Antenatal

Evidence to Decision Documents (EtDs)

Features of the Evidence to Decision Document Format

- We have *italicised* the repeated sections across all EtDs: the first paragraph of the background section, as well as the Value and Equity sections.
- Where additional material is included within one of the *italicised* sections with repeated content, it is <u>underlined</u> to indicate this portion is new.
- Each EtD includes a Values section and an Equity section, which contain summaries of information from the respective core documents (see Appendices E, F and section 1.2).
- For 'Desirable' and 'Undesirable' effects, we first interpret where the point estimate lies in relation to the threshold. We then decide how certain we are in that effect, considering where the confidence interval lies in relation to the threshold. This is captured in our overall rating in the ‘Certainty of Evidence’ section. We are careful not to 'double count' the confidence interval by somehow integrating it in our description of the point estimate.
- For the ‘Balance of Effect’ section, we take into account both certainty and the point estimate.

Question 1.

Should expression of breastmilk vs. no expression of breastmilk be used for preventing neonatal hypoglycaemia ?	
POPULATION:	Babies at risk of neonatal hypoglycaemia
INTERVENTION:	expression of breastmilk
COMPARISON:	no expression of breastmilk
MAIN OUTCOMES:	- Consideration will be given to the evidence (or lack thereof) for both Māori and non-Māori babies and their whānau. **Critical for making a decision:** 1. Hypoglycaemia (minimum effect size >=20 per 1000 babies) 2. Neurodevelopmental impairment (minimum effect size >=10 per 1000 babies) 3. Admission to special care nursery or neonatal intensive care nursery (minimum effect size >=20 per 1000 babies) 4. Adverse effects (for neonatal mortality minimum effect size >=1 per 1000 babies) 5. Fully breastfeeding at hospital discharge (minimum effect size >=20 per 1000 babies) **Important but not critical:** 1. Separation from the mother for treatment of hypoglycaemia before discharge home (minimum effect size >=20 per 1000 babies) 2. Hypoglycaemic injury on brain imaging (minimum effect size >=10 per 1000 babies) 3. Breastmilk feeding exclusively from birth to hospital discharge (minimum effect size >=20 per 1000 babies) 4. Duration of initial hospital stay (minimum effect size >=0.5 days per baby) 5. Cost (for whānau >=10 NZD per baby, for health system >=100 NZD per baby) **Less important for decision making:** 1. Time to blood glucose normalisation after intervention 2. Receipt of treatment for hypoglycaemia during initial hospital stay 3. Number of episodes of hypoglycaemia 4. Severity of hypoglycaemia 5. Duration of treatment
SETTING:	Any birth settings
PERSPECTIVE:	Clinical recommendation
BACKGROUND:	*Low blood glucose concentrations (hypoglycaemia) are common in newborn babies over the first few days after birth, particularly in those with recognised risk factors (infants of mothers with diabetes, or born preterm, low or high birthweight). Severe or prolonged hypoglycaemia can lead to brain injury, so early detection and treatment is recommended to reduce the risk of later developmental problems.*

	The expression of breastmilk may be associated with improved lactogenesis (breastmilk production) and has been incorporated into many neonatal hypoglycaemia management guidelines worldwide.
CONFLICT OF INTERESTS:	CC, DH, JA, JH, JR and LL are authors of cited paper.

ASSESSMENT

Desirable Effects
How substantial are the desirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Trivial ● Small ○ Moderate ○ Large ○ Varies ○ Don't know	**Maternal expression of breastmilk compared to no expression results in** (1): • Neonatal hypoglycaemia (RCT: small reduction (36 fewer per 1,000); Cohort study: little to no effect) [critical] • Fully breastfeeding at hospital discharge (RCT: moderate increase (73 more per 1,000); non-randomised study of intervention: little to no effect; Cohort study: large increase (279 more per 1000)) [critical] • Moderate reduction in duration of initial hospital stay (1.2 days fewer) [important] No studies reported on the following outcomes: neurodevelopmental impairment, admission to special care nursery or neonatal intensive care nursery, hypoglycaemic injury on brain imaging, breastmilk feeding exclusively from birth to hospital discharge, cost.	**Maternal expression of breastmilk compared to no expression results in** (1): Little to no effect on any breastfeeding after hospital discharge (2 RCTs: 604 babies, RR [95% CI]: 1.01 [0.94 to 1.08]) or exclusive breastfeeding three to four months after birth (2 RCTs: 604 babies, RR [95% CI]: 1.09 [0.95 to 1.25]).

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)	
				Risk with no expression of breast milk	Risk difference with expression of breast milk
Neonatal hypoglycaemia [critical]- RCT	630 (1 RCT)	⨁⨁⨁◯ Moderate[a]	**RR 0.92** (0.77 to 1.10)	Study population	
				454 per 1,000	**36 fewer per 1,000** (104 fewer to 45 more)
				Study population	

Neonatal hypoglycaemia [critical]- Cohort study	303 (1 non-randomised study)	⊕◯◯◯ Very low[a,b]	**OR 1.01** (0.74 to 1.39)	395 per 1,000	**2 more per 1,000** (69 fewer to 81 more)
Neurodevelopmental impairment [critical] - not measured	-	-	-	-	-
Admission to special care nursery or neonatal intensive care nursery [critical] - not measured	-	-	-	-	-
Fully breastfeeding at hospital discharge [critical]- RCT	632 (1 RCT)	⊕⊕◯◯ Low[a,c]	**RR 1.15** (0.99 to 1.33)	Study population	
				489 per 1,000	**73 more per 1,000** (5 fewer to 161 more)
Fully breastfeeding at hospital discharge [critical]- non-randomised study of intervention	656 (1 non-randomised study)	⊕◯◯◯ Very low[a,b]	**RR 1.01** (0.97 to 1.05)	Study population	
				930 per 1,000	**9 more per 1,000** (28 fewer to 47 more)
Fully breastfeeding at hospital discharge [critical]- cohort study	313 (1 non-randomised study)	⊕⊕◯◯ Low[b,d]	**RR 1.50** (1.29 to 1.74)	Study population	
				558 per 1,000	**279 more per 1,000** (162 more to 413 more)
Hypoglycaemic injury on brain imaging [important] - not measured	-	-	-	-	-
Breastmilk feeding exclusively from birth to hospital discharge [important] - not measured	-	-	-	-	-
Duration of initial hospital stay [important]	632 (1 RCT)	⊕⊕◯◯ Low[a,c]	-	The mean duration of initial	MD **1.2 days lower**

					hospital stay [important] was **70.9** days	(9.88 lower to 7.48 higher)
Cost - not measured	-	-	-	-	-

a.Downgraded one level for serious imprecision due to the confidence interval including the possibility of benefit and harm.
b.Downgraded two levels for very serious risk of bias due to high risk of the included study (studies).
c.Downgraded one level for serious risk of bias due to some concerns risk of the included study.
d.Upgraded one level for large effect.
*Absolute effects were calculated based on the control group risk

Considerations for Māori
No additional data available

Considerations or Pacific
No additional data available

Undesirable Effects
How substantial are the undesirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Trivial ● Small ○ Moderate ○ Large ○ Varies ○ Don't know	**Maternal expression of breastmilk compared to no expression** (1): Moderate increase in separation from mother for treatment of neonatal hypoglycaemia (58 more per 1,000) [important] No studies reported on adverse effect for the baby	The DAME randomised trial (2) conducted in Australia (n=635) in women with pre-existing or gestational diabetes compared expressing breastmilk twice per day from 36 weeks' gestation to standard care (usual midwifery and obstetric care, supplemented by support from a diabetes educator). This study reported that 17/317 (5%) of women with diabetes who expressed breastmilk developed hypoglycaemia within 30 minutes of expressing, however, maternal hypoglycaemia was

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)	
				Risk with no expression of breast milk	Risk difference with expression of breast milk
Adverse effects [critical] - not measured	-	-	-	-	-
				Study population	

Separation from mother for treatment of hypoglycaemia before discharge home [important]	89 (1 RCT)	⊕◯◯◯ Very low[a,b]	**RR 1.16** (0.69 to 1.95)	364 per 1,000	**58 more per 1,000** (113 fewer to 345 more)	

a.Downgraded one level for serious risk of bias due to some concerns risk of the included study.

b.Downgraded two levels for very serious imprecision due to the wide confidence interval and small sample size.

Considerations for Māori

No additional data available

Considerations or Pacific

No additional data available

not evident from data provided by the women of their first three blood glucose concentrations after expressing: mean 5.6 mmol/L (SD 1.04, range 3.8 to 13.6; n=199). 10/317 (3%) of women had abdominal pain, and none (0%) had vaginal bleeding within 4 hours after expressing breastmilk. Breastmilk expression did not affect neonatal deaths, preterm births, admission for respiratory support, or neonatal encephalopathy with or without seizures.

Another RCT conducted in the US randomised pregnant women (n=45) to either antenatal expression or a control group that received lactation education handouts. The study reported no significant issues with breastmilk expression. Gestational age at birth, the onset of delayed lactogenesis, neonatal intensive care unit admissions, and the use of infant formula were similar between the breastmilk expression group and the control group (3).

However, some women experienced challenges with antenatal breastmilk expression, including difficulty learning the technique, pain, discomfort, lack of privacy, hand fatigue, perceived decreased fetal movement unrelated to fetal compromise, transient uterine muscle tightening, and feelings of awkwardness during expression (3)(4).

Certainty of evidence
What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
● Very low ○ Low ○ Moderate ○ High ○ No included studies		

Outcomes	Importance	Certainty of the evidence (GRADE)
Neonatal hypoglycaemia [critical]- RCT	CRITICAL	⊕⊕⊕◯ Moderate[a]
Neonatal hypoglycaemia [critical]- Cohort study	CRITICAL	⊕◯◯◯ Very low[a,b]
Neurodevelopmental impairment [critical] - not measured	CRITICAL	-
Admission to special care nursery or neonatal intensive care nursery [critical] - not measured	CRITICAL	-
Adverse effects [critical] - not measured	CRITICAL	-
Fully breastfeeding at hospital discharge [critical]- RCT	CRITICAL	⊕⊕◯◯ Low[a,c]
Fully breastfeeding at hospital discharge [critical]- non-randomised study of intervention	CRITICAL	⊕◯◯◯ Very low[a,b]
Fully breastfeeding at hospital discharge [critical]- cohort study	CRITICAL	⊕⊕◯◯ Low[b,d]
Separation from mother for treatment of hypoglycaemia before discharge home [important]	CRITICAL	⊕◯◯◯ Very low[c,e]
Hypoglycaemic injury on brain imaging [important] - not measured	IMPORTANT	-
Breastmilk feeding exclusively from birth to hospital discharge [important] - not measured	IMPORTANT	-
Duration of initial hospital stay [important]	IMPORTANT	⊕⊕◯◯ Low[a,c]
Cost - not measured	IMPORTANT	-

a.Downgraded one level for serious imprecision due to the confidence interval including the possibility of benefit and harm.

	b.Downgraded two levels for very serious risk of bias due to high risk of the included study (studies). c.Downgraded one level for serious risk of bias due to some concerns risk of the included study. d.Upgraded one level for large effect. e.Downgraded two levels for very serious imprecision due to the wide confidence interval and small sample size. **Considerations for Māori** No additional data available **Considerations or Pacific** No additional data available	
Values Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Important uncertainty or variability ● Possibly important uncertainty or variability ○ Probably no important uncertainty or variability ○ No important uncertainty or variability	***Excerpts from Values summary document*** ***Uncertain value, possible variability*** • *Hypoglycaemia [critical]* • *Adverse effect [critical]* ***High value, no important variability*** • *Neurodevelopmental impairment [critical]* • *Fully breastfeeding at hospital discharge [critical]* • *Breastfeeding exclusively from birth to hospital discharge [important]* ***High value, probably no important variability*** • *Admission to special care nursery or neonatal intensive care nursery [critical]* • *Separation from the mother for treatment of hypoglycaemia before discharge home [important]* • *Duration of initial hospital stay [important]* ***Uncertain value and variability*** • *Hypoglycaemic injury on brain imaging [important]* • *Cost [important]*	

Balance of effects Does the balance between desirable and undesirable effects favor the intervention or the comparison?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ● Probably favors the intervention ○ Favors the intervention ○ Varies ○ Don't know	**Expression of breastmilk compared to no expression of breastmilk** Very low certainty evidence showed • Small reduction in neonatal hypoglycaemia [critical] • Large increase in fully breastfeeding at hospital discharge [critical] • Small reduction in duration of initial hospital stay [important] • Uncertain effect on the separation of the baby from the mother for any treatment [important] • No adverse effects for the baby, but some adverse effects for some mothers **Considerations for Māori** No additional data available **Considerations or Pacific** No additional data available	All the studies included are of antenatal expression, not expression of breastmilk after the birth.
Resources required How large are the resource requirements (costs)?"		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Large costs ○ Moderate costs ● Negligible costs and savings ○ Moderate savings ○ Large savings ○ Varies ○ Don't know	No evidence of the resources required.	Resources required to collect and store expressed breastmilk postnatally are expected to be variable. Some of the necessary resources for obtaining expressed breastmilk include: Breastmilk pump: This may be manual or electric with variable quality and price. Storage: If it is given to the baby within 4 hours, expressed breastmilk can be stored at room temperature. Expressed breastmilk can also be refrigerated if it will be given within 48

		hours, and frozen if given within two weeks of collection. Cleaning expressing equipment: washing with detergent and water, sterilising (boiling or sterilising solution).
Certainty of evidence of required resources What is the certainty of the evidence of resource requirements (costs)?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Very low ○ Low ○ Moderate ○ High ● No included studies	We did not find any studies about the required resources.	
Cost effectiveness Does the cost-effectiveness of the intervention favor the intervention or the comparison?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ○ Probably favors the intervention ○ Favors the intervention ○ Varies ● No included studies	We did not find any studies about the required resources.	
Equity What would be the impact on health equity?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**

○ Reduced ○ Probably reduced ○ Probably no impact ● Probably increased ○ Increased ○ Varies ○ Don't know	***Are there groups or settings that might be disadvantaged in relation to the problem or intervention of interest?*** *There is little published literature and therefore it is unclear if there are any groups or settings that might be disadvantaged in relation to the problem or intervention of interest.* ***Are there plausible reasons for anticipating differences in the relative effectiveness of the intervention for disadvantaged groups or settings?*** *There is little published literature. It is unlikely that the effectiveness of interventions would differ for disadvantaged groups or settings. However, within Aotearoa New Zealand, social determinants of health (e.g., colonisation, racism, income, education, employment and housing) are likely to have an impact on the implementation, and therefore the effectiveness, of interventions.* ***Are there different baseline conditions across groups or settings that affect the absolute effectiveness of the intervention for the importance of the problem for disadvantaged groups or settings?*** *Māori babies (190/530, 35.8%) are more likely to be at risk of hypoglycaemia than New Zealand Europeans (660/2529, 26.1%)* (7)*. However, in the Sugar Babies study of 514 babies at risk of neonatal hypoglycaemia in Aotearoa New Zealand, the proportion of babies who developed hypoglycaemia was similar in Māori babies (79/150, 53%) to that in the whole cohort (260/514, 51%)* (8)*.* *Pacific babies (282/693, 40.7%) are more likely to be at risk of hypoglycaemia than New Zealand Europeans (660/2529, 26.1%)* (7)*.* *In the Sugar Babies study of 514 babies at risk of neonatal hypoglycaemia in Aotearoa New Zealand, the number of Pacific babies was very small, but the proportion who developed hypoglycaemia was similar to that in the whole cohort (6/16, 38% vs 260/514, 51%)* (8)*.* *Asian babies (660/2068, 31.9%) are more likely to be at risk of hypoglycaemia than New Zealand Europeans (660/2529, 26.1%)*(7). ***Are there important considerations that people implementing the intervention should consider in order to ensure that inequities are reduced, if possible, and that they are not increased?*** ***Consideration for Māori*** *In the Whānau Experience study* (5)*, participants expressed appreciation for the inclusion of karakia and tikanga before certain interventions.* *Māori are more likely to experience interpersonal, institutional, and structural racism, which requires intentional action on addressing racism within these three levels of racism* (9)(10)(11)*.*	

	Additionally, a systematic literature review by Graham et al. (12) *provides a summary of 20 years of data from whānau Māori experiences in the public health and/or hospital system. A key barrier included perception of racism or discrimination amongst whānau Māori. For instance, perceiving healthcare professionals to be uninterested in their health and wellbeing. Whānau Māori had good experiences when engaging with Māori healthcare providers when they provided whanaungatanga and were "just so welcoming"* (12). ***Consideration for Pacific*** *Some Pacific women interviewed in the Whānau Experience study reported difficulties with accessing the hospital due to cost, transportation and limited availability with work* (5). ***Other considerations*** *The Ministry of Health identify four priority groups for maternity care. These are Māori, Pacific, younger women (<25 years) and women with disabilities* (6)*. Most pregnancy, hospital and well child care is free for Aotearoa New Zealand citizens and other eligible women, but accessing these services may incur costs that are challenging for families with limited resources. In addition, there may be a charge if families use some private or specialist services. In the 2014 Maternity Consumer Survey* (6)*, 71% of women reported that they had paid for at least one pregnancy-related service. Māori, Pacific and younger women were less likely to have paid for services.*	
Acceptability Is the intervention acceptable to key stakeholders?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ No ○ Probably no ● Probably yes ○ Yes ○ Varies ○ Don't know	Women felt positive and prepared for their baby's birth after engaging in the antenatal expression of breastmilk (13). Some also reported confidence and mastery of breastmilk expression (14). A study conducted in United States among non-diabetic mothers (n=45) reported that, of the 18 participants who received the antenatal milk expression intervention, most mothers practised expression at least once each day (80% (12/15) at 37 weeks; 61% (11/18) at 38 weeks; 71% (10/14) at 39 weeks, and 100% (7/7) at 40 weeks) (3). All 18 participants in the intervention group reported practising expression of breastmilk on at least 60% of days between enrolment into the RCT and the birth of their babies and 16/18 (89%) of women on at least 80% of days. Maternal breastmilk expression was, however, reported to be associated with difficulty learning the technique, pain, social pressure, discomfort, lack of privacy, time and energy	

	consumption, hand fatigue and feelings of awkwardness while expressing, which may limit acceptability (3)(14)(15). Antenatal breastmilk expression was associated with high satisfaction among the study participants (4). Another survey conducted in the UK involving 688 breastfeeding mothers reported that more than half participants (58.6%) were unsure if antenatal breast expression was a good idea; however, 80.9% would consider doing antenatal breast expression if it was found to be helpful to prepare for breastfeeding. Participants expressed concerns about the potential harm of antenatal breast expression, including procedure-related pain and the risk of inducing preterm labour (16). **Considerations for Māori** A qualitative study on factors influencing feeding practices among Māori mothers aged 15-24 years revealed that these mothers consistently emphasised the significance of healthcare professionals dedicating time to provide support and guidance in breastfeeding, including the expression of breastmilk. They valued being taught how to express breastmilk because it provided milk to feed their sick babies, even when they had cracked or sore nipples (15). Many stressed the need for both manual hand expression and the use of a breast pump to supply breastmilk for their babies and to relieve painful nipples. Some also shared their personal experiences with hand expression, highlighting its discomfort and lack of enjoyment (15). **Considerations or Pacific** No additional data available	
Feasibility Is the intervention feasible to implement?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ No ○ Probably no ● Probably yes ○ Yes ○ Varies ○ Don't know	Expression of breastmilk is feasible in Aotearoa New Zealand. **Considerations for Māori** No additional data available **Considerations or Pacific** No additional data available	

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
DESIRABLE EFFECTS	Trivial	**Small**	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Trivial	**Small**	Moderate	Large		Varies	Don't know
CERTAINTY OF EVIDENCE	**Very low**	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	**Possibly important uncertainty or variability**	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	**Probably favors the intervention**	Favors the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	Moderate costs	**Negligible costs and savings**	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			**No included studies**
COST EFFECTIVENESS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	**No included studies**
EQUITY	Reduced	Probably reduced	Probably no impact	**Probably increased**	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	**Probably yes**	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	**Probably yes**	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention	Conditional recommendation against the intervention	Conditional recommendation for either the intervention or the comparison	**Conditional recommendation for the intervention**	Strong recommendation for the intervention
○	○	○	●	○

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Question 2.

Should tighter maternal glycaemic control during pregnancy in women with diabetes vs. less-tight maternal glycaemic control during pregnancy be used for preventing neonatal hypoglycaemia?	
POPULATION:	Newborn babies whose mothers have diabetes
INTERVENTION:	tighter maternal glycaemic control during pregnancy in women with diabetes
COMPARISON:	less-tight maternal glycaemic control during pregnancy
MAIN OUTCOMES:	- Consideration will be given to the evidence (or lack thereof) for both Māori and non-Māori babies and their whānau. **Critical for making a decision:** 1. Hypoglycaemia (minimum effect size >=20 per 1000 babies) 2. Neurodevelopmental impairment (minimum effect size >=10 per 1000 babies) 3. Admission to special care nursery or neonatal intensive care nursery (minimum effect size >=20 per 1000 babies) 4. Adverse effects (for neonatal mortality minimum effect size >=1 per 1000 babies) 5. Fully breastfeeding at hospital discharge (minimum effect size >=20 per 1000 babies) **Important but not critical:** 1. Separation from the mother for treatment of hypoglycaemia before discharge home (minimum effect size >=20 per 1000 babies) 2. Hypoglycaemic injury on brain imaging (minimum effect size >=10 per 1000 babies) 3. Breastmilk feeding exclusively from birth to hospital discharge (minimum effect size >=20 per 1000 babies)

	4. Duration of initial hospital stay (minimum effect size >=0.5 days per baby) 5. Cost (for whānau >=10 NZD per baby, for health system >=100 NZD per baby) **Less important for decision making:** 1. Time to blood glucose normalisation after intervention 2. Receipt of treatment for hypoglycaemia during initial hospital stay 3. Number of episodes of hypoglycaemia 4. Severity of hypoglycaemia 5. Duration of treatment
SETTING:	Any birth settings
PERSPECTIVE:	Clinical recommendation
BACKGROUND:	*Low blood glucose concentrations (hypoglycaemia) are common in newborn babies over the first few days after birth, particularly in those with recognised risk factor (babies of mothers with diabetes, or born preterm, low or high birthweight). Severe or prolonged hypoglycaemia can lead to brain injury, so early detection and treatment is recommended to reduce the risk of later developmental problems.* Neonatal hypoglycaemia is a common problem in babies of diabetic mothers. These babies are at increased risk of low blood glucose concentrations, owing to the sudden halt in abundant glucose supply via the placenta at the time of cord clamping. Rates of diabetes, including gestational diabetes mellitus (GDM) are rising globally. This places more babies at risk of hypoglycaemia, with the subsequent risk of neurodevelopmental impairment due to this condition. A potential strategy for minimising the risk of hypoglycaemia in the baby is achieving tight glycaemic control in the mother. Therefore, we aimed to explore whether tight glycaemic control in mothers with diabetes is more effective than less tight control as a prevention strategy for neonatal hypoglycaemia and its sequelae.
CONFLICT OF INTERESTS:	CC, CM, DH, JA, JH, JR and LL are authors of the cited studies.

ASSESSMENT

Desirable Effects How substantial are the desirable anticipated effects?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Trivial ● Small	**Tighter maternal glycaemic control during pregnancy compared to less-tight maternal glycaemic control results in** (1):	The targets for glycaemic control in women with gestational diabetes vary

○ Moderate ○ Large ○ Varies ○ Don't know	• Little to no effect on neonatal hypoglycaemia [critical], and duration of initial hospital stay [important] • Small reduction in admission to special care nursery or neonatal intensive care nursery (22 fewer per 1,000) [critical] • Small reduction on adverse effects (composite of mortality or serious morbidity) [critical] (7 fewer per 1,000) • Little to no effect on duration of initial hospital stay [important] No studies reported the following outcomes: neurodevelopmental impairment, fully breastfeeding at hospital discharge, separation from the mother for treatment of hypoglycaemia before discharge home, hypoglycaemic injury on brain imaging, breastmilk feeding exclusively from birth to hospital discharge, cost. The systematic review only included women with gestational diabetes (1).	widely across international recommendations, and the evidence base that forms these recommendations is unclear.

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)	
				Risk with less-tight maternal glycaemic control during pregnancy	Risk difference with tighter maternal glycaemic control during pregnancy in women with diabetes
Neonatal hypoglycaemia [critical]	1556 (3 RCTs)	⨁⨁⨁◯ Moderate[a]	**RR 0.92** (0.72 to 1.18)	Study population	
				209 per 1,000	**17 fewer per 1,000** (59 fewer to 38 more)
Neurodevelopmental impairment [critical] - not measured	-	-	-	-	-
Admission to special care nursery or neonatal intensive care nursery [critical]	1161 (2 RCTs)	⨁⨁◯◯ Low[a,b]	**RR 0.59** (0.33 to 1.04)	Study population	
				53 per 1,000	**22 fewer per 1,000** (35 fewer to 2 more)
				Study population	

Adverse effects - Composite of mortality or serious morbidity (as defined by trial) [critical]	1550 (3 RCTs)	⨁⨁◯◯ Low[a,b]	**RR 0.84** (0.55 to 1.29)	46 per 1,000	**7 fewer per 1,000** (21 fewer to 13 more)
Fully breastfeeding at hospital discharge [critical] - not measured	-	-	-	-	-
Separation from the mother for treatment of hypoglycaemia before discharge home [important] - not measured	-	-	-	-	-
Hypoglycaemic injury on brain imaging [important] - not measured	-	-	-	-	-
Breastmilk feeding exclusively from birth to hospital discharge [important] - not measured	-	-	-	-	-
Duration of initial hospital stay [important]	1101 (1 RCT)	⨁⨁⨁◯ Moderate[b]	-	The mean duration of initial hospital stay [important] was **4.18** days	mean **0.07 days fewer** (0.75 fewer to 0.61 more)
Cost [important] - not reported	-	-	-	-	-

	a.Downgraded one level for serious risk of bias due to insufficient detail to permit a judgement about random sequence generation, allocation concealment, attrition bias, and reporting bias. b.Downgraded one level for serious imprecision due to the confidence interval including the possibility of benefit and harm. *Absolute effects were calculated based on the control group risk Another systematic review assessing glycaemic control targets was undertaken by Prutsky in 2024 (2) in observational studies involving 9433 diabetic women. These studies included women with type 1 and type 2 diabetes, in addition to gestational diabetes. The results of this review indicated that tighter glycaemic targets (fasting glucose target of <5.0 mmol/L) were associated with a significant reduction in neonatal hypoglycaemia (odds ratio 0.65 (0.49 to 0.85), p = 0.01) compared to a fasting glucose target of <6.1 mmol/L, as was the less tight glycaemic target (fasting glucose target of <5.6 mmol/L) (OR 0.68 (0.48 to 0.96), p = 0.03). **Considerations for Māori** In the TARGET randomised trial in Aotearoa New Zealand, the effects of tighter glycaemic control during pregnancy on the outcomes listed above were also very similar for the 148/1100 (13.5%) Māori babies randomised compared to the findings for the whole cohort (unpublished data from (3). *In the Sugar Babies study of 514 babies in Aotearoa New Zealand, the proportion of babies who developed hypoglycaemia was similar in Māori babies (79/150, 53%) to that in the whole cohort (260/514, 51%)*(4). **Considerations for Pacific** In the TARGET randomised trial in Aotearoa New Zealand, the effects of tighter glycaemic control during pregnancy on the outcomes listed above were also very similar for the 123/1100 (11.2%) Pacific babies randomised compared to the findings for the whole cohort (unpublished data from (3). *In the Sugar Babies study of 514 babies in Aotearoa New Zealand, the number of Pacific babies was very small, but the proportion who developed hypoglycaemia was similar to that in the whole cohort (6/16, 38% vs 260/514, 51%)*(4)	
Undesirable Effects How substantial are the undesirable anticipated effects?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**

○ Trivial ● Small ○ Moderate ○ Large ○ Varies ○ Don't know	No studies reported adverse events for babies associated with tighter glycaemic control during pregnancy (1). **Considerations for Māori** No additional evidence available **Considerations for Pacific** No additional evidence available	Tighter maternal glycaemic control during pregnancy compared to less-tight maternal glycaemic control results in some undesirable effects for mothers (1): • May increase the risk of developing hypertensive disorder of pregnancy (12 more per 1,000) • Increased use of pharmacological therapy (174 more per 1,000) • Large reduction in treatment adherence (417 fewer per 1,000)

Certainty of evidence
What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Very low ● Low ○ Moderate ○ High ○ No included studies		

Outcomes	Importance	Certainty of the evidence (GRADE)
Neonatal hypoglycaemia [critical]	CRITICAL	⊕⊕⊕◯ Moderate[a]
Neurodevelopmental impairment [critical] - not measured	CRITICAL	-
Admission to special care nursery or neonatal intensive care nursery [critical]	CRITICAL	⊕⊕◯◯ Low[a,b]
Adverse effects - Composite of mortality or serious morbidity (as defined by trial) [critical]	CRITICAL	⊕⊕◯◯ Low[a,b]
Fully breastfeeding at hospital discharge [critical] - not measured	CRITICAL	-
Separation from the mother for treatment of hypoglycaemia before discharge home [important] - not measured	IMPORTANT	-
Hypoglycaemic injury on brain imaging [important] - not measured	IMPORTANT	-

Breastmilk feeding exclusively from birth to hospital discharge [important] - not measured	IMPORTANT	-
Duration of initial hospital stay [important]	IMPORTANT	⊕⊕⊕◯ Moderate[b]
Cost [important] - not reported	IMPORTANT	-

a.Downgraded one level for serious risk of bias due to insufficient detail to permit a judgement about random sequence generation, allocation concealment, attrition bias, and reporting bias.
b.Downgraded one level for serious imprecision due to the confidence interval including the possibility of benefit and harm.

The observational nature of these studies inevitably resulted in the authors concluding they had a moderate to high risk of bias, in addition to insufficient covariate adjustment.

Considerations for Māori

Because of small numbers included in the available trials, the findings are less certain for Māori babies.

Considerations or Pacific

Because of small numbers included in the available trials, the findings are less certain for Pacific babies.

Values

Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Important uncertainty or variability ● Possibly important uncertainty or variability ○ Probably no important uncertainty or variability ○ No important uncertainty or variability	***Excerpts from Values summary document*** ***Uncertain value, possible variability*** • *Hypoglycaemia [critical]* • *Adverse effect [critical]* ***High value, no important variability*** • *Neurodevelopmental impairment [critical]* • *Fully breastfeeding at hospital discharge [critical]*	

	• *Breastfeeding exclusively from birth to hospital discharge [important]* ***High value, probably no important variability*** • *Admission to special care nursery or neonatal intensive care nursery [critical]* • *Separation from the mother for treatment of hypoglycaemia before discharge home [important]* • *Duration of initial hospital stay [important]* ***Uncertain value and variability*** • *Hypoglycaemic injury on brain imaging [important]* • *Cost [important]*	
Balance of effects Does the balance between desirable and undesirable effects favor the intervention or the comparison?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ● Probably favors the intervention ○ Favors the intervention ○ Varies ○ Don't know	Tighter maternal glycaemic control during pregnancy compared to less-tight maternal glycaemic control Low certainty evidence showed: • Little to no effect on neonatal hypoglycaemia [critical] • Small reduction in adverse effects [critical] • Small reduction on the admission to special care nursery or neonatal intensive care nursery [critical] **Considerations for Māori** Limited evidence suggests that the effects are similar for Māori babies. **Considerations or Pacific** Limited evidence suggests that the effects are similar for Pacific babies.	• May increase the risk of developing hypertensive disorder of pregnancy • Increased use of pharmacological therapy • Large reduction in treatment adherence
Resources required How large are the resource requirements (costs)?"		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**

○ Large costs ● Moderate costs ○ Negligible costs and savings ○ Moderate savings ○ Large savings ○ Varies ○ Don't know	Cost of glycaemic control medicines: Insulin glargine (5 cartridges of 100 IU) = NZ $94.50 (Pharmac, NZ). Metformin (1000 tablets of 500mg) = NZ $14.74 (Pharmac, NZ). Glibenclamide (100 tablets of 5mg) = NZ $7.50 (Pharmac, NZ). Recommending tighter glycaemic control will drive higher use of pharmacological agents to achieve such targets. Although the cost of individual medications is relatively minor, the increasing prevalence of gestational diabetes will result in a greater proportion of women requiring drug treatment, and therefore increased costs.	
Certainty of evidence of required resources What is the certainty of the evidence of resource requirements (costs)?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Very low ○ Low ○ Moderate ○ High ● No included studies	There is no evidence that directly compares the required resources for tighter versus less-tight maternal glycaemic control during pregnancy. We are reasonably sure about the costs and resource requirements in the Aotearoa New Zealand setting.	
Cost effectiveness Does the cost-effectiveness of the intervention favor the intervention or the comparison?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ● Probably favors the intervention ○ Favors the intervention ○ Varies ○ No included studies	There are no studies that assess the specific cost-effectiveness of tighter maternal glycaemic control in women with diabetes, particularly in the context of preventing neonatal hypoglycaemia. However, the finding of increased use of pharmacological therapy in women in the tighter glycaemic control group (61% in tighter vs 47% in less-tight) indicates an inevitable higher cost for this intervention group (insulin, metformin, glibenclamide were used in the included trials) (1). An Australian study found that treatment of mild gestational diabetes incurred additional health system costs of AU $53,985, but also prevented serious perinatal complications and perinatal death. The authors therefore concluded this was a justifiable cost, particularly in high-income settings (5).	While these studies indicate some benefit from a cost-effectiveness perspective in treatment of women with gestational diabetes, this evidence does not address the specific comparison of tight vs less-tight glycaemic control or women with other types of diabetes.

	A systematic review on the cost-effectiveness of screening and managing gestational diabetes concluded that treatment may be cost-effective, but this is often not outweighed by the cost of screening the whole pregnant population (6).	

Equity What would be the impact on health equity?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Reduced ○ Probably reduced ○ Probably no impact ○ Probably increased ○ Increased ● Varies ○ Don't know	A systematic review demonstrated that indigenous women (Australia, Canada, Aotearoa New Zealand, USA) had a higher prevalence of both pre-existing diabetes and gestational diabetes (10). Only one study was included from Aotearoa New Zealand, but this indicated higher rates of gestational diabetes diagnosis in Māori (7.9%) and Pacific (8.1%) māmā compared to NZ Europeans (3.3%) (11). In Aotearoa New Zealand, the prevalence of diabetes in 2022 is approximately two times higher in adults aged 25 – 39 years of Māori (11.2%), Pacific (11.4%) and Indian (16.8%) ethnicity compared to those of European ethnicity (6.1%) (12). The disproportionate burden of diabetes on different ethnic populations demands an equitable approach to intervention. However, there is no clear evidence of benefit with tighter maternal glycaemic control, suggesting minimal impact on health equity through this intervention. ***Are there groups or settings that might be disadvantaged in relation to the problem or intervention of interest?*** *There is little published literature and therefore it is unclear if there are any groups or settings that might be disadvantaged in relation to the problem or intervention of interest.* ***Are there plausible reasons for anticipating differences in the relative effectiveness of the intervention for disadvantaged groups or settings?*** *There is little published literature. It is unlikely that the effectiveness of interventions would differ for disadvantaged groups or settings. However, within Aotearoa New Zealand, social*	

	determinants of health (e.g., colonisation, racism, income, education, employment and housing) are likely to have an impact on the implementation, and therefore the effectiveness, of interventions. ***Are there different baseline conditions across groups or settings that affect the absolute effectiveness of the intervention for the importance of the problem for disadvantaged groups or settings?*** *Māori babies (190/530, 35.8%) are more likely to be at risk of hypoglycaemia than New Zealand Europeans (660/2529, 26.1%)* (13*). However, in the Sugar Babies study of 514 babies at risk of neonatal hypoglycaemia in Aotearoa New Zealand, the proportion of babies who developed hypoglycaemia was similar in Māori babies (79/150, 53%) to that in the whole cohort (260/514, 51%)* (4*).* *Pacific babies (282/693, 40.7%) are more likely to be at risk of hypoglycaemia than New Zealand Europeans (660/2529, 26.1%)* (13*).* *In the Sugar Babies study of 514 babies at risk of neonatal hypoglycaemia in Aotearoa New Zealand, the number of Pacific babies was very small, but the proportion who developed hypoglycaemia was similar to that in the whole cohort (6/16, 38% vs 260/514, 51%)* (4*).* *Asian babies (660/2068, 31.9%) are more likely to be at risk of hypoglycaemia than New Zealand Europeans (660/2529, 26.1%)* (13*).* ***Are there important considerations that people implementing the intervention should consider in order to ensure that inequities are reduced, if possible, and that they are not increased?*** ***Consideration for Māori*** *In the Whānau Experience study* (8*), participants expressed appreciation for the inclusion of karakia and tikanga before certain interventions.* *Māori are more likely to experience interpersonal, institutional, and structural racism, which requires intentional action on addressing racism within these three levels of racism* (14, 15, 16*).* *Additionally, a systematic literature review by Graham et al.* (7*) provides a summary of 20 years of data from Whānau Māori experiences in the public health and/or hospital system. A key barrier included perception of racism or discrimination amongst Whānau Māori. For instance, perceiving healthcare professionals to be uninterested in their health and wellbeing. Whānau Māori had good experiences when engaging with Māori healthcare providers when they provided whanaungatanga and were "just so welcoming"* (7*).* ***Consideration for Pacific*** *Some Pacific women interviewed in the Whānau Experience study reported difficulties with accessing the hospital due to cost, transportation and limited availability with work* (8*).*	

	Other considerations *The Ministry of Health identify four priority groups for maternity care. These are Māori, Pacific, younger women (<25 years) and women with disabilities* (9*). Most pregnancy, hospital and well child care is free for Aotearoa New Zealand citizens and other eligible women, but accessing these services may incur costs that are challenging for families with limited resources. In addition, there may be a charge if families use some private or specialist services. In the 2014 Maternity Consumer Survey* (9*), 71% of women reported that they had paid for at least one pregnancy-related service. Māori, Pacific and younger women were less likely to have paid for services.*	
Acceptability Is the intervention acceptable to key stakeholders?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ No ○ Probably no ○ Probably yes ○ Yes ● Varies ○ Don't know	Tighter glycaemic control in women with diabetes inherently requires a greater level of drug therapy to achieve these narrower targets. The acceptability of achieving tighter glycaemic control has not been adequately explored. The systematic review reported reduced medication adherence in the tight control group, suggesting that the intervention may be less acceptable or too difficult to achieve (1). **Consideration for Māori** In the Whānau Experiences study (8), Whānau Māori want the very best health outcomes for their pēpi and are highly perceptive of health care professionals and their actions. **Consideration for Pacific** In the Whānau Experience study (8), some Pacific mothers expressed anxiety about taking any medications or undergoing treatments while pregnant. A few of the Pacific women interviewed expressed concern about receiving treatments, e.g., insulin, preventatively. They did not see the benefit and were concerned about the harm.	It has been reported that metformin is more acceptable for pregnant women than insulin in the treatment of gestational diabetes (17). Treatment with metformin resulted in better post-prandial glycaemic control and lower risk of hypoglycaemic events when compared to insulin (18).
Feasibility Is the intervention feasible to implement?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ No ○ Probably no	The RCTs included in the systematic review suggest that implementing tighter glycaemic control is feasible for women with gestational diabetes, including in Aotearoa New Zealand	

○ Probably yes ○ Yes ● Varies ○ Don't know	(1). However, they found that tighter glycaemic targets were associated with a large decrease in adhering to treatment (28.9% tight control vs 70.6% less-tight control, RR 0.41 [0.32, 0.52], 1 study, 395 women) (1). Reduction in treatment adherence suggests that tighter glycaemic control may not be feasible for some women. **Considerations for Māori** No additional data available **Considerations or Pacific** No additional data available	

SUMMARY OF JUDGEMENTS

DESIRABLE EFFECTS	Trivial	**Small**	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Trivial	**Small**	Moderate	Large		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	**Low**	Moderate	High			No included studies
VALUES	Important uncertainty or variability	**Possibly important uncertainty or variability**	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	**Probably favors the intervention**	Favors the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	**Moderate costs**	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			**No included studies**
COST EFFECTIVENESS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	**Probably favors the intervention**	Favors the intervention	Varies	No included studies
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	**Varies**	Don't know

ACCEPTABILITY	No	Probably no	Probably yes	Yes		**Varies**	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		**Varies**	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention	Conditional recommendation against the intervention	Conditional recommendation for either the intervention or the comparison	**Conditional recommendation for the intervention**	Strong recommendation for the intervention
○	○	○	●	○

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Question 3.

Should tight intrapartum glycaemic control vs. less tight or no intrapartum glycaemic control be used for neonatal hypoglycaemia?	
POPULATION:	Pregnant women with diabetes and their babies
INTERVENTION:	tight intrapartum glycaemic control
COMPARISON:	less tight or no intrapartum glycaemic control
MAIN OUTCOMES:	- Consideration will be given to the evidence (or lack thereof) for both Māori and non-Māori babies and their whānau. **Critical for making a decision:** 1. Hypoglycaemia (minimum effect size >=20 per 1000 babies) 2. Neurodevelopmental impairment (minimum effect size >=10 per 1000 babies) 3. Admission to special care nursery or neonatal intensive care nursery (minimum effect size >=20 per 1000 babies) 4. Adverse effects (for neonatal mortality minimum effect size >=1 per 1000 babies) 5. Fully breastfeeding at hospital discharge (minimum effect size >=20 per 1000 babies) **Important but not critical:** 1. Separation from the mother for treatment of hypoglycaemia before discharge home (minimum effect size >=20 per 1000 babies) 2. Hypoglycaemic injury on brain imaging (minimum effect size >=10 per 1000 babies) 3. Breastmilk feeding exclusively from birth to hospital discharge (minimum effect size >=20 per 1000 babies) 4. Duration of initial hospital stay (minimum effect size >=0.5 days per baby) 5. Cost (for whānau >=10 NZD per baby, for health system >=100 NZD per baby) **Less important for decision making:** 1. Time to blood glucose normalisation after intervention 2. Receipt of treatment for hypoglycaemia during initial hospital stay 3. Number of episodes of hypoglycaemia 4. Severity of hypoglycaemia 5. Duration of treatment
SETTING:	Any birth settings
PERSPECTIVE:	Clinical recommendation

BACKGROUND:	*Low blood glucose concentrations (hypoglycaemia) are common in newborn babies over the first few days after birth, particularly in those with recognised risk factors (infants of mothers with diabetes, or born preterm, low or high birthweight). Severe or prolonged hypoglycaemia can lead to brain injury, so early detection and treatment is recommended to reduce the risk of later developmental problems.* Currently, the National Institute for Health and Care Excellence (NICE) guidelines in the UK (1) recommend maintenance of maternal blood glucose concentrations between 4 and 7 mmol/L over the intrapartum period for women with diabetes to reduce the incidence of neonatal hypoglycaemia. This guideline was based on evidence from eight observational studies which found that there was an increased chance of neonatal hypoglycaemia if the mothers had higher intrapartum blood glucose concentrations. However, others have found no association between the control of intrapartum maternal glucose concentrations and neonatal hypoglycaemia. In addition, there have been reports of an association between receipt of intravenous glucose during labour and hypoglycaemia in the baby after birth, but these are inconsistent.
CONFLICT OF INTERESTS:	CC, DH, JA, JH, JR and LL are authors of cited papers.

ASSESSMENT

Desirable Effects How substantial are the desirable anticipated effects?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Trivial ○ Small ● Moderate ○ Large ○ Varies ○ Don't know	**Tight intrapartum glycaemic control compared to less tight or no intrapartum glycaemic control** associated with (2): • Neonatal hypoglycaemia (RCT: little to no effect; Cohort studies: large reduction (112 fewer per 1,000)) [critical] • Admission to special care nursery or neonatal intensive care nursery (RCT: large increase (105 more per 1,000); Cohort studies: large reduction (146 fewer per 1,000)) [critical] • Little to no effect on duration of initial hospital stay [important] • No studies reported on the following outcomes: fully breastfeeding at hospital discharge, separation from the mother for treatment of hypoglycaemia before discharge home, neonatal hypoglycaemic injury on brain imaging, cost.	**Tight intrapartum glycaemic control compared to less tight or no intrapartum glycaemic control** associated with (2): • Receipt of treatment for neonatal hypoglycaemia during the initial hospital stay (RCT: little to no effect; Cohort studies: moderate reduction (80 fewer per 1,000) • Moderate reduction in Apgar score <7 at 5 minutes (cohort studies: 53 fewer per 1,000)

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)	
				Risk with less tight or no intrapartum glycaemic control	Risk difference with tight intrapartum glycaemic control
Neonatal Hypoglycaemia [critical]-RCT	76 (1 RCT)	⨁◯◯◯ Very low[a]	**RR 1.00** (0.45 to 2.24)	Study population	
				237 per 1,000	**0 fewer per 1,000** (130 fewer to 294 more)
Neonatal Hypoglycaemia [critical] -Cohort	6152 (11 non-randomised studies)	⨁⨁◯◯ Low[b,c,d]	**OR 0.44** (0.31 to 0.63)	Study population	
				225 per 1,000	**112 fewer per 1,000** (143 fewer to 70 fewer)
Admission to special care nursery or neonatal intensive care nursery [critical]- RCT	76 (1 RCT)	⨁◯◯◯ Very low[a]	**RR 5.00** (0.61 to 40.81)	Study population	
				26 per 1,000	**105 more per 1,000** (10 fewer to 1,048 more)
Admission to special care nursery or neonatal intensive care nursery [critical]- Cohort	1077 (4 non-randomised studies)	⨁⨁⨁⨁ High[d]	**OR 0.45** (0.28 to 0.74)	Study population	
				321 per 1,000	**146 fewer per 1,000** (204 fewer to 62 fewer)
Fully breastfeeding at hospital discharge [critical] - not measured	-	-	-	-	-
Separation from the mother for treatment of hypoglycaemia before discharge	-	-	-	-	-

home [important] - not measured					
Hypoglycaemic injury on brain imaging [important] - not measured	-	-	-	-	-
Duration of initial hospital stay [important]	53 (1 non-randomised study)	⨁◯◯◯ Very low[c,e]	-	The mean duration of initial hospital stay [important] was **4.67** days	MD **0 days** (3.6 lower to 3.6 higher)
Cost [important] - not measured	-	-	-	-	-

a. Downgraded three levels for extremely serious imprecision due to a very wide confidence interval that appreciably crosses the threshold(s) of interest.
b. Downgraded one level for serious inconsistency due to significant heterogeneity.
c. Downgraded one level for serious risk of bias due to moderate to low quality assessment results.
d. Upgraded two levels for very large effect.
e. Downgraded one level for serious imprecision due to the confidence interval including the possibility of benefit and harm.
*Absolute effects were calculated based on the control group risk

Considerations for Māori
No additional data available
Considerations or Pacific
No additional data available

Undesirable Effects
How substantial are the undesirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

○ Trivial ○ Small ● Moderate ○ Large ○ Varies ○ Don't know	**Tight intrapartum glycaemic control compared to less tight or no intrapartum glycaemic control** associated with (2): • Uncertain effect on neurodevelopmental impairment [critical] • Two cohort studies reported no difference in adverse effects • Caesarean section (RCT: moderate decrease (52 fewer per 1,000); Cohort studies: large increase (112 more per 1,000) [adverse effect, critical] • Large reduction in breastfeeding exclusively from birth to hospital discharge (RCT: 105 fewer per 1,000) [important]	**Tight intrapartum glycaemic control compared to less tight or no intrapartum glycaemic control** associated with (2) • Little to no effect on maternal hypoglycaemia

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)	
				Risk with less tight or no intrapartum glycaemic control	Risk difference with tight intrapartum glycaemic control
Neurodevelopmental impairment [critical]- Cohort	131 (1 non-randomised study)	⊕◯◯◯ Very low[a]	**OR 1.26** (0.58 to 2.73)	Study population	
				359 per 1,000	**55 more per 1,000** (114 fewer to 246 more)
Adverse effects (investigator defined) [critical]- Cohort	263 (1 non-randomised study)	⊕◯◯◯ Very low[b,c]	-	Two cohort studies reported no difference in respiratory distress syndrome, perinatal death, neonatal death or shoulder dystocia.	
Caesarean section [critical]- RCT	76 (1 RCT)	⊕◯◯◯ Very low[d]	**RR 0.78** (0.32 to 1.87)	Study population	
				237 per 1,000	**52 fewer per 1,000** (161 fewer to 206 more)
Caesarean section [critical]- Cohort	1759 (4 non-randomised studies)	⊕⊕◯◯ Low	**OR 1.62** (1.10 to 2.39)	Study population	
				314 per 1,000	**112 more per 1,000** (21 more to 208 more)

Breastmilk feeding exclusively from birth to hospital discharge [important]	76 (1 RCT)	⊕◯◯◯ Very low[d]	**RR 0.81** (0.51 to 1.28)	Study population	
				553 per 1,000	**105 fewer per 1,000** (271 fewer to 155 more)

a.Downgraded two levels for very serious imprecision due to the wide confidence interval and small sample size.
b.Downgraded one level for serious risk of bias due to moderate to low quality assessment results.
c.Downgraded one level for imprecision due to no numbers being reported
d.Downgraded three levels for extremely serious imprecision due to a very wide confidence interval that appreciably crosses the threshold(s) of interest.
*Absolute effects were calculated based on the control group risk

Considerations for Māori

No additional data available

Considerations or Pacific

No additional data available

Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
● Very low ○ Low ○ Moderate ○ High ○ No included studies		

Outcomes	Importance	Certainty of the evidence (GRADE)
Neonatal Hypoglycaemia [critical]-RCT	CRITICAL	⊕◯◯◯ Very low[a]
Neonatal Hypoglycaemia [critical] -Cohort	CRITICAL	⊕⊕◯◯ Low[b,c,d]
Neurodevelopmental impairment [critical]- Cohort	CRITICAL	⊕◯◯◯ Very low[e]

Admission to special care nursery or neonatal intensive care nursery [critical]- RCT	CRITICAL	⊕◯◯◯ Very low[a]
Admission to special care nursery or neonatal intensive care nursery [critical]- Cohort	CRITICAL	⊕⊕⊕⊕ High[d]
Adverse effects (investigator defined) [critical]- Cohort	CRITICAL	⊕◯◯◯ Very low[c,f]
Caesarean section [critical]- RCT	CRITICAL	⊕◯◯◯ Very low[a]
Caesarean section [critical]- Cohort	CRITICAL	⊕⊕◯◯ Low
APGAR score <7 at 5 miniutes [critical]	CRITICAL	⊕⊕⊕◯ Moderate[c,d]
Fully breastfeeding at hospital discharge [critical] - not measured	CRITICAL	-
Separation from the mother for treatment of hypoglycaemia before discharge home [important] - not measured	IMPORTANT	-
Hypoglycaemic injury on brain imaging [important] - not measured	IMPORTANT	-
Breastmilk feeding exclusively from birth to hospital discharge [important]	IMPORTANT	⊕◯◯◯ Very low[a]
Duration of initial hospital stay [important]	IMPORTANT	⊕◯◯◯ Very low[c,g]
Cost [important] - not measured	IMPORTANT	-

a.Downgraded three levels for extremely serious imprecision due to a very wide confidence interval that appreciably crosses the threshold(s) of interest.

	b.Downgraded one level for serious inconsistency due to significant heterogeneity. c.Downgraded one level for serious risk of bias due to moderate to low quality assessment results. d.Upgraded two levels for very large effect. e.Downgraded two levels for very serious imprecision due to the wide confidence interval and small sample size. f.Downgraded one level for imprecision due to no numbers being reported g.Downgraded one level for serious imprecision due to the confidence interval including the possibility of benefit and harm. **Considerations for Māori** No additional data available **Considerations or Pacific** No additional data available	
Values Is there important uncertainty about or variability in how much people value the main outcomes?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Important uncertainty or variability ● Possibly important uncertainty or variability ○ Probably no important uncertainty or variability ○ No important uncertainty or variability	***Excerpts from Values summary document*** ***Uncertain value, possible variability*** • *Hypoglycaemia [critical]* • *Adverse effect [critical]* ***High value, no important variability*** • *Neurodevelopmental impairment [critical]* • *Fully breastfeeding at hospital discharge [critical]* • *Breastfeeding exclusively from birth to hospital discharge [important]* ***High value, probably no important variability*** • *Admission to special care nursery or neonatal intensive care nursery [critical]* • *Separation from the mother for treatment of hypoglycaemia before discharge home [important]* • *Duration of initial hospital stay [important]* ***Uncertain value and variability***	

	• *Hypoglycaemic injury on brain imaging [important]* • *Cost [important]*	
Balance of effects Does the balance between desirable and undesirable effects favor the intervention or the comparison?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ● Probably favors the intervention ○ Favors the intervention ○ Varies ○ Don't know	**Tight intrapartum glycaemic control compared to less tight or no intrapartum glycaemic control** Very low certainty evidence showed: • Large reduction in neonatal hypoglycaemia [critical] • Uncertain effect on neurodevelopmental impairment [critical] • Large reduction in admission to special care nursery or neonatal intensive care nursery [critical] • Large increase in caesarean section [adverse effect, critical] • Uncertain effect on breastfeeding exclusively from birth to hospital discharge [important] • Uncertain effect on duration of initial hospital stay [important] **Considerations for Māori** No additional data available **Considerations for Pacific** No additional data available	• Moderate reduction in receipt of treatment for neonatal hypoglycaemia during the initial hospital stay • Little to no effect on maternal hypoglycaemia • Moderate reduction in APGAR score <7 at 5 minutes
Resources required How large are the resource requirements (costs)?"		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**

○ Large costs ● Moderate costs ○ Negligible costs and savings ○ Moderate savings ○ Large savings ○ Varies ○ Don't know	Cost for IV Insulin (Injection 100 u per ml, 3 ml) = NZ $ 94.50 (Pharmac, NZ) Intrapartum glycaemic control requires close monitoring of maternal blood glucose concentrations and the initiation of an insulin infusion if these values are elevated. Continued monitoring of glucose concentrations requires staff time and has a cost, as does the administration of IV dextrose and insulin if required.	
Certainty of evidence of required resources What is the certainty of the evidence of resource requirements (costs)?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Very low ○ Low ○ Moderate ○ High ● No included studies	We are reasonably sure about the costs of medication in the Aotearoa New Zealand setting. We are less certain about the costs of staff time.	
Cost effectiveness Does the cost-effectiveness of the intervention favor the intervention or the comparison?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**

○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ○ Probably favors the intervention ○ Favors the intervention ○ Varies ● No included studies	There is no direct evidence regarding tighter intrapartum glycaemic control and cost-effectiveness.	Newer methods of glycaemic control management may alter costs. For example, continuous subcutaneous insulin infusion which has shown to be as safe and effective as standard intravenous insulin infusion, and allows women to self-manage their insulin. Women who are already using this approach through their pregnancy don't have to swap methods in labour (3). Newer monitoring methods may also reduce costs such as electronic glucose management systems (e.g. glucostabiliser) or continuous glucose monitoring, a cost from NZ $ 1,000 to several thousand dollars.
Equity What would be the impact on health equity?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Reduced ○ Probably reduced ● Probably no impact ○ Probably increased ○ Increased ○ Varies ○ Don't know	***Are there groups or settings that might be disadvantaged in relation to the problem or intervention of interest?*** *There is little published literature and therefore it is unclear if there are any groups or settings that might be disadvantaged in relation to the problem or intervention of interest.* ***Are there plausible reasons for anticipating differences in the relative effectiveness of the intervention for disadvantaged groups or settings?*** *There is little published literature. It is unlikely that the effectiveness of interventions would differ for disadvantaged groups or settings. However, within Aotearoa New Zealand, social determinants of health (e.g., colonisation, racism, income, education, employment and housing) are likely to have an impact on the implementation, and therefore the effectiveness, of interventions.* ***Are there different baseline conditions across groups or settings that affect the absolute effectiveness of the intervention for the importance of the problem for disadvantaged groups or settings?***	

	Māori babies (190/530, 35.8%) are more likely to be at risk of hypoglycaemia than New Zealand Europeans (660/2529, 26.1%) (6). *However, in the Sugar Babies study of 514 babies at risk of neonatal hypoglycaemia in Aotearoa New Zealand, the proportion of babies who developed hypoglycaemia was similar in Māori babies (79/150, 53%) to that in the whole cohort (260/514, 51%)* (7). *Pacific babies (282/693, 40.7%) are more likely to be at risk of hypoglycaemia than New Zealand Europeans (660/2529, 26.1%)*(6). *In the Sugar Babies study of 514 babies at risk of neonatal hypoglycaemia in Aotearoa New Zealand, the number of Pacific babies was very small, but the proportion who developed hypoglycaemia was similar to that in the whole cohort (6/16, 38% vs 260/514, 51%)* (7). *Asian babies (660/2068, 31.9%) are more likely to be at risk of hypoglycaemia than New Zealand Europeans (660/2529, 26.1%)* (6). ***Are there important considerations that people implementing the intervention should consider in order to ensure that inequities are reduced, if possible, and that they are not increased?*** ***Consideration for Māori*** *In the Whānau Experience study* (4)*, participants expressed appreciation for the inclusion of karakia and tikanga before certain interventions.* *Māori are more likely to experience interpersonal, institutional, and structural racism, which requires intentional action on addressing racism within these three levels of racism* (8)(9)(10). *Additionally, a systematic literature review by Graham et al.* ((11) *provides a summary of 20 years of data from whānau Māori experiences in the public health and/or hospital system. A key barrier included perception of racism or discrimination amongst whānau Māori. For instance, perceiving healthcare professionals to be uninterested in their health and wellbeing. Whānau Māori had good experiences when engaging with Māori healthcare providers when they provided whanaungatanga and were "just so welcoming"* (11). ***Consideration for Pacific*** *Some Pacific women interviewed in the Whānau experience study reported difficulties with accessing the hospital due to cost, transportation and limited availability with work* (4). ***Other considerations*** *The Ministry of Health identify four priority groups for maternity care. These are Māori, Pacific, younger women (<25 years) and women with disabilities* (5)*. Most pregnancy, hospital and well child care is free for Aotearoa New Zealand citizens and other eligible women, but accessing these services may incur costs that are challenging for families with limited resources. In addition, there may be a charge if families use some private or specialist services. In the 2014 Maternity Consumer Survey* (5)*, 71% of women reported that they had paid for at least one*	

	pregnancy-related service. Māori, Pacific and younger women were less likely to have paid for services.	
Acceptability Is the intervention acceptable to key stakeholders?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ No ○ Probably no ● Probably yes ○ Yes ○ Varies ○ Don't know	Tighter intrapartum control would require more frequent monitoring which may be less acceptable, but we found no studies regarding healthcare providers' or consumers' views on intrapartum glycaemic control protocols. **Considerations for Māori** No additional data available **Considerations or Pacific** No additional data available	
Feasibility Is the intervention feasible to implement?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ No ○ Probably no ● Probably yes ○ Yes ○ Varies ○ Don't know	No studies have directly reported on the feasibility of tight intrapartum glycaemic control. In Aotearoa New Zealand, the gestational diabetes clinical practice guideline has no recommendations for glycaemic control in labour (12). **Considerations for Māori** No additional data available **Considerations or Pacific** No additional data available	

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
DESIRABLE EFFECTS	Trivial	Small	**Moderate**	Large		Varies	Don't know

UNDESIRABLE EFFECTS	Trivial	Small	**Moderate**	Large		Varies	Don't know
CERTAINTY OF EVIDENCE	**Very low**	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	**Possibly important uncertainty or variability**	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	**Probably favors the intervention**	Favors the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	**Moderate costs**	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			**No included studies**
COST EFFECTIVENESS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	**No included studies**
EQUITY	Reduced	Probably reduced	**Probably no impact**	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	**Probably yes**	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	**Probably yes**	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention	Conditional recommendation against the intervention	**Conditional recommendation for either the intervention or the comparison**	Conditional recommendation for the intervention	Strong recommendation for the intervention
○	○	●	○	○

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