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Question: Should warming the vaccine vs no treatment be used for reducing vaccine injection pain in people of all ages?

Settings: emergency department

Bibliography: Maiden 2003

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Warming the vaccine	No treatment	Relative (95% CI)	Absolute		
Pain ^{1,2} (measured with: validated tool (McGill Present Pain Intensity Questionnaire 0-5); Better indicated by lower values)												
1	randomised trials	serious ³	no serious inconsistency	no serious indirectness ⁴	serious ⁵	none	100	50	-	SMD 0.02 higher (0.32 lower to 0.36 higher) ^{1,2}	⊕⊕⊕⊕ LOW	CRITICAL
Pain (yes/no) ¹ (assessed with: validated tool (McGill Present Pain Intensity Questionnaire 0-5, dichotomized into pain yes/no))												
1	randomised trials	serious ³	no serious inconsistency	no serious indirectness ⁴	serious ⁵	none	34/100 (34%)	15/50 (30%)	RR 1.13 (0.68 to 1.88) ¹	39 more per 1000 (from 96 fewer to 264 more)	⊕⊕⊕⊕ LOW	CRITICAL
Distress, Preference, Satisfaction (assessed with: no data were identified for these important outcomes)												
0	No evidence available					none	-	-	-	-		IMPORTANT
								0%		-		

¹ In included study, 2 groups were combined for the warming treatment arm: 1) rubbing x 1 minute between hands (n=50) and 2) warming in an incubator x 5 minutes (n=50). This was done because resulting vaccine temperature was not different between these 2 groups but significantly different from the no treatment group (MD = 8.8 degrees Celsius, 95% CI 6.99, 10.6)

² Additional information and data provided by author (Maiden 2003)

³ Immunizer not blinded; however individual undergoing vaccination blinded (hence, outcome assessment blinded)

⁴ Setting is emergency department

⁵ Confidence interval crosses line of nonsignificance and sample size was below the recommended optimum information size (OIS) of 400 for an effect size of 0.2