## Author(s): MS/KH/KAB/KEB/AT Date: 2015-03-26 Question: Should video distraction vs no treatment be used for reducing vaccine injection pain in children >3 - 12 years?<sup>1,2</sup> Settings: clinics

**Bibliography:** Cassidy 2002, Cohen 1997 (1,2), Cohen 1999 (1), Cohen 2015 (1), Luthy 2013 (1)

Quality assessment								No of patients		Effect		Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Video distraction	No treatment	Relative (95% CI)	Absolute		
Pain <sup>3,4</sup> (n	neasured with	n: validated to	ool (Faces Pain S	Scale-Revised (	)-100, Faces	scale 1-5, 1-7, Vi	sual Analog	Scale 0-100	); Better in	dicated by lower va	lues)	
4	randomised trials	,	no serious inconsistency <sup>8</sup>	no serious indirectness	serious <sup>9</sup>	none	158	121	-	SMD 0.88 lower (1.78 lower to 0.02 higher) <sup>3</sup>	⊕OOO VERY LOW	CRITICAL
Fear (me	easured with:	validated too	I (Visual Analog	Scale 0-100); E	Better indicat	ed by lower valu	es)			1		
1	randomised trials	7.10		no serious indirectness	serious <sup>11</sup>	none	34	34	-	SMD 0.08 higher (0.25 lower to 0.41 higher)	⊕OOO VERY LOW	CRITICAL
	Pre-procedur her ; Better ind			easured with: v	validated too	ls (Child-Adult N	edical Proce	edure Intera	ction Scale	e-Revised, Behavior	ur coding	g 0-1) by
3	randomised trials	very serious <sup>7,10,14</sup>	no serious inconsistency <sup>8</sup>	no serious indirectness	serious <sup>11</sup>	none	127	93	-	SMD 0.58 lower (0.82 to 0.34 lower) <sup>3,12</sup>	⊕OOO VERY LOW	IMPORTANT
			with: validated to Better indicated			II Analog Scale 0	·100, Faces s	scale 0-5, C	hildren's H	ospital of Eastern C	Ontario P	ain Scale 0-6)
5	randomised trials	- )	40	no serious indirectness	serious <sup>11</sup>	none	183	144	-	SMD 0.96 lower (1.85 to 0.08 lower) <sup>3,12,15,16</sup>	⊕000 VERY LOW	IMPORTANT
Distress	Pre-procedu	re <sup>15,16</sup> (measu	red with: validate	ed tool (Childre	en's Hospital	of Eastern Onta	rio Pain Scal	e 0-6) by re	searcher; E	Better indicated by	ower val	ues)

inconsistency indirec	ctness					(1.18 to 0.12 lower) <sup>15,16</sup>	⊕OOO VERY LOW	IMPORTANT
ated tool (Likert scale 1	1-5); Better indicate	d by lower values)		I				
no serious no seri inconsistency indirec		none	63	29	-	SMD 2.18 lower (2.73 to 1.63 lower) <sup>3</sup>	⊕⊕OO LOW	IMPORTANT
alidated tool (Likert sca	ale 1-5); Better indic	ated by lower valu	les)	I				
no serious no seri inconsistency indirec		none	97	63	-	SMD 0.00 higher (0.36 lower to 0.35 higher)	⊕OOO VERY LOW	IMPORTANT
edure + Acute + Recove ndicated by higher valu		with: validated too	l Child-Adult	Medical Pr	ocedure Int	teraction Scale-Rev	vised, Be	haviour
no serious no seri inconsistency <sup>8</sup> indirec		none	127	93	-	SMD 2.6 higher (1.46 to 3.74 higher) <sup>3,12,13</sup>	⊕OOO VERY LOW	IMPORTAN
edure <sup>12,22</sup> (measured wit	th: validated tool (v	ideo analysis of p	roportion of t	ime watchi	ng televisio	on) by researcher; E	Better in	dicated by
no serious no seri inconsistency indirec		none	28	27	-	SMD 1.06 higher (0.5 to 1.63 higher) <sup>12,22</sup>	⊕OOO VERY LOW	IMPORTAN <sup>®</sup>
neasured with: validate	ed tool (video analy	sis of proportion o	of time watchi	ng televisi	on) byr rese	earcher; Better indi	cated by	/ higher
		none	28	27	-	SMD 0.57 higher (0.03 to 1.11 higher) <sup>22</sup>	⊕000 VERY LOW	IMPORTAN
inco r <b>oce</b>	edure + Acute + Red	nsistency indirectness edure + Acute + Recovery <sup>3,12,13</sup> (measur	edure + Acute + Recovery <sup>3,12,13</sup> (measured with: validated	edure + Acute + Recovery <sup>3,12,13</sup> (measured with: validated tool Child-Ac	edure + Acute + Recovery <sup>3,12,13</sup> (measured with: validated tool Child-Adult Medica	insistency indirectness	edure + Acute + Recovery <sup>3,12,13</sup> (measured with: validated tool Child-Adult Medical Procedure Interaction Scale-	edure + Acute + Recovery <sup>3,12,13</sup> (measured with: validated tool Child-Adult Medical Procedure Interaction Scale-Revised)

randomised trials	very serious <sup>7,10,14</sup>	no serious inconsistency	no serious indirectness	serious <sup>9</sup>	none	97	63	-	SMD 0.80 higher (0.5 to 1.1 higher) <sup>3,12,13</sup>	⊕OOO VERY LOW	IMPORTAN <sup>-</sup>
				(measured w	/ith: validated too	ol (Child-Adul	t Medical P	rocedure Ir	teraction Scale-Rev	vised, Be	ehaviour
randomised trials	serious <sup>20</sup>	no serious inconsistency	no serious indirectness	serious <sup>9</sup>	none	93	59	-	SMD 0.90 higher (0.55 to 1.24 higher) <sup>3,13</sup>	⊕⊕OO LOW	IMPORTAN
Preferences <sup>23</sup>	(assessed wi	th: validated too	l (questionnair	e regarding	preference for tr	eatment))	1		I		Į
randomised trials	serious <sup>20</sup>	no serious inconsistency	no serious indirectness	serious <sup>11</sup>	none	20/26 (76.9%)	15/21 (71.4%)	RR 1.08 (0.76 to 1.52) <sup>23</sup>	57 more per 1000 (from 171 fewer to 371 more)	⊕⊕OO LOW	IMPORTAN'
							0%		-		
references <sup>24</sup> (r	measured wit	h: questionnaire	by researcher	; Better indi	cated by lower va	alues)					
randomised trials	very serious <sup>7,10</sup>	no serious inconsistency	no serious indirectness	25	none	0	-	_24	not pooled <sup>24</sup>		IMPORTAN
ure Outcomes	, Vaccine Co	mpliance, Memo	ry, Satisfaction	(assessed	with: no data wer	e identified fo	or these im	portant out	comes)	<u> </u>	I
No evidence available					none	-	-	-	-		IMPORTAN
							0%		-		
dy by Cohen (19 istraction to no dy by Cohen (19	999), a cross-o treatment. 997), sample s	over design was u	sed whereby ch oup divided by 2	nildren receiv	ed 3 treatments (v	ideo distractio	n, topical an	esthesia, or	no treatment). Cohe -2.24 (95% CI -2.79 t		, .
	trials Use of Interve 0-1)) by resea randomised trials Preferences <sup>23</sup> randomised trials Preferences <sup>24</sup> (I randomised trials Ure Outcomes No evidence available dy by Cohen 19 dy by Cohen 19 dy by Cohen 19	trials       serious <sup>7,10,14</sup> Use of Intervention Pre-pro         0-1)) by researcher ; Better         randomised       serious <sup>20</sup> trials       serious <sup>20</sup> Preferences <sup>23</sup> (assessed wi         randomised       serious <sup>20</sup> trials       serious <sup>20</sup> randomised       serious <sup>20</sup> trials       serious <sup>20</sup> treferences <sup>24</sup> (measured with trials       serious <sup>7,10</sup> tree Outcomes, Vaccine Control trials       very serious <sup>7,10</sup> No evidence available       valiable         dy by Cohen 1997, analysis (*       dy by Cohen (1999), a cross-of istraction to no treatment.	trials       serious <sup>7,10,14</sup> inconsistency         Use of Intervention Pre-procedure + Acute - 0-1)) by researcher ; Better indicated by hig         randomised       serious <sup>20</sup> no serious inconsistency         Preferences <sup>23</sup> (assessed with: validated too trials       serious <sup>20</sup> no serious inconsistency         randomised       serious <sup>20</sup> no serious inconsistency         randomised       serious <sup>20</sup> no serious inconsistency         references <sup>24</sup> (measured with: questionnaire trials       very serious <sup>7,10</sup> no serious inconsistency         randomised       very serious <sup>7,10</sup> no serious inconsistency         ure Outcomes, Vaccine Compliance, Memo       No evidence available       lincluded parent yby Cohen 1997, analysis (1) included parent dy by Cohen (1999), a cross-over design was u istraction to no treatment.	trialsseriousinconsistencyindirectnessUse of Intervention Pre-procedure + Acute + Recovery3,13 ( 0-1)) by researcher ; Better indicated by higher values)randomised trialsseriousno serious inconsistencyno serious indirectnessrandomised trialsseriousno serious inconsistencyno serious indirectnessrandomised trialsseriousno serious inconsistencyno serious indirectnessrandomised trialsseriousno serious inconsistencyno serious indirectnessrandomised trialsseriousno serious inconsistencyno serious indirectnessrandomised trialsvery seriousno serious inconsistencyno serious indirectnessrandomised trialsvery seriousno serious inconsistencyno serious indirectnessrandomised trialsvery seriousno serious inconsistencyno serious indirectnessrandomised trialsvery seriousno serious inconsistencyno serious indirectnessrure Outcomes, Vaccine Compliance, Memory, Satisfaction availableNo evidence availabledy by Cohen 1997, analysis (1) included parent and immunizer dy by Cohen (1999), a cross-over design was used whereby chistraction to no treatment.	trialsseriousseriousinconsistencyindirectnessUse of Intervention Pre-procedure + Acute + Recovery(measured w0-1)) by researcher ; Better indicated by higher values)no seriousseriousrandomisedseriousno seriousno seriousserioustrialsseriousno seriousno seriousserioustrialsvery seriousno serious inconsistencyno seriousserioustrialsvery seriousno serious indirectness25ure Outcomes, Vaccine Compliance, Memory, Satisfaction (assessed reviableNo evidence available10No evidence availableno lincluded parent and immunizer training and dy by Cohen (1999), a cross-over design was used whereby children receiv	trials       serious <sup>7,10,14</sup> inconsistency       indirectness         Use of Intervention Pre-procedure + Acute + Recovery <sup>3,13</sup> (measured with: validated too 0-1)) by researcher ; Better indicated by higher values)         randomised       serious <sup>20</sup> no serious       no serious       serious <sup>9</sup> none         randomised       serious <sup>20</sup> no serious       no serious       serious <sup>9</sup> none         Preferences <sup>23</sup> (assessed with: validated tool (questionnaire regarding preference for traiting       serious <sup>20</sup> no serious       no serious       serious <sup>11</sup> none         randomised       serious <sup>20</sup> no serious       no serious       serious <sup>11</sup> none         randomised       serious <sup>20</sup> no serious       no serious       serious <sup>11</sup> none         trials       serious <sup>7,10</sup> no serious       no serious       serious <sup>12</sup> none         trials       serious <sup>7,10</sup> no serious       no serious       and serious       none         trials       serious <sup>7,10</sup> no serious       no serious       and serious       none         trials       serious <sup>7,10</sup> no serious       no serious       and serious       none         trials       serious <sup>7,10</sup> no serious       no serious <td>trials       serious<sup>7,10,14</sup>       inconsistency       indirectness         Use of Intervention Pre-procedure + Acute + Recovery<sup>3,13</sup> (measured with: validated tool (Child-Adul 0-1)) by researcher ; Better indicated by higher values)       Inconsistency       Inconsistency         randomised       serious<sup>20</sup>       no serious inconsistency       Inco</td> <td>trials       serious<sup>7.10.14</sup>       inconsistency       indirectness         Use of Intervention Pre-procedure + Acute + Recovery<sup>3.13</sup> (measured with: validated tool (Child-Adult Medical P 0-1)) by researcher ; Better indicated by higher values)         Irandomised       serious<sup>20</sup>       no serious inconsistency       no serious indirectness       serious<sup>9</sup>       none       93       59         Preferences<sup>23</sup> (assessed with: validated tool (questionnaire regarding preference for treatment))       Image: Serious<sup>20</sup>       no serious inconsistency       serious indirectness       serious<sup>11</sup>       none       20/26 (76.9%)       15/21 (71.4%)         Irandomised trials       serious<sup>20</sup>       no serious inconsistency       no serious indirectness       serious<sup>11</sup>       none       20/26 (76.9%)       15/21 (71.4%)         Irandomised trials       very serious<sup>7.10</sup>       no serious inconsistency       no serious indirectness       serious<sup>11</sup>       none       0       -         Irandomised trials       very serious<sup>7.10</sup>       no serious inconsistency       no serious indirectness       none       0       -         Irandomised trials       very serious<sup>7.10</sup>       no serious inconsistency       no serious indirectness       none       0       -         Irandomised trials       very serious<sup>7.10</sup>       no serious inconsistency       no serious indirectness       n</td> <td>trials       serious<sup>7:10.14</sup>       inconsistency       indirectness         Use of Intervention Pre-procedure + Acute + Recovery<sup>3:13</sup> (measured with: validated tool (Child-Adult Medical Procedure In 0-1)) by researcher ; Better indicated by higher values)         Irandomised       serious<sup>20</sup>       no serious inconsistency       no serious       no serious<sup>9</sup>       none       93       59       -         Preferences<sup>22</sup> (assessed with: validated tool (questionnaire regarding preference for treatment))       mos serious inconsistency       no serious indirectness       serious<sup>11</sup>       none       20/26 (76.9%)       15/21 (71.4%) (0.76.16 (0</td> <td>trials       serious<sup>210,14</sup>       inconsistency       indirectness       (0.5 to 1.1 higher)<sup>312,13</sup>         Use of Intervention Pre-procedure + Acute + Recovery<sup>3-19</sup> (0.5 to 1.24 higher)<sup>312,13</sup>       (0.5 to 1.4 higher)<sup>312,13</sup>       (0.5 to 1.4 higher)<sup>312,13</sup>         Image: trials       serious<sup>20</sup>       no serious inconsistency       no serious indirectness       serious<sup>9</sup>       none       93       59       -       SMD 0.90 higher (0.55 to 1.24 higher)<sup>313</sup>         Preferences<sup>24</sup> (assessed with: validated tool (questionnaire regarding preference for treatment))       inconsistency inconsistency       no serious indirectness       serious<sup>11</sup>       none       20/26 (76.9%)       15/21 (71.4%)       RR 1.08 (0.76 to 1.52)<sup>23</sup>       57 more per 1000 (from 171 fewer to 371 more)         trials       serious<sup>30</sup>       no serious inconsistency       no serious indirectness       serious<sup>11</sup>       none       0       -       -       -         trials       serious<sup>7,10</sup>       no serious inconsistency       no serious indirectness       none       0       -</td> <td>trials       serious<sup>7,10,14</sup>       inconsistency       indirectness       (0.5 to 1.1)       VERY         Use of Intervention Pre-procedure + Acute + Recovery<sup>9,13</sup> (measured with: validated tool (Child-Adult Medical Procedure Interaction Scale-Revised, Be       0-1) by researcher ; Better indicated by higher values)       Inconsistency       no serious       no serious       no serious       indirectness       serious<sup>90</sup>       no serious       indirectness       serious<sup>90</sup>       SMD 0.90 higher       (0.5 to 1.2,4)       higher)<sup>1,13</sup>       0         randomised       serious<sup>90</sup>       no serious       no serious       indirectness       serious<sup>91</sup>       none       93       59       -       SMD 0.90 higher       0.50 to 1.2,4       higher)<sup>1,13</sup>       0         Preferences<sup>20</sup>       (assessed with: validated tool (questionnaire regarding preference for treatment))       randomised       for nor per 1000 (from 171 fewer to 1.52)<sup>153</sup>       for nor per 1000 (from 171 fewer to 1.52)<sup>153</sup>       0       0       -       -       0       -       -       0       -       0       0       -       1000       0       0       0       0       0       0       0       0       -       -       0       -       -       0       -       -       0       -       -       0       -       -</td>	trials       serious <sup>7,10,14</sup> inconsistency       indirectness         Use of Intervention Pre-procedure + Acute + Recovery <sup>3,13</sup> (measured with: validated tool (Child-Adul 0-1)) by researcher ; Better indicated by higher values)       Inconsistency       Inconsistency         randomised       serious <sup>20</sup> no serious inconsistency       Inco	trials       serious <sup>7.10.14</sup> inconsistency       indirectness         Use of Intervention Pre-procedure + Acute + Recovery <sup>3.13</sup> (measured with: validated tool (Child-Adult Medical P 0-1)) by researcher ; Better indicated by higher values)         Irandomised       serious <sup>20</sup> no serious inconsistency       no serious indirectness       serious <sup>9</sup> none       93       59         Preferences <sup>23</sup> (assessed with: validated tool (questionnaire regarding preference for treatment))       Image: Serious <sup>20</sup> no serious inconsistency       serious indirectness       serious <sup>11</sup> none       20/26 (76.9%)       15/21 (71.4%)         Irandomised trials       serious <sup>20</sup> no serious inconsistency       no serious indirectness       serious <sup>11</sup> none       20/26 (76.9%)       15/21 (71.4%)         Irandomised trials       very serious <sup>7.10</sup> no serious inconsistency       no serious indirectness       serious <sup>11</sup> none       0       -         Irandomised trials       very serious <sup>7.10</sup> no serious inconsistency       no serious indirectness       none       0       -         Irandomised trials       very serious <sup>7.10</sup> no serious inconsistency       no serious indirectness       none       0       -         Irandomised trials       very serious <sup>7.10</sup> no serious inconsistency       no serious indirectness       n	trials       serious <sup>7:10.14</sup> inconsistency       indirectness         Use of Intervention Pre-procedure + Acute + Recovery <sup>3:13</sup> (measured with: validated tool (Child-Adult Medical Procedure In 0-1)) by researcher ; Better indicated by higher values)         Irandomised       serious <sup>20</sup> no serious inconsistency       no serious       no serious <sup>9</sup> none       93       59       -         Preferences <sup>22</sup> (assessed with: validated tool (questionnaire regarding preference for treatment))       mos serious inconsistency       no serious indirectness       serious <sup>11</sup> none       20/26 (76.9%)       15/21 (71.4%) (0.76.16 (0	trials       serious <sup>210,14</sup> inconsistency       indirectness       (0.5 to 1.1 higher) <sup>312,13</sup> Use of Intervention Pre-procedure + Acute + Recovery <sup>3-19</sup> (0.5 to 1.24 higher) <sup>312,13</sup> (0.5 to 1.4 higher) <sup>312,13</sup> (0.5 to 1.4 higher) <sup>312,13</sup> Image: trials       serious <sup>20</sup> no serious inconsistency       no serious indirectness       serious <sup>9</sup> none       93       59       -       SMD 0.90 higher (0.55 to 1.24 higher) <sup>313</sup> Preferences <sup>24</sup> (assessed with: validated tool (questionnaire regarding preference for treatment))       inconsistency inconsistency       no serious indirectness       serious <sup>11</sup> none       20/26 (76.9%)       15/21 (71.4%)       RR 1.08 (0.76 to 1.52) <sup>23</sup> 57 more per 1000 (from 171 fewer to 371 more)         trials       serious <sup>30</sup> no serious inconsistency       no serious indirectness       serious <sup>11</sup> none       0       -       -       -         trials       serious <sup>7,10</sup> no serious inconsistency       no serious indirectness       none       0       -	trials       serious <sup>7,10,14</sup> inconsistency       indirectness       (0.5 to 1.1)       VERY         Use of Intervention Pre-procedure + Acute + Recovery <sup>9,13</sup> (measured with: validated tool (Child-Adult Medical Procedure Interaction Scale-Revised, Be       0-1) by researcher ; Better indicated by higher values)       Inconsistency       no serious       no serious       no serious       indirectness       serious <sup>90</sup> no serious       indirectness       serious <sup>90</sup> SMD 0.90 higher       (0.5 to 1.2,4)       higher) <sup>1,13</sup> 0         randomised       serious <sup>90</sup> no serious       no serious       indirectness       serious <sup>91</sup> none       93       59       -       SMD 0.90 higher       0.50 to 1.2,4       higher) <sup>1,13</sup> 0         Preferences <sup>20</sup> (assessed with: validated tool (questionnaire regarding preference for treatment))       randomised       for nor per 1000 (from 171 fewer to 1.52) <sup>153</sup> for nor per 1000 (from 171 fewer to 1.52) <sup>153</sup> 0       0       -       -       0       -       -       0       -       0       0       -       1000       0       0       0       0       0       0       0       0       -       -       0       -       -       0       -       -       0       -       -       0       -       -

<sup>10</sup> In study by Cohen 1997, scores were not standardized
 <sup>13</sup> In study by Cohen 1997, scores were not standardized

<sup>14</sup> Outcome assessor not consistently blinded

<sup>15</sup> In study by Cassidy (2002), sample size assumed to be 29 per group

<sup>16</sup> In study by Cassidy (2002), only scores from Children's Hospital of Eastern Ontario Pain Scale included due to attrition bias

<sup>17</sup> Study by Luthy (2013) included some children < 3 years, which would not be expected to be able to provide self-report

<sup>18</sup> Heterogeneity can be explained by differences in age (2-11 years) and differences in intervention and intervention delivery

<sup>19</sup> Researcher present at procedure not blinded; unclear blinding of others

<sup>20</sup> No one is blinded during the conduct of the trial

<sup>21</sup> accepted as important outcome as may be regarded as a measure of satisfaction

<sup>22</sup> In study by Cassidy (2002), sample size assumed to be 28 for the intervention (distraction) group and 27 for the control (no treatment) group

<sup>23</sup> Sample size for the intervention (distraction) group assumed to 26 and sample size for the control (no treatment) group assumed to be 21

<sup>24</sup> In the study by Cohen (1999), children were asked about which treatment they preferred: 52% preferred distraction (1), 39% preferred topical anesthesia (another treatment condition in the trial, (2)) and 9% preferred no treatment

<sup>25</sup> Data not pooled