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Question: Should providing a verbal signal of an impending procedure vs a verbal signal of impending pain be used for by clinicians reducing vaccine injection pain in individuals of all ages?^{1,2,3,4}

Settings: medical university, phlebotomy clinic, hospital

Bibliography: Dutt-Gupta 2007, Ott 2012, Vijayan 2015

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Providing a verbal signal of an impending procedure	A verbal signal of impending pain	Relative (95% CI)	Absolute		
Pain⁵ (measured with: validated tool (Numerical Rating Scale 0-10, Likert scale 1-5); Better indicated by lower values)												
3	randomised trials	serious ⁶	no serious inconsistency ⁷	serious ⁸	serious ⁹	none	204	187	-	SMD 0.6 lower (1.37 lower to 0.16 higher) ⁵	⊕000 VERY LOW	CRITICAL
Pain (yes/no) (assessed with: validated tool (Numerical Rating Scale, Likert scale, pain yes/no))												
2	randomised trials	serious ⁶	no serious inconsistency ⁷	serious ⁸	serious ⁹	none	47/152 (30.9%)	66/138 (47.8%)	RR 0.29 (0.01 to 5.83) ¹⁰	340 fewer per 1000 (from 473 fewer to 1000 more)	⊕000 VERY LOW	CRITICAL
Distress (yes/no) patient withdrawal of arm (assessed with: observation of patient withdrawal of arm)												
2	randomised trials	serious ⁶	no serious inconsistency	serious ⁸	serious ⁹	none	2/156 (1.3%)	3/137 (2.2%)	RR 0.74 (0.03 to 21.82)	6 fewer per 1000 (from 21 fewer to 456 more)	⊕000 VERY LOW	IMPORTANT
Distress (yes/no) patient vocalization (assessed with: observation of patient vocalization)												
2	randomised trials	serious ⁶	no serious inconsistency	serious ⁸	serious ⁹	none	1/156 (0.64%)	7/137 (5.1%)	RR 0.25 (0.02 to	38 fewer per 1000 (from 50 fewer to 108	⊕000 VERY	IMPORTANT

									3.12)	more)	LOW	
								0%		-		
Fear (assessed with: no data were identified for this critically important outcome)												
0	No evidence available					none	-	-	-	-		CRITICAL
Procedure Outcomes, Parent Fear, Vaccine Compliance, Memory, Preference, Satisfaction (assessed with: no data were identified for these important outcomes)												
0	No evidence available					none	-	-	-	-		IMPORTANT

¹ Study by Dutt-Gupta (2007) compared signal 'I am going to apply the tourniquet on the arm. As I do this many people find the arm becomes heavy, numb and tingly. This allows the drip to be placed more comfortably' to "I am going to apply the tourniquet and insert the needle in a few moments. It's a sharp scratch and it may sting a little."

² Study by Ott (2013) compared signal "Beware, I am about to start" to "This will sting."

³ Study by Vijayan (2015) compared signal "Ready" to "Sharp scratch",

⁴ Study by Dutt-Gupta (2007) excluded individuals with a history of difficult previous venous access. Study by Ott (2012) excluded individuals with an extreme fear of pain or blood sampling.

⁵ Removal of the data from the study with lower pain scores (Vijayan 2015) alters the meta analytic results: pain scores are statistically lower for the verbal signaling group (SMD -0.97 (95% CI -1.26, -0.68)).

⁶ Operator not blinded; participant blinded

⁷ Heterogeneity can be explained by differences in participants (volunteers vs patients), settings, and verbal interventions

⁸ Context is venipuncture/venous cannulation

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

¹⁰ Pain defined as a numerical rating scale score or likert rating of > 1