

Recommendation 1 Evidence Profiles

Recommendation Questions:

Should culturally appropriate and trauma-informed smoking cessation services be recommended?

Should Indigenous community-led smoking cessation (*reduction*) approaches be recommended?

What are the needs (social, cultural, environmental supports) and views (barriers and facilitators) expressed by Indigenous persons of reproductive age, their partners & their families?

Recommendation 1: It is recommended that smoking reduction and cessation services are Indigenous-led and grounded in a holistic approach to health and wellness. The circle of care provides culturally safe and tailored services with perinatal Indigenous women and persons and their support network.

Population: Indigenous persons of reproductive age, their partners & their family members

Intervention: Indigenous smoking cessation approaches (culturally appropriate, community-led cessation services)

Comparison: No culturally appropriate (and trauma-informed) or Indigenous-led smoking (and reduction) cessation services (No intervention)

Outcomes: smoke free spaces [not found within this literature]; quit rates; reach/engagement; decreased smoking rates (prevalence) [not found within this literature]; quit attempts

Setting: health service organizations, Indigenous communities

Bibliography: 26, 31, 224, 837, 838, 1088, 2829

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
Reach/Engagement measured with: Numerical count of the total number and proportion (%) of participants who enrolled (reach) in and/or completed the study (engagement).													
2	Cluster RCT/ Cluster step-wedge	Not serious	Not serious	Not serious	Not serious	None	26: United States (Alaska)	Intervention group: In addition to the smoking cessation usual	n=188 (8 villages) 68% (188/276) of	N=164 (8 villages) 73% (164/208) of	Summary: Two cluster RCT studies were successful in reaching (enrolling) and engaging (completing participation) Indigenous pregnant women into these smoking cessation program trials. 26: The intervention reached 55% (352/637) of pregnant Alaska Native women.	⊕⊕⊕⊕ High	26: Patten et al. (2020)

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								care offered, intervention villages received a community-wide social marketing campaign for Alaska Native pregnant women, digital stories DVD, brochures and 6 individual peer counseling telephone sessions delivered by local Indigenous community Elders (Native Sisters). Comparison group: All participants receive the usual care provided to pregnant women in this region such as referrals to the local smoking cessation program (written materials on risks of tobacco use during pregnancy, cessation counseling provided by prenatal care providers (Ask,	eligible women enrolled were randomized to this group.	women enrolled were randomized to this group.	The enrollment rate was greater in the control group villages.		

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							31: Australia	<p>Advise) and access to advertising on the Alaska state quit line and other resources via radio, posters, newsletters and flyers.</p> <p>A multi-component intervention for HPs at Aboriginal Medical Services (AMSs) in culturally-targeted pregnancy specific smoking cessation care. Educational components included: live interactive webinars, treatment manuals, patient resources, carbon monoxide (CO) meters, and oral Nicotine Replacement Therapy (NRT).</p> <p>Comparison group: as per wedge-step</p>	31: Recruitment rates of pregnant women varied from 14% to 80%, with 47% (95% CI: 32%, 63%) overall (17/36). Service five recruited five women, and service six none.	31: Cluster step-wedge design	31: 22 pregnant women were recruited (reach) over 6 months with retention rates (engagement) of 77%		31 Gould et al. (2019)

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								study design.					
3	Single-arm/cross-sectional	Not serious	Not serious	Not serious	Serious ^a	None	838: New Zealand	Aunties (Maori community health workers), attempted to reach and recruit pregnant women who smoked. They provided culturally tailored supports that included: support and encouragement expressed in a culturally safe way, with love, compassion and support from a local community member. This included encouraging and facilitating early maternity care registration,	838: During 4 months, eight Aunties recruited a total of 67 women (3.7 women per week) who smoked during pregnancy.	NA	Summary: All 3 studies were able to reach and engage pregnant Indigenous women into smoking cessation programs. One study also reached and engaged a smaller number of significant others in the smoking cessation program. 838: Eight Aunties enrolled 67 pregnant women into the intervention study over an 8-month period. It was feasible for Aunties to recruit pregnant Maori women and deliver a variety of cessation methods to those women who would like to stop smoking.	⊕⊕○○ Low	838: Glover et al. (2016)

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							2829: Australia	strong encouragement to quit smoking, and guided the women to use local resources such as NRT and tobacco quit lines. 2829: Stop Smoking in its Tracks (SST) 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, especially developed resources, CBFRR (contingency based rewards) and peer support groups.	2829: 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.	NA	2829: The program was highly acceptable and feasible to participants. <u>Engagement:</u> Twenty-two women enrolled in the intervention. <u>Reach:</u> Nineteen women completed the intervention.		2829: Passey & Stirling (2018)
							1088:		1088: Forty-	NA			

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No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Country	Intervention	Intervention	Control		
							Australia	1088: ESF (Empowering Strong Families) had three key components: art activities; case management support; and incentivized smoking cessation support. The case managers provided individualized support to participants from recruitment until 3 months postpartum. The case managers used individualized, strengths-based, motivational interviewing strategies to encourage and enable participants to reduce or quit smoking. Free nicotine replacement therapy (NRT) was provided,	seven people were recruited: 31 pregnant women and 16 significant others (SOs). Seven pregnant women who were referred did not participate. Two referred women were ineligible: one relocated out of the study catchment and the other was incarcerated between referral and recruitment. The remaining five were eligible. Two agreed to participate, but one miscarried and the		1088: The intervention was able to reach and engage both pregnant Indigenous women and their partners/significant into the smoking reduction and cessation program. <u>Engagement:</u> Thirty-one pregnant women enrolled in the intervention. Sixteen SOs enrolled in the intervention over a 13-month period. <u>Reach:</u> Fourteen women completed the intervention. Seven SOs completed the intervention.	1088: Askew et al. (2019)

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								<p>The level of exhaled carbon monoxide (CO) was assessed using CO monitors. All participants completed assessments at baseline, 2 weeks and 1 month postpartum.</p>	<p>other became uncontactable prior to completion of the baseline assessment. Three declined to participate: two were not interested and one felt she was receiving sufficient support from the COE social worker. Sixteen women nominated significant others. Of these, 13 were the unborn child's father, two were the pregnant women's sister, and one was the woman's sister-in-law.</p>				

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Quit rates measured with: self-reported smoking abstinence (quit rate) & biochemically confirmed tobacco use (cotinine analysis).													
1	Cluster RCT	Serious ^b	Not serious	Not serious	Not serious	None	26: US (Alaska)	26: As above	N= Biochemically confirmed tobacco use at 6 months postpartumw as 86%	N= Biochemically confirmed tobacco use at 6 months postpartum was 82% for control group	No significant study group differences emerged for tobacco use rates at follow-up. Slightly more women were still using tobacco at 6 months postpartum in the intervention group, than in the comparison group.	⊕⊕⊕○ Moderate	26: Patten et al. (2020)
3	Single-arm	Very serious ^d	Not serious	Not serious	Serious ^e	None	837: New Zealand	837: Enlisting "Aunties" intervention: Aunties (Maori community health workers) identified pregnant smokers, reached out to those women, and delivered cessation support (may	n=67 participants completed baseline data collection. Total n=14 participants completed both baseline and follow-up measures. Of the 14 women who	NA	Summary: Three single-arm studies reported improvements in smoking reduction and cessation rates, late in pregnancy or one-month postpartum. 837:: Overall, 36% of the participants who completed the program were no longer smoking a the end of the pregnancy.	⊕○○○ Very Low	837: Glover, Kira & Smith (2016)

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			
							2829: Australia	include NRT). All women received cessation support at an initial visit. The number of subsequent visits was determined by the Aunties. 2829: see above	completed the program, 5 had stopped smoking during their pregnancy. 2829: Of the 19 women who completed the program, 8 were CO-confirmed as not smoking in late pregnancy.	NA	2829: Overall, 42% of the women who completed the program were not smoking in late pregnancy.		2829: Passey & Stirling (2018)
							1088: Australia	1088: See above	n=11 (Women who were able to remain quit). Four women (36%) quit at the 3 months assessment, two (15%) remain smoke free at 1 month	NA	1088: Nearly all participants reported making positive changes (reductions) to their smoking behaviours by reducing the number of cigarettes smoked each day.		1088: Askew et al. (2019)

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			
									postpartum.				
Quit attempts measured with: Numerical counts of: 1. Self-report quit attempt; 2. Self-reported quit attempts in the last 4 weeks lasting at least 24 hours; 3. Mean time (days)													
2	Cluster RCT/Cluster step-wedge	Serious ^c	Not serious	Not serious	Not serious	None	26: US (Alaska) 224: Australia	26: as above 224: See 31 above (31)	26: At delivery - 63% in intervention group reported quit attempt since enrollment. At 2 months post-delivery = 70% reported at least one quit attempt 224: Expectant mothers (n =	26: At delivery - 63% in comparison group reported quit attempt since enrollment. At 2 months post-delivery = 51% reported at least one quit attempt. Further	Summary: Both studies reported multiple quit attempts observed by participants, representing participants' motivation to quit smoking. A positive direction of effect at 2 months postpartum was noted in 1 study (quit attempts were higher in the intervention group, than in the comparison group). 26: Positive direction of effect at 2 months post-delivery. More participants in the intervention group than in comparison group reported quit attempts at 2 months post-delivery (70% vs. 51%). 224: Study participants made multiple attempts	⊕⊕⊕○ Moderate	26: Patten et al. (2020) 224: Bovill

Quality assessment							Study details		No. of participants		Reported effects/outcomes	Certainty	Reference
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								reports another outcome from the same study)	22. 15/16 women still smoking at 4 weeks, 7 (47%) made at least 1 quit attempt that lasted at least 24 hours and 3 (20%) making 2 or more quit attempts.	statistical analysis not reported due to small sample size	to quit smoking (in the last 4 weeks lasting at least 24 hours); the participants made a mean (1.67) number of quit attempts		et al. (2019)
2	Single-arm	Serious ^d	Not serious	Not serious	Serious ^e	None	2829: Australia	2829: see above	2829: n=19 Self-reported quit attempt: All participants: 16/19 (84%) Women smoking at recruitment: 12/15 (80%) Self-reported quit lasting at least 24	NA	Summary: Two single-arm studies report that pregnant Indigenous women made multiple quit attempts to stop smoking. 2829: Most women made multiple attempts before successfully quitting. Relapses to smoking were followed by further quit attempts before becoming consistently abstinent. Of the 19 women who completed the program, 15 (79%) reported a quit attempt lasting ≥24 hours.	Very Low ⊕○○○	2829: Passey & Stirling (2018)

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No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Country	Intervention	Intervention	Control			
							1088: Australia	1088: As above	hours: All participants: 15/19 (79%) Women smoking at recruitment: 11/15 (73%). 1088: Quit attempts (pregnant women) were reported by 38% (5/13) at 2 weeks, 44% (8/18) at 1 month, 64% (7/11) at 3 months and 31% at 1 month postpartum Quit attempts (SOs) were reported by 29% of SOs (2/7) at 2 weeks, 43% (3/7) at 1 month, and 60% (3/5) at both the 3 months post-baseline and	NA	1088: Nearly all participants reported making positive changes to their smoking behaviors by reducing the number of cigarettes they smoked each day or attempting to quit. Quit attempts at time points after intervention began: 2 weeks: 5/13 (38%) 1 month: 8/18 (44%) 3 months: 7/11 (64%) 1 month postpartum: 4/13 (31%)		1088: Askew et al. (2019)

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			
									1-month postpartum assessments. One SO had a successful quit attempt at 3 months. At each assessment, the majority of the 13 SOs smoking at baseline reported reducing the amount they smoked.				

Explanations

^aThe total number of events was <300. We downgraded by 1.0.

^bThe one included study was rated with some concerns for risk of bias due to methodological concerns about how the study was conducted using the ROB 2.0 tool. We downgraded by 1.0.

^cThe two included studies were rated with some concerns for risk of bias due to methodological concerns about how the study was conducted using the ROB 2.0 tool. We downgraded by 1.0

^dFrom the two included studies, 1 was rated with a critical risk of bias and the other with a serious risk of bias due to methodological concerns about how the study was conducted using the ROBINS-I tool. We downgraded by 1.0

^eThe total number of events was < 300. We downgraded by 1.0.

Recommendation 1 CERQual Evidence Profile

Recommendation Question: What are the needs (social, cultural, environmental supports) and views (barriers and facilitators) expressed by Indigenous persons of reproductive age, their partners & their families?

Recommendation 1.0: It is recommended that smoking reduction and cessation services are Indigenous-led and grounded in a holistic approach to health and wellness. The circle of care provides culturally safe and tailored services with perinatal Indigenous women and persons and their support network.

Aim: To explore the social, cultural and environmental needs and views (barriers and facilitators) identified by Indigenous persons of reproductive age, their partners & their families towards nicotine cessation.

Bibliography: 203, 231, 352, 374, 471, 644, 849, 1608, 1609, 2144, 2537, 2725

Finding: Indigenous knowledge keepers were identified by many participants as vital to supporting and promoting nicotine cessation. This includes promoting Indigenous perspectives around health and wellness such as holistic, traditional approaches that include cultural activities.							
Studies contributing to the Finding	Included study designs	CERQual Assessment				Overall CERQual Assessment of Confidence	Explanation of Judgement
		Assessment of Methodological Limitations	Assessment of Relevance	Assessment of Coherence	Assessment of Adequacy of Data		
1 evidence synthesis and meta-ethnography: 1608: Gould, McEwen & Waters (2013) 8 individual studies: 231: Patten et al. (2018) 352: Bovill et al. (2019)	231: Focus groups, individual interviews and thematic analysis 352: Yarning circles and thematic analysis 374: Yarning methodology and inductive thematic analysis 644: Yarning	Moderate concerns due to methodological limitations ^a (Several individual studies lacked consideration of researcher reflexivity. One evidence synthesis of 7 relevant studies [and meta-ethnography] was graded with a low risk of bias).	No concerns	No concerns	No concerns	⊕⊕⊕○ Moderate confidence	This finding was graded as moderate confidence because of moderate concerns regarding methodological limitations.

374: Bovill et al. (2018)	approach using a Narrative yarning methodology						
644: Lyall et al. (2020)							
849: Wyndow, Clifton & Walker (2020)	849: Yarning circles and thematic analysis						
2144: Varcoe, Bottorff, Carey, Sullivan & Williams (2010)	2144: data collected through individual and focus group interviews and participant observation of activities.						
2537: Bottorff et al. (2009)							
2725: Bottorff et al. (2018)	2725: Group consultation, semi-structured interviews and content analysis						
Finding: Persons valued having culturally relevant content integrated within nicotine cessation services.							
5 individual studies		Moderate concerns due to methodological limitations ^b (Some studies did not consider researcher	No concerns	No concerns	No concerns	⊕⊕⊕○ Moderate confidence	This finding was graded as moderate confidence because of moderate concerns regarding methodological limitations in some studies.
231: Patten et al. (2018)	231: Focus groups, individual interviews and thematic analysis						

471: Roberts et al. (2017)	471: Focus groups, semi-structured interviews and inductive thematic analysis	reflexivity or participant confidentiality)					
644: Lyall et al. (2020)	644: Yarning approach using a Narrative yarning methodology						
849: Wyndow, Clifton & Walker (2020)	849: Yarning circles and thematic analysis						
2725: Bottorff et al. (2018)	2725: Semi-structured interviews and inductive thematic analysis						
Finding: Persons preferred health providers that are non-judgmental, understanding and caring and create a comfortable, supportive environment							
1 systematic review and meta-aggregation and 1 evidence synthesis and meta-	374: Yarning methodology and inductive thematic analysis	Minor concerns due to methodological limitations ^c (Several individual studies lacked consideration of	No concerns	No concerns	No concerns	⊕⊕⊕⊕ High confidence	This finding was graded with high confidence because of minor concerns regarding methodological limitations in two individual studies (researchers did not provide reflexivity

<p>ethnography and 5 individual studies:</p> <p>203: Small, Porr, Swab & Murray (2018)</p> <p>1608: Gould, McEwen & Waters (2013)</p> <p>374: Bovill et al. (2018)</p> <p>471: Roberts et al. (2017)</p> <p>644: Lyall et al. (2020)</p> <p>849: Wyndow, Clifton & Walker (2020)</p> <p>1609: Gould, Munn, Avuri, Hoff, Cadet-James, McEwen & Clough (2013)</p>	<p>471: Focus groups, semi-structured interviews and inductive thematic analysis</p> <p>644: Yarning approach using a Narrative yarning methodology</p> <p>849: Yarning circles and thematic analysis</p> <p>1609: Focus groups and constant comparative analysis</p>	<p>researcher reflexivity. Both evidence synthesis were graded with a low risk of bias; one is a systematic review and meta-aggregation of 13 relevant studies, and the other is a qualitative evidence synthesis [and meta-ethnography] of 7 relevant studies).</p>					<p>statements)</p>
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