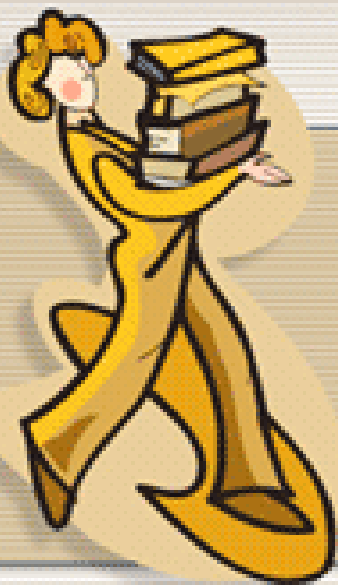


*Research*



*Research*



# Managing Injection Pain – HPV Vaccine

Vaccine Evaluation Center  
Clinical Experience



# [ Does it Hurt? ]

- Yes it does
- Does it hurt more than other teen vaccines? Yes it does...
  - Injection site
  - Muscle infiltration or pressure
  - Muscle Irritation

# What do we see occurring in clinic?

- Upset
- Anger
- Warning others (texting)
- Withdrawing from further vaccines in the series
- Syncope and other related nastiness (vomiting etc.)



# Prevention is key

- Developmentally appropriate preparation
- Set up physical environment
  - No long line ups or group gatherings
  - Limit waiting
  - Separate child from others
- Hydration
- Sugary drinks

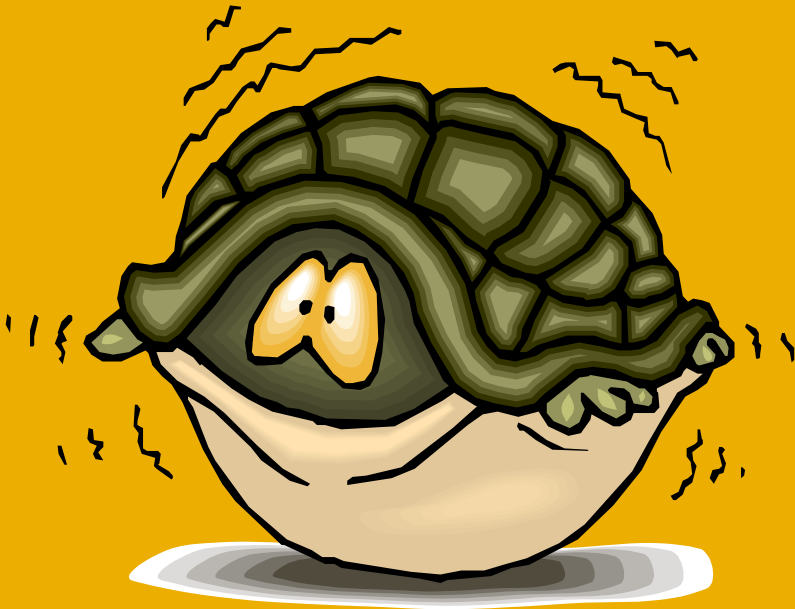
# Techniques *during* Administration

- Cognitive behaviour approaches
  - Distraction (TV, iPOD)
  - Nurse coaching
  - Deep breathing and relaxation techniques
  - Demonstration
- Assess child's state ongoing
- Lollipops (sugar during, distraction)
- Injection Techniques (90° angle, fast/no aspiration, administer other vaccines first)
- Topical Analgesic?

# After care is required

- Teen stays in clinic for 30 minutes
  - Since 2005, reports to VAERS have increased, most are females aged 11-18 years, and rarely, subsequent serious injuries have occurred. To prevent syncope-related injuries, ACIP recommends observing patients for 15 minutes. . . .
- Sugary drinks and water are provided
- Cookies are provided
- Waiting room for chatting and TV as distraction post vaccination or discussion on other more stressful topics (sex, condoms)

# Identifying pre-syncopal sx



- Observed or verbalized fear prior to vaccination
- Pallor
- 'sick to stomach'
- Sweating – 'room is hot'
- Absent mentally
- Sighing, yawning



# Recognition of syncope is important

- Onset
- Appearance
- Skin
- Breathing
- Blood Pressure
- Gastro-intestinal
- Pulse SLOW = Syncope



# VEC Background

- VEC nurses have been running vaccine clinics since 1989
- VEC has been running the HPV 2-dose versus 3-dose trial since Aug 2007
- Children 9-13 and 16-26 are included
- Trial requires a protracted first visit increasing anxiety, usual time for 2<sup>nd</sup> and (3<sup>rd</sup> dose) and blood samples pre and post

# [ Our Experience ]

- Visit 1: *shocking* difference in reported pain and teen reaction to the vaccination; prevention & treatment of issue stepped up by 3<sup>rd</sup> clinic
- By Visit 2 introduced a programme to try to reduce pain and evaluate a particular Tx (EMLA)

# EMLA vs No EMLA

## **Objective:**

Evaluate whether EMLA can reduce injection pain during HPV vaccination.

## **Study Design:**

- Completed ~ 675 HPV vaccines with only 1 near syncopal episode and <1% dropout rate
- Teens randomized at V2 to receive EMLA patch if interested in helping
- Baseline pain assessment obtained
- Patch applied by subject 1 hour pre V3
- Post vaccination assessments completed

# Outcome

## **Measurements:**

- Baseline pain assessment obtained using FLACC, NPS and subject experience at V2.
- Nurses followed the same procedures at V2 and V3 (pre-filled safety syringe, 1" needle length, 90° angle )

## **Some limitations to the study:**

- Subjects/Nurses are not blinded
- Randomization scheme was not strictly followed
- Measurement (FLACC) is for younger or non-verbal children.
- No placebo

# Interim Analysis

- N= 79 to date
- Subjective assessment between EMLA and no-EMLA group indicates no difference (NPS)
- Objective FLACC score =no difference
- Subject perception = no difference

# Discussion

EMLA seems of little use in preventing pain when applied prior to IM HPV injection in teens

- Some subjects failed to correctly place EMLA patch (not removed from analysis at interim)
- Measurements may not be sensitive enough to distinguish small differences in pain.
- Vaccine could cause muscle irritation which is not preventable by EMLA
- Sample size is not large enough

## **Conclusion:**

Not enough pain reduction or effect from using EMLA as a pain reduction technique to be worth the \$, effort and time to apply

# Acknowledgements to the VEC Team

## **Programme Evaluation Manager**

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