HSE Tobacco Free Ireland Programme

Report on consultation process and outcomes

National Stop Smoking Clinical Guidelines

December 2020

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Background:

This document outlines the consultation process undertaken as part of the development of the National Stop Smoking Clinical Guidelines.

The purpose of the consultation was to inform the Guideline Development Group (GDG) on views, information and evidence relevant to its draft Guideline so as to make decisions to finalise it. This Guideline will be proposed to the National Clinical Effectiveness Committee for approval as a National Clinical Guideline, and in designing and conducting this consultation, the GDG took account of the following key references:

- "How to develop a National Clinical Guideline: A manual for guideline developers",[1]
- "Framework for Endorsement of National Clinical Guidelines April 2015",[2] and
- "National Quality Assurance Criteria for Clinical Guidelines Version 2."[3]

A link to the final guideline document is available here: <<<<<<<<LINK>>>>>>>>

Methodology:

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

A broadcast email was distributed to all HSE staff with links to the draft guideline and online submission form. (See Appendix 1 for broadcast email) In addition, individuals or organisations identified as stakeholders in areas relevant to the guideline in Ireland were invited to review this draft guideline and provide feedback. (See Appendix 2 for stakeholder list) The broadcast email was forwarded to identified stakeholders (internal and external to the HSE) from the HSE TFI office email address.

2. Public Consultation

A public consultation on the draft guideline was advertised on HSE social media platforms. (See Appendix 3) In addition, a press release was prepared and published on the HSE website. (See Appendix 4) The guideline was available online and feedback submitted via an online template provided. The template was based on that recommended by NCEC. In line with the World Health Organisation Framework Convention on Tobacco Control (WHO FCTC), of which Ireland is a Party, measures were taken in the consultation process to protect against tobacco industry interference. (See Appendix 5)

[1] Department of Health (2019). How to develop a National Clinical Guideline: A manual for guideline developers.
https://www.gov.ie/pdf/?file=https://assets.gov.ie/11532/e2424b86508c4b928b04cf2770fab528.pdf#page=1
[2] National Clinical Effectiveness Committee (2015). Framework for Endorsement of National Clinical Guidelines April 2015.
https://www.gov.ie/pdf/?file=https://assets.gov.ie/11511/f498a946f1e147fd94429df362d07c2d.pdf#page=1
[3] National Clinical Effectiveness Committee and Health Information and Quality Authority (2015). National Quality Assurance Criteria for Clinical Guidelines Version 2.
https://www.gov.ie/pdf/?file=https://assets.gov.ie/11533/2d070cb758a44fcb8b56f28784b10896.pdf#page=1

3. International Peer Review

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 State 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. CP 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.

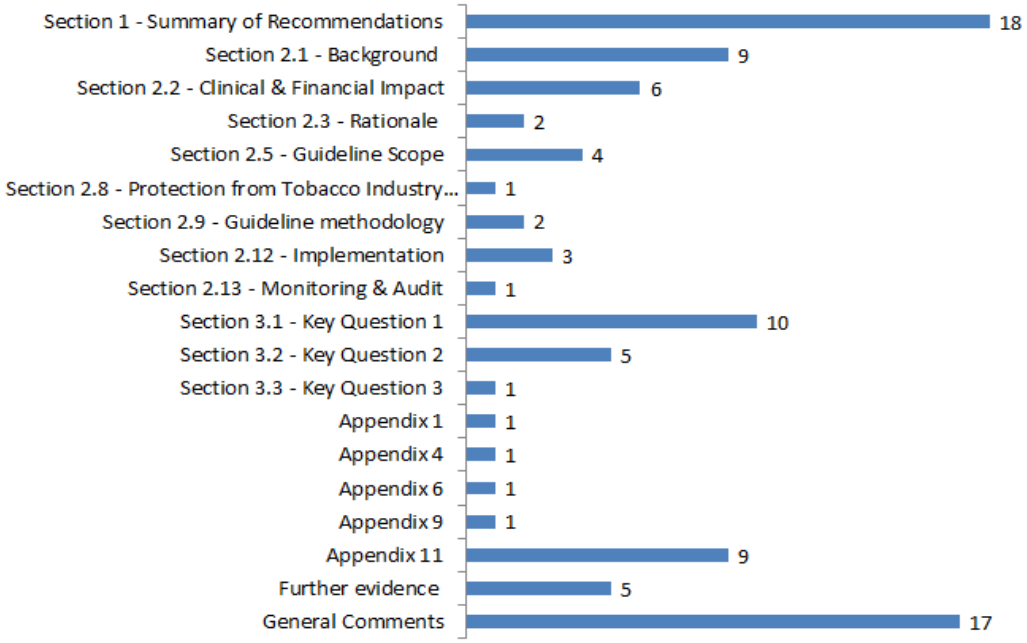
Both reviewers were forwarded a copy of the draft guideline and were asked to provide feedback to a number of questions (recommended by National Quality Assurance Criteria for Clinical Guidelines Version 2), see Appendix 6. In addition, they were asked to include any other comments or additional feedback they had. The closing date for receipt of feedback from the reviewers was Monday, 23rd November, 2020.

Results:

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 05.06 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 following figure details the sections under which feedback was submitted. 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.

Figure 1: Number of submissions made per section of online form



Review and consideration of Feedback:

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

1. Typos, Edits, Corrections, Layout of document
2. Section 2 - Background Chapter
3. Key Question 1 – General adult population
4. Key Question 2 – Smoking in pregnancy
5. Key Question 3 – Users of Secondary mental health services
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. The following Tables (1 – 8) detail the feedback received (as per categories above) and the action/response of the GDG. The feedback from our international peer reviewers is provided separately in Section B.

A. Feedback from Engagement with Stakeholders & Public Consultation

1. Feedback regarding layout of document, typos, edits & corrections

Theme of content	Comments	GDG Response
Size of Document	• The document is very long and there appears to be some repetition which could be removed. (#12)	• GDG reviewed the document and some copy editing was undertaken post consultation. The format is determined by the NCEC template. • A communications plan will be developed to support dissemination of this new guideline across the health service and this is cited in the implementation plan; a number of communication aids will be developed as part of this process including summarised and user-friendly versions of the key recommendations, linking back to the core document.
Layout of Document	• Perhaps even an accompanying simple infograph of key findings and recommendations - similar to the one used in the HIQA HTA (#12) • Page 10, Summary of Recommendations - Suggestion to include page number for the relevant supporting info (impact on health) against recommendations for advising people on the benefits of stopping smoking (#31) • To support full engagement of staff with the document, it might be helpful if there was an accompanying small handbook /one page laminated (diary size) as a prompt for health professionals - with the recommendations and key advisory info relevant to people /pregnant women relating to impact of smoking /benefits of stopping to health and wellbeing (#31)	

Theme of content	Comments	GDG Response
Typos/Edits	• The recommendations should be very clearly delineated in the executive summary (like in the full document - with grade and evidence quality). Highlighted as in the full text. This is where most will look to find key recommendations. (#12) • Page 10, Good practice point following Recommendation 2 - Change ICT System' to Patient Administrations systems (#8) • Page 15, Tobacco use is the leading cause of preventable death, disease and disability worldwide, with the World Health Organization (WHO) it as one of the biggest public health threats the world has ever faced - text missing (#32). • Page 19, Figure 6 (Page 19) – typo. Proportion of smokers , not proportion of smokes (#32) • Page 27, MYTH top left: Wording needs to be corrected. - 'The risk of harm in for people who mental health ……..' The risk of harm for people who have mental health difficulties ……. • Page 36, paragraph 2. Refers to removing barriers to accessing Nicotine Replacement Therapy. Suggest replacing NRT with stop smoking medications. (#13) • Organisation is spelled as 'Organizatioin' (American spelling) (#24) • Explain quit manager for those who are not familiar (#13) • Page 45, "A number of systematic reviews have examines* barriers..." *examined (#32)	• GDG made amendments to the final document taking account of these editing suggestions and those of the External Reviewers.

	• Page 50. Paragraph 3: I think the term 'cigarette smoking 'should not be used as we are also covering cigar or pipe smoking and maybe e-cigarette use. • Page 128 - there is no timeframe for completion assigned to prescribing tools (#18)	
	• Myths and facts tables overlap somewhat, suggest to condense or place in appendix (#13) • Page 28, Diagram on page 28 too small to read properly (#24). • Page 36, paragraph 2. '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. ' - this statement strikes me as strange as health service planners need to plan services, workplans, training etc. to ensure their staff are able to implement these guidelines. Unless changes happen to support guideline implementation they are merely recommendations (#2) - Page 36 – 2nd paragraph, 2nd sentence clarity to clarify. Surely the guidelines will assist health service planners and managers in the design and delivery of health services relevant to tobacco control? (#2) • Page 122, Diagram too small to read (#24) • Some of the language in his document is cumbersome and	• GDG made amendments to the final document taking account of these editing suggestions.

	sentences too long. (#29)	
Theme of content	**Comments**	**GDG Response**
Corrections	• Page 19, Figure 6 does NOT detail what is discussed in this statement. It details which health professionals' people talked to when considering quitting. (#32)	• GDG made amendments to the final document taking account of these editing suggestions.
	• Page 19, under Figure 6. "Almost half (52%) of those who quit smoking recently..." 52% is more than half. (#32)	
	• Page 22, Institute of Public health panel, first bullet point references care leavers – I think this should be rephrased to young adults leaving care. (#2)	
	• Page 26, Section 2.1.4 - 'Smoking among people with lived experience of mental health challenges', : "There is now 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)." - We suggest this sentence should be reviewed as it implies that prior to recent evidence, it could have been perceived that those with mental health challenges were incapable of quitting smoking. (#5)	
	• Page 30, Fig 8 – need more up to date data from HIPE (#8)	• This is the most up-to-date data currently available.
	• Page 36, Paragraph 2, line 6. As set out in support good practice points for the guideline recommendations, the role of policy-makers – if 'support good practice points' is another heading or section in the document, put it in bold and capital first letters. - ....."This sentence does not read well. (#32)	• GDG made amendments to the final document taking account of these editing suggestions.

	• Page 56, Behavioural and Pharmacological supports. NRT orodispersible film which was made Niquitin is included but this hasn't been available in Ireland for the last number of years so that needs to come out. (#17)	• This product may become available in the future and reference to same reflects the Health Technology Assessment conducted by HIQA, which was commissioned by the Dept of Health to underpin this guideline.
	• Most people would know Varenicline as Champix - it needs to be put in at least brackets .	• The GDG has focused on the use of generic names for drugs. Prescribing tools will be updated to support implementation and these reference brands.
	• Add NRT to the list of abbreviations	• GDG made amendments to the final document taking account of these editing suggestions.
	• Page 90, Appendix 4. Heading states quality of scores of included guidance. the table includes both included and excluded guidance. Suggested amend "quality scores of included and excluded guidance" (#14)	
	• Suggested text changes from Dr Annette Burns, PhD. On page 26 "In fact it may even enhance it. Taylor, Burns et al (2014) 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, 2018). " This needs to be corrected to the following as we were not	

	involved in Taylor et al.'s paper and two papers have been mixed up here in terms of findings:"In fact it may even enhance it. Taylor et al (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 s amples (Burns, 2018). • On page 3" Annette Burns, PhD candidate, Royal College of Surgeons in Ireland, shared information on her study of stop smoking services for people with mental health problems in Ireland; "If possible, this would be more accurately represented as follows: • *" 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*	

2. Section 2 – Background Chapter

Theme of content	Comments	GDG Response
Scope of the Document	• Would be useful to have included guidance for those <18 years of age also as a specific group in future updates (#13)	• The scope of this guideline includes the general adult population aged 18 years and over, however, a number of good practice points are included which address those aged <18 years. The GDG has also noted comments from the external review regarding content for those aged <18 years.
	• Unfortunately the acute setting has not been addressed directly and I feel this is a major omission and a golden opportunity to make improvements in this area. - doesn't address the unique issues in the acute setting that health care professionals meet on a daily basis. (#29)	• The guideline has been drafted to be suitable for various setting and implementation will be required to tailor to specific settings. A number of implementation tools will be developed to assist with the implementation of these guidelines in various settings. Tobacco Free Campus Policy toolkit is already in place to provide support.
Evidence included in document	• It is disappointing that the Intellectual property rights Fee precluded inclusion of UK guidance (#14).	• The UK guidance was excluded, as a request to use the guideline for adaption was met with the response from the UK NICE that it required intellectual property rights fee for adaption. This was discussed with the Department of Health in Ireland. It had recently piloted a process to adapt a UK NICE guideline under license and advised the outcome was to be evaluated before any decision on GDGs paying intellectual property right fees be made.

	• Welcome the HRB review of eCigs for the DoH (#8)	• No action required.
	• As search for guidance took place in June 2017, will there be an updated search undertaken prior to the publication? (#13)	• A scoping of evidence currency will be completed prior to submission to NCEC.
Protection from the Tobacco Industry	• Pages 36 & 37. This section acknowledges the obligation of parties to Article 5.3 of the FCTC to protect public health policy from commercial and other vested interests of the tobacco industry. With respect to these clinical guidelines, it is stated that "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". - This is welcome, however further careful consideration should be given to any reference to e-cigarettes in the context of smoking cessation and harm reduction. Many market leading e-cigarette brands in Ireland are either partially or fully-owned by the tobacco industry e.g.[stakeholder referenced various brands] . Ambiguous language around harm reduction, cessation efficacy and safety of e-cigarettes within clinical guidelines could be viewed as an endorsement of e-cigarettes, and could therefore enable tobacco companies to use e-cigarettes as a Trojan Horse to undermine public health policy. (#5)	• No action required.

3. Key Question 1 – General adult population

Theme of content	Comments	GDG Response
Evidence Statement	• 'Behavioural support options are: Brief Interventions…' Is BI a behavioural support? It raises the issue of smoking and assesses a person's readiness to change but is it technically a behaviour support? (#2) - BI as a form of support seems at odds with the other support options: The inclusion of BI as a support option in both of these recommendations is surprising. BI is what we would advise the health professional to do, rather than recommend it to the client as a support option. Also, it is generally, an opportunistic intervention, whilst the other behavioural support options offer more structured support. BI is 'how' health professionals intervene regards smoking interventions as per p.74 of this guidance rather than an cessation support option for clients to select. (#10)	• Brief Intervention is a well-established and recognised health behaviour change technique. The key concepts and supporting evidence are set out in the guideline. • These guidelines are for all healthcare professionals across a number of care settings, and therefore 'Brief Interventions' as a form of support are included.
	• We feel there could be more detail in respect to the background into the rationale for the recommendations. For instance there is little explanation as to why Varenicline rather than Bupropion is a first line pharmaceutical intervention. We understand that this is likely derived from the HIQA HTA and other sources but we feel this should be clarified in the text. In regards to e-cigarettes, there is quite a detailed piece on why ENDS are not included in the guideline but the document lacks the same detailed discussion in respect to NRT, Varenicline and Bupropion. More emphasis should be given to the proven therapies rather than unproven ones. We understand that these are well validated smoking cessation tools but more detail to their validity would help this document. (#16)	• The supporting evidence for pharmacological interventions is all clearly cited, referenced and tabulated in Appendix. • E-cigarettes are an important emerging issue and were considered in detail by the GDG. This is consistent with Department of Health policy and the request by it to HIQA to include e-cigarettes in the recent HTA of smoking cessation interventions. It's clear within the consultation feedback that there are conflicting views. The view of the GDG was that it was necessary for the Guideline to address these clearly and comprehensively to make GDG reasoning transparent.

	• Page 55, E-cigarettes. This section opens with a reference to the NZ and US guidelines in respect to e-cigarettes. The HRB and HIQA reviews provide more robust arguments for not including them so I would highlight these first. (#16)	• This is similar to the format of previous sections detailing the evidence base for the other supports.
Benefits & Harms	• Page 57, Paragraph 1, line 4. "cohort studies and trials comparing conventional cigarettes and e-cigarettes ..." - We would recommend removing this statement as there is experimental evidence now that e-cigarettes are harmful to the respiratory and cardiovascular systems even with short-term use. We would argue that this should be removed as there could be other long-term effects of e-cigarettes we do not currently know. We acknowledge that the next sentence discusses the lack of knowledge on the long-term effects and requests more studies but feel that the long term risk reduction argument should not be included here. (#16)	• This is a reference to the HRB evidence reviews and the GDG were requested by the Department of Health to consider the HRB evidence review in the process of guideline development.
Values & Preferences	• Page 59, the document makes reference to the HRB review on e-cigarettes saying "the outcome is awaited". We would suggest laying out the three major findings of the recent HRB review early in the discussion about e-cigarettes and focusing on these documents and the HIQA HTA as the rationale for not including ENDS. (#16)	• The HRB evidence reviews are clearly cited, referenced and carefully considered by the GDG. E-cigarettes are an important emerging issue and were considered in detail by the GDG. Its clear within the consultation feedback that there are conflicting views. The view of the GDG was that it was necessary for the Guideline to address these comprehensively to make GDG reasoning transparent.
Recommendation 1	• Page 51, The term 'regularly' is open to subjective interpretation – especially as the guidelines aims to reduce unnecessary variations in practice (p.6). Regularly could mean every visit, every 3 months, every year. (#10)	• This point arose and was discussed by the GDG during its development of the recommendation. Prescribing a frequency in the guideline would go out width the supporting evidence and would not provide scope for tailoring to the context. As such, making of a single "one size fits all"

		recommendation nationally would be unhelpful to healthcare professional whom it is intended the guidelines will support. As highlighted in recommendation, the development of local PPGs will define frequency which fits with local service.
Recommendation 2 – Good Practice Point – targeting of groups	The WHO recommends "Enhanced and targeted efforts to protect young people, women, socially disadvantaged groups may be needed to achieve further prevalence declines in European countries" (World Health Organization 2019). A recent literature review has also recognised that greater efforts to target smokers in disadvantaged groups for smoking cessation support are required (van Wijk, Landais et al. 2019). Smokers living in socioeconomic disadvantaged conditions experience several barriers to access smoking cessation support. These include a low motivation to quit arising from a perception of smoking as a positive coping mechanism, a lack of knowledge or concern for health risks, smoking regarded as a positive social norm within their environmental milieu, and low self-efficacy. Secondly, when considering the dimensions of support for smoking cessation, low-income smokers may experience a lack of support to quit from their own social environment (family, friends), their healthcare providers, as well as a lack of resources to seek and maintain support (transportation, access to healthcare and to NRT, knowledge of available services). It has been recognised that there is a cumulative effect of socio-economic disadvantage on women's smoking (Graham, Inskip et al. 2006). Social disadvantage contributes to smoking risk among adult women and their smoking status, including uptake, persistence, consumption, and cessation, is influenced by their biographies of disadvantage. The WHO FCTC has highlighted the need for approaches tailored to gender when developing tobacco control policies in the light of increasing cancer rates, in particular, lung cancer in women (World	• The priority groups were defined in proposing the guideline. The rationale was described and this linked to (a) national policy and (b) the HIQA HTA. • The issue of social patterning of smoking is considered in the guideline, discussed comprehensively and advice was taken from the Institute of Public Health. • The tackling of social patterning of smoking will be addressed through implementation including resource allocation and tailoring. • In terms of the content of the guideline recommendations and good practice points, these specifically signpost that individual needs should be taken into account. Healthcare professionals will assess and tailor delivery of recommendations and good practice points to the needs of the service user, which may include socio-economic disadvantage as well as a range of other aspects of individual need relevant to the specific care situation.

	Health Organization 2003). Therefore, in light of the WHO recommendations, the large number of scientific articles recognising barriers to quit for low-income smokers, and the list of considerations in section 2.1.3. (Socio-economic Inequalities in Smoking) of the present guideline, we recommend that consideration be given to the inclusion of a specific subgroup of low-income smokers in general, and to low-income non-pregnant women smokers in particular. We refer to people not currently interested in quitting or feel unable to quit because of their social circumstances, but who have successfully reached the healthcare system at least once. This is in keeping with MECC guidelines. Hence, a good practice point tailored to this specific population would be: *"Where someone/a woman is not currently interested in quitting but belongs to a socioeconomic disadvantaged/low income group/population, record this outcome and mention the following: Explain that there exists free-access support to quit by means of in person, text, call contact with a health professional. Encourage him/her to consider a quit attempt to improve their health status and remind them that support is accessible through the health services to increase their chances of success."* (#4)	
Recommendation 2 – Good Practice Point – E-Cigarettes, Page 52	• I didn't know that this was an approved treatment option. (#2) • The point re- E-cigarettes in general practice points for Rec 1& 2 need to update in light of Health Research Board evidence review on e-cigarette use. (#3) • As the long-term safety of these products is not known and dual use of e-cigarettes and tobacco is not less harmful than tobacco use alone, e-cigarettes should not be endorsed by clinicians for use by smokers and efforts should instead be directed to encouraging smokers to quit using clinically safe methods. (#5)	This was reviewed by the GDG and changed as follows: *If someone who is not currently interested in quitting raises e-cigarettes for discussion, refer to good practice points for recommendation 3 for points to use in discussion.*

	• Any ill-defined clinical reference to "consider discussing e-cigarettes as an alternative to smoking" should be reconsidered due to the commercial interests of the tobacco industry of continuing and increasing use of these products. (#5)	
	• Do not agree with wording, "also consider discussing e-cigarettes as an alternative to smoking" as noted in the good practice points. This should not be initiated by HealthCare professionals (#8)	
	• This statement on e-cigarettes is included without any context or discussion points whereas on the following page, there are 7 discussion points included in relation to e-cigarettes. The draft Guidelines contain a lot of information on e-cigarettes (pages 55-60 in particular) and on reading all of this I feel the statement to 'consider discussing e-cigarettes as an alternative to smoking' should not be included unless it is accompanied by a series of discussion points (similar to page 11) reflecting the many issues related to their effectiveness and safety. (#6)	
	• E-cigarettes are first referenced in Good Practice Points under Recommendation No. 2 (page 10). The reference is a standalone statement: 'Also consider discussing e-cigarettes as an alternative to smoking'. There is no context provided at this point on the safety, lack of regulation and evidence regarding the use of e-cigarettes. (#20)	
	• In addition 'Also consider discussing e-cigarettes as an alternative to smoking' appears to contradict the reference documents cited on page 55 where it is stated that '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' (#20)	

	• Recommendation No. 3 (P.11) and in the Good Practice section there are 7 points which can be used by practitioners when discussing E-Cigarettes . At a minimum, these points should also be included under Recommendation No. 2 (P.10). (#18)	
Recommendation 3.2, Page 59	• We are not 100% sure of the wording of "first-line treatment" as this feels very prescriptive rather than patient centred. We understand that the evidence base (and our experience in the field) supports the efficacy of Varenicline and the hierarchy of preferred treatment recommendations is stated in 3.2.1 & 3.2.2. - We just question how the wording will be interpreted on the ground, by clinicians/HCW's. For example, in a non client centred situation, Varenicline might be seen to be "pushed" to clients (with no contraindications), over other therapies when in fact the client actually wants combo NRT , hence reducing the clients feeling of ownership towards quitting. (#7)	• This is per advice to the Minister of Health by the HIQA in its HTA. The HTA was commissioned by the Department of Health to inform these national stop smoking guidelines.
	• Suggest listing contraindications here (#2)	• Contraindications are not usually listed with recommendations in a guideline. They will be provided in implementation tools including updated prescribing tools and other tools at local levels.
	• 3.2.1 If Varenicline is not suitable, combination NRT treatment should be recommended. - 'should be recommended' suggest replacing with 'is the preferred alternative'	• The language used is intended to be direct and provide clarity on expected practice. This is consistent with good practice in drafting recommendations for health care professionals to apply in clinical practice.
	• In the acute setting, Varenicline is not prescribed for in-patient use. This is due to financial reasons, pharmacy regulations, the short length of stay for in-patients, and the fact that it is often a period	• This is per advice to the Minister of Health by the HIQA in its HTA. The HTA was commissioned by the Department of Health to

	when new medications are trialled. For these reasons it is not realistic to list it as a first-line treatment in this setting. It can however, be prescribed on a Discharge Prescription if not contraindicated. (#29)	inform these national stop smoking guidelines.
	• In the acute setting, mention needs to be made of 'enforced abstinence' due to the smoke free campus policy and also the fact that people are acutely ill. In this scenario, NRT combination should be prescribed on admission irrespective of the patient's stance on quitting. This gives the patient an alternative to smoking from the point of admission and during their stay. The patient can refuse to accept NRT at the time of administration but the option is there for them if charted. In an audit I did in 2016 in the XXHospital, only 15% of in-patients were being charted NRT. Stopping in the longer term is an issue that needs to be addressed separately but should not be confused with enforced abstinence. (#29)	• This is currently addressed through HSE Tobacco Free Campus Policy which supports the implementation of these guidelines.
Recommendation 3, GPP re Young People, Page 62	• It is not evident that all of the evidence from the HRB has been considered. In particular, one of the significant findings was that 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. - This point should be included in the Good Practice notes under Recommendation No.3 which has a Sub-group consideration for 'Young People (under 18 years)'	• The GDG reviewed this good practice point and considered it was sufficient.
Recommendation 3, GPP re Unproven supports including E-Cigarettes, Page 61	• <u>Point 1</u>, - "E-cigarettes are consumer products". - Language should be included here to remind clinicians that not only are e-cigarettes consumer products, but that no e-cigarettes are currently licensed for smoking cessation in Ireland, nor have there been any applications for such licensing. (#5)	• GDG reviewed the text and considered it sufficient and future-proofed. The issue of licensing as a medicine is discussed in the guideline.

	• Point 4, "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." -This language could be viewed as positive, and the health impacts of e-cigarettes are not uncertain. (#5) - To suggest that there is uncertainty regarding the health impact of e-cigarettes can be interpreted as e-cigarettes having a positive health impact for non-users, which is patently untrue. (#5) - We would like to see the statement "They are not harm-free" be put in bold and underlined – to make it clear, dispel this myth of harmlessness and help in a very small way to counteract the major multi million euro advertising campaigns. (#7)	• GDG reviewed the text and considered it sufficient and in line with the HRB evidence reviews. It does not view the text as positive but a statement which reflects current knowledge.
	• Point 5, "Evidence regarding the effectiveness and safety profile of e-cigarettes is evolving." - A suggested conversation point to include here is that quitting e-cigarettes may in itself prove difficult. A 2019 study by Hajek et al. showed that, of those who had successfully quit smoking using an e-cigarette, four in five people were still using an e-cigarette at twelve months vs. just 9% of those who successfully quit using NRT still using NRT at twelve months. (#5)	• The GDG considered this comment but its view was that the current point is sufficient.
	• Point 7, HSE stop smoking services can provide support to those who wish to use an e-cigarette to make an attempt to quit smoking". -This language implies that HSE stop smoking services support the use of e-cigarettes for smoking cessation, and we suggest this should be reviewed. (#5)	• The GDG considered this comment but its view was that the current point is sufficient.
	• Other comments: - We would also recommend putting somewhere in the bullet	• The Guideline is already clear that e-cigarettes are not recommended and the GDG reasoning

	points of this section, a more clear statement e.g. the "HSE does not recommend the use of E-cigarettes". (#7)	for this position is set out comprehensively and transparently.
	• <u>Other comments:</u> - As eCigs are not available/permitted in the hospital setting, suggest as alternative, for patients who choose eCigs in the community setting, the HSE smoking cessation services can provide support in their quit attempt. (#8)	• The GDG considered this comment but its view was that the current point is sufficient.

4. Key Question 2 – Smoking in pregnancy

Theme of content	Comments	GDG Response
Recommendation 5, Page 68	Recommendation 5.1 We would like a reference to establishing if the pregnant woman's partner/people living with her smoke. This is key with any smoker, establishing the environment and relationships in which they are living to see how best to support a quit attempt. (#7)	• This is addressed in Recommendation 6.
	Recommendation 5.2. - I would like to see this expanded further to include specific measures for disadvantaged pregnant smokers. Although the inequalities in smoking in pregnancy are alluded to and the socially patterned distribution of smoking in pregnancy most influencing socio-economically disadvantaged (SED) women, there are no specific recommendations to address the underlying social determinants. - Most pregnant women including SED who smoke are interesting in quitting but may be unable to do so. -For these women who may be unable to quit for the whole of pregnancy quitting for at least a part of pregnancy may be an option and there is increasing evidence to suggest improved neonatal outcomes. - For these women a multifaceted strategy is needed including behavioural and improved social supports and a range of fiscal and environmental measures. (#4)	• This is a clinical practice guideline and upstream policy interventions to address social determinants are out of scope. This is set out in the introduction to the guideline. • The evidence regarding financial incentives and quitting during pregnancy is discussed in the evidence section preceding the recommendation.
Recommendation 5 GPP, Page 68	Pregnant woman that are not interested in the first instance we cannot follow up as they are not on QM so can't record the outcome of the intervention (#21)	• This point relates to the electronic referral system for stop smoking referrals and not the guideline recommendations.
Section 3.2.2 Behavioural Supports, Page 70	Given that counselling has the largest body of evidence to support its effectiveness (page 70), should this be mentioned here?) (#2)	• The role of behavioural supports is clearly discussed in the prelims to the recommendation.

Recommendation 7.1, Page 72	Recommending is one thing but who actually provides the behavioural support? (#2)	• The guideline document has a detailed implementation plan.
Recommendation 7.2, re Use of NRT in Pregnancy, Page 72	• Please consider the evidence in relation to NRT use in pregnancy and breastfeeding (#3)	• These comments relate to prescribing, which is outside the scope of the guideline. Prescribing tools will be developed as part of implementation.
	• While we support the use of NRT in pregnancy, we would like somehow add extra clarity to this statement listing "NRT" to reflect that: - all NRT types are not necessarily suitable (or possibly even contraindicated for pregnant women e.g. liquorice flavoured gum) and - referencing various manufacturer listed contraindications for use in pregnancy. (#7) - Would oral & shorter acting forms be preferable in the first instance? (#10)	• These comments relate to prescribing, which is outside the scope of the guideline. Prescribing tools will be developed as part of implementation.
	• '….. Support the woman to make an informed choice regarding her stop smoking plan, ensuring respect for her preferences'. - Who supports her to make the stop smoking plan? Is this a verbal plan or a written plan? (#2)	• There are a range of paper (quit guides) and online quit plans available from Quit.ie. These are listed at the back of this document.
	• Should the recommendation include more direction? Recommendation 7.2 refers to 'informed choice' so ideally, a shared decision making tool should be available and recommended in view of the lack of studies of NRT use in pregnancy.	• Healthcare professionals are used to shared-decision making with patients and this is outside the scope of the guideline.
	• Should pregnant women of all ages be specified in the recommendation? (#10)	• Recommendations 4, 5, 6 & 7 are applicable to women of all ages, as outlined in the guideline.
	• Is NRT to be advised regardless of dependency level? (#10)	• The GDG reviewed and considered that this is addressed sufficiently

	• It is noted on page p.71, that the HIQA recommendation is that NRT should only be offered to women when psychosocial interventions have been unsuccessful (#10)	through the current recommendation and reference to shared decision-making.
	• I would have preferred more information on the use of NRT in pregnancy are we leaving ourselves open to litigation if we encourage pregnant women to use NRT and something happens with the baby. We can discuss the potential harms and the benefits and ok it is a shared decision between the pregnant woman and the healthcare professional. Most of the time it's the smoking cessation officer that is encouraging the use of NRT and not the Obstetrician who doesn't encourage in my experience. • - Provides some clarity on the use of NRT in pregnancy. As an area that was previously open to the interpretation by the individual practitioner, it gives a recommendation that it may be used. I feel it doesn't definitively clarify that it can be used in pregnancy. Previous difficulties experiences in supporting pregnant women who smoke was the diversity of opinions among prescribers in relation to NRT. I feel the guidelines address this but not conclusively and that ambiguity will remain among prescribers. (#17)	
	• Further clarification would be beneficial as Practitioners might not feel they should be the ones to explain about potential risks . (#23)	
	• The maternity hospitals have not been promoting this. I think this needs to be clarified in the guidelines as healthcare professionals may be unaware of the licensing stance in this area. (#29)	• A detailed communication plan will disseminate this guideline and recommendations to the various healthcare professionals in various settings.
	• Most practitioners seem to be unaware that NRT is licenced in pregnancy. Realistically, the decision to use NRT will not be shared. It is up to the practitioner to advise. This is a very woolly statement compared to the general population.	• The GDG reviewed and considered that this is addressed sufficiently through the current recommendation and reference to shared decision-making.
Request re guidance	• There should be a point referencing "Not recommending E-cigarettes during	• The GDG reviewed and considered

on e-cigarette use in pregnancy	pregnancy" (#7) • There doesn't appear to be a mention in the pregnancy sections on e-cigarettes. Requires a reference to it and guide to healthcare professionals in maternity units on advice to be given to pregnant women. (#14)	that this is addressed sufficiently through the current recommendation and overall guideline.

5. Key Question 3 – Users of Secondary mental health services

Content	Comments	GDG Response
Recommendation 10.2, Page 81	• 10.2.1 If Varenicline is not suitable, combination NRT treatment should be recommended, - "combination NRT should be recommended" suggest alternative as combination NRT is the preferred alternative.	• The GDG reviewed and considered that this is addressed sufficiently through the current recommendation
Recommendation 10.3, Page 81	Re: 'Monitor the person's mental health and pharmacotherapy carefully….. - Should blood level monitoring of certain drugs, be included in the recommendation? Monitoring is a term that could be subjectively interpreted - Following smoking cessation, doses of these medications need to be reduced to prevent toxicity 26: • Clozapine and olanzapine: 25% dose reduction during first week of cessation and then further blood levels taken on a weekly basis until levels have stabilised • Fluphenazine and some benzodiazepines: 25% dose reduction in first week • Tricyclic antidepressants: 10-25% dose reduction in first week - Ensure plasma levels of medication affected by smoking/stopping smoking are checked soon after discharge (see Box 4 and Appendix). A return to smoking, or an increase in cigarette use, may reduce plasma levels within 1 to 2 weeks of discharge from a smokefree environment and medication dosage may need to be altered accordingly.11	• The GDG reviewed and considered that this is addressed sufficiently through the current recommendation. • Local protocols can prescribe how this should be implemented in practice.
Recommendation 9.1	• 9.1 worth noting to record the outcome into the care plan.	• The GDG reviewed and considered that this is addressed sufficiently through the current recommendations which including documentation of care.
Recommendation 10.2	• Offering medication to support with quitting will need to be done in a gentle and informative way as people may be coping with medication reviews and introduction of new medications so may feel extra concerns over more	• The GDG reviewed and considered that this is addressed sufficiently through the current

	mediation being offered. Extra time needed to discuss choice, alternatives, benefits, side effects.	recommendations. Healthcare professionals who work with users of secondary mental health services will be used to working in a way which is sensitive to needs.
Recommendation 10.3	• Clarity needed - if this is reduction in mental health medication this should be stated clearly, if it is for other medication, then that should be stated. • Consider use of term 'monitor'. Not so much if this is application across the whole document for all people, however if this is only for people with mental health challenges consider using more person-centred language such as 'work with the person to determine the effectiveness of the intervention'.	• The GDG reviewed and considered that this is addressed sufficiently through the current recommendations. Separate prescribing tools will address some of the practical aspects of medication management.

6. Implementation

Theme of Content	Comments	GDG Response
Challenges of Implementation	Page 45, '…..Among these factors, lack of knowledge, skills and need for additional training as well as lack of time occurred most commonly.' - The same issues have been raised for MECC and need addressing. When introducing a service that requires training for implementation there is an immediate push back from the powers that be but the front line staff who are asked to do so much need to be supported through proper training & supports. I understand management have to ensure services are delivered but there is no point creating guidelines unless there is a clear policy or plan for implementation. (#2)	• GDG noted this point. The implementation process will link with MECC implementation to examine opportunities to address this point.
	Page 44-Page 45, The COM-B model whilst useful, focuses on the individual and does not allow for acknowledging that the current recording /documentation systems don't always support the documentation of tobacco interventions. Systems must also support human behaviour (#10)	• MECC includes work on health behaviour recording tools which will address this concern.
	Page 127, the following barrier is listed (relating to recommendations 8 & 9)-'Myths & negative attitudes towards smoking cessation in mental health settings' Myths and negative attitudes towards tobacco use and quitting exist among staff working in more than just mental health services. -I feel this barrier should be added under 'All Recommendations' (Page 124). Proposed wording for this could be: Barrier: Myths & negative attitudes towards smoking cessation among healthcare staff. The actions already listed at the top of Page 124 would help address this. (#6)	• GDG development group have noted this point. There are specific challenges in the mental health sector which are well recognised and discussed in the guideline. But the GDG agree that this point can be noted across wider areas.
	Page 127, Making Every Contact Count (MECC) is not a mandatory training programme - the significance of this as a barrier to staff completion of on-line modules in the current healthcare climate should not be underestimated. (#20)	• GDG noted this point. The implementation process will link with MECC implementation to examine opportunities to address this point.

	I wonder about MECC recording tool kit I think that people will have huge opposition to filling in this as they already have a huge amount of writing to do especially when it is in a separate booklet. - Maybe they should have looked at it to be incorporated into the patients' assessment when they are being reviewed in a hospital or as part of a patients nursing admission form. I know there was a lot of reluctance to using the form when we were doing the MECC training. (#17)	• GDG noted this point. The implementation process will link with MECC implementation to examine opportunities to address this point.
Suggested Enablers	Consider the development of a multidisciplinary Tobacco cessation 'care passport' for use by Health Professionals in acute, maternity and mental health settings to enable better care continuity for patients who are being supported to suspend smoking while hospitalised and in the community. This would be reflective of the overall Slainte Care vision. (#8)	• GDG noted this point.
	We would like the group to consider adding in that appropriate training on smoking cessation should be included at undergraduate level for all HCP training courses. (#16)	• MECC includes a curriculum for healthcare professional undergraduate education.
	Specific approaches, such as financial incentives may be required to recruit and retain participants in community-based cessation programmes. A recruitment strategy to coordinate the delivery of community based approaches and a referral system for GPs and HCPs to refer participants into community-based programmes should also be developed. (#5)	• Financial incentives are examined in the evidence base for the guidelines
	Have the reviewers considered the evidence for having a Smoking Cessation officer/midwife in each maternity unit/hospital and on site as recommended in the National maternity strategy. Some units have same --and it appears to be a game changer for the implementation of policy, guidelines and roll- out of education and training. - I note there is a function for the Smoking Cessation Officers in the monitoring and auditing. Who will this fall on in the absence of said posts on site in the maternity unit. In addition the roll out of the recommendation to have BCO levels checked at booking --the Smoking Cessation officer will	• The HSE TFIP has commissioned a review of stop smoking service provision to assess capacity versus need.

	be key for this implementation of change and introduction of a new intervention by midwives. (#14)	
Data Capture	This Implementation Plan should make reference to proposals for the widening of access to clinical interventions for smokers in socially disadvantaged communities, as identified by the IPH's summary. - We suggest that plans to ensure the applicability of these guidelines to all patients be captured in both the Activities/ Outputs section and the Long-Term Outcomes section. (#5)	• The HSE TFIP has commissioned a review of stop smoking service provision to assess capacity versus need. This specifically includes capacity to address needs to socio-economically disadvantaged groups.
Other Comments	The table 'Recommendations: 3, 7, 10' highlights that a barrier to delivery of the respective guidelines is medicine availability and current eligibility criteria, while the corresponding action is "Engagement with the Department of Health re eligibility issues to support better access to medicine". This is a welcome action. Government must demonstrate its commitment to a Tobacco Free Ireland by subsidising clinically proven quit tools for those who want to stop smoking. As part of this, and recognising the effectiveness of Nicotine Replacement Therapy (NRT) with behavioural interventions, we believe there is a need to improve access to Nicotine Replacement Therapy and it should be made available free of charge to all those enrolled in HSE smoking cessation programmes. The Irish Cancer Society encourages the HSE and Department of Health to agree an investment plan to ensure clinicians are supported in advising patients to quit and that funding is made available to support the use of proven quit tools among all patients. (#5)	• No action required.
	The inclusion in the document of further detail on planned actions to improve access to quit services among socially disadvantaged groups would be particularly welcome. (#5)	• The HSE TFIP has commissioned a review of stop smoking service provision to assess capacity versus need. This specifically includes capacity to address needs to socio-economically disadvantaged groups
	Prescribing tools for stop smoking medication for various populations is a great idea. (#17)	• No action required.

	Pages 128. Under Action/ Intervention….. 'Communications campaigns specific to nurses and midwives to encourage inclusion of stop smoking medications in t heir scope of practice' This is an essential point and badly needed however it's not specific at all. In the acute setting this has been a huge difficulty despite many efforts to change it. Following on from these guidelines, this point needs to be worked on and enacted effectively with concrete measures.	• No action needed.

7. Further evidence for the attention of the GDG

Subject	Evidence	GDG response
E-Cigarettes	1. https://www.bat.com/ecigarettes#	• This is not research evidence to consider in guideline formulation.
	2. https://www.jti.com/news-views/newsroom/jti-acquires-logic-leading-independent-us-e-cigarette-company	
	3. Ibid	
	4. Levy, D. et al. 2019. Altria-Juul Labs deal: why did it occur and what does it mean for the US nicotine delivery product market. Tobacco Control. Available at: https://tobaccocontrol.bmj.com/content/early/2019/08/30/tobaccocontrol-2019-055081 [Accessed 05.11.2020]	
	5. Hajek et al. 2019, A Randomized Trial of E-cigarettes versus Nicotine-Replacement Therapy, NEJM 380 pp. 629-637	• This study was examined by the HRB evidence review, which was considered by the GDG in formulating recommendations
	6. Australia Tobacco Harm Reduction Association. https://www.athra.org.au/qanda/	• This is not research evidence to consider in guideline formulation.
	7. Canadian Tobacco and Nicotine Survey (CTNS), 2019, detailed tables. https://www.canada.ca/en/health-canada/services/canadian-tobacco-nicotine-survey/2019-summary/2019-detailed-tables.html	
	8. Ontario Student Drug Use and Health Survey, 2019. https://www.camh.ca/-/media/files/pdf---osduhs/drugusereport_2019osduhspdf.pdf?la=en&hash=7F149240451E7421C3991121AEAD630F21B13784	
	9. Monitoring the Future, 2019. https://www.drugabuse.gov/drug-topics/trends-statistics/monitoring-future/monitoring-future-study-trends-in-prevalence-various-drugs	

	10. Nugent, R, 2020. Presentation to Canadian Public Health Association Tobacco and Vaping Forum Conference, September 2020	
	11. Public Health England, 2018. "E-cigarettes and heated tobacco products: evidence review." https://www.gov.uk/government/publications/e-cigarettes-and-heated-tobacco-products-evidence-review	• The HRB evidence review is more up to date. It was commissioned by the Department of Health in Ireland for the purpose of it being considered by the GDG so as to determine its recommendations. •
	12. Royal College of Physicians, 2016. "Nicotine without smoke: Tobacco harm reduction."	
	13. Shapiro, H. 2018. "No fire, no smoke: the global state of tobacco harm reduction." Knowledge-Action-Change, London. Statistics Canada, "Smokers by age group."	• This is not research evidence to consider in guideline formulation.
	14. https://www150.statcan.gc.ca/t1/tbl1/en/tv.action?pid=1310009610&pickMembers%5B0%5D=1.1&pickMembers%5B1%5D=3.1&cubeTimeFrame.startYear=2015&cubeTimeFrame.endYear=2019&referencePeriods=20150101%2C20190101	
	15. Statistics Canada, "Tobacco, sales and inventories, monthly production." CANSIM Table: 16-10-0044-01 (formerly CANSIM 303-0062). https://www150.statcan.gc.ca/t1/tbl1/en/tv.action?pid=1610004401	
	16. Stratégie pour un Québec sans Tabac, 2020-2025, 2020. https://cdn-contenu.quebec.ca/cdn-contenu/adm/min/sante-services-sociaux/publications-adm/strategie/STR_19-006-04W_MSSS.pd	
	17. Letter from 36 International Experts and Academics in Tobacco Control On Tobacco Harm Reduction and the Dutch National Prevention Agreement the subject of smoking cessation, 2019 (https://www.clivebates.com/documents/NLLetterMarch2019.pdf)	• This is not research evidence concerning the effectiveness of e-cigarettes as an intervention to help people stop smoking and so not evidence to consider in guideline formulation.

	18. https://www.cochrane.org/CD010216/TOBACCO_can-electronic-cigarettes-helppeople-stop-smoking-and-are-they-safe-use-purpose	• The Cochrane review is addressed through scoping of evidence currency.
	19. Polosa R et al. Health effects in COPD smokers who switch to electronic cigarettes: a retrospective-prospective 3-year follow-up. International Journal of COPD 2018:13 2533–2542 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6113943/	• The issue of the effectiveness of e-cigarettes as an intervention to help people stop smoking is addressed through the HRB evidence review.
	20. Polosa, R. et al. (2016) 'Persisting long term benefits of smoking abstinence and reduction in asthmatic smokers who have switched to electronic cigarettes', Discovery Medicine, 21(114), p. AB5. doi: 10.1016/j.jaci.2015.12.017	
	21. Polosa R, Morjaria JB, Prosperini U, et al. (2020). COPD smokers who switched to e-cigarettes: health outcomes at 5-year follow up. Therapeutic Advances in Chronic Disease. doi:10.1177/2040622320961617	
	22. George, J. et al. (2019) 'Cardiovascular Effects of Switching from Tobacco Cigarettes to Electronic Cigarettes', Journal of the American College of Cardiology, 74(25), pp. 3112–3120. doi: 10.1016/j.jacc.2019.09.067.	
	23. McNeill A, Brose LS, Calder R, Bauld L & Robson D (2018). Evidence review of ecigarettes and heated tobacco products 2018. A report commissioned by Public Health England. London: Public Health England.https://www.gov.uk/government/publications/e-cigarettes-and-heated-tobacco-products-evidence-review/evidence-review-of-e-cigarettes-and-heated-tobacco-products-2018-executive-summary	
	24. Joanna Astrid Miler, Bernhard-Michael Mayer and Peter Hajek. Changes in the Frequency of Airway Infections in Smokers Who Switched To Vaping: Results of an Online Survey. J Addict Res Ther 7:290. doi:10.4172/2155-6105.1000290. https://dspace.stir.ac.uk/handle/1893/29768#.X4lPvsIUlQ8	
	25. Lucchiari 2020 Benefits of e-cigarettes in smoking reduction and in pulmonary health among chronic smokers undergoing a lung cancer screening program at 6 months. https://www.sciencedirect.com/science/article/abs/pii/S0306460319301832?via%3Dihub	

	26. Glasser, A., et al. (2020). "Patterns of e-cigarette use and subsequent cigarette smoking cessation over two years (2013/2014 to 2015/2016) in the Population Assessment of Tobacco and Health (PATH) Study." Nicotine & Tobacco Research. https://www.unboundmedicine.com/medline/citation/32939555/Patterns_of_e-cigarette_use_and_subsequent_cigarette_smoking_cessation_over_two_years_(2013/2014_to_2015/2016)_in_the_Population_Assessment_of_Tobacco_and_Health_(PATH)_Study	
	27. Cancer Research UK's commissioned report on effectiveness of e-cigarettes for those quitting smoking (https://www.ucl.ac.uk/news/2019/may/e-cigarettes-may-double-success-rates-those-quitting-smoking).	This is not research evidence concerning the effectiveness of e-cigarettes as an intervention to help people stop smoking and so not evidence to consider in guideline formulation.
	28. New Zealand Ministry of Health, (2020). 'Position statement on vaping', Available at: https://www.health.govt.nz/our-work/preventative-health-wellness/tobacco-control/vaping-smokefree-environments-and-regulated-products/position-statement-vaping	
	29. National Institute for Health and Care Excellence (2018) 'Stop smoking interventions and services', NICE Guideline, (March), pp. 1–5. Available at: https://www.nice.org.uk/guidance/ng92/resources/stop-smoking-interventions-and-services-pdf-1837751801029.	
	30. https://publications.parliament.uk/pa/cm201719/cmselect/cmsctech/505/50502.htm	
	31. McRobbie, H. and McEwen, A. (2016) Electronic_cigarettes: A briefing for stop smoking services, National Centre for Smoking Cessation and Training. Available at: http://www.ncsct.co.uk/usr/pub/Electronic_cigarettes._A_briefing_for_stop_smoking_services.pdf	
	32. NCSCT (2018) 'Working with vape shops ': Available at: https://www.ncsct.co.uk/usr/pub/Working with vape shops 02.10.18 update.pdf	
	33. Chan, G. C. K. et al. (2020) 'Gateway or common liability? A systematic review and meta-analysis of studies of adolescent e-cigarette use and future smoking initiation', Addiction, pp. 0–3. doi: 10.1111/add.15246.	
	34. https://ash.org.uk/wp-content/uploads/2020/10/Use-of-e-cigarettes-vapes-among-adults-in-Great-Britain-2020.pdf	

Other	35. Fiore MC, Jaén CR, Baker TB, et al. Treating Tobacco Use and Dependence: 2008 Update. Quick Reference Guide for Clinicians. Rockville, MD: U.S. Department of Health and Human Services. Public Health Service. April 2009.	A process to scope the currency of guidelines used for adaption has taken place post consultation.
	36. NICE public health intervention guidance – Brief interventions and referral for smoking cessation in primary care and other settings2006	
	37. NSW Government Factsheet: https://www.health.nsw.gov.au/tobacco/Factsheets/nrt-in-pregnancy.pdf;accessed 28.10.20	
	38. American College of Obstetrics & Gynaecology- Committee Opinion No. 907; May 2020; https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2020/05/tobacco-and-nicotine-cessation-during-pregnancy; Accessed 28.10.2020	
	39. Primary Care Guidance on Smoking and Mental Disorders; 2014 update; https://www.rcpsych.ac.uk/docs/default-source/improving-care/better-mh-policy/policy/primary-care-guidance-on-smoking-and-mental-disorders-2014-update.pdf?sfvrsn=5824ccd5_2; accessed 29.10.20	
	40. Robson, D & A. McEwen (2018) Smoking cessation and smokefree policies: Good practice for mental health services ; NCSCT	
	41. Imelda Kearns (2019), BSc Occupational Therapy, NUIG. "A qualitative exploration of the impact of smoking regulations on the daily routine of patients within mental health settings". A qualitative research study was completed by the undersigned in 2019 within an acute mental health service in the West of Ireland. Full ethical approval was permitted to complete the research study. This research is currently being prepared for publication.	• This is not research evidence concerning the effectiveness of interventions to help people stop smoking and so not evidence to consider in guideline formulation.

	Please consider the following publications: 42. Allen Carr's Easyway to Stop Smoking - A randomised clinical trial Sheila Keogan, Shasha Li, http://orcid.org/0000-0003-2407-2263Luke Clancy Author affiliations TobaccoFree Research Institute Ireland, Focas Research Institute, DIT, Dublin 8, Dublin, Ireland Correspondence to Professor Luke Clancy, TobaccoFree Research Institute Ireland, Focas Research Institute, DIT, Dublin 8, Dublin, Ireland; lclancy@tri.ie 43. Comparison of Allen Carr's Easyway programme with a specialist behavioural and pharmacological smoking cessation support service: a randomized controlled trial. Frings D, Albery IP, Moss AC, Brunger H, Burghelea M, White S, Wood KV. Addiction. 2020 May;115(5):977-985. doi: 10.1111/add.14897. Epub 2020 Jan 22. PMID: 31968400 Free PMC article. Study protocol for a randomised controlled trial of Allen Carr's Easyway programme versus Lambeth and Southwark NHS for smoking cessation. 44. Wood KV, Albery IP, Moss AC, White S, Frings D. BMJ Open. 2017 Dec 14;7(12):e016867. doi: 10.1136/bmjopen-2017-016867. PMID: 29247083 Free PMC article. Clinical Trial. 45. [Efficacy and cost-effectiveness of smoking cessation courses in the statutory health insurance: a review]. Rasch A, Greiner W. Gesundheitswesen. 2009 Nov;71(11):732-8. doi: 10.1055/s-0029-1214400. Epub 2009 Jun 2. PMID: 19492280 Review. German.	• Allen Carr Easyway is dealt with through scoping evidence currency.

8. Other comments (not mentioned above)

Comments	
Quit Mid West welcomes the forthcoming publication of this strategic and important clinical guideline as it will help to highlight and to complement all the work of the TFI and its various stop smoking support services. The guideline will support the current work and ongoing development of the cessation services and will strengthen partnership working between cessation service, primary care, mental health & maternity services. Many thanks to all members of the Guideline Development Group. (#10)	• GDG noted - no action.
Thank you to all involved in development of this guidance, a fantastic development for all of us working in Stop Smoking Services, on behalf of CHO 1.	• GDG noted - no action.
Very comprehensive guideline and thank you for the opportunity to feedback.	• GDG noted - no action.
The Department of Health warmly welcomes the development of evidence-based recommendations for healthcare professionals on the management of smoking cessation. In addition to fulfilling a recommendation of our national tobacco control policy, Tobacco Free Ireland, the Department hopes that the Guidelines will contribute to empowering and encouraging healthcare professionals to address cessation with patients and ultimately assist more of our population to quit smoking. The Department also welcomes that the recent evidence reviews on e-cigarettes, carried out by the Health Research Board on behalf of the Minister for Health, were considered in the development of the Guidelines.	• GDG noted - no action.
The group should be very proud of the work they have collated here. We would advice to keep the focus on validated therapies and put less detail/focus on unproven therapies. Even though there is not much new here, we feel that this document will provide physicians and healthcare professionals with guidance on what is the best methods to help people quit smoking. The guideline will hopefully streamline how we deliver tobacco cessation therapy across Ireland and the group should be commended for their significant work on this important	• GDG noted - no action.

document. The publication of the clinical guideline should be widely promoted to ensure that everyone knows it is available. Well done everyone. (#16)	
The guidelines are well laid out,. Easy to find the relevant sections.	• GDG noted - no action.
I think it odd that there were 2 RCTs of Allen Carr's Easyway, one of them, the first ever in the world, from Ireland since the HIQA report and it is still not dealt with a 'new' guideline book from Ireland. You will remember HIQA made extensive recommendations on the basis of 2 poor RCTs on e-cigarettes. I am disappointed.	• GDG noted - no action.
This is a very welcome document and badly needed. It is a great theoretical basis for improving the treatment of tobacco use as a care issue. The challenge following from this will be moving the recommendations from paper to practice.	• GDG noted - no action.
The document was developed with extensive input on the working group. There was two 'patient reps' but it is unclear if either was bringing lived experience of mental health and smoking. Great to see the care plan being referred to as this will support everyone with goal setting and hopefully can be retained in the community for review purposes post discharge. For consistency of language suggest using people with lived experience of mental health challenges and people with mental health challenges throughout.	• Patient representation was managed in lined with NCEC guidelines. One representative worked with an NGO in the mental health sector. • GDG will review language in the document in final editing. The document is concerned with users of secondary mental health services who have lived experience of mental health challenges and not wider groups.

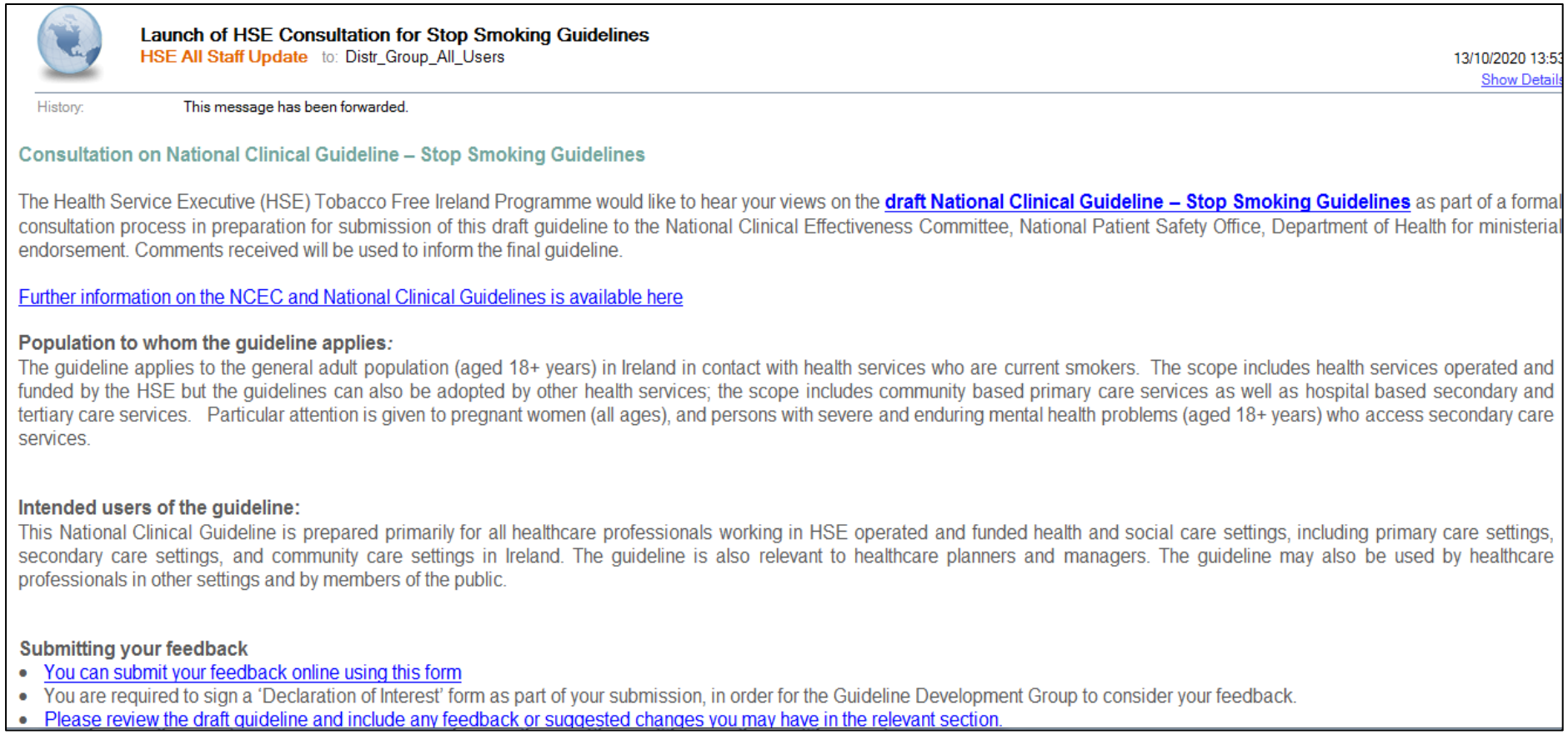
B. Feedback from International Review

Review Questions	Comment from Expert Opinion 1	Comment from Expert Opinion 2	Response from GDG
Question 1: ***Has the appropriate evidence been identified and reviewed in line with the scope and clinical questions posed by this guideline?***	Yes. There has been a thorough and systematic review of the literature and newer smoking cessation guidelines from several countries.	Yes. The GDG conducted a rigorous and comprehensive review of several relevant evidence sources, including published health outcomes/behavioural data on the Irish situation, international clinical practice guidelines, and systematic reviews from a variety of sources including HIQA Health Technology Assessment.	GDG noted - no action.
Question 2: ***Are there specific links between decisions and the available scientific evidence?***	Yes, the decisions and recommendations are correctly based on the scientific findings.	Yes. Recommendations are well-supported by reviews of benefits/harms, quality of evidence, values/preferences, and details about resources used in decision-making. The GDG used a considered judgement process, adapted from GRADE (Alonso-Coello, 2016) to determine strength of recommendations, which is thorough and appropriate. Evidence is clearly linked to the document's 4 key questions and 10 recommendations.	GDG noted - no action.
Question 3: ***Have the risks and potential harms of recommendations been fully considered in the context of clinical practice?***	Benefits and harms are systematically described. It is mentioned that pharmacological interventions for smoking cessation are largely safe and well-tolerated in the general adult population. A small increased risk of CVD in users of Varenicline could have been mentioned. Harms of nicotine on the immature brain, when recommending NRT for minors could also have been mentioned.	Yes. The risks and potential harms have been adequately considered for all recommendations. Of special note is that recommendations have been carefully considered and justified regarding unsettled clinical issues, including use of e-cigarettes as a cessation aid for the general population of smokers and use of cessation pharmacotherapy by pregnant women. Consider modifying the statement "*Also consider discussing e-cigarettes as an alternative to smoking*" which is included as a	GDG reviewed and amended the text on potential adverse effects of pharmacotherapies. GDG reviewed and amended the Good Practice Point for Recommendation 2.

		"Good practice point" for Recommendation 2 (p. 10 and p. 52). The current wording appears to suggest that healthcare providers initiate a discussion about using e-cigarettes to aid in cessation although the patient does not use, or express interest in using, e-cigarettes. Given uncertain efficacy and safety, it would be beneficial to phrase this Good Practice Point so that it does not appear to conflict with GDG's decision not to recommend e-cigarettes and so that it better aligns with the "Good practice points" for Recommendation 3.	
Question 4: ***Is the guideline clearly written, user friendly and allow for individual clinician decisions?***	Yes, it is clearly written. However, the guideline is 'heavy'. There is a lot about aim, method, process, authors, reviewers, search methods etc. etc. Only pages 48-74 are relevant for busy clinicians. It could be considered also to publish this section alone, as a short guideline, and make it even more reader friendly. (not instead of this guideline but as an shorter clinic oriented alternative) Yes, the guideline allows for minor individual clinician decisions.	Yes. The document is well-written and clearly expresses the GDG's recommendations and the rationale for these recommendations. Healthcare providers' ability to engage in individualized decision-making is appropriately emphasized.	GDG have noted the comments. User friendly materials will be developed to support implementation.
Question 5: ***Is the guideline suitable for routine use as intended (in so far as you are able to comment on the Irish situation)?***	I am not able to comment on the Irish situation, but I think the guideline describes very systematically who has the responsibility etc. I think it is too long and too method oriented. Could easily be transformed to a very short version for clinicians. I also know that many clinicians have	One suggestion to improve its user-friendliness and increase its routine use, if appropriate for the Irish situation, is to embed clinical decision algorithms and suggested clinician intervention statements in the document or in an appendix. As examples, see Figures 2.1 and Strategies A2-A5 in: Fiore MC, Jaén CR, Baker TB, et al. Treating Tobacco Use and Dependence: 2008Update. Clinical Practice	GDG have noted the comments. User friendly materials will be developed to support implementation.

	many practical questions: what shall I do with the reluctant smoker or the very heavy smoker who has relapsed ten times? Can I use 2 or 3 patches if the patient smokes 2 or 3 packs of cigarettes? Is half-dose of Varenicline as effective as full dose? Is there an effect of longer duration of Bupropion, NRT or Varenicline? How soon after a myocardial infarction can I prescribe Varenicline or NRT? Are there specific What about addicted users of e-cigarettes or smokeless tobacco who want to quit, shall I treat them with the same medication? What kind of psychotropic medication is interacting with smoking? Will NRT affect the serum level of psychotropic medication? Shall I prescribe patch or p.n. NRT for pregnant women?….etc. This guideline does not help them with these clinical questions. It could be considered to add some more (short) details in a short clinician-oriented version.	Guideline. Rockville, MD: U.S. Department of Health and Human Services.	
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)***	There are a few differences in recommendations (e.g. pharmacotherapy for pregnant women) across the world but this is relevantly discussed and reflected upon.	No; no conflicts were identified. Recommendations that differ amongst international guidelines are presented clearly in side-by-side fashion in Appendix 6, which allow for easy comparison.	

Appendix 1 – Copy of Email distributed to all HSE Staff



Launch of HSE Consultation for Stop Smoking Guidelines
HSE All Staff Update to: Distr_Group_All_Users
13/10/2020 13:53
Show Details

History: This message has been forwarded.

Consultation on National Clinical Guideline – Stop Smoking Guidelines

The Health Service Executive (HSE) Tobacco Free Ireland Programme would like to hear your views on the **draft National Clinical Guideline – Stop Smoking Guidelines** as part of a formal consultation process in preparation for submission of this draft guideline to the National Clinical Effectiveness Committee, National Patient Safety Office, Department of Health for ministerial endorsement. Comments received will be used to inform the final guideline.

Further information on the NCEC and National Clinical Guidelines is available here

Population to whom the guideline applies:
The guideline applies to the general adult population (aged 18+ years) in Ireland in contact with health services who are current smokers. The scope includes health services operated and funded by the HSE but the guidelines can also be adopted by other health services; the scope includes community based primary care services as well as hospital based secondary and tertiary care services. Particular attention is given to pregnant women (all ages), and persons with severe and enduring mental health problems (aged 18+ years) who access secondary care services.

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.

Submitting your feedback
- You can submit your feedback online using this form
- You are required to sign a 'Declaration of Interest' form as part of your submission, in order for the Guideline Development Group to consider your feedback.
- Please review the draft guideline and include any feedback or suggested changes you may have in the relevant section.

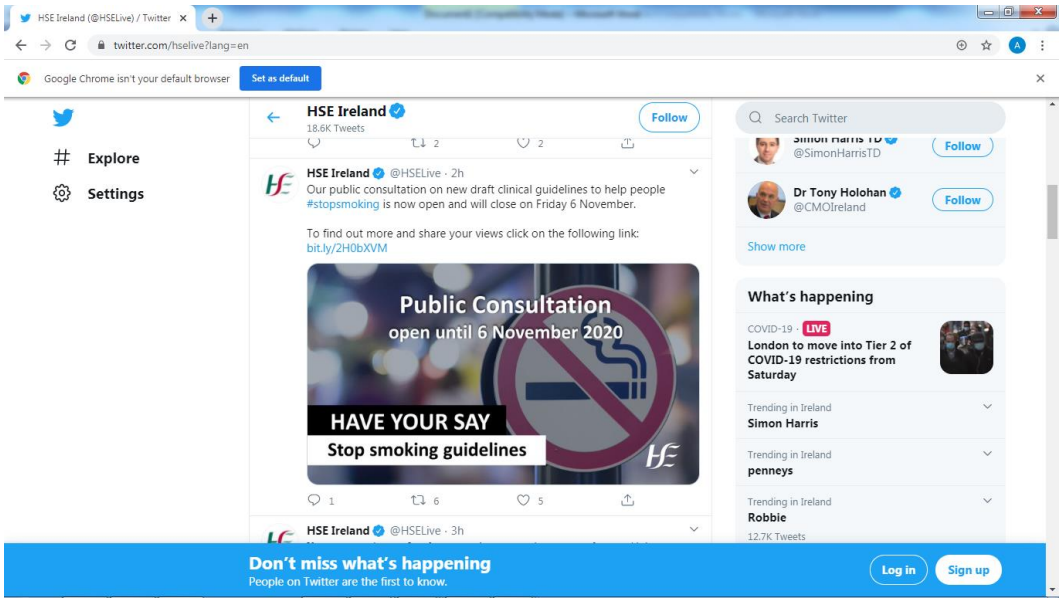
Appendix 2 – Identified Stakeholders (Internal to HSE) in area of Tobacco Control invited to make submissions on draft guideline

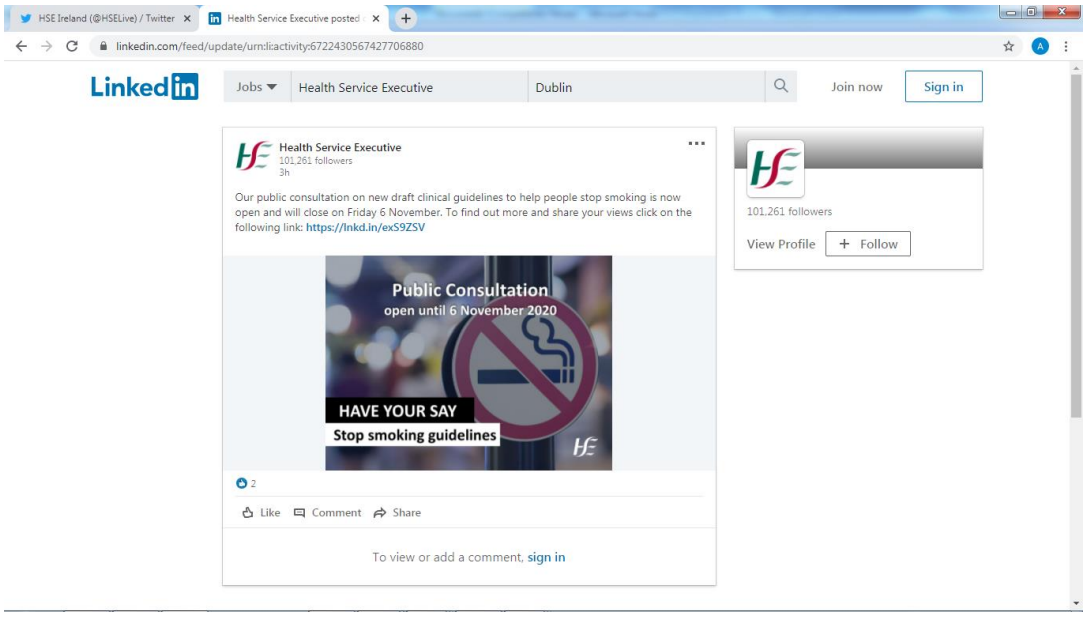
Stakeholders (Internal to HSE) invited to make submissions on draft guidelines
HSE Leadership Team
Office of the Chief Clinical Officer
National Director, Quality Assurance & Verification Division
National Director, Quality Improvement Division
National Director, National Cancer Control Programme
National 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

Appendix 2 - Identified Stakeholders (External to HSE) in area of Tobacco Control 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

Appendix 3 – Copies of posts relating to guideline consultation on HSE Social Media





Appendix 4 – HSE Press Release

HSE Tobacco Free Ireland launches Stakeholder Consultation on Draft National Stop Smoking Clinical Guidelines

https://www.hse.ie/eng/about/who/tobaccocontrol/consultation-feedback-form-stop-smoking-guidelines/

Today (13 October 2020) the HSE Tobacco Free Ireland Programme invites feedback from colleagues and stakeholders on the draft Clinical Guidelines for the Identification, Diagnosis and Treatment of Tobacco Addiction (National Stop Smoking Clinical Guidelines). The guidelines are available to view or download on the HSE website until 5pm on Friday 6 November 2020.

Dr Paul Kavanagh, HSE Tobacco Free Ireland Programme states: "Developing National Clinical Effectiveness Committee (NCEC) approved Stop Smoking Guidelines are a significant step forward for tobacco control in Ireland that will improve and assure the effectiveness of the HSE's role in helping smokers quit. The guideline sets out evidence-based statements on best practices to help people stop smoking and will assist healthcare professionals and service users make decisions together about care. We want to ensure nobody who smokes misses out on the chance to get the best support from our healthcare professionals to help them quit. These guidelines will strengthen the role of healthcare in responding to the needs of people who smoke, improve care for our service users and support every healthcare professional to contribute towards a Tobacco Free Ireland".

These will be Ireland's first ever National Clinical Guidelines in the area of smoking cessation. They will contribute to the implementation of Tobacco Free Ireland and Healthy Ireland policies, and will be integral to Sláintecare's vision for a health service which prioritises population health and disease prevention. A Clinical Guideline Development Group was established by the HSE Tobacco Free Ireland Programme in April 2017. The group is chaired by Dr Paul Kavanagh and is comprised of clinical experts, senior managers, service providers, research experts and service user representatives.

Dr Paul Kavanagh, HSE Tobacco Free Ireland Programme continues: "To date, the Clinical Guideline Development Group has screened and critically appraised existing international guidelines and evidence so as to draft recommendations for the clinical guidelines. But we now need to hear views on these recommendations and, critically, how these can be translated into improved provision of care and better outcomes for health service users. The next step in the process requires that these draft guidelines are widely communicated and consulted on by all concerned stakeholders. We welcome feedback from our colleagues and other interested parties. Following this consultation we will finalise the guidelines, submit them to the National Clinical Effectiveness Committee and we look forward to endorsement by the Minister for Health. Smoking continues to claim over 100 lives each week in Ireland and is responsible for over 1,000 episodes of hospital care each week. These guidelines will help us take a further step towards Tobacco Free Ireland. "

Clinical guidelines are systematically developed statements, based on a thorough evaluation of the evidence, to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances, across the entire clinical spectrum.

These guidelines:

- 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 quit.

- Recommend that healthcare professionals across our health services routinely ask people about their smoking, advise them to stop and provide or arrange safe and effective support. These simple but powerful steps which when delivered routinely in care can increase the chance that someone will quit and remain smoke-free by 2 to 3 fold.
- Set out the recommended behavioural and pharmacological supports that can be arranged to help people who smoke quit. The evidence supporting these recommendations using the HIQA Health Technology Assessment on smoking cessation interventions and more recent evidence reviews from the Health Research Board.

An implementation plan developed with support from the Centre for Effective Services describes how the HSE Tobacco Free Ireland Programme will help translate these guidelines into practice across health services in Ireland.

For more information on the draft Clinical Guidelines for the Identification, Diagnosis and Treatment of Tobacco Addiction please see https://www.hse.ie/eng/about/who/tobaccocontrol/consultation-feedback-form-stop-smoking-guidelines/

Ends

Last updated on: 13 / 10 / 2020

Appendix 5 – Declaration of Interest & Consultation Form

Consultation Feedback Form
National Clinical Guideline – Stop Smoking Guidelines

Introduction:

The Health Service Executive (HSE) Tobacco Free Ireland Programme is seeking your feedback on this draft National Clinical Guideline as part of a formal consultation process in preparation for submission of this draft guideline to the National Clinical Effectiveness Committee, National Patient Safety Office, Department of Health for ministerial endorsement.
Further information on the NCEC and National Clinical Guidelines is available from the following link: https://www.gov.ie/en/publication/90221b-clinical-effectiveness/

About this guideline:

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. The scope includes health services operated and funded by the HSE but the guidelines can also be adopted by other health services; the scope includes community based primary care services as well as hospital based secondary and tertiary care services. Particular attention is given 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 population-based tobacco control measures to prevent smoking initiation and/or promote quitting (e.g. legislation, taxation, mass media campaigns etc.).

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.

How to submit your feedback?

- You can submit your feedback online using this form.
- You are required to sign a 'Declaration of Interest' form as part of your submission, in order for the Guideline Development Group to consider your feedback.
- Please review the draft guideline and include any feedback or suggested changes you may have in the relevant section.
- All suggested changes must be accompanied by a full reference to the evidence for the suggested change. The Guideline Development Group (GDG) cannot consider any suggested changes without the relevant evidence.
- The GDG will consider all feedback, and decide whether or not to use it in the development of the final guideline.

Closing Date:

The closing date for this consultation and receipt of feedback is **06/11/2020**.

Thank you for taking the time to give us your feedback

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 Organisations' 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 ☐

Your Feedback:

Section	Your comments/feedback and supporting evidence
1.1 – Summary of Recommendations	
2.1 – Background	
2.2 - Clinical and financial impact	
2.3 - Rationale for this Guideline	
2.4 - Aims & objectives	
2.5 - Guideline scope	
2.6 - Conflict of interest statement	
2.7 - Sources of funding	
2.8 - Protection from Tobacco Industry Interference	
2.9– Guideline Methodology	
2.10 – Consultation Summary	
2.11 – External Review	
2.12 – Implementation	
2.13 – Monitoring & Audit	
2.14 – Plan to update guideline	
3.1 – Key question 1 & evidence statement	
3.2 – Key question 2 & evidence statement	
3.3 – Key question 3 & evidence statement	
3.4 – Summary of budget Impact Analysis	
Appendix (1 to 14)	
Do you have any additional comments to make on the guidelines	
Is there any further evidence in relation to these Guidelines which you would like to bring to the attention of the Guideline Development Group	

Appendix 6 – 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