HEALTH EVIDENCE REVIEW COMMISSION (HERC)

COVERAGE GUIDANCE AND MULTISECTOR INTERVENTION REPORT:

TOBACCO CESSATION DURING PREGNANCY

Approved 8/11/2016

HERC Coverage Guidance

For women who use tobacco during pregnancy, the following interventions to aid in tobacco cessation are recommended for coverage:

- Behavioral interventions (*strong recommendation*)
- Financial incentives (incentives contingent upon laboratory tests confirming tobacco abstinence are the most effective) (*weak recommendation)*
- Prenatal ultrasound with feedback around smoking impacts on the fetus *(weak recommendation)*

The following interventions are not recommended for coverage:

- Electronic nicotine delivery systems *(strong recommendation)*
- Counseling-based interventions to reduce secondhand smoke exposure (*weak recommendation)*

Federal law requires coverage of tobacco cessation services, including FDA-approved pharmacotherapy, for pregnant women. There is insufficient evidence of effectiveness of pharmacotherapy on critical pregnancy-related outcomes. Coverage should be based on evidence for the use of pharmacological smoking cessation therapies in adults and adolescents with attention to their safety profiles in pregnant women.

Note: Definitions for strength of recommendation are provided in Appendix A *GRADE Informed Framework Element Description*.

Multisector Interventions

To reduce the use of tobacco during pregnancy and improve associated outcomes, the evidence supports the following interventions:

- Financial incentives (incentives contingent upon laboratory tests confirming tobacco abstinence are the most effective) (*weak recommendation)*
- Smoke-free legislation
- Tobacco excise taxes

No or insufficient evidence is available for the following:

- Internet or text messaging based interventions
- Mass media campaigns specific to pregnant women

RATIONALE FOR DEVELOPMENT OF COVERAGE GUIDANCES AND MULTISECTOR INTERVENTION REPORTS

Coverage guidances are developed to inform coverage recommendations for public and private health plans in Oregon as they seek to improve patient experience of care, population health and the cost-effectiveness of health care. In the era of the Affordable Care Act and health system transformation, reaching these goals may require a focus on population-based health interventions from a variety of sectors as well as individually-focused clinical care. Multisector intervention reports will be developed to address these population-based health interventions or other types of interventions that happen outside of the typical clinical setting.

HERC selects topics for its reports to guide public and private payers based on the following principles:

- Represents a significant burden of disease or health problem
- Represents important uncertainty with regard to effectiveness or harms
- Represents important variation or controversy in implementation or practice
- Represents high costs or significant economic impact
- Topic is of high public interest

Our reports are based on a review of the relevant research applicable to the intervention(s) in question. For coverage guidances, which focus on clinical interventions and modes of care, evidence is evaluated using an adaptation of the GRADE methodology. For more information on coverage guidance methodology, see Appendix A.

Multisector interventions can be effective ways to prevent, treat or manage disease at a population level. For some conditions, the HERC has reviewed evidence and identified effective interventions, but has not made coverage recommendations, as many of these policies are implemented in settings beyond traditional healthcare delivery systems.

GRADE-INFORMED FRAMEWORK

The HERC develops recommendations by using the concepts of the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) system. GRADE is a transparent and structured process for developing and presenting evidence and for carrying out the steps involved in developing recommendations. There are several elements that determine the strength of a recommendation, as listed in the table below. The HERC reviews the evidence and makes an assessment of each element, which in turn is used to develop the recommendations presented in the coverage guidance box. Estimates of effect are derived from the evidence presented in this document. The level of confidence in the estimate is determined by the Commission based on assessment of two independent reviewers from the Center for Evidence-based Policy. Unless otherwise noted, estimated resource allocation, values and preferences, and other considerations are assessments of the Commission.

Coverage question: Should pharmacotherapy or electronic nicotine delivery systems be recommended for coverage for tobacco cessation in pregnancy?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
Pregnancy complications *(Critical outcome)*	Miscarriage and spontaneous abortion: 7/923 (0.7%) in NRT groups vs. 4/859 (0.4%) in control groups RR 1.47 (95% CI 0.45 to 4.77) ●●●○ *(Moderate confidence, based on 4 RCTs, N=1782)* Preterm birth (<37 weeks): 101/1053 (9.5%) in NRT groups vs. 104/995 (10.4%) in control groups RR 0.87 (95% CI 0.67 to 1.14) ●●●○ *(Moderate confidence, based on 6 RCTs, N=2048)*	The costs of medications for smoking cessation are moderate, but there are no projected savings given the lack of proven effectiveness and lack of impact on health outcomes.	Pregnancy can be a motivating time for many women who wish to quit using cigarettes. However, pregnant women may be concerned about the use of medications which have not been proven safe, or effective during pregnancy. There is likely significant variability in	The only pharmacotherapies for which studies were found were nicotine replacement therapies. Bupropion is considered relatively low risk in pregnancy (pregnancy class B), varenicline has some potential level of risk and it is

Coverage question: Should pharmacotherapy or electronic nicotine delivery systems be recommended for coverage for tobacco cessation in pregnancy?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
Low birth weight *(Critical outcome)*	<2500 grams: 107/1043 (1.0%) in NRT groups 112/994 (1.1%) in control groups RR 0.74 (95% CI 0.41 to 1.34) ●●●○ *(Moderate confidence, based on 6 RCTs, N=2037)*		women's interest in using medications to assist smoking cessation.	unclear if risk outweighs benefit (pregnancy class C), and nicotine and nortriptyline have evidence of risk (pregnancy class D).
Perinatal/infant death *(Critical outcome)*	Stillbirth: 14/920 (1.5%) in NRT groups vs. 10/857 (1.1%) in control groups RR 1.24 (95% CI 0.54 to 2.84) ●●●○ *(Moderate confidence, based on 4 RCTs, N=1777)* Neonatal death: 4/898 (0.4%) in NRT groups vs. 5/848 (0.5%) in control groups RR 0.66 (95% CI 0.17 to 2.62) ●●●○ *(Moderate confidence, based on 4 RCTs, N=1746)*			
Tobacco abstinence during pregnancy *(Important outcome)*	All trials: 143/1133 (12.6%) in NRT groups vs. 91/1066 (8.5%) in control groups ARD 4.1% (95% CI 0.25% to 8%) NNT=25: For 1000 patients treated, 40 will be tobacco abstinent during pregnancy (RR 1.41, 95% CI 1.03 to 1.93)			

Coverage question: Should pharmacotherapy or electronic nicotine delivery systems be recommended for coverage for tobacco cessation in pregnancy?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
	●●●● *(High confidence, based on 8 RCTs, N=2199)* Placebo controlled trials: 118/965 (12.2%) in NRT groups vs. 90/961 (9.3%) in control groups (RR 1.28, 95% CI 0.99 to 1.66) ●●●○ *(Moderate confidence, based on 5 RCTs, N=1926)*			
Tobacco abstinence after pregnancy *(Important outcome)*	At 3 to 6 months postpartum: 61/346 (17.6%) in the NRT groups vs. 40/279 (14.3%) in the control groups RR 1.22 (95% CI 0.84 to 1.77) ●●●○ *(Moderate confidence, based on 3 RCTs, N=625)*			
Balance of benefits and harms: There was no definite evidence of benefit from NRT in the highest quality trials, but also no evidence that NRT was harmful. Looking at all randomized trials of NRT (including those without a placebo control arm), there appears to be a benefit of NRT for tobacco abstinence during pregnancy. Inadequate evidence is available to address the relative benefits and harms of other types of pharmacotherapy or electronic cigarettes.				
Rationale: Pharmacotherapy with NRT appears to be ineffective at reducing maternal and fetal harms. Nicotine replacement therapy may improve tobacco abstinence during pregnancy, however, this does not appear to translate to improved health outcomes. In comparison with behavioral interventions, there is an improvement in abstinence and an improvement in preterm birth and low birth weight. Given a lack of proven benefit, an effective alternative (behavioral counseling), a possibility of harm, associated costs, and mixed values and preferences, a recommendation against coverage would be considered. Federal law requires some payers (including Medicaid) to cover pharmacotherapy for pregnant women who smoke tobacco.				

Coverage question: Should pharmacotherapy or electronic nicotine delivery systems be recommended for coverage for tobacco cessation in pregnancy?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
There are no studies on electronic nicotine delivery systems in pregnant women. Given the lack of proven benefit, unknown harms, and costs, they are recommended for noncoverage.				
Recommendation: No recommendation about pharmacotherapy given federal law requiring coverage. Electronic nicotine delivery systems are not recommended for coverage *(strong recommendation).*				

Note: GRADE framework elements are described in Appendix A. A GRADE Evidence Profile is provided in Appendix B.

Coverage question: Should behavioral interventions be recommended for coverage for tobacco cessation in pregnancy?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
Pregnancy complications *(Critical outcome)*	Preterm birth (<37 weeks): 251/3992 (6.3%) in intervention groups vs. 307/3860 (7.9%) in control groups ARR 1.6% (95% CI 0.3% to 2.4%) NNT=62: For 1000 patients treated, 16 fewer will have a preterm birth RR 0.82 (95% CI 0.70 to 0.96) ●●●○ *(Moderate confidence, based on 14 RCTs and cluster-randomized trials, N=7852)*	The cost for behavioral interventions is likely moderate. The benefits of decreased low birth weight and preterm labor could result in substantially lower costs.	Many women who are motivated to quit smoking during pregnancy would likely be interested in behavioral interventions to quit smoking. There may be some groups of women or some particular types of behavioral interventions that drive women to smoke more, and	Behavioral interventions can encompass a wide range of types and intensity of interventions. The 5As approach is widely endorsed.
Low birth weight *(Critical outcome)*	<2500 grams: 304/4298 (7.1%) in intervention groups vs. 381/4264 (8.9%) in control groups ARR 1.8% (95% CI 0.5% to 2.6%) NNT=55: For 1000 patients treated, 18 fewer will have low birth weight babies			

Coverage question: Should behavioral interventions be recommended for coverage for tobacco cessation in pregnancy?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
	RR 0.82 (95% CI 0.71 to 0.94) ●●●○ *(Moderate confidence, based on 14 RCTs and cluster-randomized trials, N=8562)*		these should be better understood.	
Perinatal/infant death *(Critical outcome)*	Stillbirth: 38/2676 (1.4%) in intervention groups vs. 31/2738 (1.1%) in control groups ARR? RR 1.22 (95% CI 0.76 to 1.95) ●●○○ *(Low confidence, based on 7 RCTs and cluster-randomized trials, N=5414)* Neonatal death: 8/1014 (0.8%) in intervention groups vs. 4/1081 (0.4%) in control groups RR 2.06 (95% CI 0.61 to 6.92) ARR ●●○○ *(Low confidence, based on 4 RCTs and cluster-randomized trials, N=2095)*			
Tobacco abstinence during pregnancy *(Important outcome)*	All trials: 1691/11111 (15.2%) in intervention groups vs. 1213/10837 (11.2%) in control groups ARD 4.0% (95% CI 3% to 7.2%) NNT=25: For 1000 patients treated, 40 will be tobacco abstinent during pregnancy RR 1.45 (95% CI 1.27 to 1.64)			

Coverage question: Should behavioral interventions be recommended for coverage for tobacco cessation in pregnancy?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
	●●●○ *(Moderate confidence, based on 70 RCTs and cluster-randomized trials, N=21,948)* Counseling trials with biochemical validation: 453/4478 (10.1%) in intervention groups vs. 402/4772 (8.4%) in control groups ARD 1.7% (95% CI 0.15% to 4.2% NNT=59: For 1000 patients treated, 17 will be tobacco abstinent during pregnancy RR 1.25 (95% CI 1.03 to 1.50) ●●●○ *(Moderate confidence, based on 18 RCTs and cluster-randomized trials, N=9250)*			
Tobacco abstinence after pregnancy *(Important outcome)*	At 12 to 17 months postpartum: 56/298 (18.8%) in the intervention groups vs. 12/133 (9.0%) in the control groups ARD 9.8% (95% CI 2% to 27%) NNT=10: For 1000 patients treated, 100 will be tobacco abstinent after pregnancy RR 2.2 (95% CI 1.23 to 3.96) ●●●○ *(Moderate confidence, based on 2 RCTs and cluster-randomized trials, N=431)* At >18 months postpartum: 21/466 (4.5%) in the intervention groups vs. 17/468 (3.6%) in the control groups RR 1.25 (95% CI 0.57 to 2.73)			

Coverage question: Should behavioral interventions be recommended for coverage for tobacco cessation in pregnancy?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
	●●●○ *(Moderate confidence, based on 2 RCTs, N=934)*			
Balance of benefits and harms: Evidence demonstrates that behavioral interventions are effective for reducing preterm labor and low birth weight and also in improving tobacco cessation during, and for a short time after, pregnancy. There was no definite evidence of harms related to behavioral interventions reported in the trials, though a possible paradoxical effect of increased smoking resulting from resistance to anti-smoking messages was observed in 4 trials.				
Rationale: There is moderate confidence that behavioral interventions increase tobacco abstinence during pregnancy and up to 17 months postpartum. The benefit does not persist beyond 18 months. Behavioral interventions are effective at reducing the incidence of low birth weight and preterm birth. A potential harm is a paradoxical increase in smoking that occurred in four of the seventy studies, but otherwise the intervention carries little risk. The strength of the recommendation is based on evidence demonstrating the significant impact on morbidity, few harms, moderate cost, and some pregnant women who would have a strong interest in the intervention.				
Recommendation: Behavioral interventions are recommended for coverage *(strong recommendation).*				

Coverage question: Should ultrasound with high feedback around the impact of tobacco use on the fetus be recommended for coverage for tobacco cessation in pregnancy?				
Outcomes	**Estimate of Effect for Outcome/** ***Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
Pregnancy complications *(Critical outcome)*	No data	This would involve an increase in reimbursement for additional physician counseling during a prenatal ultrasound and would likely have minimal to modest costs associated with it.	Many women would want to have additional detailed information provided by physicians at the time of an ultrasound, however, the clinical significance of variable findings may be difficult to interpret. If specific harms to the fetus related to tobacco were shown to the pregnant woman, this could create psychological distress.	
Low birth weight *(Critical outcome)*	No data			
Perinatal/infant death *(Critical outcome)*	No data			
Tobacco abstinence during pregnancy *(Important outcome)*	Absolute rate (of cessation): 28.4% in ultrasound with high feedback group vs. 8.1% in controls group ARD 20.3% (95% CI 2% to 55%) NNT=5: For 1000 patients treated, 200 will be tobacco abstinent during pregnancy RR 2.93 (95% CI 1.25 to 6.86) ●●○○ *(Low confidence, based on 1 RCT, N=129)*			
Tobacco abstinence after pregnancy *(Important outcome)*	No data			

Coverage question: Should ultrasound with high feedback around the impact of tobacco use on the fetus be recommended for coverage for tobacco cessation in pregnancy?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
Balance of benefits and harms: The evidence suggests there is a benefit to high feedback ultrasound for tobacco abstinence during pregnancy, but other pregnancy related outcomes have not been studied. The potential harms of this intervention are not well established by this single trial, but since the ultrasound is being performed regardless of the level of feedback, any harms would have to be attributable to the enhanced feedback itself.				
Rationale: There is no evidence available on any of the critical outcomes and on only one of the important outcomes. While the increase in absolute rate of cessation was noteworthy (and higher than any other intervention), it is a single, small RCT with a moderate risk of bias and there is low certainty of the benefit. Additionally, this study was published in 1982 and apparently has not been replicated (or published), which may undermine our confidence in these findings. However, the cost of this may be quite modest. A recommendation for coverage is made at this time; it is a weak recommendation because there is potential for this to change, particularly if additional studies confirm the large increase in tobacco abstinence and if associated health benefits or if harms to the mother were demonstrated.				
Recommendation: Ultrasound with high feedback is recommended for coverage (*weak recommendation*).				

Coverage question: Should financial incentives be recommended for coverage for tobacco cessation in pregnancy?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
Pregnancy complications *(Critical outcome)*	No data	There is a direct, somewhat predictable financial expenditure for the financial incentives. The amounts of incentives used in studies were modest in nature. Performing a	Financial incentives may be quite appealing to many women. One could argue that incentivizing those in poverty raises some ethical concerns, but the	
Low birth weight *(Critical outcome)*	No data			
Perinatal/infant death *(Critical outcome)*	No data			

<table>
<tr><th colspan="5">Coverage question: Should financial incentives be recommended for coverage for tobacco cessation in pregnancy?</th></tr>
<tr><th>Outcomes</th><th>Estimate of Effect for Outcome/
Confidence in Estimate</th><th>Resource allocation</th><th>Values and Preferences</th><th>Other considerations</th></tr>
<tr><td>Tobacco abstinence during pregnancy
(Important outcome)</td><td>180/675 (26.6%) in the incentive groups vs.
56/622 (9.0%) in the control groups
ARD 17.6%
NNT=6: For 1000 patients treated, 167 will be tobacco abstinent during pregnancy
OR 3.79 (95% CI 2.74 to 5.25)
●●●○ (Moderate confidence, based on 8 RCTs, N=1297)</td><td rowspan="2">contingent model of incentives would lower the overall costs based on individual efficacy (a woman would stop receiving incentives if the intervention failed).</td><td rowspan="2">clear potential benefit to the woman and the fetus of smoking cessation, with a lack of harm, mitigates those concerns.</td><td rowspan="2"></td></tr>
<tr><td>Tobacco abstinence after pregnancy
(Important outcome)</td><td>Absolute rate (at 10-24 weeks postpartum):
15.4% in the incentive groups vs.
4.8% in the control groups
ARD 10.6%
NNT=9: For 1000 patients treated, 111 will be tobacco abstinent after pregnancy
OR 3.60 (95% CI 2.39 to 5.43)
●●●○ (Moderate confidence, based on 8 RCTs, N=1295)</td></tr>
<tr><td colspan="5">Balance of benefits and harms: The evidence demonstrates that financial incentives are effective for tobacco abstinence during pregnancy and postpartum, but other pregnancy related outcomes have not been studied. The potential harms of financial incentives have not been well described, but there is the possibility that participants could manipulate the system to earn unmerited financial rewards.</td></tr>
<tr><td colspan="5">Rationale: The evidence supports financial incentives to improve tobacco abstinence during and after pregnancy. The costs of this are relatively modest, and many women would be interested in participating in this model if motivated to quit for additional financial gain. Contingent financial incentives appear to be the most effective. Therefore, this is recommended for coverage. It is a weak recommendation because of the lack of evidence on critical outcomes.</td></tr>
<tr><td colspan="5">Recommendation: Financial incentives (especially those contingent on demonstrated tobacco abstinence) are recommended for coverage (weak recommendation).</td></tr>
</table>

Coverage question: Should financial incentives be recommended for coverage for tobacco cessation in pregnancy?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
As financial incentives are provided in clinical settings, but not typically billed as clinical services, this recommendation is listed both in the Coverage Guidance box and in the Multisector Recommendations box.				

<table>
<tr><td colspan="5">Coverage question: Should clinical interventions to reduce secondhand smoke exposure be recommended for coverage for tobacco cessation in pregnancy?</td></tr>
<tr><td>Outcomes</td><td>Estimate of Effect for Outcome/ Confidence in Estimate</td><td>Resource allocation</td><td>Values and Preferences</td><td>Other considerations</td></tr>
<tr><td>Pregnancy complications
(Critical outcome)</td><td>Preterm birth:
OR 1.24 (95% CI 0.70 to 2.10)
●○○○ (Very low confidence, based on 1 RCT, N=1,025)</td><td rowspan="5">Cost would likely be incremental on top of behavioral counseling or regular clinical visits provided to the tobacco user.</td><td rowspan="5">Most patients interested in tobacco cessation would likely desire reduced exposure to secondhand smoke. Preferences of nearby smokers would be highly variable.</td><td rowspan="5">These studies looked at self-report of exposure to secondhand smoke.</td></tr>
<tr><td>Low birth weight
(Critical outcome)</td><td>OR 1.31 (95% CI 0.77 to 2.24)
●○○○ (Very low confidence, based on 1 RCT, N=1,025)</td></tr>
<tr><td>Perinatal/infant death
(Critical outcome)</td><td>No data</td></tr>
<tr><td>Tobacco abstinence during pregnancy (Important outcome)</td><td>No data</td></tr>
<tr><td>Tobacco abstinence after pregnancy
(Important outcome)</td><td>No data</td></tr>
<tr><td colspan="5">Balance of benefits and harms: Interventions to reduce secondhand smoke appear to be effective for reducing self-reported secondhand smoke exposure, but do not reduce preterm births or low birthweight. There is insufficient information on the harms of interventions to reduce secondhand smoke exposure.</td></tr>
<tr><td colspan="5">Rationale: Clinical interventions to reduce secondhand smoke exposure have very limited quality evidence showing inconclusive results. Therefore, these interventions are not recommended for coverage. The recommendation is weak because additional research may show a benefit.</td></tr>
<tr><td colspan="5">Recommendation: Counseling-based interventions to reduce secondhand smoke exposure are not recommended for coverage (weak recommendation)</td></tr>
</table>

EVIDENCE TABLES FOR MULTISECTOR INTERVENTIONS

Intervention: Smoke-free legislation				
Setting/sector: Local, state and federal governments				
Outcomes	**Estimate of Population Health Effect**	**Resource Impact**	**Public Values and Preferences**	**Other considerations**
Pregnancy Complications *(Critical outcome)*	Smoke-free legislation is associated with an approximately 10% risk reduction for preterm birth (95% CI -18.80 to -2.00) Evidence type: Systematic review of interrupted time series	Limited direct public resource impact to implement legislation; legislation would likely reduce tobacco-related health care and disability-related costs but reduce state tobacco tax revenue due to reduced tobacco use.	Oregon has an existing smoke-free workplace law, including bars and restaurants. Smoke-free legislation has often faced opposition from those with a financial interest in tobacco sales.	
Low birth weight *(Critical Outcome)*	Smoke-free legislation is associated with a -1.70% risk reduction of low birth rate, but the result is not statistically significant (95% CI -5.10 to 1.60) Evidence type: Systematic review of interrupted time series			

Intervention: Tobacco excise taxes				
Setting/sector: Local, state and federal governments				
Outcomes	**Estimate of Population Health Effect**	**Resource Impact**	**Public Values and Preferences**	**Other considerations**
Pregnancy Outcomes *(Critical outcome)* **Preterm birth**	Each $1 increase in tobacco taxes is associated with small reduction (0.07% to 0.08%) in the rate of preterm births Evidence type: Quasi-experimental analysis of US natality files	Increases to tobacco taxes generate revenues to the jurisdiction imposing them and reduce health care costs because of reduced tobacco consumption. Oftentimes, tobacco tax revenue is used to help fund addiction and other health services. Tobacco taxes would reduce tobacco-related healthcare costs to the extent they reduce tobacco use.	Tobacco taxes are common in the United States at the state level, though increases in tobacco taxes face opposition from businesses that generate revenue from tobacco sales. Nonsmokers are generally more in favor of tobacco control policies than smokers. Some argue that tobacco taxes are regressive because low-income and less well-educated populations have higher rates of smoking. Counter arguments are that low-income populations show greater decreases in tobacco use after tax increases, and new tobacco tax revenues can be used to fund tobacco control programs and other health and social services.	
Low birth weight *(Critical Outcome)*	Each $1 increase in tobacco taxes is associated with a small reduction (0.08% to 0.12%) in the rate of low birth weight Evidence type: Quasi-experimental analysis of US natality files			
Perinatal/infant Death *(Critical Outcome)*	Each $1 increase in tobacco taxes is associated with a small reduction (0.19 per 1000) in infant death rate Evidence type: Time series modeling			

Intervention: Tobacco excise taxes				
Setting/sector: Local, state and federal governments				
Outcomes	**Estimate of Population Health Effect**	**Resource Impact**	**Public Values and Preferences**	**Other considerations**
Tobacco abstinence during pregnancy *(Important Outcome)*	Each $1 increase in tobacco taxes is associated with a 2% to 5% reduction in smoking during pregnancy Evidence type: Quasi-experimental and cross-sectional ecological study			
Tobacco abstinence after pregnancy *(Important outcome)*	Each $1 increase in tobacco taxes is associated with a 4% reduction in smoking at 4 months postpartum Evidence type: Cross-sectional ecological study			

EVIDENCE OVERVIEW

Clinical background

In 2014, the rate of smoking at any time during pregnancy was estimated at 8.4% based on the National Vital Statistics Report (Curtin et al., 2016). While this rate represents a substantial improvement over prior decades, smoking during pregnancy remains a major public health problem. Smoking during pregnancy is more common among women aged 20-24 (13%), unmarried women (15%), American Indians or Alaska Natives (18%), Women Infants and Children nutrition assistance recipients (13%), and Medicaid beneficiaries (14%). There is also significant geographic variation in the rate of smoking during pregnancy, ranging from 1.8% in California to 27.1% in West Virginia. In Oregon, the rate of smoking during pregnancy is slightly higher than the overall national average at 10.3%. Among women who smoke in the first or second trimester, only 1 in 5 will successfully quit smoking by the third trimester.

Indications

In addition to the well-established risks of smoking for individual health, smoking in pregnancy entails risks to the fetus, including miscarriage and stillbirth, preterm birth, growth restriction, placental abnormalities and abruption, and premature rupture of membranes (Siu, 2015; American Congress of Obstetricians and Gynecologists (ACOG, 2010). Smoking in the postpartum period is associated with a heightened risk of sudden infant death syndrome and childhood respiratory illnesses (ACOG, 2010). Older data from 2006 suggests that the costs of smoking during pregnancy are substantial and that interventions to promote smoking cessation during pregnancy may be not only cost-effective but cost-saving (ACOG, 2010).

Exposure to secondhand smoke also increases health risks for individuals and can impact pregnancy outcomes. For example, maternal exposure to secondhand smoke increases the risk of having a low birth weight baby and exposure to secondhand smoke increases the risk of sudden infant death syndrome (U.S. Department of Health and Human Services, 2006).

Technology description

Clinical services to aid in tobacco cessation include pharmacological treatments and behavioral interventions. Nicotine (pregnancy category D) is the addictive drug found in tobacco, and nicotine replacement therapy (NRT) can be used to reduce cravings during a quit attempt. NRT is available as transdermal patches, gum, lozenges, sprays, and inhalers. Varenicline (pregnancy category C) is a partial agonist to nicotinic receptors, and it reduces cravings and decreases the pleasurable effects of nicotine. Anti-depressants, such as bupropion (pregnancy category B) and nortriptyline (pregnancy category D) are also used to aid in tobacco cessation.

Behavioral interventions to aid tobacco cessation can be delivered using a variety of methods and in a variety of settings, as summarized by Patnode and colleagues (2015):

> Specific behavioral interventions include, but are not limited to: self-help materials (e.g., written materials, videos, audiotapes, computer), phone-based interventions, quitlines, brief provider-delivered interventions (e.g., advice from a physician or nurse), intensive counseling delivered on an individual basis or in a group including motivational interviewing, mobile phone and text messaging interventions, biomedical risk assessment, and combinations of these approaches (p. 5).

A relatively straightforward behavioral intervention known as the "5As approach" is commonly endorsed by professional societies. The 5As direct providers to ask about tobacco use, advise cessation, assess readiness for change, assist with development of a quit plan, and arrange follow-up. An older systematic review (Melvin et al., 2000) concluded that the use of the 5As approach was associated with a relative risk of 1.7 for smoking cessation (95% CI 1.3 to 2.2).

Financial incentives have been used to increase motivation to quit. These interventions can be implemented in a clinic or in other settings. A behavioral intervention specifically targeting pregnant women is high feedback ultrasounds, where women can see the monitor screen and receive detailed visual and verbal explanations of the ultrasound.

Behavioral interventions can also target a woman's partner or other family members who use tobacco. For women who do not use tobacco, a partner or family member quitting can reduce exposure to secondhand smoke. Interventions that ban smoking in public places, such as smoke-free workplace laws, can also lead to reduced maternal exposure to secondhand smoke.

Increasing the price of tobacco leads to reductions in use, including increasing successful quit attempts. Jurisdictions have increased the price of tobacco by raising tobacco taxes at the local, state, and federal levels.

Key Questions and Outcomes

The following key questions (KQ) guided the evidence search and review described below. For additional details about the review scope and methods, please see Appendix C.

1. What interventions are most effective and most cost-effective to:
    a. Reduce tobacco-related perinatal/infant morbidity and mortality?
    b. Reduce tobacco use in pregnant women?
    c. Sustain tobacco abstinence among women who quit tobacco use during pregnancy?
2. Does effectiveness vary by socioeconomic factors such as race, ethnicity, income, and educational attainment?
3. What models of care would allow these interventions to be implemented most effectively and cost-effectively?

Critical outcomes selected for inclusion in the GRADE table are pregnancy complications, low birth weight, and perinatal/infant death. Important outcomes selected for inclusion in the GRADE table are abstinence from tobacco during pregnancy and long-term tobacco abstinence.

Evidence review

Pharmacologic Treatments

The core sources search identified a Cochrane systematic review of randomized controlled trials (RCTs) of pharmacologic treatments for smoking cessation in pregnancy that was published in December 2015 (Coleman, 2015). The Medline search did not identify any new RCTs published after the search dates of the systematic review, but did identify an economic analysis (Essex et al., 2015) derived from data from one of the included studies in the Cochrane review.

Coleman and colleagues identified nine RCTs for inclusion. Eight of these trials studied nicotine replacement therapy (NRT) using various doses and delivery systems. Five of the trials compared NRT to a placebo control, while three of the trials compared NRT with behavioral support to behavioral support alone. The ninth trial was a small (n=11) RCT of bupropion compared to placebo that reported limited follow-up at nine weeks. There were no trials of other pharmacologic treatments (such as varenicline and nortriptyline) or the use of electronic nicotine delivery systems. Four of the nine trials were conducted in the United States; the remaining trials were conducted in Australia, Canada, or Western Europe. The authors concluded that the risk of bias in the included trials was generally low, notwithstanding concerns over blinding in the three NRT studies that did not use a placebo control. All of the included trials used biochemical validation to ascertain smoking cessation during pregnancy, although the thresholds for positive testing varied.

In the meta-analysis of the eight trials of NRT spanning nearly 2,200 participants, NRT demonstrated a statistically significant improvement in smoking cessation during pregnancy (RR 1.43, 95% CI 1.03 to 1.93). However, when only the five placebo controlled trials of NRT were included, the effect failed to reach statistical significance (RR 1.28, 95% CI 0.99 to 1.68). In the trials that reported continued abstinence from tobacco after pregnancy, NRT did not demonstrate a statistically significant benefit at 6 months (RR 1.15, 95% CI 0.75 to 1.77), nor at 12 or 24 month follow-up.

Four trials of NRT reported on rates of miscarriage or spontaneous abortion; in the meta-analysis, there was no statistically significant effect of NRT on these outcomes (RR 1.47, 95% CI 0.45 to 4.77). Similarly, in the four studies that reported on stillbirth, there was no statistically significant difference between the NRT and control groups (RR 1.24, 95% CI 0.54 to 2.84).

Among six studies reporting birth weights, NRT did not have a statistically significant effect on birth weight (mean difference 100.54 grams, 95% CI -20.84 to 221.91). Similarly, while the incidence of low birth weight was lower in the NRT group, the effect was not statistically significant (RR 0.74, 95% CI 0.41 to 1.34). It should be noted that both analyses found substantial heterogeneity in the studies.

Six studies reported on preterm birth; in the meta-analysis NRT did not have a statistically significant effect on preterm delivery (RR 0.87, 95% CI 0.67 to 1.14). Similarly, meta-analytic results of studies

reporting on neonatal intensive care unit admissions (four studies, RR 0.90, 95% CI 0.64 to 1.27) and neonatal deaths (four studies, RR 0.66, 95% CI 0.17 to 2.62) did not demonstrate a statistically significant effect of NRT.

Earlier systematic reviews had raised concerns that NRT could be associated with a greater risk of Cesarean birth. However, meta-analysis of data from approximately 1,400 women in two studies included in the Coleman review showed no statistically significant difference in the rate of Cesarean section (RR 1.18, 95% CI 0.83 to 1.69). Two of the included studies reported detailed information on serious harms including maternal hypertension, 5 minute Apgar score, arterial cord blood pH, intraventricular hemorrhage, neonatal convulsions, necrotizing enterocolitis, assisted vaginal delivery, and maternal death. With the exception of one study that showed a small (8 mmHg) but statistically significant increase in maternal diastolic blood pressure, there were no other statistically significant differences in serious harms. Non-serious harms were reported in five studies and included headache, dizziness, fatigue, heartburn, nausea, vomiting, and skin irritation. Non-serious harms were not meta-analyzed but generally occurred in less than 10-15% of patients in most studies.

Overall, the authors conclude that there is high-quality evidence of "borderline significance suggesting that nicotine replacement used with behavioural support by pregnant women for smoking cessation may increase smoking abstinence in late pregnancy…." The authors caution that the actual efficacy of NRT for smoking cessation in pregnancy may be closer to the non-statistically significant effect observed in the placebo controlled trials. NRT did not have apparent effects on sustained smoking abstinence after pregnancy, nor on birth outcomes. There was extremely limited evidence on bupropion and no evidence on other pharmacologic treatments such as varenicline and nortriptyline, nor on electronic nicotine delivery systems.

One study identified in the Medline search conducted an economic analysis based on the results of the Smoking, Nicotine, and Pregnancy (SNAP) trial. This economic analysis was done from the perspective of the British National Health Service with a time horizon of up to 7 months. In the SNAP trial (which used nicotine patches as the intervention), the biochemically validated rate of smoking cessation was slightly higher in the NRT group (9.4%) compared to the placebo group (7.6%), though the difference was not statistically significant (RR 1.26, 95% CI 0.82 to 1.96). The authors estimated the incremental cost-effectiveness ratio of NRT to be about £5,000 per quitter (95% CI £-114,128 to £126,747) but also noted the wide confidence interval and the high level of statistical uncertainty.

Behavioral Interventions

The core sources search identified a review of systematic reviews of behavioral interventions for smoking cessation during pregnancy that was prepared by the Agency for Health Research and Quality (AHRQ) in September 2015 (Patnode et al., 2015). The authors of the AHRQ review relied on a good quality Cochrane systematic review of behavioral interventions published by Chamberlain and colleagues in 2013. The Medline search identified one additional RCT published after the search dates of the AHRQ review. The additional trial examined the effectiveness of a physical activity intervention in additional to behavioral support for smoking cessation during pregnancy (Ussher et al., 2015).

The Chamberlain review included 86 RCTs of behavioral interventions for smoking cessation in pregnancy. The included RCTs enrolled healthy pregnant women older than age 16 and most of the studies included women of low socioeconomic status. The interventions in the trials were varied. Among the 77 studies that were included for meta-analysis, 48 examined behavioral counseling interventions, 7 examined clinician feedback, 7 examined health education, 4 examined incentives, and 10 examined social support. Forty-four of the trials compared the behavioral interventions to usual care (information and advice to quit), while in 31 trials the comparator was a less intensive or alternative behavioral intervention. There was no evidence on internet- or text messaging-based interventions in pregnant women, but trials are underway.

The meta-analysis of the effect of behavioral interventions on smoking cessation in late pregnancy included 60 RCTs and 10 cluster-randomized trials spanning nearly 22,000 patients. In the pooled analysis of all behavioral interventions, there was a statistically significant improvement in smoking cessation in late pregnancy (RR 1.45, 95% CI 1.27 to 1.64), albeit with moderate heterogeneity. In the exploratory analysis, a statistical test for sub-group differences found no difference by the type of intervention. When only trials of behavioral counseling interventions were included, the results were similar (RR 1.37, 95% CI 1.17 to 1.59). In the restricted analyses of other intervention types (social support, financial incentives, and feedback), the results were uniformly in the positive direction, but did not achieve statistical significance. It is important to note that not all trials of behavioral interventions used biochemical validation of smoking cessation, but the authors did not find evidence of significant between-group heterogeneity based on the presence or absence of biochemical validation. Indeed, in the subset of behavioral counseling trials that used biochemical validation, the results were attenuated but still statistically significant (RR 1.25, 95% CI 1.03 to 1.50). The AHRQ review did not summarize information on the effects of behavioral interventions on smoking abstinence after pregnancy, though outcomes at 12 to 17 months and >18 months postpartum are reported in the Chamberlain review.

Seven of the trials included in the review reported on stillbirth. The stillbirth event rates in both arms of the study group were very low, and while there was a numerically greater number of stillbirths in the behavioral intervention groups (38/2676 vs. 31/2738 in the control groups), there was no statistically significant difference between the groups (RR 1.22, 95% CI 0.76 to 1.95).

Fourteen trials contributed to the meta-analysis of low-birth weight outcomes (defined as <2500 grams). Behavioral interventions were effective in reducing the incidence of low birth weight (RR 0.82, 95% CI 0.71 to 0.94).

Fourteen trials contributed to the meta-analysis of preterm birth (<37 weeks gestation). Behavioral interventions were effective in reducing the incidence of preterm birth (RR 0.82, 95% CI 0.70 to 0.96).

In the trials of behavioral interventions, there were too few neonatal deaths to draw valid conclusions.

The authors note that reporting of adverse events in trials of behavioral interventions was limited and sporadic. They note that four studies include the possibility of a paradoxical effect of increased smoking (the range of possible effects could include escalation of tobacco use) after a behavioral intervention. Other speculative harms include nicotine withdrawal and the social costs imposed by the loss of partner support, but no trials reported on these potential adverse events.

Overall, the authors of the AHRQ review conclude that there is evidence that behavioral interventions result in statistically significant improvements in smoking cessation during pregnancy as well as some birth outcomes.

As noted, the Medline search identified an additional RCT of a physical activity intervention for smoking cessation in pregnancy (Ussher et al., 2015). The London Exercise and Pregnancy smoking (LEAP) trial, randomized 789 pregnant smokers to behavioral support with a supervised physical activity intervention or to behavioral support alone. The primary outcome was biochemically validated abstinence from smoking during pregnancy. A secondary outcome was self-reported abstinence at 6 months after pregnancy. In the intention-to-treat analysis, there was no statistically significant difference in smoking abstinence at the end of pregnancy (8% in the physical activity group vs. 6% in the control group; OR 1.21, 95% CI 0.70 to 2.10). Similarly, at six months after pregnancy the smoking abstinence rate was 6% in the physical activity group compared to 4% in the control group (OR 1.55, 95% CI 0.81 to 2.97). Thus, the authors conclude that the addition of a structured, supervised physical activity intervention to behavioral support does not improve smoking cessation in pregnancy.

Prenatal Ultrasound with High Feedback

The core sources search identified one Cochrane systematic review of high feedback versus low feedback prenatal ultrasound during pregnancy that included a smoking cessation outcome (Nabhan & Aflaifel, 2015). The CEbP Medline search did not identify any new RCTs published after the search dates of the Cochrane systematic review.

In high feedback ultrasound, "women can see the screen and receive detailed explanations of the images." The authors of the review identified a single RCT of 129 women that demonstrated that high feedback ultrasound led to a statistically significant improvement in smoking cessation during pregnancy (RR 2.93, 95% CI 1.25 to 6.86). The authors assessed the GRADE quality of this evidence to be low.

Financial Incentives

The core sources search identified a Cochrane systematic review of randomized controlled trials and controlled before-and-after studies of financial incentives for smoking cessation during pregnancy (Cahill et al., 2015). The Medline search did not identify any new RCTs published after the search dates of the systematic review.

The Cochrane review included nine studies of financial incentives spanning almost 1,800 pregnant smokers. Eight of the nine studies were conducted in the United States, mostly in clinical settings. The financial incentives in these studies were vouchers for goods or services, not cash payments. The value of the financial awards was up to $250. Four of the trials used incremental awards in which the vouchers reset to baseline values after relapse or missed visits, but could be restored to the previous value when abstinence was re-established. All of the trials also offered standard cessation support to all participants in addition to routine care. All of the studies examined smoking cessation at the end of pregnancy and six of the studies followed participants after pregnancy. Financial incentives for smoking cessation can be included as part of insurance benefit design, but are also provided as direct benefits from employers or other groups.

In the meta-analysis, financial incentives showed statistically significant improvements over controls for smoking cessation at end of pregnancy (OR 3.79, 95% CI 2.74 to 5.25) and at longer follow-up of up to 6 months postpartum (OR 3.60, 95% CI 2.39 to 5.43). In the overall meta-analysis for the primary outcome of smoking cessation at longest follow-up, the likelihood of smoking cessation in the control group was 4.8% compared with 15.4% in the financial incentive group. For all adults, long-term smoking cessation (6-24 months) was 8.4% in the control group and 11.2% in the incentives group.

The authors gave a GRADE quality assessment of moderate for this outcome. The effects on fetal, neonatal, and pregnancy outcomes were not reported.

The authors of the Cochrane review address several operational questions about the use of financial incentives, but these conclusions should be interpreted with caution as they are based on the results of smaller numbers of studies. The authors were unable to draw firm conclusions about the effect of reward size. In four studies, contingent rewards (i.e., incentives that increase with prolonged abstinence) appeared to be more effective than fixed payments (OR 6.26, 95% CI 2.35 to 16.68). In one study, front-loading the reward schedule did not improve the odds of quitting (OR 1.17, 95% CI 0.35 to 3.84). Similarly, there was no statistically significant difference between programs that used participant-initiated verification of abstinence compared with researcher-initiated verification (OR 1.70, 95% CI 0.60 to 4.82).

The authors of the Cochrane review note a paucity of economic analysis of financial incentives. One study cited a report from the National Institute for Health and Clinical Evidence (NICE) that concluded that financial incentives produced a net cost-benefit of £2,261. A second study reported short-term incremental cost per quitter of £1,127 and longer-term cost per quality-adjusted life year of £482 based on projected improvements in maternal outcomes.

None of the pregnancy trials included in the Cochrane review reported on harms or adverse events.

Overall, the authors of the Cochrane review conclude that contingent financial incentives improve smoking abstinence in late pregnancy and into the postpartum period.

A separate study (Lopez et al., 2015) was conducted to explore characteristics associated with successful cessation in three of the trials included in the Cochrane review. The authors of this study conclude that contingent incentives, lower-baseline smoking rate, and a history of quit attempts before pregnancy all predicted successful cessation during pregnancy, but no characteristics were associated with sustained postpartum cessation.

Interventions to Reduce Secondhand Smoke Exposure

The core sources search identified one narrative systematic review of interventions to reduce non-smoking pregnant women's exposure to secondhand smoke (SHS) (Tong et al., 2014). The Medline search did not identify any new RCTs published after the search dates of the systematic review.

The narrative review included five RCTs. Four examined psychosocial interventions of varying intensity, while one combined psychosocial interventions with NRT for partners of pregnant women. The psychosocial interventions ranged from brief clinical interventions performed by obstetricians to eight

sessions spanning pregnancy and the postpartum period that focused on cognitive behavioral strategies delivered by trained counselors. Only one of the studies was done in the United States. The primary outcome was secondhand smoke exposure. Three of the five studies relied on patient reported outcomes rather than biochemical validation of secondhand smoke exposure. Birth outcomes were only reported in one study. Overall, results for secondhand smoke exposure were mixed in the five studies, but the single US-based study (which tested the intensive behavioral counseling intervention detailed above), found a statistically significant reductions in self-reported secondhand smoke exposure (OR 0.57, 95% CI 0.38 to 0.84). The US study was also the only to report birth outcomes; there were no statistically significant differences in the incidence of low birth weight or preterm delivery (<37 weeks).

The overall conclusion offered by the authors is that intervention to reduce SHS exposure during pregnancy may be effective, but firm conclusions are limited by weaknesses in the studies.

Multisector Interventions

Smoke-free legislation

The core sources search identified one systematic review and meta-analysis of the effects of smoke-free legislation on perinatal and child health (Been et al., 2014). The Medline search did not identify any new studies published after the search dates of the systematic review.

Been and colleagues included eleven interrupted time series examining the effects of smoke-free legislation in various countries (five studies in North America and six in Europe). The analysis of perinatal outcomes includes more than 2.5 million births. Most studies were deemed to be at low or moderate risk of bias; only one was felt to be at high risk of bias.

Meta-analytic results were available for two outcomes of interest. Smoke-free legislation was associated with a statistically significant reduction in the risk of preterm birth (risk change -10.4%, 95% CI -18.80 to -2.00) and a non-statistically significant reduction the risk of low birth weight (-1.70%, 95% CI -5.10 to 1.60).

Overall, the authors conclude that there is clear evidence that smoke-free legislation is associated with a reduction in preterm births. The authors further contend that smoke-free legislation is cost-effective because there are no established adverse economic effects of smoking bans, but also note that formal cost-effectiveness studies are lacking.

Tobacco excise taxes

The core sources search did not identify relevant systematic reviews of tobacco taxes and their effects on smoking during pregnancy or birth outcomes. The Medline search identified three observational studies of the effects of tobacco taxes on smoking during pregnancy and perinatal outcomes.

Patrick and colleagues (2015) created a time series model based on data from all fifty states between 1999 and 2010. Based on their multivariate regression model, they concluded there was a statistically significant effect of tobacco taxes such that every $1 increase in the per pack cigarette tax was associated with a reduction in infant deaths (before one year of age) of 0.19 per 1000 live births (95% CI -0.33 to -0.05). The estimated effect was greater for African American infants with a reduction of 0.46 infant death per 1000 live births (95% CI -0.90 to -0.01) for each $1 increase in the per pack tax.

Hawkins and colleagues (2014) performed a quasi-experimental analysis using US natality files of over 16 million singleton births in 28 states between 2000 and 2010 to explore the association of tobacco control policies with birth outcomes. The statistical analysis was done using two models and the results were analyzed by race and educational attainment. In the first model, each $1 increase in the tobacco tax was associated with a reduction in the rate of smoking during pregnancy of 2.4% for white mothers with 0-11 years of education and 2.1% for black mothers with 0-11 years of education. The association of tobacco taxes with reduced smoking in pregnancy continued, but was attenuated, for black mothers of all levels of educational attainment. In the second model, each $1 increase in cigarette taxes was associated with increases in birth weight (5.4 grams among white mothers and 4.0 grams among black mothers, both with 0-11 years of education). Similarly, in the group with 0-11 years of education, each $1 increase in tobacco taxes was associated with a reduction in low birth weight infants (0.08% for white mothers, 0.12% for black mothers) and preterm births (0.07% for white mothers, 0.08% for black mothers). Of note, each $1 increase in tobacco taxes was associated with an increased number of large for gestational age infants of 0.18% for white mothers and 0.10% for black mothers, both with 0-11 years of education. Overall, the authors conclude that increased tobacco taxes are associated with lower rates of smoking during pregnancy and improvements in birth outcomes, including low birth weight and preterm births. These effects are most apparent among women with the lowest levels of educational attainment.

Adams and colleagues (2012) performed a pooled cross-sectional analysis of live births in 29 states and New York City between 2000 and 2005. Using regression modeling, they estimated the effects of various tobacco control interventions including smoking bans, taxes, and overall tobacco control spending on the rates of smoking during pregnancy. The authors found that each $1 increase in tobacco taxes or prices results in a 4% to 5% increase in third trimester smoking abstinence after controlling for other tobacco control policies. Furthermore, each $1 increase in tobacco taxes was also associated with a 4.2% increase in the probability of sustained tobacco cessation at 4 months postpartum.

Full private worksite smoking bans were found to be associated with an estimated increase in third trimester abstinence of approximately 5%.

Of note, cumulative spending on tobacco control did not have an apparent effect on smoking during pregnancy. The results for these outcomes varied by age group and the results appear to be attenuated in older populations.

Models of Care

The available summary literature provides no direct evidence regarding models of care that are associated with effectiveness for these interventions, except where noted for specific interventions above. Overwhelmingly, the individual interventions that were studied were delivered in clinical settings, including interventions like financial incentives. Many of the behavioral interventions rely on the use of interdisciplinary care providers, including trained counselors. The outcomes of maternity care homes for high-risk pregnant women are currently being evaluated by the Center for Medicare and Medicaid Innovation. The included tobacco control policies were mostly implemented at a statewide level, though in some cases local efforts were also included in the analyses. There is limited cost-

effectiveness information that is specific to pregnant smokers. The economic analyses that do exist, particularly for financial incentives, suggest that these interventions are either cost-saving or cost-effective and well below commonly accepted willingness-to-pay thresholds.

EVIDENCE SUMMARY

A number of interventions, both at the individual and community levels, have been studied for their effects on smoking cessation during and after pregnancy as well as birth outcomes. At the individual level, behavioral interventions are effective. Among multisector interventions, financial incentives and tobacco control policies (including smoke-free legislation and tobacco taxes) appear to have the best evidence of effectiveness.

Among pharmacologic interventions, only NRT is well studied. NRT may have a modest effect on reducing smoking during pregnancy, but does not appear to encourage sustained smoking abstinence and does not have apparent effects on birth outcomes. No evidence was identified that examined the effectiveness or harms of other pharmacologic treatments such as varenicline, nortriptyline, or electronic/vaporized cigarettes in pregnant women.

Behavioral interventions (among which behavioral counseling is most commonly studied) appear to be effective in reducing smoking during pregnancy and appear to reduce the incidence of low birth weight and preterm birth.

On the basis of a single RCT, ultrasound with high feedback may increase smoking cessation in late pregnancy.

Contingent financial incentives for smoking cessation appear to be among the most promising interventions and are associated with increased smoking abstinence both during and after pregnancy.

There is limited evidence on programs to reduce secondhand smoke exposure for pregnant women. Data from a US-based RCT suggests that intensive behavioral counseling may reduce self-reported secondhand smoke exposure in pregnancy, but there were no apparent effects on birth outcomes.

Evidence from interrupted time series examining the effects of smoking bans on perinatal outcomes suggests that these interventions reduce the risk of preterm births.

Much of the evidence for behavioral interventions was conducted in populations of low socioeconomic status. In general, studies of tobacco control policies, particularly tobacco taxes, suggest greater effects in African Americans, those with lower levels of educational attainment, and younger populations.

In conclusion, selected individual clinical interventions, financial incentives, and tobacco control policy interventions appear to be effective in reducing smoking during pregnancy and thus improving birth outcomes.

OTHER DECISION FACTORS

Resource Allocation

Complications associated with smoking such as preterm birth and low-birth weight can be very high cost and have significant social implications on a future child's development and productivity. Interventions that are effective at reducing these complications would be highly appealing for coverage. Of the clinical interventions, behavioral interventions have the strongest evidence of benefit of health outcomes. Financial incentives have upfront costs, but these costs were modest and the intervention effective. The multisector interventions would have minimal costs for plans but may face concerns from other sectors.

Values and preferences

Pregnant smokers are often motivated to quit because of the potential health risks for their pregnancy and their infant. Some pregnant women would be highly motivated to find safe and effective strategies to assist them. Behavioral interventions, while effective at improving quit rates and health outcomes, take an additional time commitment on behalf of the woman and would be more appealing to some than others. Financial incentives may be quite sought after by some women. For pharmacotherapy, many women are very uncomfortable with use of medications during pregnancy that are not well studied and proven safe. For them, the risks associated with this without a proven benefit is likely to dissuade their use. For the multisector interventions, there are strong stakeholder interest groups that would have significant concerns about increasing various tobacco control policies. However, such policies already exist in Oregon and other states, and much of the public favors using tobacco taxes to help fund healthcare services.

POLICY LANDSCAPE

Quality measures

The National Quality Measures Clearinghouse includes a large variety of quality measures related to screening/assessment for tobacco use, tobacco use status, and access to treatment. None of these measures specifically focus on women who are pregnant.

Starting in 2016, Oregon's Coordinated Care Organization (CCO) Incentive Measures includes: Percentage of adult Medicaid members (ages 18 and older) who currently smoke cigarettes or use other tobacco products.

Payer coverage policies

Section 4107 of the Affordable Care Act requires state Medicaid programs and most commercial insurance plans to cover comprehensive tobacco cessation services for pregnant women, including counseling and pharmacotherapy, without cost sharing (Centers for Medicare and Medicaid Services, 2011).

The Washington Medicaid program covers prescription (including bupropion SR (Zyban®) and varenicline tartrate Chantix®) and over-the-counter smoking cessation products (including NRT) for pregnant

women through the state's Quitline Program or through a pharmacy. The client must be receiving smoking cessation counseling to be eligible to receive medications. Eight cessation counseling sessions are allowed every 12 months (Washington State Department of Health, 2015).

Multisector Interventions

All the included studies in the systematic review of smoke-free legislation (Been et al., 2014) assessed jurisdictions that had implemented smoke-free legislation for workplaces including bars and restaurants. Thirty states, including Oregon, have implemented smoke-free legislation for workplaces, bars, and restaurants (Campaign for Tobacco-Free Kids [CTFK], 2016a). Oregon's law was passed in 2007 and implemented on January 1, 2009.

Tobacco taxes have been implemented at the federal levels, state, and local levels. The current federal cigarette tax is $1.01 per pack. The average state cigarette tax is $1.61 per pack, ranging from $.017 per pack in Missouri to $4.35 per pack in New York. The tax per pack in Oregon is $1.32 and in Washington it is $3.025 (CTFK, 2016b). In the U.S., over 600 local jurisdictions (e.g., cities, counties) have levied cigarette taxes, as high as $3.00 per pack in Cook County, Illinois, and Juneau, Alaska (CTFK, 2015). In Oregon, state law preempts cities and counties from levying tobacco taxes.

Recommendations from others

United States Preventive Services Task Force

The United States Preventive Services Task Force (USPSTF) guideline was published in September 2015 and is informed by the evidence review conducted by AHRQ (Patnode, 2015). The USPSTF reached the following conclusions:

- Clinicians should "ask all pregnant women about tobacco use, advise them to stop using tobacco, and provide behavioral interventions for cessation…" (A recommendation)
- "[C]urrent evidence is insufficient to assess the balance of benefits and harms of pharmacotherapy interventions for tobacco cessation in pregnant women." (I statement)
- "[C]urrent evidence is insufficient to recommend electronic nicotine delivery systems for tobacco cessation in adults, including pregnant women." (I statement)

The USPSTF also provided information on the components of effective behavioral interventions (for adults in general, not specific to pregnant women) which are excerpted below:

Intensity

- Both minimal (<20 min in 1 visit) and intensive (≥20 min plus >1 follow-up visit) physician-advice interventions effectively increase the proportion of adults who successfully quit smoking and remain abstinent for ≥6 mo.
- There is a dose–response relationship between the intensity of counseling and cessation rates (i.e., more or longer sessions improve cessation rates).

Duration

- Brief, in-person behavioral counseling sessions (<10 min) effectively increase the proportion of adults who successfully quit smoking and remain abstinent for 1 y.

- Although less effective than longer interventions, even minimal interventions (<3 min) have been found to increase cessation rates in some studies.

Frequency

- Multiple sessions should be provided; according to the Public Health Service guidelines, patients should receive ≥4 in-person counseling sessions.
- Cessation rates may plateau after 90 min of total counseling contact time.

Format

- In-person behavioral counseling sessions (individual or group counseling)
- Telephone counseling
- Tailored, print-based self-help materials

Provider

- In-person behavioral counseling sessions: Various types of primary care providers, including physicians, nurses, psychologists, social workers, and cessation counselors
- Telephone counseling: Professional counselors or health care providers who are trained to offer advice over the telephone

Content

- Assessment of smoking status:
    - Ask every patient about tobacco use
    - Advise all tobacco users to quit
    - Assess willingness of all tobacco users to make an attempt to quit
    - Assist all tobacco users with their attempt to quit
    - Arrange follow-up
- Effective counseling interventions provide social support and training in practical problem-solving skills:
    - Training in problem-solving skills includes helping persons who smoke to recognize situations that increase their risk for smoking, develop coping skills to overcome common barriers to quitting, and develop a plan to quit
    - Basic information about smoking and successful quitting should also be provided
    - Complementary practices that improve cessation rates include motivational interviewing, assessing readiness to change, and offering more intensive counseling or referrals

Washington State Department of Health

The Washington State Department of Health issued a revised smoking cessation during pregnancy guideline in 2015. For most clinics, the guideline endorses the use of a brief behavioral intervention based on the "5As" approach created by the American Congress of Obstetricians and Gynecologists. The 5As are ask, advise, assess, assist, and arrange. For clinics that are not able to implement a full 5As approach, the guideline suggests the "2A & R" approach that includes asking about smoking, advising cessation, and referring to cessation resources outside the clinic. The Washington guideline includes advice for implementation at clinics, provider scripts, and suggestions for sustaining cessation postpartum. The guideline does not recommend the routine use of pharmacotherapy for cessation, but

states that in heavy smokers who have failed behavioral interventions that pharmacotherapy may be considered. The guideline also provides additional information about the covered benefits for smoking cessation in the Medicaid program and offers a compendium of outside resources.

North American Quitline Consortium

The North American Quitline Consortium (NAQC) released an issue paper in 2014. Although it is not strictly a clinical practice guideline, it is notable for recommending that pregnant smokers should be offered in-person counseling and that quitlines should be considered an adjunct. It endorses further research into both the effectiveness of quitlines and measures to increase their utilization. It provides established counseling protocols for pregnant and recently postpartum women.

World Health Organization

The World Health Organization released a GRADE-informed guideline in 2013 regarding the prevention and management of tobacco use and secondhand smoke exposure in pregnant women. The recommendations, including the strength of recommendation and evidence quality, is excerpted in the table below on the next page.

WHO recommendations for the prevention and management of tobacco use and second-hand smoke exposure in pregnancy (2013)

No.	Recommendation	Strength of recom-mendation	Quality of Evidence
Identification of tobacco use and second-hand smoke exposure in pregnancy			
1	Health-care providers should ask all pregnant women about their tobacco use (past and present) and exposure to SHS, as early as possible in the pregnancy, and at every antenatal care visit	Strong	Low
Psychosocial interventions for tobacco-use cessation in pregnancy			
2	Health-care providers should routinely offer advice and psychosocial interventions for tobacco cessation to all pregnant women, who are either current tobacco users or recent tobacco quitters.*	Strong	Moderate
Pharmacological interventions for tobacco-use cessation in pregnancy			
3	The panel cannot make a recommendation on use or nonuse of nicotine replacement therapy to support cessation of tobacco use in pregnancy.	Not applicable	Moderate
4	The panel does not recommend use of bupropion or varenicline to support cessation of tobacco use in pregnancy.	Strong	Very Low
5	The panel recommends that further research be carried out in pregnant women on safety, efficacy and factors affecting adherence to pharmacotherapeutic cessation agents.	Strong	Not applicable
Protection from second-hand smoke in pregnancy (smoke-free public places)			
6	All health-care facilities should be smoke-free to protect the health of all staff, patients, and visitors, including pregnant women.	Strong	Low
7	All work and public places should be smoke-free for the protection of everyone, including pregnant women	Strong	Low
Protection from second-hand smoke in pregnancy (smoke-free homes)			
8	Health-care providers should provide pregnant women, their partners and other household members with advice and information about the risks of SHS exposure from all forms of smoked tobacco as well as strategies to reduce SHS in the home.	Strong	Low
9	Health-care providers should, wherever possible, engage directly with partners and other household members to inform them of the risks of SHS exposure to pregnant women from all forms of smoked tobacco, and to promote reduction of exposure and offer smoking cessation support.	Strong	Low

*Recent tobacco quitters may include women who used tobacco before the pregnancy and who have either spontaneously quit or stopped using tobacco in the pre-conception period or in early pregnancy, before their first antenatal visit.

Association of State and Territorial Health Officials

In 2013, the Association of State and Territorial Health Officials (ASTHO) issued recommendations for smoking cessation strategies for women before, during, and after pregnancy. The eight ASTHO recommendations are excerpted below:

1. Provide training and technical assistance to healthcare and public health providers on helping women quit using tobacco before, during, and after pregnancy.
2. Extend pregnancy-specific and postpartum-specific quitline services to women during and after pregnancy.
3. Promote awareness of cessation benefits and effectiveness of treatment by implementing coordinated media campaigns that specifically target women during childbearing years.
4. Develop customized programs for specific at-risk populations of women who are smokers and of reproductive age
5. Include Women, Infants, and Children (WIC) sites as points for intervening with pregnant and postpartum women.
6. Design and promote barrier-free cessation coverage benefits for pregnant and postpartum women in public and private health plans.
7. Promote cessation service integration aimed at improving birth outcomes.
8. Implement evidence-based tobacco control policies that augment tobacco cessation for women before, during, and after pregnancy.

American Congress of Obstetricians and Gynecologists

In 2010, the American Congress of Obstetricians and Gynecologist (ACOG) released a clinician-directed self-instructional guide and toolkit to help pregnant women quit smoking. ACOG endorses the use of the "5As" approach for screening and brief intervention. The 5As are:

- Ask about smoking
- Advise to quit
- Assess willingness to quit
- Assist patient with the process
- Arrange follow-up

The ACOG instructional guide also provides implementation advice and tools for clinics and providers. ACOG endorses the use of tobacco quitlines. ACOG states that pharmacologic treatments should not be used as first-line smoking cessation strategies, but may be considered with close supervision in women who are unable to quit after a trial of behavioral interventions like the 5As approach.

National Institute for Health and Care Excellence

In 2010, the National Institute for Health and Care Excellence (NICE) released a public health guideline regarding smoking cessation in pregnancy and after childbirth. NICE provides eight recommendations directed at midwives, general practitioners, and staff at the National Health Service (NHS) Stop Smoking Services. Salient features of the NICE recommendations include comprehensive screening using history

and exhaled carbon monoxide testing, early referral to behavioral support through Stop Smoking Services program of the NHS, and education for partners who also smoke. Like others, NICE also recommends that NRT not be considered unless other attempts at cessation are unsuccessful and should only be prescribed for two week intervals contingent on validation of smoking cessation.

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Coverage guidance is prepared by the Health Evidence Review Commission (HERC), HERC staff, and subcommittee members. The evidence summary is prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center). This document is intended to guide public and private purchasers in Oregon in making informed decisions about health care services.

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APPENDIX A. GRADE INFORMED FRAMEWORK–ELEMENT DESCRIPTIONS

Element	Description
Balance of benefits and harms	The larger the difference between the desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted. An estimate that is not statistically significant or has a confidence interval crossing a predetermined clinical decision threshold will be downgraded.
Quality of evidence	The higher the quality of evidence, the higher the likelihood that a strong recommendation is warranted.
Resource allocation	The higher the costs of an intervention—that is, the greater the resources consumed in the absence of likely cost offsets—the lower the likelihood that a strong recommendation is warranted.
Values and preferences	The more values and preferences vary, or the greater the uncertainty in values and preferences, the higher the likelihood that a weak recommendation is warranted.
Other considerations	Other considerations include issues about the implementation and operationalization of the technology or intervention in health systems and practices within Oregon.

Strong recommendation

In Favor: The subcommittee concludes that the desirable effects of adherence to a recommendation outweigh the undesirable effects, considering the balance of benefits and harms, resource allocation, values and preferences, and other factors.

Against: The subcommittee concludes that the undesirable effects of adherence to a recommendation outweigh the desirable effects, considering the balance of benefits and harms, resource allocation, values and preferences, and other factors.

Weak recommendation

In Favor: The subcommittee concludes that the desirable effects of adherence to a recommendation probably outweigh the undesirable effects, considering the balance of benefits and harms, resource allocation, values and preferences, and other factors, but further research or additional information could lead to a different conclusion.

Against: The subcommittee concludes that the undesirable effects of adherence to a recommendation probably outweigh the desirable effects, considering the balance of benefits and harms, cost and resource allocation, values and preferences, and other factors, but further research or additional information could lead to a different conclusion.

Confidence in estimate rating across studies for the intervention/outcome[1]

High: The subcommittee is very confident that the true effect lies close to that of the estimate of the effect. Typical sets of studies are RCTs with few or no limitations and the estimate of effect is likely stable.

Moderate: The subcommittee is moderately confident in the estimate of effect: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different. Typical sets of

[1] Includes risk of bias, precision, directness, consistency and publication bias

studies are RCTs with some limitations or well-performed nonrandomized studies with additional strengths that guard against potential bias and have large estimates of effects.

***Low*:** The subcommittee's confidence in the estimate of effect is limited: The true effect may be substantially different from the estimate of the effect. Typical sets of studies are RCTs with serious limitations or nonrandomized studies without special strengths.

***Very low*:** The subcommittee has very little confidence in the estimate of effect: The true effect is likely to be substantially different from the estimate of effect. Typical sets of studies are nonrandomized studies with serious limitations or inconsistent results across studies.

APPENDIX B. GRADE EVIDENCE PROFILE

Pharmacotherapy Quality Assessment (Confidence in Estimate of Effect)							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Pregnancy complications							
Miscarriage 4	RCTs	Low	Not serious	Not serious	Serious	None	Moderate quality ●●●○
Preterm birth 6	RCTs	Low	Not serious	Not serious	Serious	None	Moderate quality ●●●○
Low birth weight							
6	RCTs	Low	Not serious	Not serious	Serious	None	Moderate quality ●●●○
Perinatal/infant death							
4	RCTs	Low	Not serious	Not serious	Serious	None	Moderate quality ●●●○
Tobacco abstinence during pregnancy							
All trials 8	RCTs	Low	Not serious	Not serious	Not serious	None	High quality ●●●●
Placebo Controlled 6	RCTs	Low	Not serious	Not serious	Serious	None	Moderate quality ●●●○
Tobacco abstinence after pregnancy							
3	RCTs	Low	Not serious	Not serious	Serious	None	Moderate quality ●●●○

Behavioral Interventions Quality Assessment (Confidence in Estimate of Effect)							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Pregnancy complications							
Preterm birth 14	RCTs and cluster-randomized trials	Moderate	Not serious	Not serious	Not serious	None	Moderate quality ●●●○
Low birth weight							
14	RCTs and cluster-randomized trials	Moderate	Not serious	Not serious	Not serious	None	Moderate quality ●●●○
Perinatal/infant death							
Stillbirth 7 Neonatal Death 4	RCTs and cluster-randomized trials	Moderate Moderate	Not serious Not serious	Not serious Not serious	Serious Serious	None None	Low quality ●●○○ Low quality ●●○○
Tobacco abstinence during pregnancy							
70	RCTs and cluster-randomized trials	Moderate	Not serious	Not serious	Not serious	None	Moderate quality ●●●○
Tobacco abstinence after pregnancy							
2	RCTs and cluster-randomized trials	Moderate	Not serious	Not serious	Not serious	None	Moderate quality ●●●○

Ultrasound with High Feedback Quality Assessment (Confidence in Estimate of Effect)							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Pregnancy complications							
0							N/A
Low birth weight							
0							N/A
Perinatal/infant death							
0							N/A
Tobacco abstinence during pregnancy							
1	RCT	Moderate	Unknown	Not serious	Serious	None	Low quality ●●○○
Tobacco abstinence after pregnancy							
0							N/A

Financial Incentives Quality Assessment (Confidence in Estimate of Effect)							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Pregnancy complications							
0							N/A
Low birth weight							
0							N/A
Perinatal/infant death							
0							N/A
Tobacco abstinence during pregnancy							
8	RCTs	Low to moderate	Not serious	Not serious	Not serious	None	Moderate quality ●●●○
Tobacco abstinence after pregnancy							
8	RCTs	Low to moderate	Not serious	Not serious	Not serious	None	Moderate quality ●●●○

Secondhand Smoke Interventions Quality Assessment (Confidence in Estimate of Effect)							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Pregnancy complications							
Preterm birth 1	RCT	High	N/A	Not serious	Not serious	None	Very low quality ●○○○
Low birth weight							
1	RCT	High	N/A	Not serious	Not serious	None	Very low quality ●○○○
Perinatal/infant death							
0							N/A
Tobacco abstinence during pregnancy							
0							N/A
Tobacco abstinence after pregnancy							
0							N/A

APPENDIX C. METHODS

Scope Statement

Populations

Women during pregnancy and the postpartum period

Population scoping notes: Includes all forms of tobacco, including e-cigarettes

Interventions

Screening for tobacco use, pharmacotherapy, behavioral interventions (telephonic, in person, individual, group), Internet based interventions, and multisector interventions such as policy, systems, and environmental change

Intervention exclusions: None

Comparators

No care, usual care, other studied interventions

Outcomes

Critical: Pregnancy complications, low birth weight, perinatal/infant death

Important: Abstinence from tobacco during pregnancy, long-term tobacco abstinence

Considered but not selected for the GRADE table: Maternal exposure to secondhand smoke, health benefits to mothers

Key Questions

KQ1: What interventions are most effective and most cost-effective to

a. Reduce tobacco-related perinatal/infant morbidity and mortality?
b. Reduce tobacco use prevalence in pregnant women?
c. Sustain tobacco abstinence after delivery among women who quit tobacco use during pregnancy?

KQ2: Does effectiveness vary by socioeconomic factors such as race, ethnicity, income and educational attainment?

KQ3: What models of care would allow these interventions to be implemented most effectively and cost-effectively?

Search Strategy

A full search of the core sources was conducted to identify systematic reviews, meta-analyses, technology assessments, and clinical practice guidelines using the terms tobacco cessation and pregnancy or pregnant. Searches of core sources were limited to citations published after 2010.

The core sources searched included:

Agency for Healthcare Research and Quality (AHRQ)
Blue Cross/Blue Shield Health Technology Assessment (HTA) program
BMJ Clinical Evidence

Canadian Agency for Drugs and Technologies in Health (CADTH)
Cochrane Library (Wiley Interscience)
Hayes, Inc.
Institute for Clinical and Economic Review (ICER)
Medicaid Evidence-based Decisions Project (MED)
National Institute for Health and Care Excellence (NICE)
Tufts Cost-effectiveness Analysis Registry
Veterans Administration Evidence-based Synthesis Program (ESP)
Washington State Health Technology Assessment Program

A MEDLINE® (Ovid) search was then conducted to identify systematic reviews, meta-analyses, and technology assessments published since 2010. The search was limited to publications in English. For each intervention, a MEDLINE® (Ovid) search was conducted to identify randomized control trials published since the end of the search period for the most recent systematic review.

Searches for clinical practice guidelines were limited to those published since 2010. A search for relevant clinical practice and public health practice guidelines was also conducted, using the following sources:

Australian Government National Health and Medical Research Council (NHMRC)
Centers for Disease Control and Prevention (CDC) – Community Preventive Services
Choosing Wisely
Institute for Clinical Systems Improvement (ICSI)
National Guidelines Clearinghouse
New Zealand Guidelines Group
NICE
Scottish Intercollegiate Guidelines Network (SIGN)
United States Preventive Services Task Force (USPSTF)
Veterans Administration/Department of Defense (VA/DOD)

Inclusion/Exclusion Criteria

Studies were excluded if they were not published in English, did not address the scope statement, or were study designs other than systematic reviews, meta-analyses, technology assessments, or clinical practice guidelines.

APPENDIX D. APPLICABLE CODES

CODES	DESCRIPTION
ICD-10 Diagnosis Codes	
O99.330	Smoking (tobacco) complicating pregnancy, unspecified trimester
O99.331	Smoking (tobacco) complicating pregnancy, first trimester
O99.332	Smoking (tobacco) complicating pregnancy, second trimester
O99.333	Smoking (tobacco) complicating pregnancy, third trimester
O99.334	Smoking (tobacco) complicating childbirth
O99.335	Smoking (tobacco) complicating the puerperium
P96.81	Exposure to environmental tobacco smoke in the perinatal period
F17.200	Nicotine dependence, unspecified, uncomplicated
F17.201	Nicotine dependence, unspecified, in remission
F17.210	Nicotine dependence, cigarettes, uncomplicated
F17.211	Nicotine dependence, cigarettes, in remission
F17.220	Nicotine dependence, chewing tobacco, uncomplicated
F17.221	Nicotine dependence, chewing tobacco, in remission
F17.290	Nicotine dependence, other tobacco product, uncomplicated
F17.291	Nicotine dependence, other tobacco product, in remission
Z71.6	Tobacco abuse counseling
Z87.891	Personal history of nicotine dependence
ICD-10-CM (Procedure Codes)	
HZ90ZZZ	Pharmacotherapy for substance abuse treatment, nicotine replacement
CPT Codes	
99406	Smoking and tobacco cessation counseling visit; intermediate, greater than 3 minutes up to 10 minutes
99407	Smoking or tobacco cessation counseling visit, intensive, greater than 10 minutes
HCPCS Codes	
G0436	Smoking and tobacco cessation counseling visit for the asymptomatic patient; intermediate, greater than 3 minutes, up to 10 minutes
G0437	Smoking and tobacco cessation counseling visit for the asymptomatic patient; intensive, greater than 10 minutes

Note: Inclusion on this list does not guarantee coverage