Author(s): VS/AT **Date:** 2015-03-23

Question: Should breastfeeding vs control be used for reducing vaccine injection pain in children up to 2 years?¹

Settings: clinics

Bibliography: Dilli 2009 (1), Efe 2007, Goswami 2013 (1), Iqbal 2014, Modarres 2013, Abdel Razek 2009, Shah Ali 2009, Taavoni 2009, Thomas 2011

Quality assessment								No of patients		Effect		Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Breastfeeding	Control	Relative (95% CI)	Absolute		
						l Scale 0-10, Neonat earchers; Better i				Baker Faces Scal	e 0-5, Mo	dified
8 ³		- ,	no serious inconsistency ⁶	no serious indirectness	no serious imprecision	none	371	421 ⁷	-	SMD 1.78 lower (2.35 to 1.22 lower) ^{2,3,4}	⊕⊕OO LOW	CRITICAL
Distress	Acute yes/no ⁷	(assesse	d with: validated	tool (Neonatal I	nfant Pain Sca	le 0-7, yes/no witl	h score cut-off	of 3))				
1		, ,	no serious inconsistency	no serious indirectness	serious ⁸	none	12/73 (16.4%) ⁷	64/85 (75.3%)	RR 0.22 (0.13 to 0.37) ⁷	587 fewer per 1000 (from 474 fewer to 655 fewer)	⊕OOO VERY LOW	CRITICAL
Distress	Recovery (me	asured wi	th: validated tool	(Modified Neor	natal Facial Co	ding System 0-6,	Modified Neona	atal Infan	t Pain Scale	e 0-7); Better indic	ated by l	ower values)
2		- ,	no serious inconsistency	no serious indirectness	serious ⁸	none	60	60	·	SMD 0.98 lower (1.36 to 0.6 lower)	⊕OOO VERY LOW	CRITICAL
Distress	Acute + Reco	very (meas	sured with: valida	ated tools (cry o	luration) by re	searcher; Better in	ndicated by low	er value	s)		<u> </u>	
4		very serious ⁵	no serious inconsistency ⁶	no serious indirectness	no serious imprecision	none	206	218 ⁷	-	SMD 1.89 lower (3.19 to 0.59 lower)	⊕⊕OO LOW	CRITICAL
Procedu	re Outcomes (duration,	success) (measu	red with: electro	onic timer; Bet	ter indicated by lo	ower values)					

1	randomised trials	serious ⁵	no serious inconsistency	no serious indirectness	serious ⁹	none	33	33	-	SMD 0.21 lower (0.7 lower to 0.27 higher)	⊕⊕OO LOW	IMPORTANT
Safety (a	ssessed with:	aspiratio	n, cyanosis, res	piratory change	es, vomiting)			•				
2	randomised trials	serious ⁵	no serious inconsistency	no serious indirectness	serious ⁸	none	_10	-	not pooled	not pooled	⊕⊕OO LOW	IMPORTANT
Use of in	tervention (as	sessed w	ith: observation	of infant breas	tfeeding)							
1	randomised trials	serious ¹¹	no serious inconsistency	no serious indirectness	serious ⁸	none	_7	-	-	-	⊕⊕OO LOW	IMPORTANT
Parent F	ear, Vaccine C	Complianc	e, Preference, S	atisfaction (ass	essed with: n	o data were ide	ntified for these im	portant o	outcomes)			-
0	No evidence available					none	-	0%	-	-		IMPORTANT
								0%		-		

¹ Control group included infant holding in 4 studies, infant supine position in 3 studies and unclear position in 2 studies

² Additional information and data provided by 1 author (Taavoni 2009)

³ Data from Taavoni (2009) and Shah Ali (2009) from the same study

⁴ Sample size for breastfeeding group divided by 2 for studies by Taavoni (2009) and Shah Ali (2009)

⁵ Immunizer, parent, researcher not blinded; outcome assessor not consistently blinded; studies not consistently truly random

⁶ Heterogeneity can be explained by potential differences in the implementation of the intervention (breastfeeding); age of infant. Breastfeeding may not have been consistently maintained throughout the vaccine injection.

⁷ In 1 study (Dilli 2009 (1)), 4 infants (5%) in the breastfeeding group were excluded because they did not want to feed. Infants in this study were under 6 months of age.

⁸ Sample size was below the recommended optimum information size (OIS) of 400 for an effect size of 0.2

⁹ Confidence intervals cross the line of nonsignificance and the sample size was below the recommended optimum information size (OIS) of 400 for an effect size of 0.2

¹⁰ In 2 studies (Abdel Razek 2009, Efe 2007) including 93 infants, there were no reports of any adverse events as defined above.

¹¹ Immunizer, parent, researcher not blinded; outcome assessor not blinded