Appendix 2 – PH48 evidence summary

Summary of new evidence from 2-year surveillance	Summary of new intelligence from 2-year surveillance	Impact
PH48– 01 Recommendation 1 Provide information for planned or anticipated use of secondary care evidence statements 1.1.2.2, 3.1.7, 5.2.7, 5.15.1; expert paper 1		
No new evidence identified.	Topic experts indicated through feedback within the questionnaire that there was a feeling in practice that more clarity is required around ECs as they are the most widely used aid in quitting smoking. In particular clarity on consumer ECs use impacts on 'smoke free' policies. Feedback has indicated that services require assistance in detailing an appropriate means of addressing policy and practice around the use of consumer e-cigarettes and existing smoke free policy. Public Health England has published 'Use of e-cigarettes in public places and workplaces: Advice to inform evidence-based policy making' (July 2016).	**Potential changes to recommendations due to update of other guidance** If recommendation 6 is updated to include e-cigarettes then recommendation 1 should be re-reviewed to ensure it is in line. Likewise if the update of Stop smoking services PH10 results in any changes to recommendations in Quitting smoking in pregnancy and following childbirth (PH 26) the impact on recommendation 3 or 4, PH48 should be checked for consistency. The Public Health England has published 'Use of e-cigarettes in public places and workplaces: Advice to inform evidence-based policy making' (July 2016) could potentially be a good implementation tool to aid practice relating to PH48.
PH48– 02 Recommendation 2 Identify people who smoke and offer help to stop evidence statements 1.2.9, 3.1.3, 3.1.7, 3.2.4, 5.2.3, 5.2.7, 5.3.2, 5.3.5, 5.12.1, 5.14.2, 5.15.4, 6.1.2, 7.2.28, CE1.7.0; expert papers 1, 2, 3, 4, 5, 6, 7		
No new evidence identified.	Topic experts indicated through feedback within the questionnaire that there was a view in practice that more clarity is required around EC as they are the most widely used aid in quitting.	**Potential changes to recommendations due to update of other guidance** Recommendation 2 cross refers to the options regarding licensed nicotine-containing products or other pharmacotherapies in recommendation 6. If recommendation 6 is updated to include e-cigarettes then recommendation 2 should be re-reviewed to ensure it is in line. Recommendation 2 also advises that midwives should follow recommendation 1 in NICE guidance on Quitting smoking in pregnancy and

Summary of new evidence from 2-year surveillance	Summary of new intelligence from 2-year surveillance	Impact
		following childbirth (PH26) and gives specific cut off points regarding levels of CO. This recommendation is currently being updated and hence recommendation 2 PH48 will need to be aligned to any changes from this update.
PH48– 03 Recommendation 3 Provide intensive support for people using acute and mental health services evidence statements 1.2.9, 1.3.5, 2.1.3, 2.1.5, 2.1.8, 2.1.10, 4.1.1, 4.1.2, 4.4.3, 4.4.4, 4.9.1, 4.9.4, 4.10.1, 4.12.1, 4.13.2, 4.13.2, 5.2.3, 5.3.6, 6.1.5, CE1.1.0, CE1.2.0, CE1.2.1, CE1.2.2, CE1.2.3, CE1.3.0, CE1.6.0, CE1.7.0; expert papers 4, 5, 6, 7		
E-cigarettes in mental health services Two cohort studies were identified that provide conflicting evidence on the potential effectiveness of e-cigarettes (ECs) in people using mental health services, including acute mental health services: The first cohort of adult smokers recruited during acute psychiatric hospitalisation (n= 956) examined the frequency and correlates of ECs use reported over an 18-month period. The likelihood of ECs use was greater with each additional year of recruitment (2009-2013) and for individuals aged 18-26 years[1]. ECs use was unrelated to gender, psychiatric diagnosis, and measures of tobacco dependence at baseline. ECs use was not associated with changes in smoking status or, among continued smokers, with reductions in cigarettes per day. The second small 12 month cohort investigating the impact of an electronic cigarette on smoking reduction and cessation in smokers with schizophrenia not intending to quit found that at 1 year, 50% of the participants had reduced the number of cig/day by 50% with additionally 14% of participants being smoking abstinent[2]. Common side effects in the first 24 weeks included nausea, throat irritation, headache, and dry cough. Positive and negative symptoms of schizophrenia were not increased after smoking reduction/cessation in patients using e-cigarettes.	Topic experts indicated through feedback within the questionnaire that there was a view in practice that more clarity is required around EC as they are the most widely used aid in quitting.	**Potential changes to recommendations due to update of other guidance** Recommendation 3 currently cross-refers to Tobacco: harm-reduction approaches to smoking (PH45) recommendation 8 which recommends that for anyone who does not want, is not ready or is unable to stop completely, encourage the use of licensed nicotine-containing products to help them abstain, and provide intensive behavioural support to maintain abstinence from smoking while in secondary care. These areas are potentially an area for review and update within Tobacco: harm-reduction approaches to smoking (PH45) to establish the potential use of e-cigarettes. Likewise P10 and PH1 are currently in update and will be considering the use of both consumer and licensed e-cigarettes for smoking cessation. Recommendation 3 cross refers to the options for people regarding licensed nicotine-containing products or other pharmacotherapies in recommendation 6. If recommendation 6 is updated to include e-cigarettes then recommendation 3 should be re-reviewed to ensure it is in line.

Summary of new evidence from 2-year surveillance	Summary of new intelligence from 2-year surveillance	Impact
PH48– 04 Recommendation 4 Provide intensive support for people using maternity services evidence statements 1.2.9, 2.2.3, 2.2.9, 3.2.6, CE1.4.0, CE1.4.1; expert papers 3, 4		
No new evidence identified.	No committee feedback was provided by the expert questionnaire that related to this area. No additional intelligence indicated that this area required updating.	**Potential changes to recommendations due to update of other guidance** PH48 recommendation 4 currently cross refers to recommendation 3 and 4 on contacting referrals and initial and ongoing support in NICE guidance on Quitting smoking in pregnancy and following childbirth (PH26). Recommendation 4 in PH26 is scheduled for update and as such this recommendation in PH48 will need to be aligned.
PH48 - 06 Recommendation 6 Advise on and provide stop smoking pharmacotherapies evidence statements 1.1.2.2, 1.1.2.3, 1.3.5, 5.2.1, 5.9.1, 5.9.2, 7.2.28		
E-cigarettes in secondary care See evidence for recommendation 3. **Varenicline safety for individuals with mental health problems** 20 relevant studies were identified on the safety of varenicline in individuals with a mental health problem[3-22]. The studies indicate that there is inconsistent evidence on whether varenicline results in adverse psychiatric events (including suicidal ideation, depression, self-harm and suicide) in individuals with a history of mental health problems. As such it would appear that care in prescribing this medication in this population is still warranted. A number of studies reported that varenicline did not exacerbate mental health symptoms in patients with a range of mental health problems: • Evidence from 4 systematic reviews which include 39 RCTs (n=10,761)[3], a Cochrane review including 34 RCTs (n=340)[4], 17 RCTs (n=8,027)[5] and 7 RCTs (n=439)[6] noted that there were no increased adverse	Expert feedback indicated that the use of electronic cigarettes as unlicensed products should reflect the Public Health England viewpoint as highlighted in the PHE E cigarettes an evidence update as providing a substantial increase in the evidence base in the area[23] and felt that all clinical interventions to promote smoking cessation should be modified to add the use of electronic cigarettes as a second-line alternative to short-acting nicotine replacement therapy. They highlighted 2 publications specifically from within this report as providing important evidence on the use of EC: A PHE publication report Electronic cigarettes - that indicated EC are a safer source of nicotine compared to tobacco cigarettes however they need appropriate regulation, careful monitoring and risk management [24]. A second paper included E-cigarette uptake and marketing was highlighted as relevant as it details the current electronic cigarette market in the UK[25]. The guidance should also address the problem that many users of secondary care services are already regular users of electronic cigarettes; NHS services should not prohibit their use in these circumstances.	**Potential changes to recommendations due to update of other guidance** **E-cigarettes in secondary care** Currently recommendation 6 states that people who are already using an unlicensed nicotine-containing product (such as unlicensed electronic cigarettes) are to be encouraged to switch to a licensed product. The recommendation also indicates that the person is advised of local policies on indoor and outdoor use of unlicensed nicotine-containing products. There is limited evidence on the use and effectiveness of e-cigarettes within the specific populations covered by PH48 (all secondary care including, maternity or mental health services). However, the policy and regulations regarding the consumer (and potentially future licenced) use of e-cigarettes is changing. Additionally, expert feedback indicates a change in the frequency of use of these products and a need for guidance in

Summary of new evidence from 2-year surveillance	Summary of new intelligence from 2-year surveillance	Impact
effects with the use of varenicline. However there were reports of sleep disorders[3], an increased risk of nausea[5,6] and 2 cases of suicidal ideation which suggest possible psychiatric adverse effects cannot be ruled out with varenicline[4]. • Evidence from 4 RCTs in patients with depression (n=525)[7], and schizophrenia or bipolar disorder (n=247)[8] or schizophrenia or schizoaffective disorder (n= 69, 127 respectively)[9,10] indicated that the use of varenicline did not worsen existing psychiatric symptoms. There was 1 suicide attempt, by a varenicline patient with a lifetime history of similar attempts, but no suicides in these studies[10]. • A 12 week non-comparative effectiveness trial of varenicline in patients with schizophrenia spectrum disorder (n=112) noted improved psychotic symptoms when treated with varenicline and weekly group cognitive behaviour therapy[11]. • A retrospective cohort of smokers most with significant medical and psychiatric comorbidity (n=723) indicated that varenicline and combination pharmacotherapy did not increase psychological distress in smokers with co-morbidities treated at a specialty clinic[12]. However, evidence from 10 studies suggests that varenicline potentially does exacerbate mental health symptoms in patients with a history of ongoing mental health problems: • One systematic review including 13 studies of varying types in patients with schizophrenia and schizoaffective disorder (n=260) noted that 5% of patients experienced worsening of their psychiatric symptoms, but none experienced suicidal behaviours[13]. • One RCT in people with bipolar disorder (n=60) found	**Varenicline** Topic experts highlighted that potentially there was evidence that varenicline had a better safety profile than when first licensed and approved as a Technology appraisal for use (Varenicline for smoking cessation TA123). The experts indicated that they felt that there should be a stronger focus on encouraging the use of varenicline within hospitals, especially in mental health care as a first line treatment. They stated that the access to adequate NRT is variable, with the majority of care and mental health settings not stocking varenicline. This was noted to be inconsistent with the available evidence of success and low risk of harm. It was stated that this could be an inequality as if individuals had not been hospitalised they would have access to this effective drug. A number of refences were provided including the trials by Harrison-Woolrych *et al*[19], Thomas *et al*[3] and Evins *et al*[8] that were identified by the literature search. In addition: • A retrospective cohort study of patients who received a prescription of nicotine replacement treatment bupropion, or varenicline in England (n=164,766) was highlighted as evidence for the potential wider use of varenicline[26]. This study in a general population indicates that neither bupropion nor varenicline showed an increased risk of any cardiovascular or neuropsychiatric event compared with NRT. • A population based cohort (n=69 757) indicated that varenicline treatment was associated with an increase in the risk of anxiety conditions and mood conditions in people with pre-existing psychiatric disorders[27].	practice. As there is a lack of direct population specific evidence it may be premature to produce stand alone guidance for these populations. It should be noted that Tobacco: harm-reduction approaches to smoking (PH45) may potentially need to be reviewed to include both consumer and licensed EC for harm reduction. Likewise P10 and PH1 are currently in update and will be considering the use of both consumer and licensed e-cigarettes for smoking cessation. **Varenicline** Recommendation 6 states: offer licensed nicotine-containing products (usually a combination of transdermal patches with a fast-acting product such as an inhalator, gum, lozenges or spray) to all people who smoke or varenicline or bupropion as sole therapy as appropriate. Varenicline and bupropion can be used with caution in people with mental health problems. This recommendation is to be delivered in line with Varenicline (TA 123) and its licensed indications. The Summary of Product Characteristics for varenicline indicates 'care should be taken with patients with a history of psychiatric illness and patients should be advised accordingly'. Expert feedback suggested that the recommendation could be more emphatic on the use of varenicline in mental health settings based on a number of references. However, the references that were provided did not all substantiate this potential use with a number indicating that adverse psychiatric events occurred with the use of varenicline. This was supported by a literature search which identified 20 relevant studies on the safety of varenicline in individuals with a mental health problem[3-22] . The studies indicate that there is inconsistent

Summary of new evidence from 2-year surveillance	Summary of new intelligence from 2-year surveillance	Impact
that 61% of patients who took varenicline suffered from abnormal dreams and 13% expressed fleeting suicidal ideation suggesting that caution should be used when taking this drug[14] . Whereas another RCT in smokers (n=505) noted that an increase in depressive symptoms occurred in the first 2 weeks after starting treatment with varenicline in those with a history of depression[15]. A RCT in outpatients with schizophrenia or schizoaffective disorder and concurrent alcohol and nicotine dependence enrolled 55, but only managed to start 10 individuals in the study due to safety concerns around medication and loss to follow-up. Gastrointestinal adverse effects, such as severe abdominal pain, limited study completion to only 4 participants[16]. • Three large post marketing cohorts were identified. A large registry-based cohort of all new users of varenicline and bupropion (n=59,790) found that both drugs caused higher rates of psychiatric adverse events amongst those with a history of psychiatric disorder than in patients without such history[17]. In a large cohort people receiving varenicline (n=12,159) 1.7% of patients reported neuropsychiatric events to their general practitioners[18]. Likewise a cohort in New Zealand of patients prescribed varenicline (n=3415) reported minor psychiatric events in 4%, increased depression in 3% and serious psychiatric reactions including suicide (1 case), suicidal ideation (2 cases) and psychotic reactions 3 cases), 6 self-harm events (1 fatal) were also identified[19]. • Two cohorts in specific sub populations were identified. A retrospective cohort of patients with and without psychotic illness stopping smoking (n=196) indicates that varenicline results in nausea in 13% of individuals and overall reporting of any neuropsychiatric effect was 32% in those using varenicline[20].The second cohort of opioid-dependent patients with psychiatric illness (n=575) reported no		evidence on whether varenicline results in adverse psychiatric events (including suicidal ideation, depression, self-harm and suicide) in individuals with a history of mental health problems. As such it would appear that care in prescribing this medication in this population is still warranted. This recommendation could potentially be refreshed to alter the wording to be in line with SPC.

Summary of new evidence from 2-year surveillance	Summary of new intelligence from 2-year surveillance	Impact
serious adverse effects with varenicline use in the 82 cases assessed[11]. However, 15% discontinued varenicline use due to adverse events including exacerbation of depressive symptoms. • One case series in smokers with a psychotic illness (n=14) reported sleep disturbance and nausea as common adverse events and 1 individual dropped out due to psychiatric problems and 2 due to other side effects[21]. Whereas a second study following up 217 cases indicates that varenicline may result in suicidal ideations in 6% of all patients but these are mainly associated with current depressive symptoms not a history of depression[22].		
PH48 - 11 Recommendation 11 Develop smokefree policies evidence statements 3.1.0, 3.1.1, 3.1.5, 3.2.3, 5.1.6, 5.4.2, 5.4.3, 5.5.4, 6.1.2, 6.1.3, 6.1.4, 6.1.5, 6.1.6, 6.1.10, 6.2.1, 6.2.2, 6.2.3, 6.2.5, 6.3.1, 6.3.2, 6.3.3, 6.3.5, 6.3.6, 6.3.8, 7.1.1, 7.2.7, 7.2.10, 7.2.11, 7.2.13, 7.2.15, 7.2.16, 7.2.17, 7.2.18, 7.3.3, 7.3.4, 7.3.8, 7.3.12, 7.3.14; expert papers 6, 8		
No new evidence identified The search on e-cigarettes did not identify any studies relating to smokefree policy. However, in the surveillance review of Tobacco: harm-reduction approaches to smoking (PH45) passive (second hand) exposure to nicotine although lower from EC use than tobacco cigarettes was still found to occur in 2 studies[28,29] but there was no exposure to toxic tobacco-specific combustion products associated with EC use[29,30]. Likewise third hand exposure from surfaces indicated that EC use could result in exposures to nicotine in 2 studies[31,32] but this was reduced compared to cigarette smoking[32].	Expert feedback indicated that there was need for guidance on the use of e-cigarettes within secondary care and for clarity on their use in regards to smoke free policy. It was noted by experts that many services users already regularly use electronic cigarettes as a means to cut down their smoking. It was questioned by the experts whether e-cigarette use should be considered the same as smoking or whether NHS services should not prohibit their use in these circumstances. The Public Health England view as detailed in E cigarettes an evidence update[23] was provided, and cited by the experts as a substantial increase in the evidence base supporting the use of e-cigarettes as being less harmful than smoking. But how their use should be managed within secondary care and hospital grounds was noted as a very contentious issue. The potential for legal challenges and parliamentary challenges was also highlighted. However, it was also noted that trusts were reticent to remove e-cigarettes from smokefree site policies due to debate about the effectiveness of e-cigarettes as aids to cessation, and the re-normalisation of smoking associated with their use. Concern	**Potential changes to recommendations due to update of other guidance** Currently it would appear that advice on e-cigarette use on hospital premises is at a local level and is often included in the smoke free policy. When e-cigarettes remained unlicensed or where not recommended as a smoking cessation, or harm reduction aid then it could remain within the local remit to determine the policy for each trust. However, if Tobacco: harm-reduction approaches to smoking (PH45) is updated to include EC, recommendation 6 (PH48) on consumer e-cigarettes as a potential harm reduction /cessation approach may need to be refreshed. Likewise the update of PH10 and PH1 may provide more clarity on the use of licensed EC

Summary of new evidence from 2-year surveillance	Summary of new intelligence from 2-year surveillance	Impact
	was expressed over the potential for staff using them whilst at work, patients using them in their beds and groups of patients and visitors using them, probably around doorways and entrances creating potential obstruction issues.	which can be applied to secondary care. Public Health England has published 'Use of e-cigarettes in public places and workplaces: Advice to inform evidence-based policy making' (July 2016), which could potentially be a good implementation tool to aid practice relating to PH48.
Research recommendations		
RR – 03 What is the effect and acceptability of approaches that aim to match nicotine dose (through licensed nicotine-containing products) to level of smoking addiction among women who are using maternity services?		
Please see evidence under recommendation 4	Please see intelligence under recommendation 4	This area is currently included as part of the review and proposed update of PH26 Quitting smoking in pregnancy and following childbirth
RR – 04 Are stop smoking interventions that include incentives to quit effective and cost effective for people using secondary care services, including women who are pregnant or have recently given birth?		
Please see evidence under recommendation 4	Please see intelligence under recommendation 4	This area is currently included as part of the review and proposed update of PH26 Quitting smoking in pregnancy and following childbirth .
RR – 09 How can people who use secondary care services (particularly mental health services), staff and visitors, best be helped to temporarily abstain from smoking while in secondary care settings?		
Please see evidence under recommendation 3 and 6.	Please see intelligence under recommendation 3 and 6	Area suggested for update in Tobacco: harm-reduction approaches to smoking PH45 rec 8.

No new evidence was identified that would impact on recommendations: 5, 7-10, 12-16, or research recommendations: 1-2, 5-8.

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