Intensive advice versus Group behaviour therapy	3	351	1.05	(0.63 – 1.75)	0.853	0.00 (0.00 – 0.33)
Acupuncture versus Group behaviour therapy	3	396	1.34	(0.80 – 2.24)	0.270	0.64 (0.00 – 0.90)

Source: HIQA HTA on Smoking Cessation Interventions in Ireland, 2017

Table 2: Treatment effects based on direct evidence: pharmacological interventions, HIQA HTA

Comparison	Studies (n)	Participants (n)	Risk Ratio (95% CI)	p-value	95% prediction Interval	I^2 (95% CI)
NRT versus Control	116	53,066	1.59 (1.50 – 1.69)	<0.001	(1.12, 2.25)	0.34 (0.16 – 0.47)
Bupropion versus Control	30	13,363	1.65 (1.51 – 1.79)	<0.001	(1.47 – 1.84)	0.02 (0.00 – 0.42)
NRT + Bupropion versus Control	3	1,240	1.73 (1.39 – 2.15)	<0.001		0.31 (0.00 – 0.93)
Combination versus Control	3	904	1.71 (1.30 – 2.25)	<0.001		0.00 (0.00 – 0.64)
Varenicline versus Control	17	9,275	2.66 (2.25 – 3.15)	<0.001	(1.52 – 4.66)	0.58 (0.27 – 0.75)
Bupropion versus NRT	8	5,485	1.03 (0.88 – 1.21)	0.696	(0.66 – 1.61)	0.56 (0.03 – 0.80)
Varenicline versus NRT	8	4,277	1.28 (1.12 – 1.47)	<0.001	(0.96 – 1.70)	0.25 (0.00 – 0.66)
NRT + Bupropion versus NRT	6	3,277	1.29 (0.94 – 1.76)	0.109	(0.46 – 3.61)	0.81 (0.59 – 0.91)
Combination NRT versus NRT	12	7,239	1.31 (1.16 – 1.47)	<0.001	(1.05 – 1.62)	0.13 (0.00 – 0.53)
NRT + Bupropion versus Bupropion	5	2,644	1.15 (0.93 – 1.42)	0.210	(0.56 – 2.34)	0.64 (0.04 – 0.86)

Comparison	Studies (n)	Participants (n)	Risk Ratio (95% CI)	p-value	95% prediction Interval	I^2 (95% CI)
Combination NRT versus Bupropion	3	1,216	1.27 (1.08 – 1.50)	0.003		0.64 (0.00 – 0.90)
Varenicline versus Bupropion	6	3,994	1.42 (1.29 – 1.57)	<0.001	(1.24 – 1.63)	0.00 (0.00 – 0.62)
Combination NRT versus NRT + Bupropion	2	1,076	1.06 (0.89 – 1.26)	0.512		0.63
Varenicline versus Combination NRT	3	1,511	1.04 (0.88 – 1.23)	0.628		0.68 (0.00 – 0.91)
Varenicline + Bupropion versus Varenicline	1	506	1.26 (0.95 – 1.68)	0.109		
NRT + Varenicline versus Varenicline	2	787	1.42 (1.13 – 1.79)	0.003		0.60

Source: Adapted from HIQA HTA on Smoking Cessation Interventions in Ireland, 2017

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