

**Recommendation 2 Evidence Profile (Indirect Evidence)**

**Recommendation Question:** Should smoking reduction and cessation counseling be recommended for Indigenous women and persons during pregnancy and the post-partum period?

**Recommendation 2:** It is recommended that the circle of care offers smoking reduction and cessation counselling with Indigenous women and persons during pregnancy and the post-partum time. It is important that counseling is provided in a culturally safe way and that it is part of an overall holistic approach to health and wellness.

**Population:** Women and persons during pregnancy and the post-partum period

**Intervention:** All forms of smoking reduction and cessation counselling (individual, group-based, multifaceted, etc.) provided by any health providers in the circle of care

**Comparison:** Usual care and less intensive interventions

**Outcomes:** Abstinence in late pregnancy, abstinence 6-11 months postpartum

**Setting:** All settings

**Bibliography:** 352

Quality assessment							Study details		No. of participants		Reported effects/outcomes	Certainty	Reference
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Country	Intervention	Intervention	Control			
<b>Abstinence in late pregnancy</b> (self-report and/or biochemically validated)													
1 SR (examining 30 primary studies)	Systematic review and meta-analysis of 30 RCTs	Not serious	Not serious	Not serious	Not serious	None	Various	Counselling interventions such as motivational interviewing, cognitive behavior therapy, psychotherapy, relaxation, problem solving	771/6350	546/6082	For every 100 people who receive counseling, there will be 4 more women who abstain from smoking in late pregnancy (ranges from 2 more to 7 more based on confidence	⊕⊕⊕⊕ High <sup>a</sup>	352: Chamberlain et al., 2017

Quality assessment							Study details		No. of participants		Certainty	Reference	
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Country	Intervention	Intervention	Control			Reported effects/outcomes
								facilitation, etc. vs. usual care			intervals).  However, no clear effect when compared to an alternative counselling intervention (RR 1.15, 95% CI 0.86 to 1.53) or if 1 component of a broader maternal health intervention (RR 0.93, 95% CI 0.69 to 1.25).		
<b>Abstinence 6-11 months postpartum (self report and/or biochemically validated)</b>													
1 SR (examining 6 RCTs)	Systematic review and meta-analysis of RCTs	Not serious	Not serious	Not serious	Not serious	None	Various	Counselling interventions such as motivational interviewing, cognitive behaviour therapy, psychotherapy, relaxation, problem	Across 6 primary studies:  Total events = 111/1259	Across 6 primary studies:  Total events = 74/1199	For every 100 people who receive counseling, there will be 2 more women who abstain from smoking at 6-11 months postpartum (ranges from 0 more to 5 more based on confidence	⊕⊕⊕⊕ High	352: Chamberlain et al., 2017

Quality assessment							Study details		No. of participants		Reported effects/outcomes	Certainty	Reference
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Country	Intervention	Intervention	Control			
								solving facilitation, etc. vs. usual care			intervals).		

**Explanations**

- a. As per Chamberlain et al. (2017), “not downgraded for moderate heterogeneity (49%) as while there was some inconsistency in the magnitude, most RRs favoured counselling”.

**Recommendation 2 Evidence Profile (Direct Evidence)**

**Recommendation Question:** Should smoking reduction and cessation counseling be recommended for Indigenous women and persons during pregnancy and the post-partum period?

**Recommendation 2:** It is recommended that as part of a holistic approach to health and wellness, the circle of care offers culturally safe smoking reduction and cessation counselling with Indigenous women and persons during pregnancy and the post-partum time.

**Population:** Indigenous women and persons during pregnancy and the post-partum period

**Intervention:** All forms of smoking reduction and cessation counselling (individual, group-based, multifaceted, etc.) provided by any health providers in the circle of care

**Comparison:** No counselling

**Outcomes:** Reach/engagement, smoking rates (prevalence) (not found within this literature), amount smoked (not found within this literature)

**Setting:** Primary and community care

**Bibliography:** 5, 120, 838, 2829, 26, 31, 1088

Quality assessment							Study details		Reported outcomes		Summary of results	Certainty	Reference
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Country	Intervention	Intervention	Control			
<b>Reach/engagement</b> (measured with: numerical count of the total number and proportion (%) of participants who enrolled (reach) in and/or completed the study (engagement)).													

4	RCT	Not serious	Not serious	Not serious	Serious <sup>a</sup>	None						Overall, there was moderate reach and high engagement across participants.	⊕⊕⊕○ Moderate	
							5: US (Alaska)	5: Treatment component in both groups: Quit Tobacco Program (QTP): counselors provide 3 proactive one-on-one counseling phone calls, educational materials  Intervention group in addition, received biomarker feedback (pts. mailed cotinine test results and counselors reinforced behavior change using motivational interviewing	5: Total n = 30  Study completed by 80% (n=24) completed delivery assessment: n=23, 77%  Treatment Acceptability 87% indicating they would def recommend the program; 62% reported program was very helpful biomarker feedback pts. Rated intervention components as highly acceptable.	5: Total n = 30  Study completed by 80% (n=24) completed delivery assessment: n=23, 77%  Treatment Acceptability 71% indicating they would def recommend the program; 79% reported the program was very helpful.	5: overall, completion rates were relatively high across both groups (80%).		5: Patten et al. (2016)	

							120: Australia and New Zealand	120: Intervention group - counselor encouraged persons to set a quit date. Then 1. cessation guide and 5 A's 2. watch video in private (stories of Alaska Native women who stopped using tobacco during pregnancy); followed by counselor discussion the video, teaching cessation skills, importance of tobacco free homes and families and problem solving of potential barriers to enhance self-efficacy to quit (video was also provided to women to watch at	120: Intervention group: Study retention = 71% (12/17 participants)	120: Comparison group: Study retention = 94% (N=16/17 participants)	120: participation rate was very low with only 12% of eligible women (35/293) enrolled. Among enrolled pts, retention rates were high in both intervention and control group.  Feasibility of recruitment reported: 293 women were referred to study coordinator. Two hundred and twelve (81%) were screened by study coordinator. One hundred and fourteen (54%) were not eligible (reported no tobacco use at screening). Fifty-nine (28%) declined to participate in study. The	120: Patten et al. (2010)
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								<p>home with family) 3. 10-15 min pro-active telephone sessions at weeks 1, 2, 4 &amp; 6</p> <p>Comparison group: counselor encouraged persons to set a quit date. First visit, received 5 min face to face intervention based on 5 A's and 4 pregnancy and culturally specific brochures.</p>			<p>remaining 35 (16%) women were enrolled.</p>		
						26: US (Alaska)	<p>26: Intervention group: All participants receive the usual care provided to Alaska Native (AN) pregnant women in this</p>	<p>26: 188 people (8 villages)</p> <p>Intervention group: Retention at delivery = 86% Retention at 2 months = 75%</p>	<p>26: 164 people (8 villages)</p> <p>Comparison group: Retention at delivery = 92% Retention at 2 months = 80.5%</p>	<p>26: retention was comparable for control and intervention participants at delivery and at 2 months postpartum. However,</p>		26: Patten et al. (2020)	

								<p>region. In addition, interventions villages received a community-wise social marketing campaign, digital stories DVD, brochures and 6 individual peer counseling telephone sessions delivered by Native Sisters.</p> <p>Comparison group: All participants receive the usual care provided to pregnant women in this region (written materials on risks of tobacco use during pregnancy, cessation counseling provided by prenatal care providers (Ask, Advise)</p>	<p>Completion of assessment at 6 months = 84%</p>	<p>Completion at 6 months = 95%</p>	<p>control group participants were more likely to complete the assessment at 6 months</p>		
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								and access to advertising on the Alaska state quit line and other resources via radio, posters, newsletters and flyers.					
							31: Australia	31: health providers who give counselling were provided educational resource packages including live interactive webinars, treatment manuals, patient resources, carbon monoxide (CO) meters, and oral Nicotine Replacement Therapy (NRT). There was no comparison group in this RCT step-wedge trial.	31: Recruitment rates could only be calculated in services one, two, three and four; these varied from 14% to 80%, with 47% (95% CI: 32%, 63%) overall (17/36)	31: step-wedge cluster RCT	31: 22 pregnant women were recruited over 6 months with retention rates of 77%		31: Gould et al., 2019





							and tobacco quit lines.					
							2829: Australia	2829: Stop Smoking in its Tracks (SST) Program: program delivered by Aboriginal Maternal Infant Health Services (AMIHS) midwife and AHWs that included individually tailored counseling, free nicotine replacement therapy after 2 failed quit attempts, engagement with household members, specially developed resources, CBFR (contingency based rewards) and peer support groups.	2829: Acceptability: Twenty-two of 38 eligible women (58%) enrolled in the program. Among enrolled women, 19 (86%) remained in the program to the end of their pregnancy, two were lost to follow-up and one withdrew.	2829: NA	2829: The program was highly acceptable to participants.	2829: Passey & Stirling (2018)
							1088: Australia	1088: ESF	1088: 47	1088: N/A	1088: in	1088: Askew et al., 2019

								<p>(Empowering Strong Families) With 3 components: art activities; case management support; and incentivized smoking cessation support. The case managers provided individualized support to participants from recruitment until 3 months, using individualized, strengths-based, motivational interviewing strategies to encourage and enable participants to reduce or quit smoking. Free NRT was provided. There was no control group.</p>	<p>people were recruited: 31 pregnant women and 16 significant. Seven pregnant women who were referred did not participate</p>		<p>terms of engagement, nearly all participants reported making positive changes to their smoking behaviours by reducing the number of cigarettes they smoked each day or attempting to quit. Many reported building trusting relationships with case managers.</p>		
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## Explanations

- a. Across the 4 included studies, the number of participants was less than 400. We downgraded by 1.0.
- b. From the 3 included studies, 1 was rated with a serious risk of bias and the other two were rated with a low risk of bias using the ROBINS-tool. Reasons for downgrading the one study included serious concerns with confounding and deviation from intended intervention. We downgraded by 0.5.
- c. Across the 3 included studies, the number of participants was less than 400. We downgraded by 1.0.