

SAGE Technical Consultation Group on Reducing Pain and Distress at the Time of Vaccination

Systematic Review of Effectiveness and Safety of Interventions

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Organization**

Prioritized Interventions

By consensus, SAGE Secretariat, 3 HELPinKids&Adults 2.0 CPG* authors prioritized and grouped most globally relevant interventions for review

1. no aspiration
2. injecting the most painful vaccine last
3. positioning (holding infant/child, sitting up, parental presence)
4. neutral language
5. caregiver presence
6. breastfeeding before and during vaccine injection
7. sweet tasting solutions for infants
8. topical anaesthetics
9. distraction
10. education of clinicians regarding pain, distress
11. education of caregivers regarding pain, distress

Reviewed : Benefits and harms, Resource use and value for money, Impacts on equity, Acceptability, Feasibility and Other.

**** Reminder: CPG2.0 GRADE methods applied and adhered to.***

No Aspiration for IM Vaccine Injections



WHO

No Aspiration for IM Vaccine Injections

Recommendation: No aspiration during intramuscular vaccine injections in all ages

Benefits and harms: shorter contact time with needle;
↓lateral movement, ↓pain.
No established harms

Resource use and value for money: No additional resources required beyond provider education

Impacts on equity: none

Acceptability: no cultural concerns

Feasibility: highly feasible

Other: Correct site of injection is not near major vessels; hence no need to aspirate

- If slight bleeding reflects minor surface vessels
- WHO recommends auto-disable (AD) syringes for vaccination most do ***not allow*** for aspiration.

Administer Vaccines in Order of Increasing Painfulness



WHO/B. Bayutas

Administer Vaccines in Order of Increasing Painfulness

Recommendation: Most painful vaccine last in all ages

Benefits and harms: clear benefits; no harms

Resource use and value for money: No additional resources required beyond provider education

Impacts on equity: none

Acceptability: no cultural concerns

Feasibility: limited research regarding relative painfulness of different vaccines to provide guidance; HCW experience
- these data **not** required by National Regulatory Authorities

Other: may prevent pain sensitization

Positioning: Holding 0-3y; Sitting >3y



WHO/Sergei Deshevoi

Positioning: Holding 0-3y; Sitting >3y

Recommendation: Holding children 0-3 years and having individuals >3 years sit up when receiving vaccinations

Benefits and harms: helps reduce fear; no identified harms

Resource use and value for money: requires chair, provider education

Impacts on equity: none

Acceptability: no cultural concerns

Feasibility: highly feasible
HCW training on:

- a) positioning
- b) courtesy in how to advise caregiver (holding) or vaccine recipient on positioning

Other: none

Neutral Verbal Cues



WHO

Neutral Verbal Cues

Recommendation: Avoid anxiety provoking language, excessive reassurance, and false suggestions about pain in all ages

Benefits and harms: does not reduce pain, may even increase pain, and potential to promote distrust

Resource use and value for money: requires provider education

Impacts on equity: none

Acceptability: no cultural concerns

Feasibility: highly feasible;
HCW need training on

- a) use of neutral words
- b) avoid excessive reassurance, false suggestion

Other: none

Caregiver Presence



FSG photo

*[http://www.fsg.org/KnowledgeExchange/
Blogs/GlobalHealth/PostID/374.aspx](http://www.fsg.org/KnowledgeExchange/Blogs/GlobalHealth/PostID/374.aspx)*

Caregiver Presence

Other: none

caregivers should be doing)

Breastfeeding: at time of or before vaccination



Breastfeeding: at time of or before vaccination

Conditional Recommendation: Breastfeeding during or before vaccination for infants

Benefits and harms: clear benefits; combines positive interventions of holding, sweet-tasting substances, sucking, skin-to-skin contact; no identified harms

Resource use and value for money: requires provider education

Impacts on equity: none

Acceptability: culturally acceptable in some areas, not others

Feasibility: WHO recommends breastfeeding ≥ 6 months; but not always possible if mother not with infant at vaccination or infant refuses to suck

Other: bottle feeding may simulate breastfeeding; requires safe water and/or clean equipment and is expensive

Sweet Tasting Solution for Infants



Sweet Tasting Solution: Sucrose/Glucose ~25-50%

Conditional Recommendation: Sweet tasting solution before vaccination *if not breastfeeding during vaccination* in infants

Benefits and harms: clear benefit (can give by syringe, dropper, cup, bottle);

- rotavirus vaccines may have adequate sucrose conc.
- not harmful as one-off interventions.

Resource use and value for money: Requires sucrose or glucose, clean water, delivery device, provider education

Impacts on equity: potential

Acceptability: no cultural concerns; not in conflict with baby friendly initiatives

Feasibility: requires additional time and resources;

- if breastfeeding, where **rotavirus vaccine** used, give it, then oral polio, then IM vaccines

Other: do not use honey due to risk of botulism

Topical Anaesthetics

NOT Recommended: Topical anaesthetics are effective BUT not practical or feasible for all ages

Benefits and harms: clear benefit for SC and IM vaccination. Does not affect immune response. Risks from self-compounded (not commercial) products

Resource use and value for money: Cost is major concern; In LIC may cost more than vaccine; requires provider education

Impacts on equity: not available globally; inequitable

Acceptability: preferences for intervention variable

Feasibility: requires preplanning for timely application; may need a prescription in some countries

Other: recommendations should be as per product monograph; studies demonstrate safety/effectiveness in <3 months of age; can be used with all injected vaccines

Distraction: Effective Type Varies by Age



Distraction

Conditional Recommendation: Distraction, age-specific type

Benefits and harms: evidence of benefit of different distractors in different ages:

- young child : toys and videos
- older child : music, videos, verbal distraction, toys
- adults: breathing interventions

Harms: effectiveness variable; may prevent the use of more effective interventions

Resource use and value for money:
May require resources, provider education

Impacts on equity: potential inequities except for breathing interventions

Acceptability: individual preferences

Feasibility: Children – music most feasible; adults – breathing;
Concerns about fidelity of implementation

Other: culturally acceptable interventions; singing/live music requires further study; adolescents – no data

Other *HELPinKids&Adults 2.0* CPG Interventions Reviewed and ***NOT*** Recommended for Global Use

1. Non-nutritive sucking
 - *pacifiers – not always acceptable*
 - *finger/thumb – not always feasible*
2. Simultaneous injections
 - *not feasible; can frighten*
3. Warming the vaccine
 - *not effective; may change vaccine quality*
4. Vapocoolants
 - *limited data (compared to topical anaesthetics); potentially painful administration and expensive*

Other *HELPinKids&Adults*

2.0 CPG

NOT Recommended for Global Use

5. Oral Analgesics *(at time injection)*

Benefits and harms:

Benefits and harms:

- lack evidence of clear benefits
- potential harm in reducing efficacy of vaccines

6. Manual Tactile Stimulation

Benefits and harms:

- lack evidence clear benefits
- not harmful per se but distract from using interventions that do mitigate pain

Other Interventions NOT presented

Other Interventions NOT presented

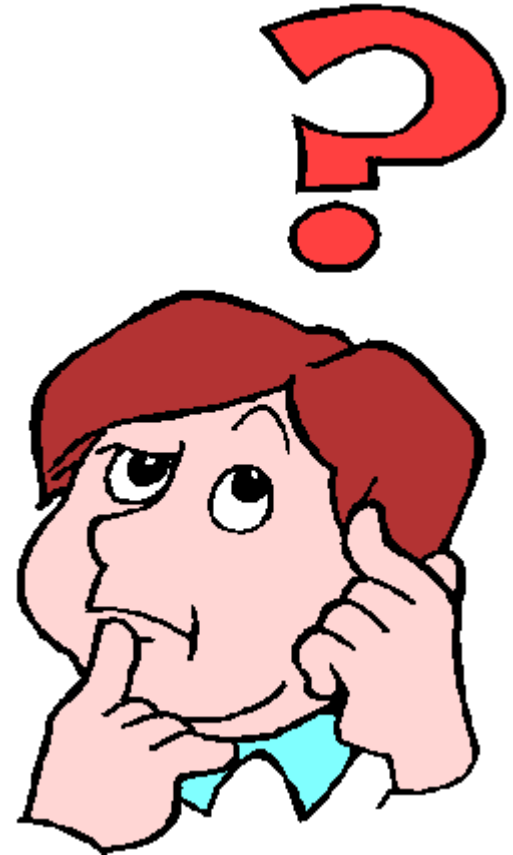
HELPinKids & Adults 2.0 CPG

2.0 CPG

1. Muscle tension to decrease fainting
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2. Tactile stimulation using vibration
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3. Skin to skin contact in neonates
4. Strategies to address those with high levels

Interventions without Evidence: Therefore Not Recommended at this time

1. Changing the needle after drawing the vaccination solution
2. Looking at versus away from the needle during injection
3. Vaccination setting privacy: patient alone versus being able to be observed by others



Limitations-1

Effective , feasible, culturally acceptable evidence based interventions exist but:

- evidence predominately but not exclusively from HIC
- many of the trials done in clinical settings not reflective of the range of conditions in LMIC.

Evidence presented limited to what had been included in HELPinKids&Adults 2.0 CPG.

- HELPinKids&Adults 2.0 CPG applied GRADE rigorously; thus for some interventions - reported high levels of uncertainty of evidence.
- Complementary and alternative medicine excluded

Limitations-2

Evidence base for many interventions does **not** cover all the age groups hence extrapolation for recommendations.

Trials rarely examined multiple pain mitigations strategies being used at the same time.

Psychological interventions maybe very operator dependent as well as having inter-subject variability (e.g. distraction).

- Complex psychological interventions such as hypnosis were excluded as impractical.

IM vs SC **not** assessed - requires more study.