Recommendation 4 Evidence Profile (Quantitative)

Recommendation Question: Should pharmacotherapy (nicotine replacement therapy [NRT], varenicline, bupropion) for smoking cessation in pregnant and post-partum women and persons be recommended?

Recommendation 4: It is suggested that the circle of care offers nicotine replacement therapy, in addition to counseling, when needed with Indigenous women and persons during pregnancy.

Population: Persons who are pregnant and after childbirth
Intervention: Pharmacotherapy (NRT, varenicline and/or bupropion)
Comparison: No pharmacotherapy (NRT, varenicline and/or bupropion)
Outcomes: Quit rates, miscarriage & spontaneous birth, mean birthweight

Setting: Acute care, community

Bibliography: 10

Quality assessment							Study details		No. of participants			Certainty	Reference
№ of studies	**Study design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Country**	**Intervention**	**Intervention**	**Control**	**Reported effects/outcomes**		
Quit Rates (self-reported abstinence at late pregnancy, and where available, validated using biochemical means)													
1 SR (examining 9 primary studies)	Systematic review of RCTs	Serious[a]	Not serious	Not serious	Serious[b]	None	Various (US: 4 primary studies; Australia, Canada, Denmark, France, England: 1 primary study from each country)	NRT with behavioral support compared with identical placebo and behavioral support of similar intensity	Across 9 primary studies: Total events = 150/1203	Across 9 primary studies: Total events=103/1133	For every 100 people who take NRT with behavioral support, 3 more people will abstain from smoking (ranges from 1 more to 7 more based on confidence intervals).	⊕⊕◯◯ Low	10: Claire et al., 2020

Quality assessment							Study details		No. of participants			Certainty	Reference
№ of studies	**Study design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Country**	**Intervention**	**Intervention**	**Control**	**Reported effects/outcomes**		
Miscarriage and spontaneous abortion													
1 SR (examining 5 primary studies)	Systematic review of RCTs	Not serious	Not serious	Not serious	Very serious[c]	None	Various (US: 3 primary studies; France & England: 1 primary study from each country)	NRT with behavioral support compared with identical placebo and behavioral support of similar intensity	Across 5 primary studies: Total events = 8/990	Across 5 primary studies: Total events = 4/926	For every 1000 people who take NRT with behavioral support, there will be 1 more miscarriage/spontaneous abortion (ranges from 0 more to 2 more based on confidence intervals).	⨁⨁◯◯ Low	10: Claire et al., 2020
Mean birthweight (g)													
1 SR (examining 7 primary studies)	Systematic review of RCTs	Not serious	Serious[d]	Not serious	Serious[e]	None	Various (US: 4 primary studies; France, England & Denmark: 1 primary study from each	NRT with behavioral support compared with identical placebo and behavioral support of similar	1128 infants in intervention group	1074 infants in control group	The mean difference between the intervention and control group was 99.73g (95% CI ranging from -6.65g to 206.1g), favoring the intervention group.	⨁⨁◯◯ Low	10: Claire et al., 2020

Quality assessment							Study details		No. of participants			Certainty	Reference
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Country	Intervention	Intervention	Control	Reported effects/outcomes		
							country)	intensity					

Explanations

a. According to Claire et al., "Downgraded one level due to serious risk of bias: in the subgroup of studies at low or unclear risk of bias the elect was no longer statistically significant, and there were significant subgroup differences when comparing these studies to the three studies judged to be at high risk of bias (P = 0.008)."
b. According to Claire et al., "Downgraded one level due to serious imprecision: there were only 253 events in total (300 to 400 recommended for dichotomous outcomes), and confidence intervals span both minimal clinical benefit and considerable clinical benefit."
c. According to Claire et al., "Downgraded two levels due to very serious imprecision: there were only 12 events in total (300 to 400 recommended for dichotomous outcomes), and confidence intervals encompass both no difference and potential harm."
d. According to Claire et al., "Downgraded one level due to serious inconsistency: I2 = 70%, not explained by subgroup differences".
e. According to Claire et al., "Downgraded one level due to serious imprecision: confidence intervals encompass no difference as well as a clinically significant benefit"