




Texas EMSC State Partnership

Implementation of an Evidence-Based, Standardized Pediatric Prehospital Respiratory Distress Protocol

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Objectives

- To provide an overview of the past, present and future of national prehospital evidence-based guideline (EBG) **development**
- To describe the successes and challenges of prehospital EBG **implementation**
- To define important considerations in prehospital EBG **outcome assessment**

Texas EMSC State Partnership

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Guideline Development

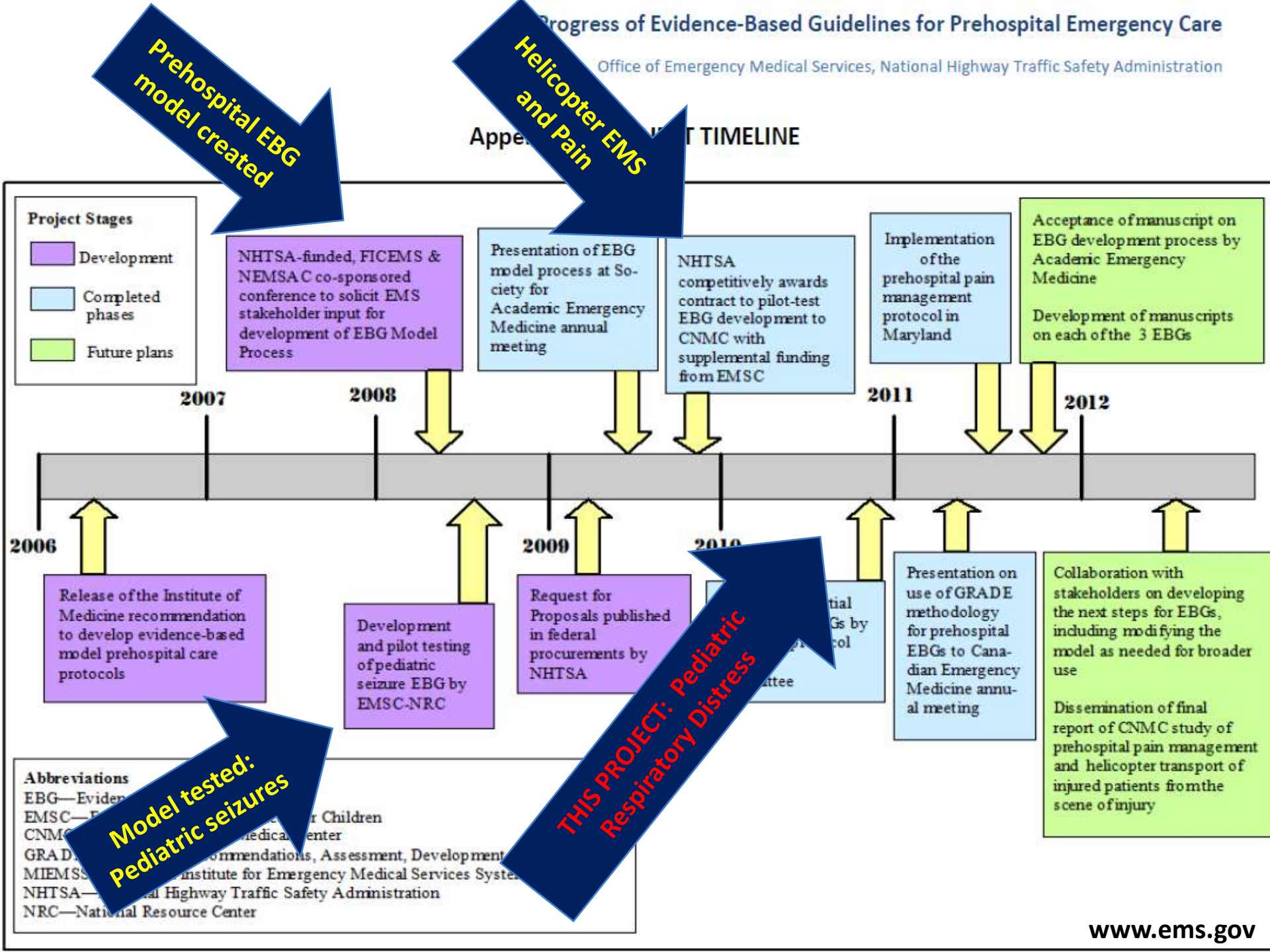
Role of Evidence-Based Guidelines

- What are they?
  - "Systematically developed statements to assist practitioner and patient decision(s) about appropriate health care for specific clinical circumstances" -Institute of Medicine
- Help translate research → practice
- Relevance to EMS: providers operate under the delegated practice of a physician medical director

Potential Benefits

- Summarize available evidence on broad clinical topics
- Improved effectiveness and safety of care
- Provide clinicians with relevant and reliable summaries of evidence
- Address treatment uncertainties
- Help maximize use of health care resources
- Enhance shared decision-making between patients and physicians

Penney and Foy. Best Practice and Research, 2007


Progress of Evidence-Based Guidelines for Prehospital Emergency Care
Office of Emergency Medical Services, National Highway Traffic Safety Administration
Prehospital EBG model created
Helicopter EMS and Pain
Project Stages
Development
Completed phases
Future plans
NHTSA-funded, FICEMS & NEMSAC co-sponsored conference to solicit EMS stakeholder input for development of EBG Model Process
Presentation of EBG model process at Society for Academic Emergency Medicine annual meeting
NHTSA competitively awards contract to pilot-test EBG development to CNMC with supplemental funding from EMSC
Implementation of the prehospital pain management protocol in Maryland
Acceptance of manuscript on EBG development process by Academic Emergency Medicine
Development of manuscripts on each of the 3 EBGs
2006
2007
2008
2009
2011
2012
Release of the Institute of Medicine recommendation to develop evidence-based model prehospital care protocols
Development and pilot testing of pediatric seizure EBG by EMSC-NRC
Request for Proposals published in federal procurements by NHTSA
Presentation on use of GRADE methodology for prehospital EBGs to Canadian Emergency Medicine annual meeting
Collaboration with stakeholders on developing the next steps for EBGs, including modifying the model as needed for broader use
Dissemination of final report of CNMC study of prehospital pain management and helicopter transport of injured patients from the scene of injury
Model tested: Pediatric seizures
THIS PROJECT: Pediatric Respiratory Distress
Abbreviations
NHTSA—National Highway Traffic Safety Administration
NRC—National Resource Center

www.ems.gov

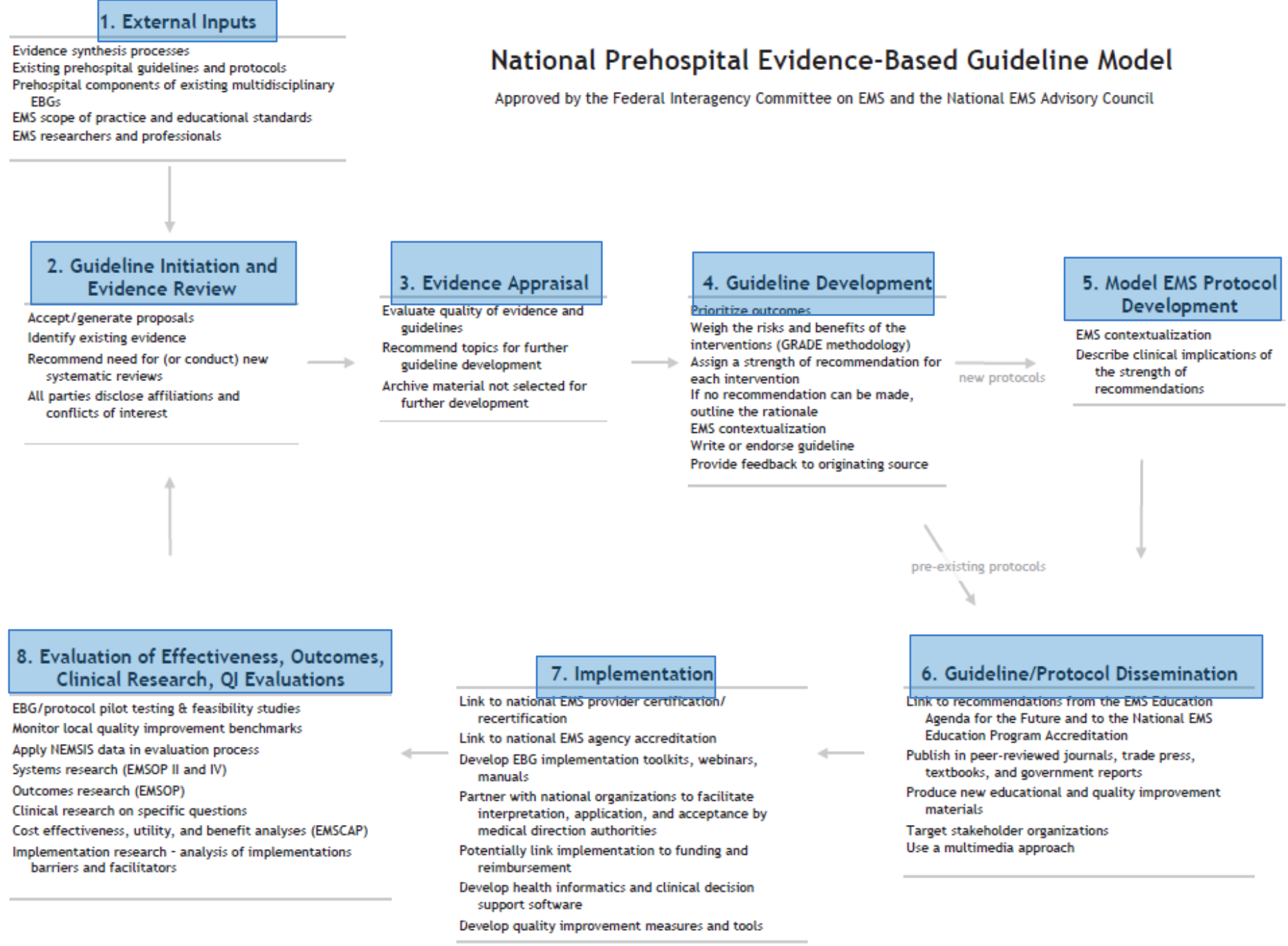
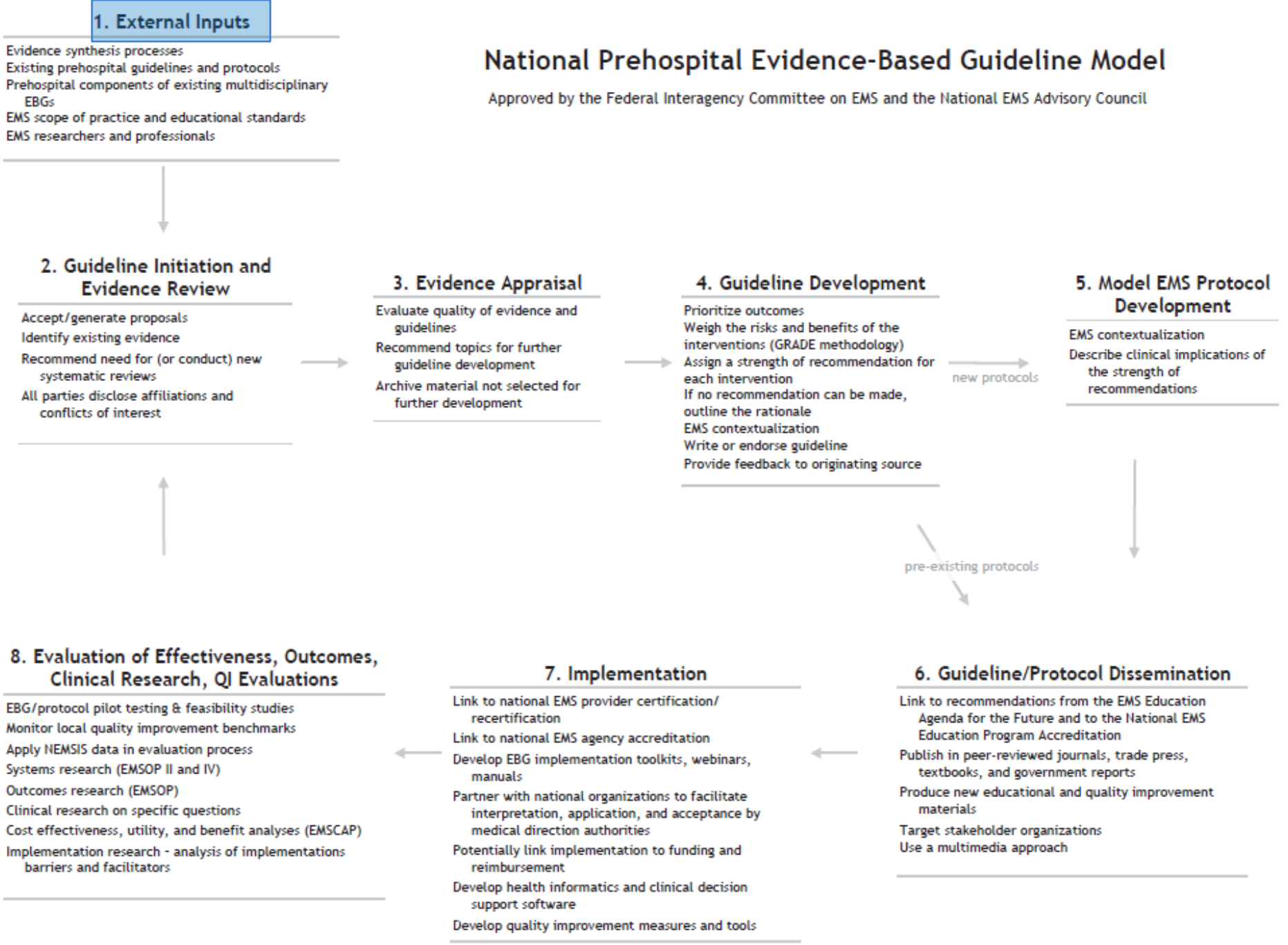


Figure 1. National prehospital EBG model. EBG = evidence-based guideline.

Lang, *Acad Emerg Med, 2012*

National Prehospital Evidence-Based Guideline Model

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



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Project Aims

OVERALL AIM: To create a model statewide infrastructure for the development, implementation, and measurement of outcomes of evidence-based pediatric prehospital protocols in a state with independently functioning Emergency Medical Services (EMS) systems

SPECIFIC AIMS

- To establish and evaluate a process for the development of evidence-based pediatric prehospital protocols for the state of Texas through the existing Emergency Medical Services for Children (EMSC) State Partnership and the Texas Children's Hospital Evidence Based Outcomes Center (TCH EBOC)
- To implement a pediatric prehospital protocol in 3 targeted EMS systems in Houston, Dallas, and Austin through training of prehospital personnel in the use of the protocol
- To evaluate the impact of a pediatric prehospital protocol by tracking process and outcomes measures after its implementation in multiple systems

Multi-Site Engagement of EMS

- 3 of the largest urban EMS systems in the U.S. participating
  - Houston Fire Department EMS
  - City of Austin / Travis County EMS
  - Bio Tel EMS (Dallas)
- Medical directors and paramedics from each system actively engaged in protocol development process
- Has potential to impact care for thousands of children in respiratory distress
- Results will be generalizable to other urban EMS systems

Multi-disciplinary engagement is essential:

- EMS Medical Directors x3
- Pediatric Emergency Medicine (PEM) physicians x3
- Paramedics x3
- Parent x1

Project Personnel

Site-Specific Principal Investigators (PEM)

- Dr. Halim Hennes (Dallas)
- Dr. Sujit Iyer (Austin)

Medical Directors

- Dr. Ray Fowler (Dallas)
- Dr. Paul Hinchey (Austin)
- Dr. Chris Souders (Houston)
- Dr. Paul Sirbaugh (Houston)

Project Personnel

Data Managers

- Jon Duckert (Dallas)
- Ben King (Austin)
- Jennifer Jones (Houston)

Prehospital Providers on Protocol Development Committee

- Stephen Bock (Dallas)
- Liz Yankiver (Austin)
- Chris Kelley (Houston)

Project Personnel

Other Protocol Development Personnel

- Patrick Barrera (Assistant Director, TCH EBOC)
- Quinn Franklin (Research Specialist, TCH EBOC)

EMSC State Partnership Personnel

- Tony Gilchrest (Program Manager)
- Betsy Furler and Elaine Hime (FAN Representatives)

Online Curriculum Development

- Dr. Jenna Miller

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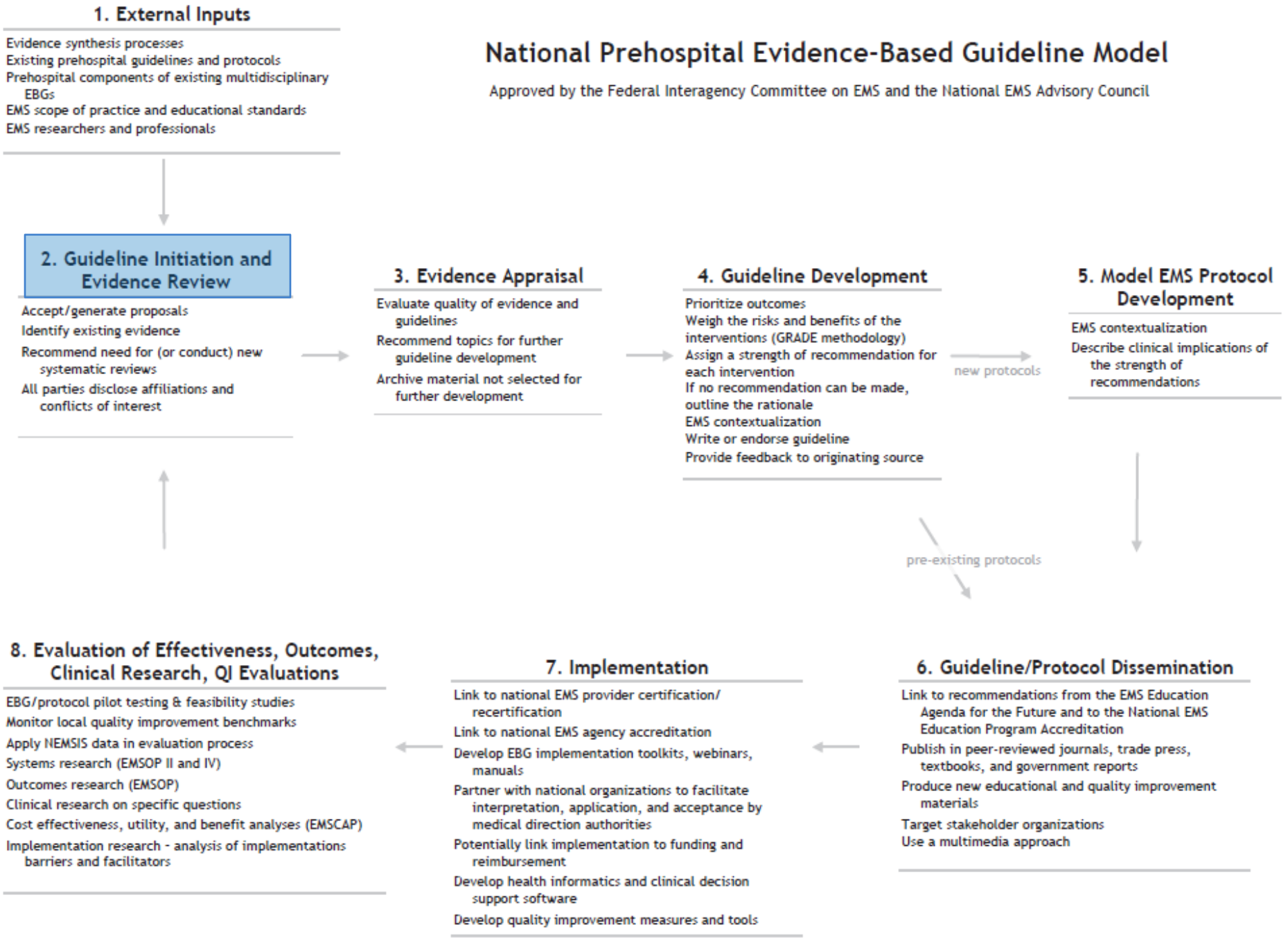

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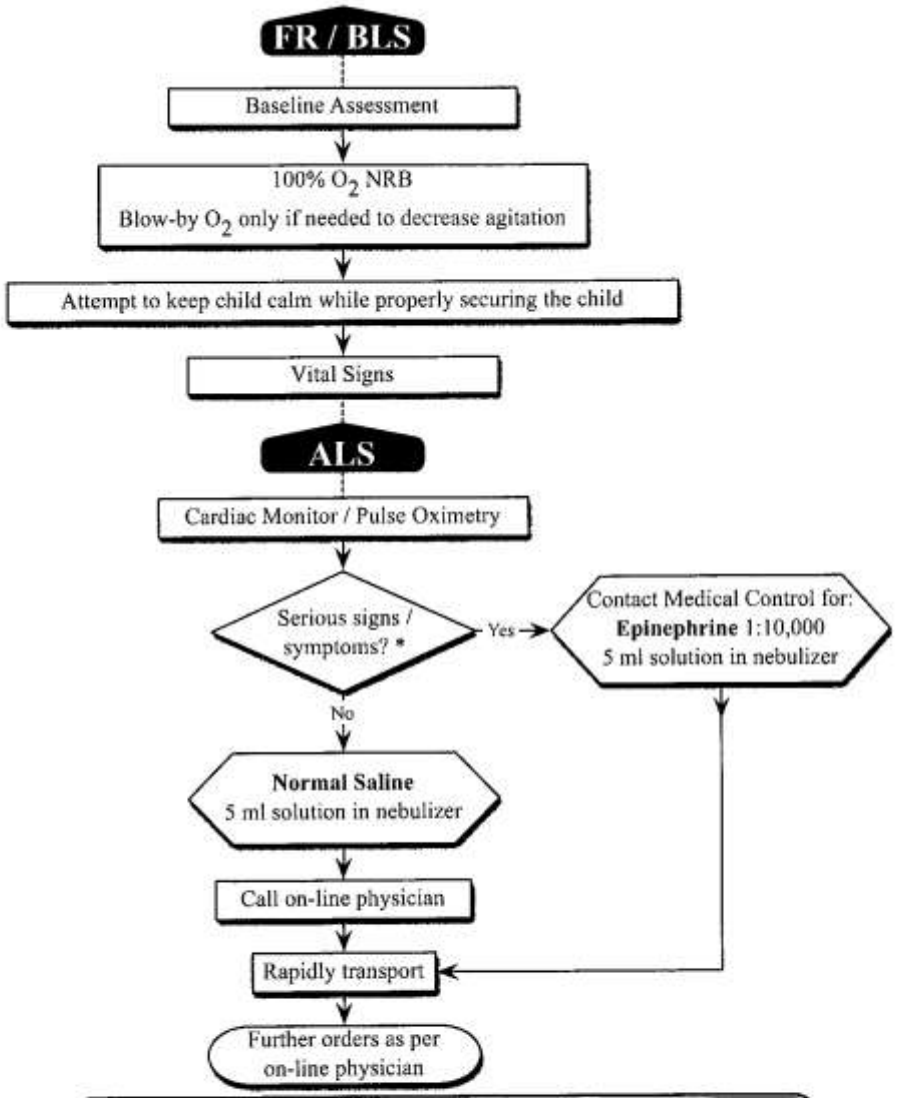
Guideline Initiation: Topic Selection

- Aggressive behavior
- Allergic reactions
- Altered mental status
- Cardiac arrest
- C-spine immobilization
- Fever
- Heat exposure
- Injury
- Nontransport criteria
- Pain
- Poisoning
- Respiratory distress
- Restraint devices for transport
- Seizures
- Shock/Hypotension/Tachy cardia
- Submersion
- Transition of care from EMS to EC
- Vomiting/Diarrhea

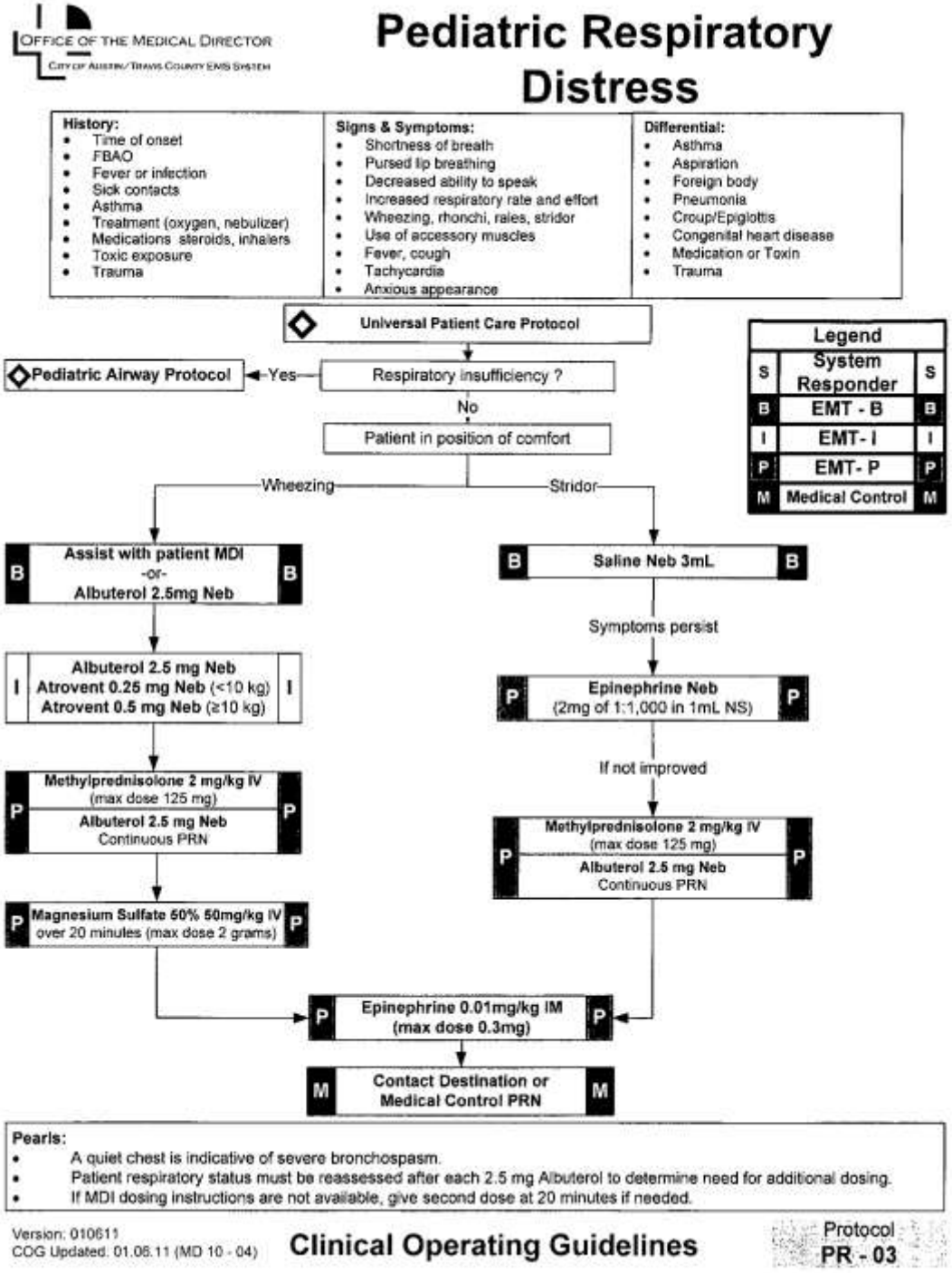
- High prevalence
- Variations in practice
- Resource intensive
- Morbidity/mortality risk for the patient
- Evidence exists
- Feasibility in collecting data
- Diagnostic and therapeutic options exist for the condition

8.03 T. Croup / Inspiratory Stridor - PEDIATRIC ONLY



Need to look at existing protocols to ensure the following:

- Evidence exists on the topic
- Current evidence is not being applied in care
- Variability in care exists


Office of the Medical Director
City of Austin/Travis County EMS System
Pediatric Respiratory Distress
History:
Time of onset
FBAO
Fever or infection
Sick contacts
Asthma
Treatment (oxygen, nebulizer)
Medications steroids, inhalers
Toxic exposure
Trauma
Signs & Symptoms:
Shortness of breath
Pursed lip breathing
Decreased ability to speak
Increased respiratory rate and effort
Wheezing, rhonchi, rales, stridor
Use of accessory muscles
Fever, cough
Tachycardia
Anxious appearance
Differential:
Asthma
Aspiration
Foreign body
Pneumonia
Croup/Epiglottis
Congenital heart disease
Medication or Toxin
Trauma
Universal Patient Care Protocol
Pediatric Airway Protocol
Yes
Respiratory insufficiency ?
No
Patient in position of comfort
Wheezing
Stridor
Legend
S System Responder S
B EMT - B B
I EMT- I I
P EMT- P P
M Medical Control M
B Assist with patient MDI -or- Albuterol 2.5mg Neb B
I Albuterol 2.5 mg Neb
Atrovent 0.25 mg Neb (<10 kg)
Atrovent 0.5 mg Neb (≥10 kg) I
P Methylprednisolone 2 mg/kg IV (max dose 125 mg)
Albuterol 2.5 mg Neb Continuous PRN P
P Magnesium Sulfate 50% 50mg/kg IV over 20 minutes (max dose 2 grams) P
B Saline Neb 3mL B
Symptoms persist
P Epinephrine Neb (2mg of 1:1,000 in 1mL NS) P
If not improved
P Methylprednisolone 2 mg/kg IV (max dose 125 mg)
Albuterol 2.5 mg Neb Continuous PRN P
P Epinephrine 0.01mg/kg IM (max dose 0.3mg) P
M Contact Destination or Medical Control PRN M
Pearls:
A quiet chest is indicative of severe bronchospasm.
Patient respiratory status must be reassessed after each 2.5 mg Albuterol to determine need for additional dosing.
If MDI dosing instructions are not available, give second dose at 20 minutes if needed.
Version: 010611
COG Updated: 01.06.11 (MD 10 - 04)
Clinical Operating Guidelines
Protocol PR - 03

b.

Wheezing

Adult and Pediatric

- Mild to moderate wheezing, administer nebulized
  - Albuterol 2.5 mg. If wheezing persists but the patient is
    - Improving, administer up to two additional albuterol doses
    - Not improving with the first albuterol dose, combine 2nd and 3rd albuterol doses with ipratropium 0.5 mg (ipratropium dose for infant less than 1 year is 0.25 mg).

If no significant improvement, following nebulizer therapy

Adult	Pediatric
• Apply CPAP at 5 cm H_2O pressure, if available o If the distress does not improve and the patient is tolerating CPAP, increase CPAP pressure to 10 cm H_2O, if available	• Contact BioTel

If no significant improvement following application of CPAP, simultaneously

Adult	Pediatric
• Administer methylprednisolone 60 mg – 125 mg IVP • Add 2 grams magnesium sulfate to 250 ml normal saline bag and infuse IV piggyback over 6 - 10 minutes o BioTel authorization required if dialysis patient o Avoid if history of COPD	• Contact BioTel

If no response to nebulizers, CPAP or magnesium sulfate, administer

Adult	Pediatric
• 1:1,000 Epinephrine 0.3 - 0.5 mg SQ	• Contact BioTel

c.

For status asthmaticus, simultaneously

Adult	Pediatric
• Administer albuterol 2.5 mg mixed with ipratropium 0.5 mg every five minutes up to 3 doses • Apply CPAP at 5 cm H_2O pressure, if available o If the distress does not improve and the patient is tolerating CPAP, increase CPAP pressure to 10 cm H_2O • Administer methylprednisolone 60 mg – 125 mg IVP • Add 2 grams magnesium sulfate to 250 ml normal saline bag and infuse IV piggyback over 6 - 10 minutes. o BioTel authorization required if dialysis patient o Avoid if history of COPD	• Administer albuterol 2.5 mg mixed with ipratropium 0.5 mg every five minutes up to 3 doses (ipratropium dose for infant less than one year is 0.25 mg) • Contact BioTel

8. For additional patient care considerations not covered under standing orders, consult BioTel.

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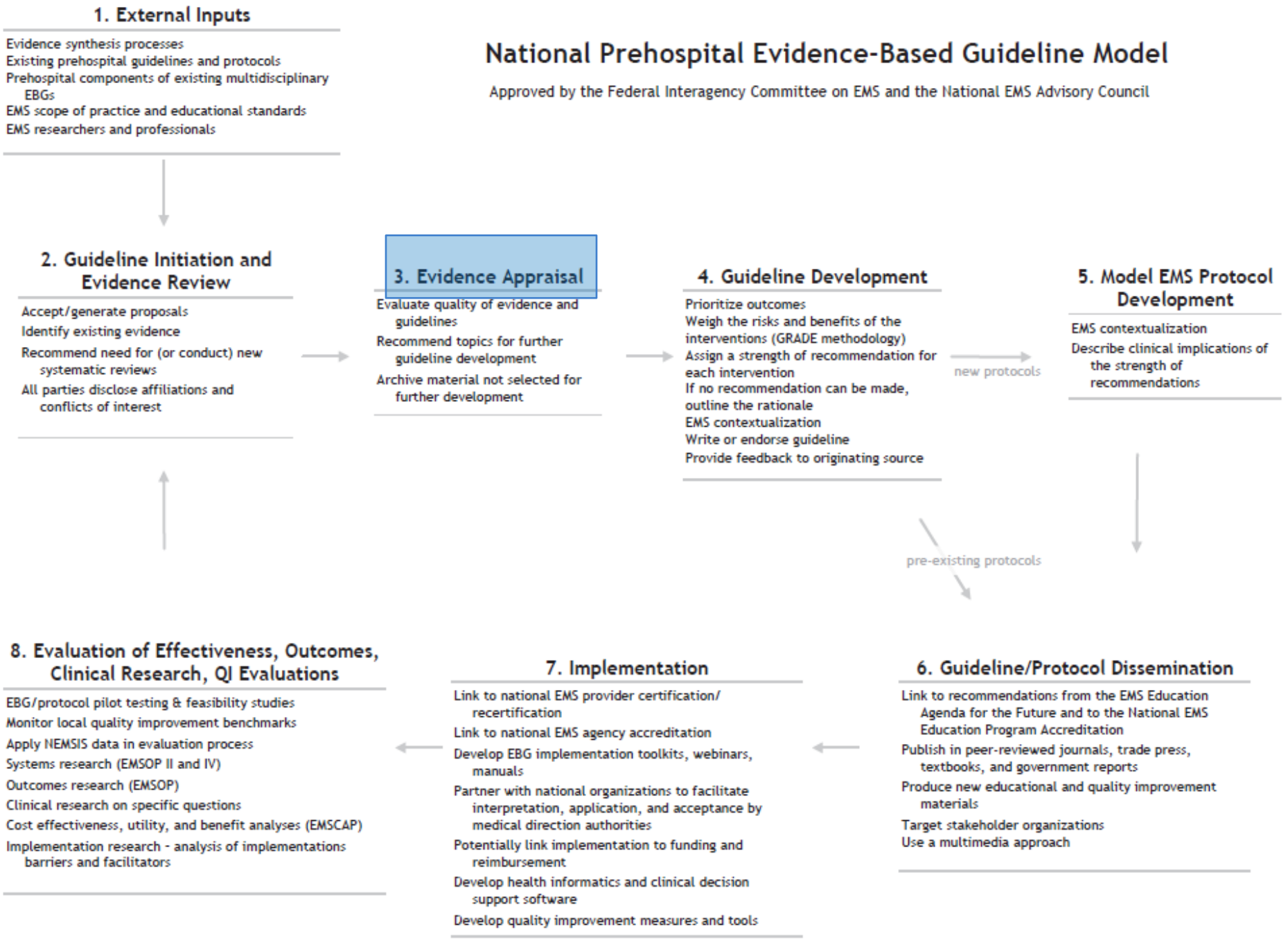

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Lang, *Acad Emerg Med, 2012*

Evidence Appraisal

- **Evidence-based medicine course** curriculum adapted to train protocol development committee
- **Research specialists** experienced in guideline development for hospital and clinic-based care
- Research specialists guided search and appraisal process between meetings #1 and #2
- EBOC staff was instrumental in making the 2-day workshops in 01/11 and 03/11 highly productive

Evidence Appraisal

- PICO questions defined by a multidisciplinary committee
  - **P**atient
  - **I**ntervention
  - **C**omparison
  - **O**utcome
- Recommendations made using the Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) approach

Use of consistent methodology is also necessary

Evidence Appraisal: PICO Questions

- In children with respiratory distress in the prehospital setting…
  - Which respiratory assessment tools have been validated?
  - Is a pulse oximetry sufficient in monitoring a child's respiratory status?
  - Is electrocardiogram/cardiac monitoring necessary in monitoring a child's respiratory status?
  - Is the routine application of oxygen in the absence of hypoxia clinically effective?
  - Is airway suctioning effective in improving:
    - Oxygenation?
    - Clinical signs of distress?

Clinically-relevant questions must drive guideline development

Evidence Appraisal: PICO Questions

- In children with respiratory distress in the prehospital setting…
  - Are the following inhaled medications clinically effective:
    - Albuterol?
    - Levalbuterol (Xopenex)?
    - Ipratropium (Atrovent)?
    - Hypertonic saline (3%, 5%...)?
    - Racemic epinephrine?
    - Magnesium sulfate?
  - Is it efficacious (e.g. lead to better clinical outcomes) to place an IV?

Evidence Appraisal: PICO Questions

- In children with respiratory distress in the prehospital setting…
  - Do steroids (any route) lead to improved clinical outcomes?
  - When are IV fluids clinically effective and useful?
  - Does epinephrine (IM/SQ/IV) lead to improved clinical outcomes?
  - What are the clinical situations in which the following non-invasive airway adjuncts improve oxygenation and/or respiratory distress:
    - Continuous positive airway pressure (CPAP)?
    - Bag valve mask ventilation?
    - Heliox?
  - Do supraglottic devices lead to improved clinical outcomes?

Evidence Appraisal: PICO Questions

- In children with respiratory distress in the prehospital setting…
  - Does intubation lead to improved clinical outcomes?
  - Under what clinical conditions is capnography (end tidal CO2) clinically effective and useful?
  - Are there improved patient outcomes when online medical direction is contacted versus no online medical direction is contacted?
  - Are there improved patient outcomes when patients are transported by Advanced Life Support (ALS) providers compared to Basic Life Support (BLS) providers?
  - Is it clinically efficacious (e.g., improve patient outcomes) to transport as a Code 3 (i.e., lights, sirens) in comparison to a Code 1?

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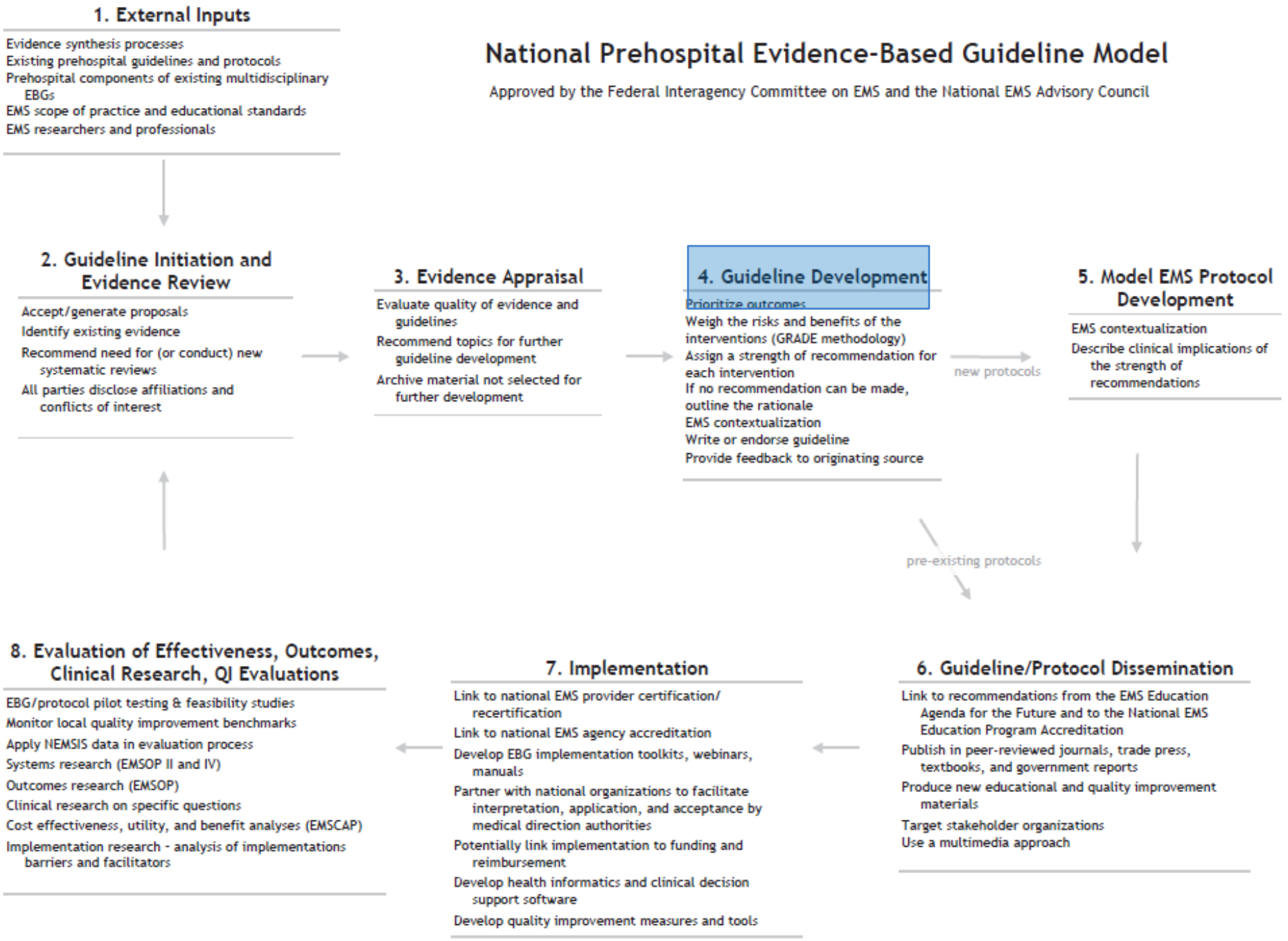

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Guideline Development

Integrating Evidence-Based Pediatric Prehospital Protocols into Practice

Week/Dates	Objectives	Assignments	Important Dates
Week 1 January 24- January 28	Participate in Workshop A	Refine PICO questions	Research Specialists to submit PICO questions to Dr. Shah ***by Friday, February 4***
Week 2 January 31- February 4	PICO Questions/Searching	Finalize PICO questions Begin search utilizing preidentified limits [Human, English, last 10 years, All children (0-18years)]	Research Specialist to submit PICO questions to Dr. Shah ***by Friday, February 4th*** Protocol Committee Members forward any/all literature needs to jmnichol@texaschildrenhospital.org or tmburke@texaschildrenshospital.org
Week 3 February 7- February 11	Searching/Literature Review	Continue searching/article retrieval Begin evaluating the evidence	Conference Call #1 - Searching results
Week 4 February 14- February 18	Searching/Literature Review	Continue to evaluate the evidence	
Week 5 February 21- February 25	Evidence Appraisal	Continue to evaluate the evidence Begin drafting GRADE table and Review Summary	Protocol Committee Members submit a draft of GRADE table and EB summary to Research Specialist by ***Friday, February 25th***
Week 6 February 28- March 4	Evidence Appraisal	Revise GRADE table and Review Summary	Research Specialist will forward feedback to Protocol Committee Members prior to Conference Call #2 Data Collectors Conference Call- December Pilot, Feasibility of proposed measures Conference Call #2 - GRADE tables and EB Summary
Week 7 March 7- March 11	Practice Recommendations	Revise GRADE table and Review Summary	Conference Call #3- Develop plan for workshop presentations
Week 8 March 14- March 18	Practice Recommendations	Finalize workshop presentations, EB summary and GRADE tables	Protocol Committee Members submit FINAL EB summary and GRADE tables to Research Specialist by ***Friday, March 18th***
Week 9 March 21- March 25	Participate in Workshop B	Present Literature Review/Practice Recommendations	

Periodic conference calls to ensure progress:

- Literature search
- Literature appraisal
- Drafting recommendations

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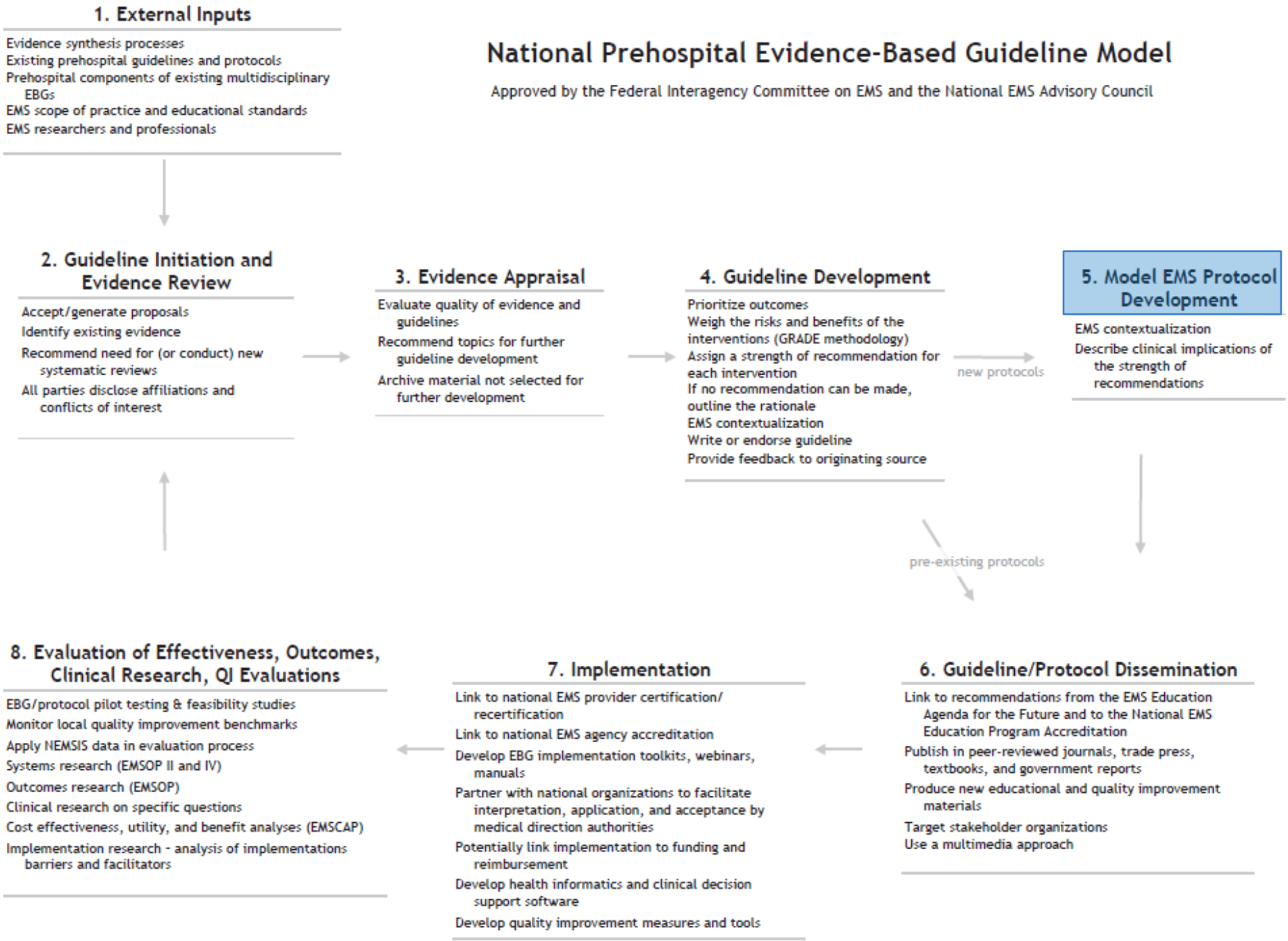

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Guideline Development

Question 6d: In children with respiratory distress, does the use of inhaled hypertonic saline (i.e., 3% or 5%) in the prehospital setting result in a clinical improvement (i.e., decreased distress, shorter ED length of stay, decreased admission rates to the hospital)?

Recommendation: Hypertonic saline should not be administered to children in respiratory distress in the prehospital setting.

Grade Criteria: Weak recommendation, Low quality evidence [1-2]

Two studies evaluating the use of hypertonic saline the emergency department for infants with respiratory distress due to bronchiolitis showed differing results in improvement in respiratory scores, but no difference in revisit rates to the emergency department. [1,2] For the one study that did show a difference in respiratory scores at 48 hours, there was no significant difference at 24 hours. [1] This study also showed no difference in mean length of stay. The other study showed no difference in rate of hospital admission or change in oxygen saturation. [2] Use of 3% saline in the inpatient setting reduced hospital length of stay. [2]

Recommendation: Weak recommendation with low quality evidence that hypertonic saline should not be administered to children in respiratory distress in the prehospital setting.
Number of Studies: Total # 3 ☒ Systematic review/meta-analysis [2] ☒ RCT [1,2] ☐ Cohort ☐ Observational ☐ Case Reports Publication Bias Evident ☐ Yes ☒ No

Design Limitations	Summary of Consistency	Indirectness of Comparison	Imprecision of Results
☐ None ☐ Insufficient sample size ☐ Lack of blinding ☒ Lack of allocation concealment [2] ☐ Large losses to F/U ☐ Incorrect analysis of ITT ☐ Stopped early for benefit ☐ Selective reporting of measured outcomes (e.g., no effect outcome)	☐ No inconsistencies ☐ Wide variation of treatment effect across studies ☒ Populations varied (e.g., sicker, older) [1-2] ☒ Interventions varied (e.g., doses) [1] ☒ Outcomes varied (e.g., diminishing effect over time) [1-2]	☐ Head-to-head comparison in correct population ☐ Indirect comparisons (e.g., interventions to placebo but not each other) ☒ Different populations [1-2] ☐ Different interventions ☐ Different outcomes measured ☐ Comparisons not applicable to question/outcome	☐ Dichotomous outcomes ☐ Sample size lower than calculated optimal information size ☐ Total # of events is < 300 based on simulations & dependent on baseline risk & effect sizes ☐ 95% CI (or alternate measure) includes negligible effect and appreciable benefit or harm

Sample	CI/RR
1) RCT of 171 infants < 18 months old with moderate to severe bronchiolitis who received either 5 ml of 5%, 3%, or 0.9% saline with 1.5 ml epinephrine every 4 hours in a short-stay unit. 2) RCT of 46 infants 6 weeks to 12 months with mild to moderate bronchiolitis who received 1-2 doses of either 2.5 ml of nebulized 3% hypertonic saline or 0.9% saline, both with 3 ml of 2.25% racemic epinephrine, in the emergency department. 3) 4 RCTs of infants with bronchiolitis (189 inpatients; 65 outpatients) treated with nebulized 3% saline vs. 0.9% saline.	1) **Wang bronchiolitis severity score improvement at 48 hours (diff b/t 5% and 0.9%):** 0.43 (0.02-0.88); there is a trend toward significance between 8-72 hours after administration, but it was not significant at 24 hours. **Mean length of stay:** 1.56 +/-1.38 days (5%); 1.4 +/-1.41 days (3%); 1.88 (+/-1.76 days (0.9%), p = 0.36 (no difference) **Revisit rates:** no difference (61%, 59%, 63%, respectively) 2) **Respiratory Assessment Change Score (RACS-mean):** 0.74 (-1.45-2.93); no difference **Change in oxygen saturation (mean):** 1.78 (-0.50-4.06); no difference **Rate of hospital admission (RR):** 0.61 (0.22-1.19); no difference, though there was a trend towards decreased admission in the hypertonic saline group that may have been significant if treatment had been provided for a longer duration of time. **Return to the ED (RR):** 0.74 (0.11-2.91); no difference 3) **Length of hospital stay (MD):** -0.94 days (-1.48 to -0.40; p = 0.0006); shorter LOS favoring 3% saline **Post-inhalation clinical scores over 3 days (MD):** • Day 1: -0.75 (-1.38 to -0.12; p = 0.02) • Day 2: -1.18 (-1.97 to -0.39; p = 0.003) • Day 3: -1.28 (-2.57 to 0.00; p = 0.05) **Rate of hospitalization (RR):** 0.67 (0.12-3.75); no difference

1) Al-Ansari, K., Sakran, M., Davidson, B. L., El Sayyed, R., Mahjoub, H., & Ibrahim, K. (2010). Nebulized 5% or 3% hypertonic or 0.9% saline for treating acute bronchiolitis in infants. *Journal of Pediatrics, 157*(4), 630-634.

2) Grewal, S., Ali, S., McConnell, D. W., Vandermeer, B. V., & Klassen, T. P. (2009). A randomized trial of nebulized 3% hypertonic saline with epinephrine in the treatment of acute bronchiolitis in the emergency department. *Archives of Pediatrics & Adolescent Medicine, 163*(11), 1007-1012.

Funded by the Health Resources and Services Administration EMSC Targeted Issues Grant #H34MC19347

Summarize the evidence

GRADE Approach

- **G**rades of **R**ecommendation, **A**ssessment, **D**evelopment, and **E**valuation (GRADE)
- Classifies evidence
  - High
  - Moderate
  - Low
  - Very low
- Classifies strength of recommendations
  - Strong
  - Weak

Brozek et al., *Allergy,* 2009.

Guideline Development

Texas Children's

DATE: July 201

Practice Recommendations

Respiratory Assessment Tools

Prehospital providers should be taught to assess and document components of the Respiratory Distress Assessment Instrument (RDAI), Pediatric Asthma Severity Score (PASS), and Westley Croup respiratory scores. – Strong recommendation, Moderate quality evidence [1-9]

Monitoring

Pulse oximetry should be routinely used in children with respiratory distress as an adjunct to other forms of respiratory monitoring. – Strong recommendation, Low quality evidence [10,11]

Electrocardiogram (ECG) should not be routinely used for children with respiratory distress. If there are no signs of clinical improvement after treating the respiratory distress, consider ECG monitoring to assess for cardiac concerns. – Weak recommendation, Very low quality evidence [12]

Measuring end-tidal CO_2 ($ETCO_2$) is safe, reliable and non-invasive and demonstrates a strong correlation with pulse oximetry; it should used as an adjunct to other forms of respiratory monitoring. – Strong recommendation, Low quality evidence [13-16]

Treatment

Supplemental oxygen should be provided to all children with respiratory distress. – Strong recommendation, Very low quality evidence [17]

A child's nose and/or mouth should be suctioned (via bulb, Yankauer, suction catheter) if excessive secretions are present. – Strong recommendation, Very low quality evidence [17]

Inhaled Medications

Beta-agonists should be administered to all children in respiratory distress with signs of bronchospasm (e.g. known asthmatics, quiet wheezers) in the prehospital setting, either via nebulized route or metered dose inhaler, by basic life support (BLS) or advanced life support (ALS) providers. – Strong recommendation, Moderate quality evidence [18-24]

Nebulized anticholinergic medication (i.e., ipratropium) should be administered in multiple doses with short acting beta-agonist to children ≥ 2 years of age with known asthma who are in severe respiratory distress in the prehospital setting. – Strong recommendation, Moderate quality evidence [25-27]

Summarize the recommendations

- Strength
- Quality

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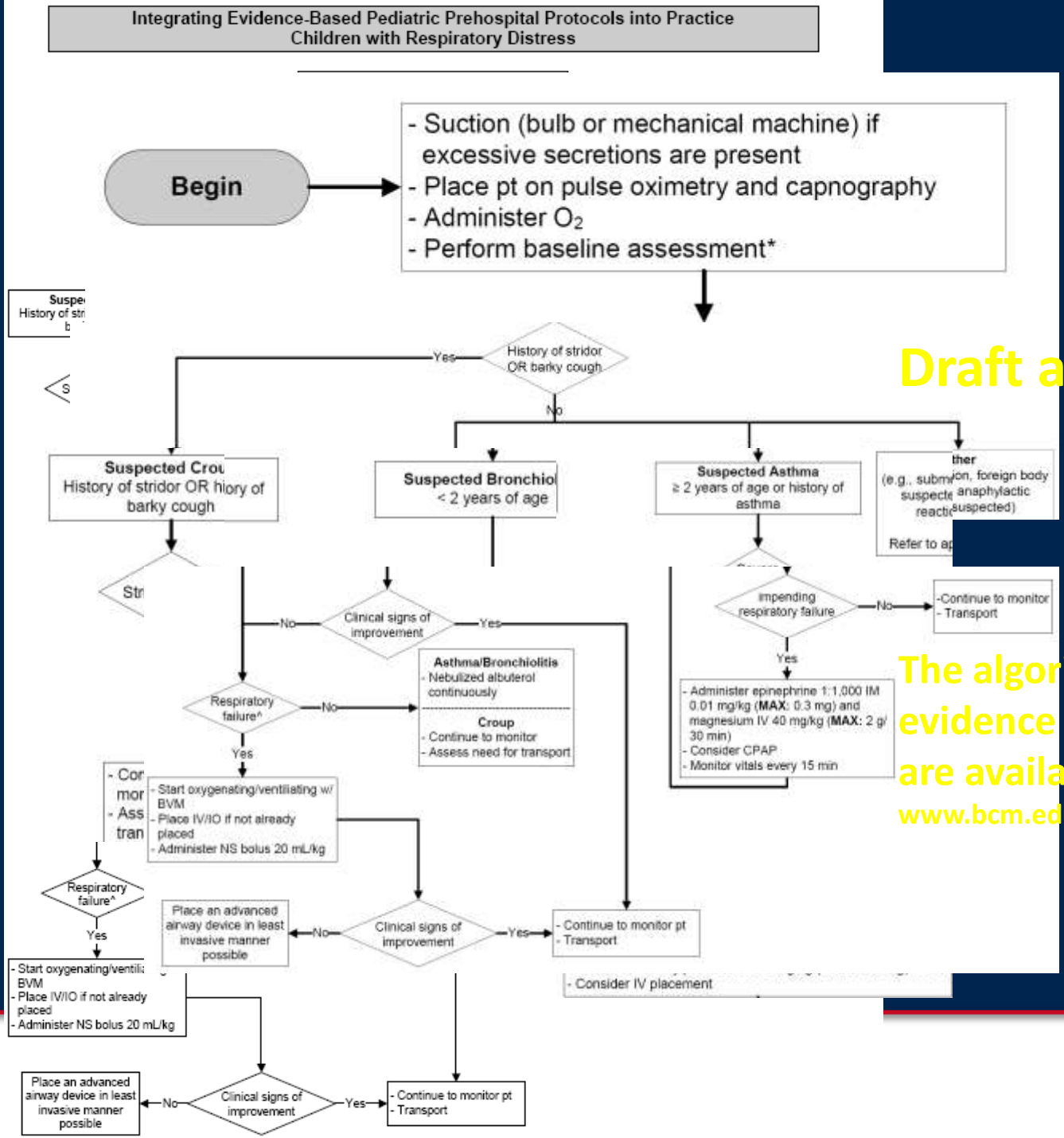

Draft a guideline

The algorithm and evidence summaries are available at www.bcm.edu/pediatrics/emsc

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Guideline Implementation

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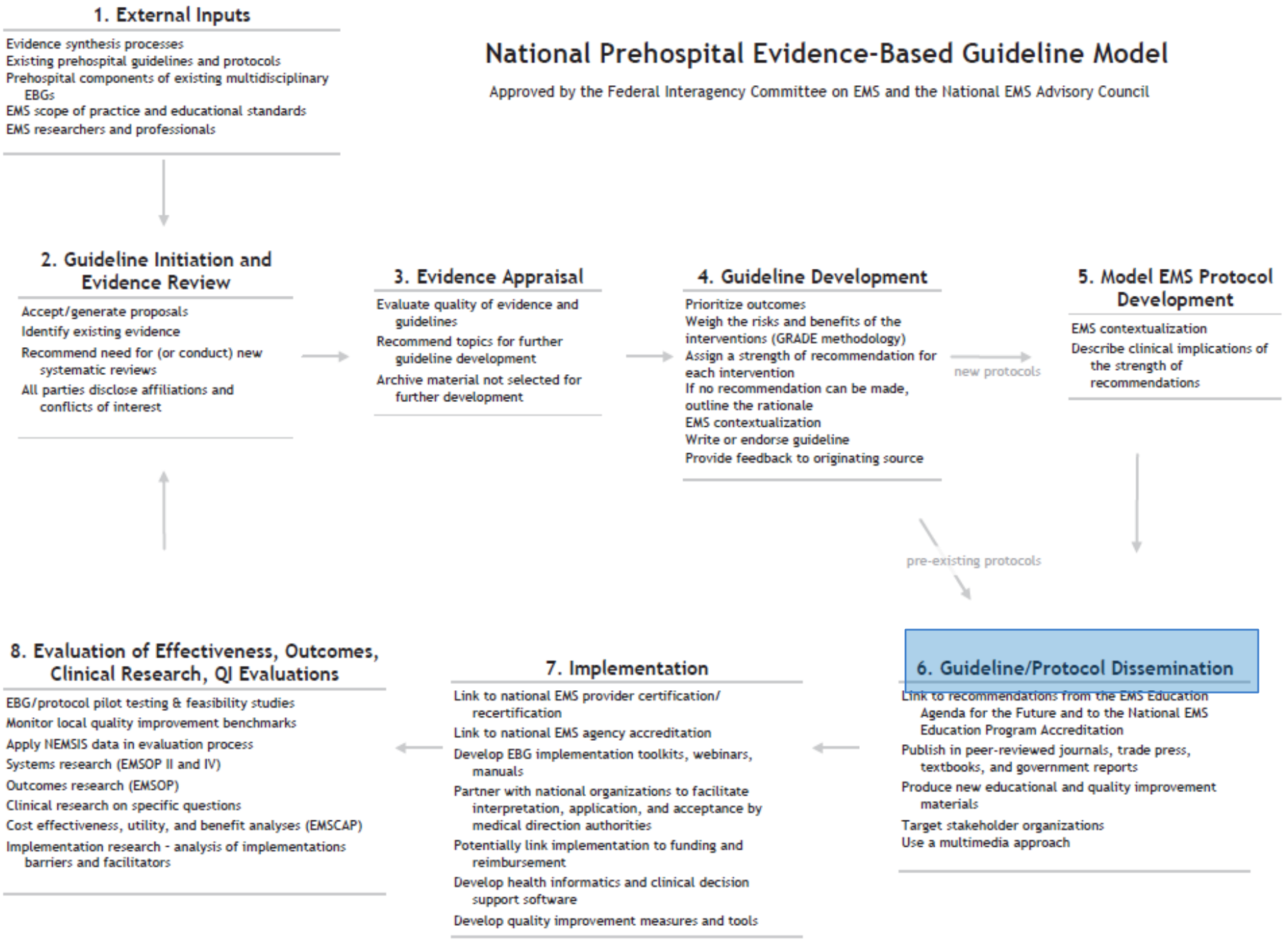

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EMSC State Partnership Involvement

- Informed stakeholders of project through
  - Bi-monthly newsletters distributed
  - Updates at the quarterly Governor's EMS and Trauma Advisory Council (GETAC) meetings
- Assisted in identifying a parent to serve on the protocol development committee
- Will assist in dissemination of the protocol to stakeholders after implementation in the 3 study sites
- Has partnered with EBOC for development of evidence summaries for 4 other topics

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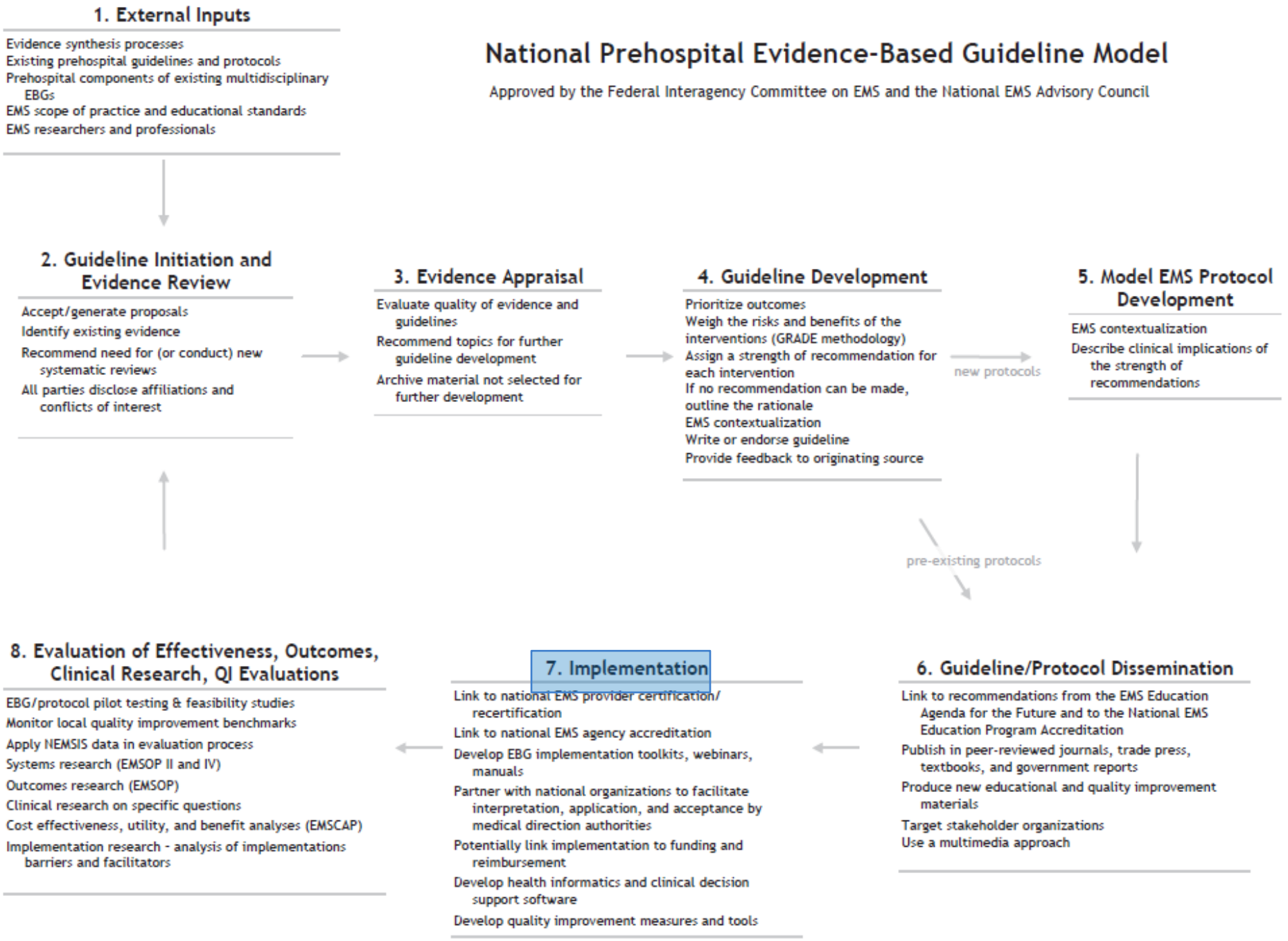

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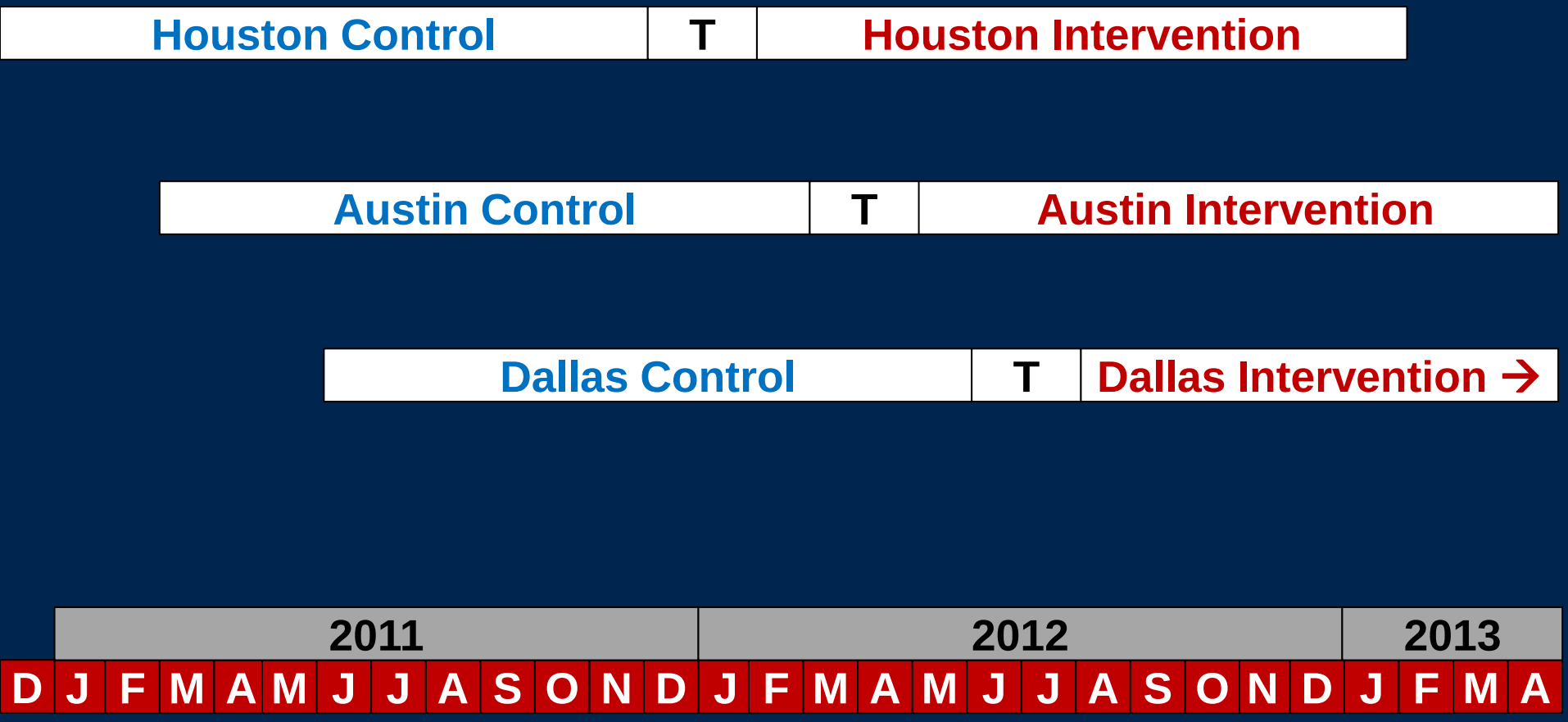
Protocol Implementation

- Adapted respiratory distress curriculum for paramedics to both paramedic and EMT-basic learner groups
- Modified in-person 8 hour curriculum to a <1 hour on-line curriculum
- Trained approximately 4000 EMT-Bs and 400 EMT-Ps in Houston; EMT-Ps mainly in Austin/Dallas
- Partnering with EMS educators for successful education implementation and adherence to module completion
- Coordinated timing of protocol implementation with EMS agencies

Implementation Timeline



Phased In Approach for Implementation

- Advantageous to account for temporal effects that would not be seen with simultaneous implementation
- Opportunity to identify and improve upon implementation barriers in each implementation
  - Limited somewhat based on design
  - Future projects could be aimed at using quality improvement methodology (Plan, Do, Study, Act (PDSA) cycles)
- Allows for balance of resource allocation, since 3 sites are not being implemented simultaneously

Implementation Challenges

- Each EMS system has different methods for educating their prehospital providers about a protocol revision
- Mandatory online education, but enforcement and compliance may be variable between systems
- Certain EMS systems have differing capabilities to supplement the online training via videos, e-mail communication, or in-person updates
- Improvement in 1 system may be due to how training was implemented and enforced

Implementation Challenges

- Difficult to measure protocol compliance on an individual level
- Measured via surrogates on a system-wide level with secondary outcomes in the prehospital setting
  - Time to administration of specific interventions in the protocol
  - Determination of prehospital administration of accepted therapy based on matching to the discharge ED diagnosis

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Guideline Assessment

National Prehospital Evidence-Based Guideline Model

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

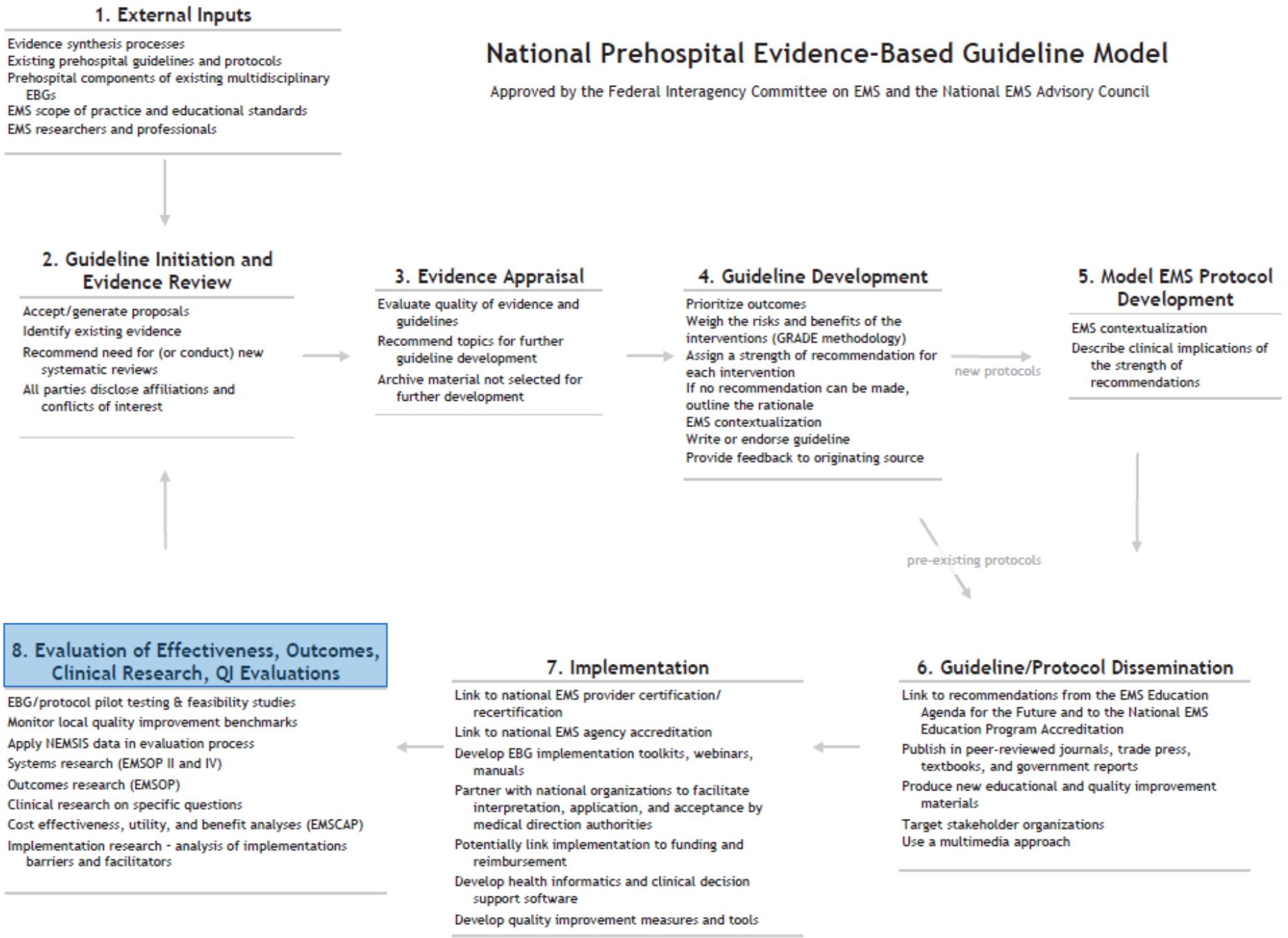

Figure 1. National prehospital EBG model. EBG = evidence-based guideline.

Lang, *Acad Emerg Med, 2012*

Guidelines and Research

- Little known about the effectiveness of evidence-based guideline implementation
  - Especially in the prehospital setting
  - Even more so for prehospital pediatrics
- Therefore any pediatric prehospital guideline implementation should be studied

Guidelines and Research

- **Research Question:** In pediatric patients who are transported by Emergency Medical Services (EMS) to an Emergency Department (ED) for presumed respiratory distress, do patients who are treated with a prehospital evidence-based, standardized protocol have shorter overall treatment times (prehospital + hospital) than those treated with existing protocols?

Inclusion Criteria

- Pediatric patients: ages 0-18 years of age

- Transported by one of the following EMS systems:
  - City of Houston Fire Department (HFD) EMS
  - City of Austin/Travis County EMS
  - BioTel EMS in the Dallas Metroplex

- Transported to an ED at one of the following hospitals:
  - Texas Children's Hospital
  - Dell Children's Hospital of Central Texas
  - Children's Medical Center, Dallas

Inclusion Criteria

- Presumed respiratory distress based on a documented prehospital chief complaint **and** working assessment in the prehospital database consistent with a condition for which respiratory distress could be present

Inclusion Criteria

•Chief Complaints

- Allergic reaction
- Anxiety
- Aspiration
- Cold
- Discoloration
- Fainted
- Foreign body
- Infection
- Irritation
- Light headedness
- No complaints
- Overdose
- Panic
- Slow to respond
- Snoring
- Tremors
- Unconscious
- Unresponsive
- Altered mental status
- Apneic and pulseless
- Can't speak
- Cyanosis
- Faint
- Fever
- Hyperventilation
- Irritable
- Lethargic
- Loss of consciousness
- NONE
- Pale
- Passed out
- Sluggish
- Syncope
- Turned blue
- UNKNOWN

•Working Assessments

- Allergic reaction
- Bronchitis
- Cardiac dysrhythmia
- Cardiac rhythm disturbance
- Chest discomfort
- Choking
- COPD
- Drowning
- Edema, pulmonary
- Fainting
- Infection
- Inhalation injury
- Other
- Pain-chest
- Poisoning/drug ingestion
- Psychological problems
- Pulmonary edema
- Respiratory distress
- Asthma
- Cardiac arrest
- Chest pain
- Coma
- DOA
- Drug/alcohol abuse
- Emphysema
- Fever
- Influenza
- Neonatal emergency
- Overdose
- Pneumonia
- Respiratory arrest
- Syncope

Exclusion Criteria

- Interfacility transports between hospitals

Recruitment Methods

- Waiver of consent approved by IRB for patient data
- **All** patients who meet inclusion criteria 12 months before and after implementation will be enrolled

Group Assignment

- **Intervention**: Patients cared for **after** implementation of the new protocol
- **Comparison**: Patients cared for **before** implementation of the new protocol
  - Systems vary in availability of protocols for common respiratory conditions in children
  - Interventions utilized in each protocol vary from one system to another
- Individual treatment randomization is feasible in the prehospital setting
- Entire treatment protocol cannot be randomized

Masking

- **Prehospital providers:** Will need to know the details of the new protocol during the study period
- **Patients or their caregivers**: Will not be intentionally informed of the change in protocol
- **Investigators**: Will know which site is utilizing the control vs. the new protocol → required for protocol implementation
- **ED providers**: Will be informed of the change in protocol to enhance continuity in the care of the patient

Refining Measures for Data Collection

- Initial measures developed by protocol development committee based on group input
- Measures refined based on feasibility of collecting data and clinical relevance
- Questions developed for further investigation related to ability to modify medical record to gather desired information

Data must be gathered and analyzed to demonstrate whether the change was effective or not

Outcomes Assessment

- Through data that is already collected in the electronic patient care records
- No data forms required
- Match prehospital and hospital records using probabilistic linkage
- Charts will be reviewed for instances when data is missing from the electronic record

Outcomes

- **Primary Outcome**
  - Total time of care = Time from on-scene arrival to time of ED/hospital discharge
- **Secondary Outcomes**
  - ED length of stay (LOS)
  - Hospital admission rates
  - ED obs unit, inpatient, PICU LOS
  - Prehospital on-scene and transport times
  - Change in vital signs
  - Time to administration of interventions
  - Prehospital administration of accepted therapy
  - # of prehospital advanced airway attempts
  - Mortality

Outcomes Assessment: Challenges

- 6 data sources, each with its own challenges
- Data transfer between sites
- Probabilistic linkage to match patients from prehospital and hospital settings

Limitations: Study Design

- Staggered implementation prolongs the overall time for the study relative to one with implementation at one point in time
- Prone to contamination
  - One site might inform the other about the intervention
  - Medical directors at each site may not be willing to wait 12 months prior to implementing certain changes found in the new protocol
- More complex data analysis, especially with the use and interpretation of SPC charts to determine a meaningful difference

Limitations: Inclusion Based on Destination Hospital

- Ideal: Assess outcomes for all patients transported by the 3 EMS systems to **any** hospital
- ED LOS and decision to admit based on a variety of factors inherent to the hospital and not to the intervention
- Prehospital providers may be biased to transport more children in respiratory distress to the hospitals in the study
- Data collection dependent on linkage of prehospital and hospital records → more destinations, more complex

Limitations: Inclusion Based on Age

- Most EMS systems differentiate a child from an adult based on an age cut-off between 12-16 years or a weight cut-off of 30-40 kg
- Patients affected by the intervention protocol will predominately be <12 years old and/or <30 kg in weight
- Impact of the protocol on teenagers will be difficult to ascertain

Limitations: Definition of Respiratory Distress

- Use of a prehospital protocol based on subjective assessment
- Providers' subjective assessment will not be measured immediately after patient care has occurred
- Chief complaints and working assessments vary by system and will be surrogate indicators

Limitations: Bundled Interventions

- Timing and frequency of administration of specific interventions addressed in the protocol will be collected before and after implementation as process measures
- Simultaneous implementation of each intervention contained within the protocol will make it difficult to determine which interventions are most or least effective
- Impact of individual interventions within the protocol will not be assessed

Limitations: Existing Cofounders

- Independently associated with both the new treatment protocol and one of the outcomes, but not part of the causal chain
- Experience level of providers
  - City of Houston downsized EMS workforce; may have impacted the less experienced providers in a disproportionate manner
  - Texas Children's Hospital begins simulation training program with the Houston Fire Department in January, 2012

Data Analysis Plan

- **Statistical Process Control (SPC) charts**
  - -Significant shift in mean and standard deviation values between the pre and post-implementation phases of the study for each site

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The Future of Prehospital EBGs

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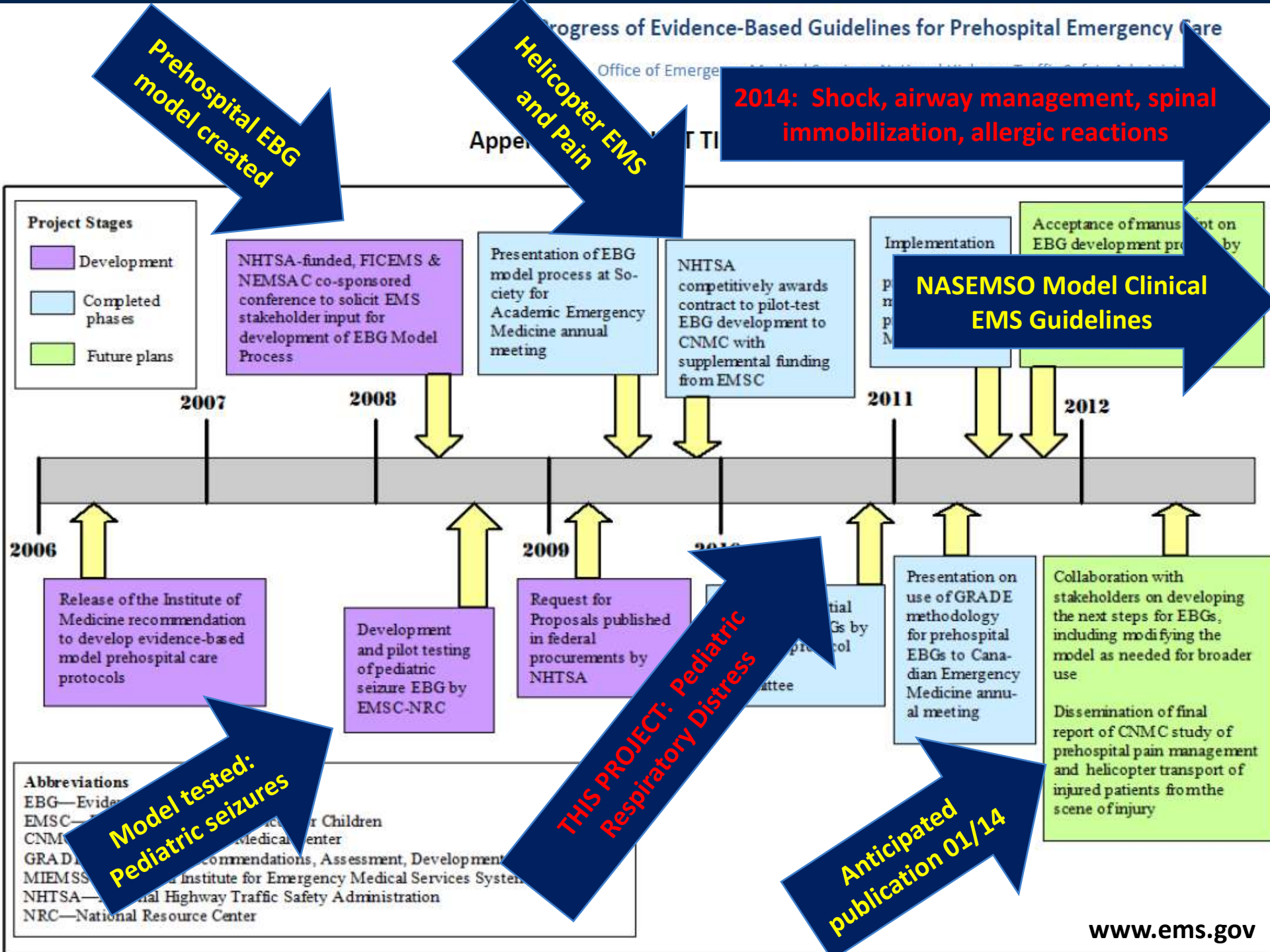
rogress of Evidence-Based Guidelines for Prehospital Emergency Care
Office of Emerge
Appe T TI
Prehospital EBG model created
Helicopter EMS and Pain
2014: Shock, airway management, spinal immobilization, allergic reactions
NASEMSO Model Clinical EMS Guidelines
Project Stages
Development
Completed phases
Future plans
2006
2007
2008
2009
2011
2012
Release of the Institute of Medicine recommendation to develop evidence-based model prehospital care protocols
NHTSA-funded, FICEMS & NEMSAC co-sponsored conference to solicit EMS stakeholder input for development of EBG Model Process
Development and pilot testing of pediatric seizure EBG by EMSC-NRC
Presentation of EBG model process at Society for Academic Emergency Medicine annual meeting
Request for Proposals published in federal procurements by NHTSA
NHTSA competitively awards contract to pilot-test EBG development to CNMC with supplemental funding from EMSC
Implementation
Acceptance of manus ipt on EBG development pr by
Presentation on use of GRADE methodology for prehospital EBGs to Canadian Emergency Medicine annual meeting
Collaboration with stakeholders on developing the next steps for EBGs, including modifying the model as needed for broader use
Dissemination of final report of CNMC study of prehospital pain management and helicopter transport of injured patients from the scene of injury
Abbreviations
EBG—Evide
EMSC— r Children
CNM Medica enter
GRA D commendations, Assessment, Development
MIEMSS Institute for Emergency Medical Services Syste
NHTSA— al Highway Traffic Safety Administration
NRC—National Resource Center
Model tested: Pediatric seizures
THIS PROJECT: Pediatric Respiratory Distress
Anticipated publication 01/14
www.ems.gov

NASEMSO Clinical Guidelines

- NASEMSO has 2 projects funded by NHTSA
  - Model EMS Guidelines
    - To develop national model EMS guidelines, intended to help state EMS systems ensure a more standardized approach to the practice of patient care, and to encompass evidence-based guidelines *as they are developed*
  - Statewide Implementation of Care
    - To support the use and further refinement of the National EBG Model Process, developed by FICEMS and NEMSAC

www.nasemso.org

NASEMSO Clinical Guidelines

Cunningham and Kamin

EMSC Targeted Issues Grants (9/13-8/16)

- **Category I award (1):** Development of an EMS research network, aligned with the Pediatric Emergency Care Applied Research Network
  - **CHaMP**: Charlotte, Houston, and Milwaukee Prehospital Research Node
- **Category II award (5):** Prehospital-focused topics by individual investigators
  - Pediatric Evidence-based Guidelines: Assessment of EMS Utilization in States **(PEGASUS)**
  - EBG development of guidelines for shock, airway management, spinal immobilization, and allergic reactions
  - Pilot 2 guidelines in Houston, and implement them in New England with outcomes assessment

Summary

- Multidisciplinary involvement is essential when using the Prehospital EBG Model Process
- Implementation requires provider training to ensure successful change
- Patient outcomes must be studied along the continuum of emergency care to know if the change is effective
- Ongoing national projects will lead to more prehospital EBGs soon