

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

Introduction and Session Overview

N. Turner, SAGE Member

SAGE Meeting

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**World Health
Organization**

Background

- Vaccine injections are a common source of iatrogenic pain
- Fear of needles very common
 - Children, adults and parents/caregivers
 - Health Care Workers
- Fear of multiple injections in one visit
- Fear can intensify pain
- Negative experiences can lead to avoidance, and needle phobias

Taddio A, et al.. CMAJ. 2010 Dec 14;182(18):E843–55.

Kennedy A, et al. Pediatrics. 2011;127:S92-9.

Vervoort T, et al.. Pain. 2011;152:1751–7.

George SZ, et al. European Journal of Pain. 2006;10(5);457-65.

Background

Relief of pain or distress during health-related procedures is a basic human right

Child-Friendly-Healthcare Initiative*

- developed by Child Advocacy International in UK
- endorsed by WHO and UNICEF
- recommended development standards & guidelines:
 - for assessment of pain and discomfort
 - that invasive procedures be accompanied by adequate analgesia

**Southall DP et al. The Child-Friendly Healthcare Initiative (CFHI): Healthcare Provision in Accordance With the UN Convention on the Rights of the Child. Pediatrics. 2000;106 :1054-64.*

Background

↑ attention on measuring and tracking adverse events with immunization

Pain ***following vaccination*** – well studied

Understanding and mitigating pain ***at the time*** of the vaccination- less attention

Pain at the time of vaccine injection:

Brighton Collaboration

- has defined as AEFI
- in need of assessment and management



Immunization site pain: Case definition and guidelines for collection, analysis, and presentation of immunization safety data[☆]

Jane F. Gidudu^{a,*}, Gary A. Walco^b, Anna Taddio^c, William T. Zempsky^d, Scott A. Halperin^e, Angela Calugar^a, Neville A. Gibbs^f, Renald Hennig^g, Milivoj Jovancevic^h, Eva Netterlidⁱ, Terri O'Connor^j, James M. Oleske^k, Frederick Varricchio^{l,1}, Theodore F. Tsai^m, Harry Seifertⁿ, Anne E. Schuindⁿ, The Brighton Immunization Site Pain Working Group²

WHO SAGE Working Group on Vaccine Hesitancy.

Oct 2014

Section 6A.2 Other Strategies : Pain Mitigation

No evidence on mitigation of immunization pain retrieved

- in the systematic reviews of strategies to address hesitancy (*Jarret et al.2015*)
- in the review of reviews (Dube E. et al. 2015)

Noted:

- injection pain shown to cause distress: recipients, parents, adults, those giving injection
- “....fear of injection can lead to hesitancy”
- Evidence based guidelines on pain mitigation with immunization published in 2010 (Taddio et al 2010).

http://www.who.int/immunization/sage/meetings/2014/october/SAGE_working_group_revised_report_vaccine_hesitancy.pdf

Landscape - 1

Specific recommendations for pain mitigation at time of vaccination:

USA

- **CDC** has recommendations on website: Tips for a less stressful shot visit

<http://www.cdc.gov/vaccines/parents/tools/tips-factsheet.html>

- **AAP** : Lessening the pain with immunization .

https://www2.aap.org/immunization/families/Lessening_the_Pain.pdf

UK

- Practical advice for parents who want vaccination without tears, including how to dress your child and choosing pain relief.

<http://www.nhs.uk/Conditions/vaccinations/Pages/vaccination-appointment-tips-for-parents.aspx>

Landscape - 2

Europe: ECDC newsletter 2007

- article on injection techniques (from Canada)
- ECDC comment: This randomized study emphasizes the need for more systematic evidence to evaluate guidelines about vaccine administration techniques.

http://www.ecdc.europa.eu/en/healthtopics/VI%20Newsletter/392_070815%20XXVIII_final.pdf

India: Some research e.g. *Kumar et al A study of 'cough trick' technique in reducing vaccination prick pain in adolescents.* Indian J Pain 2014. 28:95-98. (10 articles in HelpinKIDS review)

Low and Middle Income Countries (LMIC)

- **Scoping review by Pottie and Siu, WHO 2015**
 - Some research on iatrogenic pain, esp. post operative
 - WHO Delphi priority exercise on addressing pain (practitioners can be a barrier to interventions to prevent pain)
- **Guide to Pain Management in Low Resource Settings**

Kopf A. Patel NB 2010: International Association for the Study of Pain.

- Focus on acute and chronic pain – not on injection related pain

[http://www.iasp-pain.org/files/Content/ContentFolders/Publications2/FreeBooks/Guide to Pain Management in Low-Resource Settings.pdf](http://www.iasp-pain.org/files/Content/ContentFolders/Publications2/FreeBooks/Guide%20to%20Pain%20Management%20in%20Low-Resource%20Settings.pdf)

Landscape - 3

Polio Eradication Program Feb 2014

Are there things that health care providers or workers can do to decrease or minimize the pain from multiple vaccine injections?

Yes. Studies have found that pain during immunization can be decreased by:

1. Having the child sit up to receive injections or by having a caregiver or provider hold an infant during the vaccinations;
2. *Stroking the skin or applying pressure close to the injection site before and during injection; ****
3. Injecting the least painful vaccine first when two vaccines are being administered sequentially during a single office visit; and
4. Performing a rapid intramuscular injection without aspiration.

**** NOT evidence based in HelpinKids&Adults 2.0 CPG and in process of being removed from current WHO recommended vaccination practice.*

http://www.who.int/immunization/diseases/poliomyelitis/inactivated_polio_vaccine/multiple_injections_acceptability_safety.pdf

Landscape - 4

Canada

- evidence based guidelines to mitigate pain and distress at the time of vaccination

Canada **HelpinKids 1.0 CPG** – published CMAJ in 2010
focus on infants and children

CMAJ REVIEW

CLINICAL PRACTICE GUIDELINE

Reducing the pain of childhood vaccination:
an evidence-based clinical practice guideline

Anna Taddio BScPhm PhD, Mary Appleton BA, Robert Bortolussi MD, Christine Chambers PhD, Vinita Dubey MD, Scott Halperin MD, Anita Hanrahan RN, Moshe Ipp MD, Donna Lockett PhD, Noni MacDonald MD, Deana Midmer RN EdD, Patricia Mousmanis MD, Valerie Palda MD MSc, Karen Pielak RN MSc, Rebecca Pillai Riddell PhD, Michael Rieder MD PhD, Jeffrey Scott MD, Vibhuti Shah MD MSc

- updated systematic review and revised guidelines
HelpinKids&Adults 2.0 CPG- *completed Feb 2015*
 - updated previous intervention recommendations
 - added further new evidence based interventions
 - now included evidence based interventions for adults

Purpose of WHO Technical Consultation

Determine whether recommendations from the Canadian systematic review on reducing pain and distress from vaccine injections can and should be adapted for a global context

Applicable:

- to infants, children, adolescents and adults
- around the globe: high, middle, low income countries

NB:

- rationale: reducing pain/distress will likely also prevent development of high levels of needle fear
- specific interventions for individuals with high levels of needle fear **not** to be included

Technical Consultation

- **Nikki Turner**, University of Auckland, New Zealand (SAGE Focal Point)
- **K. O. Antwi-Agyei**, Ghana Health Service, Accra, Ghana (expert consultant, member of IPAC)
- **Christine Chambers**, Dalhousie University, Centre for Pediatric Pain Research, IWK Health Centre, Canada (co-author HELPinKIDS&Adults 2.0 CPG)
- **Liesbet Goubert**, Ghent University, Belgium (expert consultant)
- **Darunee Jongudomkarn**, Faculty of Nursing, Khon Kaen University, Thailand (expert consultant)
- **Noni MacDonald**, Dalhousie University, Canadian Center for Vaccinology, Canada (co-author HELPinKIDS&Adults 2.0 CPG)
- **Anna Taddio**, University of Toronto, and The Hospital for Sick Children, Canada (Lead author HELPinKIDS &Adults 2.0 CPG)
- **WHO Secretariat: Philippe Duclos, Neeta Gurnani, Kevin Pottie, Melanie Schuster, Winnie Siu.**
- **Industry Rep: Lidia Oliveira**, Senior Medical Manager - Europe – Vaccines, Pfizer as an industry representative

Methods - 1

Reviewed **HelpinKids&Adults 2.0 CPG** Methods & Recommendations to determine quality and if fit with SAGE processes

HelpinKids&Adults 2.0 CPG Methods:

- Broad membership **HelpinKids&Adults** team
– independent

GRADE and Cochrane methods followed for general framework for development of recommendations for systematic reviews to appraise, synthesize research evidence, formulate clinical practice recommendations

Methods - 2

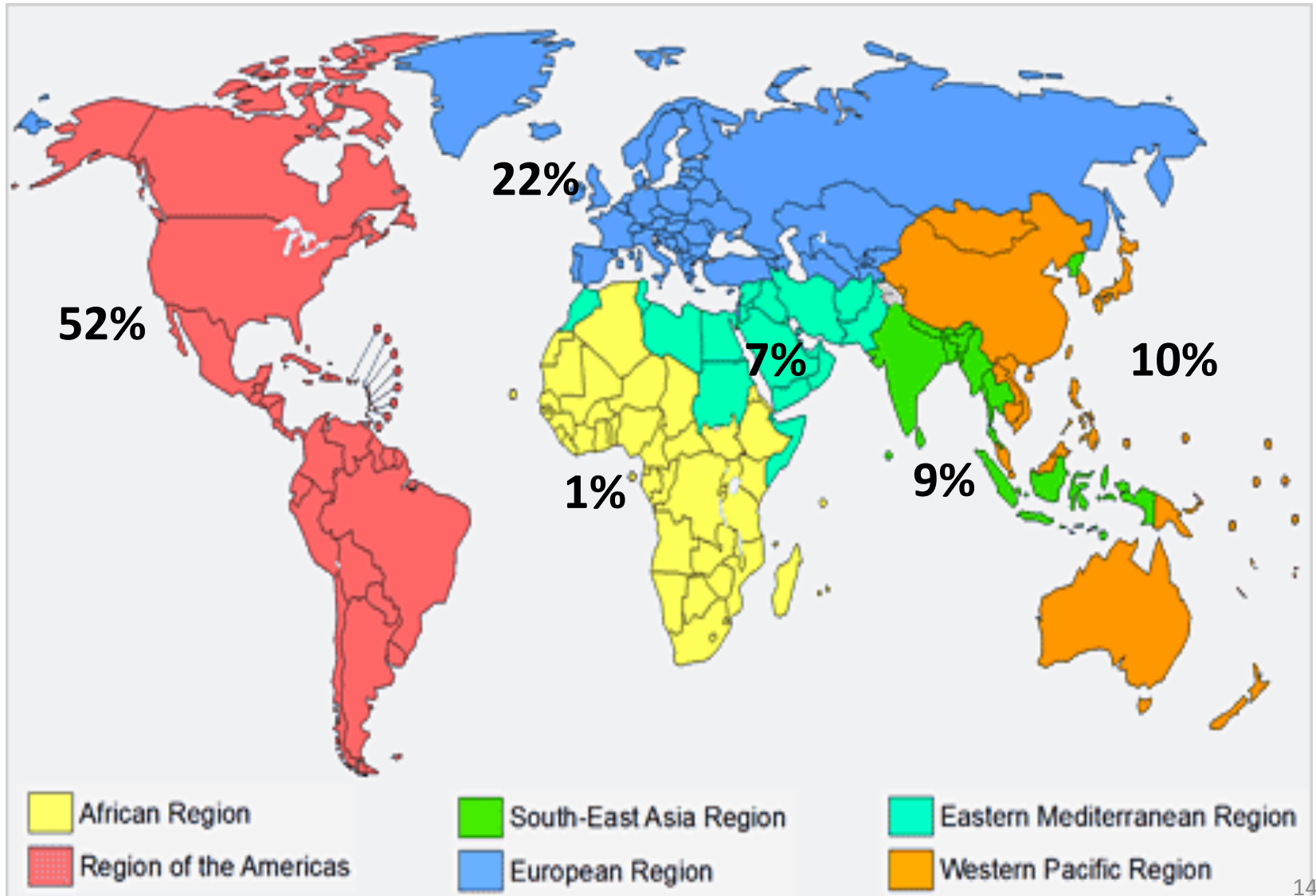
HelpinKids&Adults 2.0 CPG Methods cont'd :

- broad search strategy:
 - relevant articles from the following databases:
 - MEDLINE,
 - EMBASE,
 - PsycINFO,
 - CINAHL
 - ProQuest Dissertations.
- systematic evidence interpretation and summary
- GRADE approach to recommendations (rigorous application)
 - **Helpinkids&Adults** team review and discussion
 - 55 recommendations accepted
 - then external review > 30 experts and 15 organizations

searched databases
from date of
inception until 26
Feb 2015

Methods - 3

WHO Regions- 136 Articles Reviewed for HelpinKids&Adults Guideline



Methods - 4

WHO Technical Consultation

Used *GRADE-DECIDE* process to adapt existing evidence for:

- low and middle income countries (LMIC)
 - differing geographical settings
 - differing cultural settings
1. Identified potential interventions relevant, culturally acceptable for LMIC
 2. Identified systematic review evidence to determine the trade-offs: **benefits and harms, patient values and preferences, equity impacts, feasibility, acceptability, and costs.**
 3. Process provided evidence to determine interventions recommended and those not recommended.

Methods - 5

Consultation with industry

Attempted through the International Federation of Pharmaceutical Manufacturers & Associations and the Developing Countries Vaccine Manufacturers Network

Implementation Pilot Survey March 2015

- 25 African countries
- Reviewed strategies for pain mitigation (e.g. breastfeeding) that WHO Technical Consultation Group recommended with respect to:
 - Culture/gender
 - Preferences/values
 - Feasibility
 - Barriers
 - Acceptability
 - Cost

Further Presentations

1. Impact of pain and distress at the time of vaccination (N. MacDonald)
2. Systematic review of effectiveness and safety of interventions aimed at reducing pain and distress at time of vaccination (A. Taddio)
3. Proposed Recommendations (N. Turner)