Implementation of an Evidence-Based Guideline for Prehospital Pain Management

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Acknowledgement

- National Highway Traffic and Safety Administration – Office of EMS

- With support from the federal EMS for Children program
Oligoanalgesia

• The under-treatment, ineffectual treatment, or lack of treatment of acute pain.

• Underuse of analgesics in the face of valid indications
EMS providers often encounter patients suffering from pain secondary to traumatic injuries. However, these patients are often not provided with optimal pain relief in the prehospital setting. In this session we will discuss an evidence-based approach to prehospital pain management. Implementation of the algorithm into the Maryland Institute for Emergency Medical Services Systems’ (MIEMSS) statewide protocols will be highlighted.
Learning Objectives

- Recognize the national prehospital evidence based guideline (EBG) model.

- Describe the clinical distinction in prehospital pain management based on adoption of an EBG-derived patient care algorithm,

- Discuss the challenges associated with implementation of an EBG approach to prehospital protocol development at the jurisdictional level.
• In the past 12 months, I have not had a significant financial interest or other relationship with the manufacturer(s) of the products or provider(s) of the services that will be discussed in my presentation.

• This presentation will not include discussion of pharmaceuticals or devices that have not been approved by the FDA.
Secretary LaHood Appoints New Members to the National Emergency Medical Services Advisory Council

WASHINGTON (July 23, 2010):

U.S. Transportation Secretary Ray LaHood announced the appointment of 23 leaders in the emergency medical services field to serve on the National Emergency Medical Services Advisory Council.

- Sitting member of the NEMSAC since 2007 (3rd term)
- Past member Institute of Medicine study team [2004-2007]
The IOM Future of Emergency Care Series (2007)
The federal government should support the development of national standards for emergency care performance measurement, the categorization of all emergency care facilities, and protocols for the treatment, triage and transport of prehospital patients.
IOM Recommendation: “Building a 21st Century EMS System”

- The National Highway Traffic Safety Administration, in partnership with professional organizations, should convene a panel of individuals with multidisciplinary expertise to develop evidence-based model prehospital care protocols for the treatment, triage, and transport of patients, including children.
GOBSAT
Why Evidence Based Guidelines (EBG)?

• To apply the best available information derived from scientific investigation to inform medical decision making.

• To improve patient outcomes and advance the field of prehospital medicine.
Why Evidence-Based Guidelines?

• Historical consequences:
  - Diethyilsbesterol (DES) to prevent miscarriage
  - Estrogen with progestin in post-menopause
  - 100% Oxygen in premature infants
**Historic Consequences**

<table>
<thead>
<tr>
<th>DES</th>
<th>Vaginal cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estrogen w/progestin</td>
<td>Invasive breast cancer</td>
</tr>
<tr>
<td>100% Oxygen</td>
<td>Blindness (retinopathy of prematurity)</td>
</tr>
</tbody>
</table>
• Historical consequences – EMS examples:
  ➢ MAST Trousers
  ➢ Hyperventilation in Head Injury
  ➢ Volume Resuscitation in Penetrating Trauma
Historic Consequences

- MAST Trousers
- Hyperventilation
- Volume in penetrating trauma
- Ventilatory impedance
- Cerebral vasoconstriction
- Clotting dislodgement
From Evidence to EMS Practice

• The process for national EMS evidence-based guidelines development will:
  ➢ Be organized, operated and sustained
  ➢ Evaluate evidence and develop guidelines
  ➢ Translate evidence into practice
  ➢ Ensure an ongoing method for guideline revision
• **Sponsors:**
  - Federal Interagency Committee on EMS (FICEMS)
  - National EMS Advisory Council (NEMSAC)

• **Two National Meetings:**
  - September 2008
  - December 2008
National Prehospital Evidence-Based Guideline Model

Approved by the Federal Interagency Committee on EMS and the National EMS Advisory Council

1. External Inputs
   - Evidence synthesis processes
   - Existing prehospital guidelines and protocols
   - Prehospital components of existing multidisciplinary EBGs
   - EMS scope of practice and educational standards
   - EMS researchers and professionals

2. Guideline Initiation and Evidence Review
   - Accept/gonorate proposals
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   - Recommend need for (or conduct) new systematic reviews
   - All partisans disclose affiliations and conflicts of interest

3. Evidence Appraisal
   - Evaluate quality of evidence and guidelines
   - Recommend topics for further guideline development
   - Archive material not selected for further development

4. Guideline Development
   - Prioritize outcomes
   - Weigh the risks and benefits of the interventions (GRADE methodology)
   - Assign a strength of recommendation for each intervention
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   - EMS contextualization
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5. Model EMS Protocol Development
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   - Link to recommendations from the EMS Education Agenda for the Future and to the National EMS Education Program Accreditation
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   - Produce non-educational and quality improvement materials
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7. Implementation
   - Link to national EMS provider certification/recertification
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8. Evaluation of Effectiveness, Outcomes, Clinical Research, QI Evaluations
   - EBG/protocol pilot testing & feasibility studies
   - Monitor local quality improvement benchmarks
   - Apply MiEISIS data in evaluation process
   - System research (EMSOP II and IV)
   - Outcomes research (EMSOP)
   - Clinical research on specific questions
   - Cost effectiveness, utility, and benefit analyses (EMSCAP)
   - Implementation research - analysis of implementation barriers and facilitators
The GRADE Process

• Grading of Recommendations Assessment, Development and Evaluation

➢ A standardized method for evaluating and summarizing the quality of evidence and the strength of a given recommendation.
Literature Hierarchy

Systematic Reviews, high quality RCTs

Observational Studies, prospective

Observational Studies, retrospective

Case Series

Textbooks and Expert Opinion without Critical Appraisal
What are we GRADING?

• Two components:
  
  ➢ Quality of body of evidence
    » extent to which confidence in estimate of effect is adequate to support decision
  
  ➢ Strength of recommendation
    » strong vs. weak

• Allows for contextual issues to be incorporated into “values and preferences”
Strong Recommendations

- strong methods
- large precise effect
- few downsides of therapy
- expect non-variant clinician and patient behavior
Weak Recommendations

- weak methods
- imprecise estimate
- small effect
- substantial downsides
- expect variability in clinician and patient actions
Primary Domains of EBG Development

- Options
- Questions
- Search
- Selection
- Appraisal
- Strength of evidence
- Combining studies
- Effect size
Primary Domains of EBG Development

Evidence Mastery

Context
Risk/benefits
Values
Preferences
Graded Recommendations
Graded Recommendations

- Valid
- Reliable, Clear
- Implementable

- Credible
- Transparent
- Unbiased
GRADE is Outcome-centric

Old system

GRADE

Outcome #1
- Quality: High

Outcome #2
- Quality: Moderate

Outcome #3
- Quality: Low
The EBG Process: In Practice

Published Evidence
- Cultural
- Operational

Topic Selection
- Formal Search
- Appraisal

Protocol
- Operationalization Dissemination
- Evaluate Performance
OH, NO! It’s protocol revision time again!
Date: August 5, 2009

Subject: Letter of Invitation – Application(s) for Federal Assistance to NHTSA Solicitation DTNH22-09-R-00244

To All Interested Parties:

The National Highway Traffic Safety Administration (NHTSA) is providing federal financial assistance to support a project that will develop an evidence-based guidelines for prehospital care for a specified condition. In addition, it will provide feedback on the proposed model process used to develop the protocol and recommendations for implementation. This feedback will be used to further validate and improve the proposed guidelines.
The major focus of this program is twofold: (1) to beta-test the proposed national Model, providing feedback on the implementation of the Model and the inter-relationships between the various Model components, and (2) to develop an evidence-based guideline that can be implemented at a national level by State and Tribal EMS systems. The Model, although initially tested on a limited level, will become the nationally-recognized process for the system-wide development, integration, and evaluation of national evidence-based protocols for EMS. For this reason, it is important to the success of the evidence-based guideline in a limited geographic region [i.e. EMS system partner].

- Implement the evidence based guideline in a limited geographic region [i.e. EMS system partner]

- Provide recommendations for strategies and next steps to implement the National Model
Evidence Based Guidelines for Prehospital Care:
A Pilot Test

Project Narrative
Evidence Based Guideline Development Pilot Study, 2010

• Pain Management in Trauma:

  ➢ Seated expert panel to implement GRADE methodology, including members of EMS partner agency (MIEMSS)

  ➢ Evidence Based Practices Expert Panel Meeting, July 2010
**Systematic review**

- **PICO**
  - Outcome: Critical
  - Outcome: Critical
  - Outcome: Important
  - Outcome: Not important

**Create evidence profile with GRADEpro**

**Rate quality of evidence for each outcome**

- High
- Moderate
- Low
- Very low

**Summary of findings & estimate of effect for each outcome**

**Guideline development**

- **Formulate recommendations:**
  - For or against (direction)
  - Strong or weak (strength)

- **By considering:**
  - Quality of evidence
  - Balance benefits/harms
  - Values and preferences

- **Revise if necessary by considering:**
  - Resource use (cost)

- **Rate overall quality of evidence across outcomes based on lowest quality of critical outcomes**

- “We recommend using...”
- “We suggest using...”
- “We recommend against using...”
- “We suggest against using...”
**Pain Management EBG**

**Moderate to Severe Acute Traumatic Pain**

Patients who demonstrate normal age appropriate mentation and experiencing acute pain due to trauma/injury.

All patients should be considered for pain management regardless of transport interval. *(Strong recommendation, moderate quality evidence)*

**GENERAL PATIENT CARE**

**Assess Pain**

*(Strong recommendation, low quality evidence)*

Consider an age appropriate pain scale:
- Age <4 (FLACC)
- Age 4-12 (FPS, FPS-revised, Wong-Baker or CAS)
- Age >12 (NRS)
*(Choice of Pain Scale: Weak recommendation, low quality evidence)*

**Cautions and Relative Contraindications**

- Hypotension
- SPO2 < 90
- Allergy
- Condition preventing administration (blocked nose, no IV/IO)
*(Weak recommendation, very low quality evidence)*

**Use analgesics to relieve pain in trauma patients with moderate to severe pain.**

*(Strong Recommendation, high quality evidence)*

Consider the following choices:
- IV Morphine (0.1 mg/kg), or
- IV Fentanyl (1 mcg/kg), or
- IN Fentanyl (1 mcg/kg)
*(Strong recommendation, moderate quality evidence)*

**Reassess every 5 minutes (end of dose time) based on pain assessment. Evidence of sedation or other adverse effects should preclude further drug administration.**

*(Strong recommendation, low quality evidence)*

**Re-dose if patient is still experiencing significant pain.**

*(Strong recommendation, low evidence)*

**Re-dose at half the initial dose.**

*(Weak recommendation, very low quality evidence)*
Protocol Development in Maryland

- Year round process
- Educational rollout each Spring
- Operational update each July
Protocol Development in Md: Timeline and Vetting Process

• Protocol Review Committee (PRC)
  ➢ Jan-Jun: Fields recommendations for addition and/or revisions
  ➢ July-Oct: Recommendations finalized for EMS Board submission
  ➢ Nov-Dec: Final approvals, formatting, clean-up
• **New Protocol Roll-out**
  - Jan-Mar: Formal dissemination of training resources
  - Mar-Jun: Introduction at CE major conferences
  - July 1st: New protocols become operational
GG. PAIN MANAGEMENT

1. Initiate General Patient Care

2. Presentation
   Pain may be present in many different conditions. Management of pain in the field can help to reduce suffering, make transport easier, and allow the emergency department personnel to initiate specific treatment sooner. Use of certain drugs for analgesia (reduction of pain) may also interfere with diagnostic procedures in the emergency department, and their use in such circumstances must be judicious, with medical control consulted when necessary.

3. Treatment indications
   a) Measure level of pain. Ask adults to rate their pain on a scale from 0 (no pain) to 10 (worst pain imaginable). Young children can be asked to rate their pain using the FACES scale, which provides 5 levels of pain perception.

   Pain Rating Scale
   - No Hurt
   - Little Bit
   - Little Worse
   - Even More
   - Whole Lot
   - Worst Pain Possible
     Unbearable
     Unable to do any activities because of pain

   b) Allow patient to remain in position of comfort unless contraindicated.
   c) Monitor airway and vital signs every 5 minutes for unstable patients

   d) Indications for pain management
      1. Acute myocardial infarction
      2. Burns
      3. Isolated injuries requiring pain relief
      4. Acute sickle cell pain crisis
      5. Abdominal pain with consult
      6. EMS/DNR Palliative Care Protocol (Option A or B)

   e) Contraindications for pain management
      1. Head injury
      2. Hypotension
      3. Sensitivity to morphine, codeine, or percodan
      4. Allergy to morphine

   f) Administer morphine intravenously or intramuscularly
      1. Adult:
         a) AMI: Administer 2-5 mg slow IVP, followed by 1 mg every 5 minutes to a maximum of 10 mg or until pain is relieved.
         b) Isolated injury (including burns, frostbite, eye trauma): Administer 2-10 mg slow IVP at 1-2 mg/min increments to 10 mg or until pain is relieved (Paramedic may perform without consult.) For doses above 10 mg, contact medical direction. OR
         c) May also be administered IM dose 5-15 mg based on patient weight
      2. Pediatric: 0.1 mg/kg IVP/IO/IM (slow 1-2 mg/min). Maximum dose of 5 mg.
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*(Choice of Pain Scale: Weak recommendation, low quality evidence)*

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**Cautions and Relative Contraindications**
- Hypotension
- SPO2 < 90
- Allergy
- Condition preventing administration (blocked nose, etc. IV/IO)
*(Weak recommendation, very low quality evidence)*

**Use analgesics to relieve pain in trauma patients with moderate to severe pain.** *(Strong Recommendation, high quality evidence)*
Consider the following choices
- IV Morphine (0.1 mg/kg), or
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**Reassess every 5 minutes (end of dose time) based on pain assessment. Evidence of sedation or other adverse effects should preclude further drug administration.** *(Strong recommendation, low quality evidence)*

**Re-dose if patient is still experiencing significant pain.** *(Strong recommendation, low evidence)*

**Re-dose at half the initial dose.** *(Weak recommendation, very low quality evidence)*
MIEMSS Pain Management 2011

PAIN MANAGEMENT (Continued)

(2) Contraindications for pain management with morphine
   (a) Head injury
   (b) Hypotension
   (c) Sensitivity to morphine, codeine, or percodan
   (d) Allergy to morphine

(3) Administer morphine intravenously or intramuscularly
   (a) Adult: Administer 0.1 mg/kg IV/IO titrated to effect at a rate of 2 mg/min to a maximum single dose of 20 mg. Repeat in 5-10 minutes after reassessment with 0.05 mg/kg titrated to effect at a rate of 2 mg/min to a maximum single dose of 10 mg. For IM, administer 0.1 mg/kg. (NEW ’11)
   (b) Isolated injury (including burns, frostbite, eye trauma): Administer 0.1 mg/kg IV/IO titrated to effect at a rate of 2 mg/min to a maximum single dose of 20 mg. Repeat in 5-10 minutes after reassessment with 0.05 mg/kg titrated to effect at a rate of 2 mg/min to a maximum single dose of 10 mg. For IM, administer 0.1 mg/kg. (Paramedic may perform without consult.) (NEW ’11)
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e) Moderate to severe pain
   (1) Indications for pain management
       (a) Acute myocardial infarction
       (b) Burns
       (c) Isolated injuries requiring pain relief such as suspected fractures or dislocations
       (d) Acute sickle cell pain crisis
       (e) Abdominal pain (NEW ’12)
       (f) EMS/DNR A, A (DNI), or B Protocol
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• Fentanyl added
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Next Steps - Manuscripts Submitted: Stay Tuned…

- The Implementation and Evaluation of an Evidence-based Statewide Prehospital Pain Management Protocol Developed Using the National Prehospital Evidence-based Guideline Model

- An Evidence-Based Guideline for Prehospital Analgesia in Trauma

- An Evidence-Based Guideline for Pediatric Prehospital Seizure Management Using GRADE Methodology

- An Evidence-Based Guideline For the Transportation of Prehospital Trauma Patients

- The Development of Evidence-based Prehospital Protocols Using a GRADE-based Methodology
COMMENTARY

If You’ve Seen One EMS System, You’ve Seen One EMS System...

In this month’s issue of Academic Emergency Medicine, Newgard and colleagues report on out-of-hospital airway procedures performed on injured adults and children. The data for this report were collected from the Resuscitation Outcomes Consortium ROC EMS sites. We know that the agencies carry different airway equipment, so it would stand to reason that there are differences in airway protocols between the EMS agencies—but how substantial are these differences? Does training differ? We know that para-
Next Steps...advancing from “in vitro to in vivo”

- NHTSA Office of EMS cooperative agreement awards to the National Association of State EMS Officials (NASEMSO):
  - Support the use and further refinement of the National Evidence-Based Guideline Model Process
  - Diverse system designs and protocol development functions
Questions??