

EMS Focus

A Collaborative Federal Webinar Series



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The Future of Evidence-Based Guidelines in EMS

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Today

- ▶ The Role of Evidence-Based Guidelines in a People-Centered EMS System
- ▶ Reviewing the Relevant Research to Create an EBG
- ▶ Creating and using the Naloxone EBG
- ▶ What's Next for Prehospital EBGs
- ▶ Questions



EMS 2050 AGENDA

Envision the Future

In a people-centered EMS system, “EMS care in every community is based on the best available evidence.”



Today's Speakers

- ▶ **David Niebuhr, MD, MPH, MSc**
 - ▷ Medical Officer, Evidence-Based Practice Center Program, Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality
- ▶ **Kenneth Williams, MD**
 - ▷ Medical Director, Rhode Island Department of Health Center for EMS
- ▶ **Christian Martin-Gill, MD, MPH**
 - ▷ Associate Professor of Emergency Medicine, University of Pittsburgh
 - ▷ Chair, Prehospital Guidelines Consortium
- ▶ **Max Sevareid, MPH**
 - ▷ EMS Specialist, NHTSA Office of EMS

Management of Suspected Opioid Overdose With Naloxone by EMS Personnel: A Systematic Review

Chou R, Korthuis PT, McCarty D, Coffin P, Griffin J, Davis-O'Reilly C, Grusing S, Daya M. Management of Suspected Opioid Overdose With Naloxone by Emergency Medical Services Personnel. Comparative Effectiveness Review No. 193. (Prepared by the Pacific Northwest Evidence-based Practice Center under Contract No. 290-2015-00009-I.) AHRQ Publication No. 17(18)-EHC025-EF. Rockville, MD: Agency for Healthcare Research and Quality; November 2017.
www.effectivehealthcare.ahrq.gov/reports/final.cfm. DOI: <https://doi.org/10.23970/AHRQEPCCER193>.

David Niebuhr, MD, MPH, MSc




Disclosures

- ▶ This report is based on research conducted by the Pacific Northwest Evidence-based Practice Center under contract to the Agency for Healthcare Research and Quality (AHRQ), Rockville, MD (Contract No. 290-2015-00009-I). The findings and conclusions in this document are those of the authors, who are responsible for its contents; the findings and conclusions do not necessarily represent the views of AHRQ. Therefore, no statement in this report should be construed as an official position of AHRQ or of the U.S. Department of Health and Human Services.
- ▶ None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this report.

What is Evidence Review?



- ▶ Comprehensive review of the world's literature
- ▶ Critical appraisal of the evidence
- ▶ Synthesizes and summarizes results from multiple existing studies






Evidence Synthesis
 - Guidelines
 - Measures
 - Coverage
 Practice Change
 Improved Health Outcome

Federal agencies, medical professional societies, and health systems can make

- ▶ Better healthcare policy
- ▶ Better clinical guidelines
- ▶ Better health decisions

Leading to **longer, healthier lives** for all Americans

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Purpose of Systematic Review

- ▶ To compare different routes, doses, and dosing strategies of naloxone administration for suspected opioid overdose by emergency medical services (EMS) personnel in field settings.
- ▶ To compare effects of transport to a health care facility versus nontransport following successful reversal of opioid overdose with naloxone.

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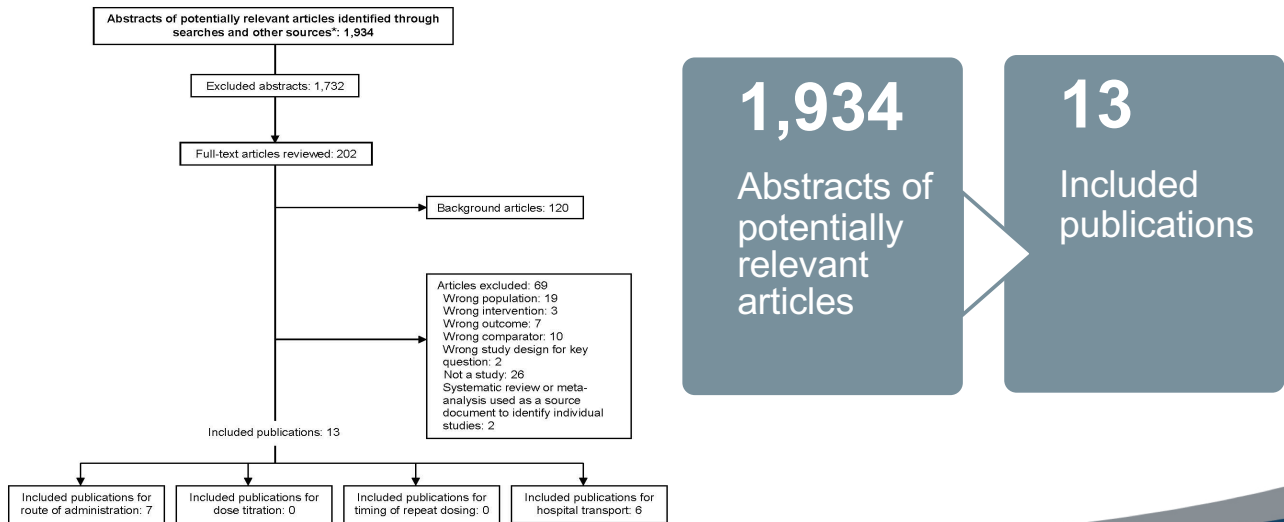
Key Questions

- ▶ What are the comparative benefits and harms of out-of-hospital **administration of naloxone** by various routes of administration and doses?
- ▶ What are the comparative benefits and harms of titration of naloxone until the patient resumes sufficient **spontaneous respiratory effort** versus regains **consciousness**?
- ▶ What are the comparative benefits and harms of differences in **timing of repeat dosing**?
- ▶ What are the benefits and harms of **transporting** patients to a health care facility **versus not transporting**?

Methods

- ▶ Topic Refinement and Review Protocol
- ▶ Literature Search Strategy
- ▶ Search Strategy
- ▶ Inclusion and Exclusion Criteria
- ▶ Data Extraction
- ▶ Risk of Bias Assessment of Individual Studies
- ▶ Assessing Research Applicability
- ▶ Data Synthesis and Rating the Body of Evidence
- ▶ Peer Review and Public Commentary

What evidence is available?



Key Question 1: Routes of Administration

- ▶ Higher concentration intranasal naloxone may be similarly effective and safe compared with intramuscular naloxone.
 - ▷ IN versus IM
 - 4 Randomized Clinical Trials and 4 cohort studies
 - Low strength of evidence (SOE)
 - ▷ IN versus IV
 - 1 RCT and 2 cohort studies
 - Insufficient SOE
- ▶ Are there differences in effectiveness between doses and routes of administration?
 - ▷ No studies
 - ▷ Insufficient SOE

Key Question 2: Titration of Naloxone Until Spontaneous Respiratory Effort Versus Regains Consciousness

- ▶ While field administration of naloxone is generally effective in reversing opioid overdoses, there is not strong evidence concerning this question.
 - ▷ No studies
 - ▷ Insufficient SOE

Key Question 3: Timing of Repeat Doses

- ▶ More research is needed to determine optimal doses of naloxone, appropriate timing of repeat dosing, and whether it is necessary to dose patients to full consciousness.
 - ▷ No studies
 - ▷ Insufficient SOE

Key Question 4: Transport Versus Not Transported

- ▶ More research is needed to determine whether transporting patients to a hospital after successful reversal of overdose is necessary.
 - ▷ Six uncontrolled studies in not transported patients found a low death rate
 - ▷ Insufficient SOE

Conclusion

- ▶ Additional research is urgently needed to optimize administration of naloxone by EMS personnel.
- ▶ Future research could leverage existing EMS registries with naloxone administration data, which are available from a number of local and state agencies.
- ▶ Research is needed on the comparative effectiveness of the FDA-approved naloxone auto-injectors and highly concentrated IN naloxone formulations, different doses, and dosing strategies.

The Naloxone Evidence-Based Guideline

Williams K, Lang ES, Panchal AR, Gasper JJ, Taillac P, Gouda J, Lyng JW, Goodloe JM, Hedges M. Evidence-based guidelines for EMS administration of naloxone. Prehospital emergency care. 2019 Apr 16:1-5.

DOI: doi.org/10.1080/10903127.2019.1597955

nasemso.org/projects/naloxone-evidence-based-guidelines/

Ken Williams, MD

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 **ems.gov**

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Disclosures

- ▶ Chaired the NASEMSO/NAEMSP/ACEP Naloxone EBG Project funded by the NHTSA Office of EMS and HRSA EMS for Children program.
- ▶ Later retained by Adapt Pharma, makers of Narcan® Nasal Spray, to offer opinions in patent litigation.
- ▶ Comments are my own, and do not represent NHTSA or any other entity.
- ▶ Some slides are adapted from the Naloxone EBG training module, available at nasemso.org/projects/naloxone-evidence-based-guidelines/.

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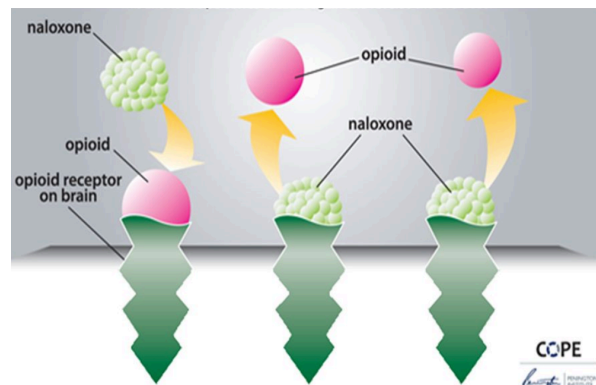
Naloxone



- ...is an effective part of treatment for opioid overdose
- ...takes time to work (2-3 minutes)
- ...is temporary (30-90 minutes)
- ...has potential side effects (withdrawal and worse)
- ...is approved for both *pediatric* and *adult* patients
- ...can be given multiple ways

How Naloxone Works

- ▶ It displaces opioid on receptor
- ▶ Takes about 2-3 minutes to work
- ▶ Takes about 1-2 minutes if given via IV



- ▶ Can be administered via nasal spray, intranasal injection, auto-injector or a standard syringe injection

Fentanyl (And Analogs)

DO give

naloxone if:

the patient is unconscious or semi-conscious,

AND

has abnormally slow, gasping, or absent breathing

DO NOT give

naloxone if:

the patient is breathing normally even if unconscious or semiconscious,

OR

the patient is conscious



Okay, so what about EMS?

WIDE variation across the US in:

- ▶ Scope of Practice
- ▶ Route
- ▶ Dose
- ▶ Transport Decisions

Partnership and Funding from



National Association of State EMS Officials



American College of Emergency Physicians®



National Association of EMS Physicians

Evidence-Based Guideline Development



Technical Expert Panel

- ▶ Emergency Physicians
- ▶ Performance Measure Development
- ▶ GRADE Methodology
- ▶ Patient Advocate
- ▶ EMS Practitioners
- ▶ Addiction / Harm Reduction Coalition
- ▶ EMS Administration
- ▶ Staff Support
- ▶ Federal Partners

PICO Questions (Population, Intervention, Comparison, Outcome)



GRADE Table for Recommendation 1 — IN vs IM

Intranasal naloxone compared to intramuscular naloxone for suspected opioid poisoning					
Patient or population: suspected opioid poisoning Setting: prehospital Intervention: intranasal naloxone Comparison: intramuscular naloxone					
Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	N of participants (studies)	Certainty of the evidence (GRADE)
	Risk with intramuscular naloxone	Risk with intranasal naloxone			
GCS > 11 at 8 minutes (GCS > 11 at 8 minutes)	718 per 1,000	0 per 1,000 (0 to 0)	not estimable	155 (1 RCT) [†]	⊕○○○ VERY LOW ^{b,c,d,*}
Mean Response Time (min) (Mean Response Time)	The mean mean Response Time (min) was 0	The mean mean Response Time (min) in the intervention group was 0 (0 to 0)	-	14 (2 RCTs) [*]	⊕○○○ VERY LOW ^{b,c,d,*}
Proportion requiring rescue naloxone (Proportion requiring rescue naloxone)	not pooled	not pooled	not pooled	155 (2 RCTs) ^{†*}	⊕○○○ VERY LOW ^{b,c,d,*}
Adverse Response (Major; e.g. seizure) (Adverse Response (Major))	not pooled	not pooled	not pooled	155 (2 RCTs) [*]	⊕○○○ VERY LOW ^{b,c,d,*}
Adverse Response (Minor; e.g. agitation, irritation, nausea/vomiting, headache, tremor, sweating) (Adverse Response (Minor))	not pooled	not pooled	not pooled	155 (2 RCTs) [*]	⊕○○○ VERY LOW ^{b,c,d,*}

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).
CI: Confidence interval

Naloxone EBG Published IN PEC

The screenshot shows the Taylor & Francis Online interface. At the top, there is a navigation bar with 'Log in', 'Register', and 'Cart' options. A banner message states: 'On Tuesday 29 October 07:00 - Wednesday 30 October 00:30 GMT, we'll be making some site updates. You'll still be able to search, browse and read our articles, but you won't be able to register, edit your account, purchase content, or activate tokens or eprints during that period.' Below this is a search bar with the text 'Enter keywords, authors, DOI, ORCID etc' and a 'This Journal' dropdown menu. The main content area features the journal 'Prehospital Emergency Care' and the article 'Evidence-Based Guidelines for EMS Administration of Naloxone' by Kenneth Williams, MD, Eddy S. Lang, MDCM, CCFP (EM), Ashish R. Panchal, PhD, MD, James J. Gasper, PharmD, BCPP, Peter Tallac, MD, and John Gouda, MB BCH BAO. The article has 5,664 views and 23 citations. It includes an abstract, a full article link, and a 'People also read' section with a link to 'An Evidence-based Guideline for Prehospital'.

Answers

Route	Dose	Titration	Repeat Dosing	Transport
(IN=IV)>IM	Varies 0.4 – 4 mg	To adequate respiratory function	2-3 minutes	Yes, or treat at scene

Sample Protocol

Submitted to National Model EMS Clinical Guidelines

Available at:

nasems.org/wp-content/uploads/Model-EMS-Protocol-Relating-to-Naloxone-Administration-by-EMS-Personnel.pdf

Opioid Poisoning/Overdose

Aliases

Carfentanyl, Darvocet®, Demers®, Dilaudid®, drug abuse, EVZIO®, fentanyl, heroin, hydrocodone, hydromorphone, meperidine, methadone, morphine, naloxone, Narcan®, opiate, opioid, overdose, oxycodone, Oxycontin®, Percocet®, Percodan®, propoxyphene, Suboxone, U-47700, Vicodin®

Patient Care Goals

1. Rapid recognition and intervention of a clinically significant opioid poisoning or overdose
2. Prevention of respiratory and/or cardiac arrest

Patient Presentation

Inclusion Criteria

Patients decreased mental status, and respiratory depression of all age groups with known or suspected opioid use or abuse.

Exclusion Criteria

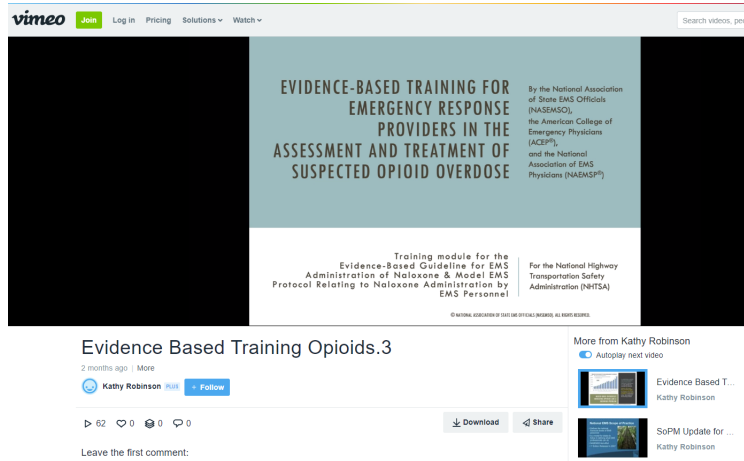
Patients with altered mental status exclusively from other causes (e.g. head injury, or hypoglycemia).

Patient Management

1. Don appropriate PPE^{1, 2}
2. Be aware that unsecured hypodermic needles may be on scene and if so that there is a higher risk of needle sticks during the management of this patient population which may also have an increased incidence of blood-borne pathogens
3. Therapeutic interventions to support the patient's airway, breathing, and circulation should be initiated prior to or simultaneously with the administration of naloxone
4. If possible, identify specific substance (including immediate release versus sustained release), the route and time of exposure, and quantity
5. Obtain and document pertinent cardiovascular history or other prescribed medications for underlying disease
6. Naloxone, an opioid antagonist, should be administered to patients with respiratory depression in a suspected or confirmed opioid overdose
7. Naloxone administration via the intravenous (IV) route provides the most predictable bioavailability, flexibility in dosing/titration, and clinical response
8. Naloxone administration via the intranasal or intramuscular routes provide additional options of medication delivery
9. Intranasal and intramuscular dosing are similarly efficacious. Intranasal is preferred over intramuscular due to:
 - a. ability to titrate multiple smaller doses to avoid precipitating withdrawal
 - b. avoidance of provider risk of needle injury

Training Module

Narrated version
available at
vimeo.com/354168233



Recommendations for EMS Use of Naloxone

The important steps are:

- ▶ Activation of the 911 System
- ▶ Assessment of scene and patient (including safety)
- ▶ Start First Aid (CPR, BVM, recovery position, etc., as indicated)
- ▶ Naloxone (and AED if indicated)
- ▶ Monitor / Further Treatment

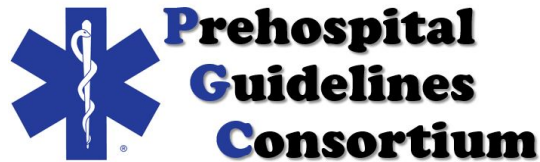
The Order Does Not Matter (much)

If your naloxone is closer than your phone...

Lessons

This is how evidence-based EMS enhances respect and professionalism

Facilitating EMS Evidence-Based Guideline Projects: A Pathway to the Future



Christian Martin-Gill, MD, MPH

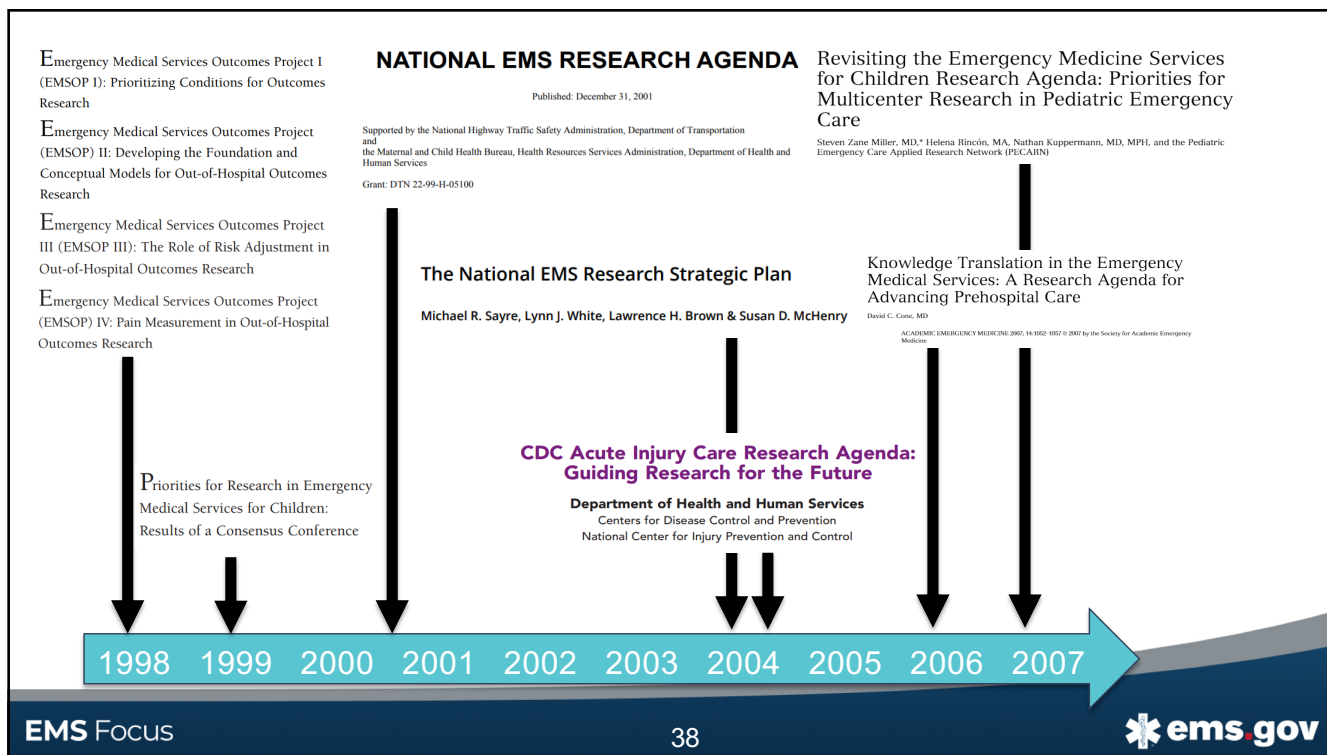
Disclosures

▶ Current Grants

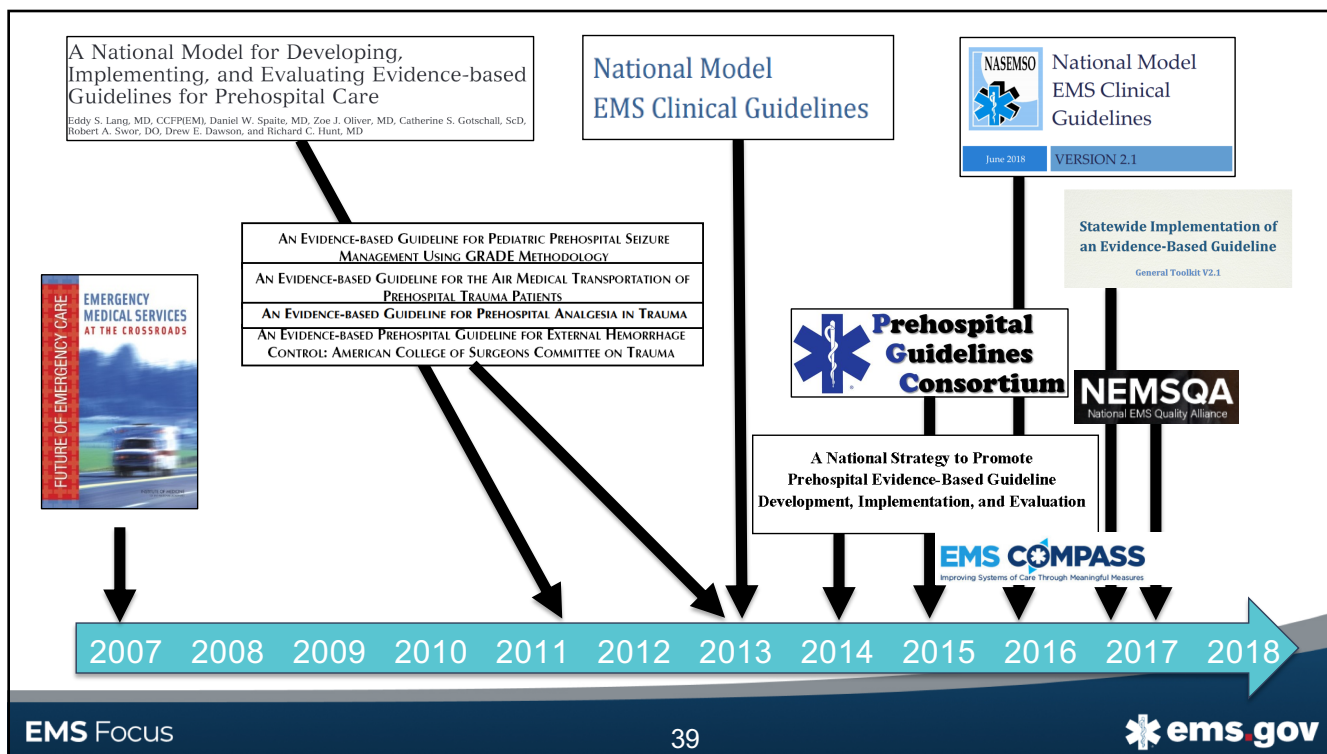
- ▶ W81XWH-16-R-0033 Department of Defense 2016-2021 (Co-I)
Linking Investigators in Trauma and Emergency Services (LITES)
- ▶ 1R01HL137761-01A1 NHLBI 2018-2022 (Co-I)
Electrocardiographic Detection of Non-ST Elevation Myocardial Events for Accelerated Classification of Chest Pain Encounters (ECG-SMART)
- ▶ PEMF 0061488 PEMF 2018-2020 (PI)
Pittsburgh Prehospital Care Registry
- ▶ W81XWH18F0426 Department of Defense 2018-2022 (Site PI)
Prehospital Airway Control Trial (PACT)

▶ Completed Grants

- ▶ DTNH22-13-H-00435 NHTSA / NAEMSP 2013-2015 (PI)
National Prehospital Evidence-Based Guidelines Strategy
- ▶ DTNH22-15-C-00029 NHTSA / NASEMSO 2016-2018 (Co-I)
Developing Fatigue Risk Management Guidelines for Emergency Medical Services



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Recent EBG Projects (2018-2019)

Evidence-Based Guidelines for Fatigue Risk Management in Emergency Medical Services

P. Daniel Patterson, J. Stephen Higgins, Hans P. A. Van Dongen, Daniel J. Buysse, Ronald W. Thackery, Douglas F. Kupas, David S. Becker, Bradley E. Dean, George H. Lindbeck, Francis X. Guyette, Josef H. Penner, John M. Violanti, Eddy S. Lang & Christian Martin-Gill

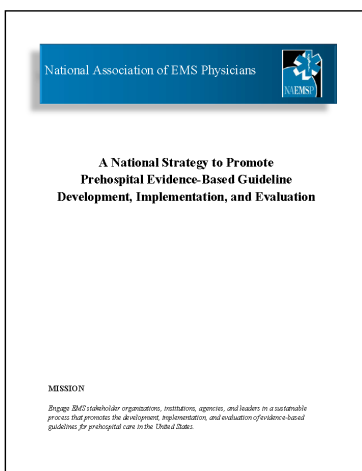
PROJECTS

Naloxone Evidence-Based Guidelines

Overview

The National Association of State EMS Officials (NASEMSO), in collaboration with the National Association of EMS Physicians (NAEMSP) and the American College of Emergency Physicians (ACEP), is leading a project to develop and disseminate an evidence-based guideline for the administration of naloxone for opioid overdoses.

The National Prehospital Evidence-Based Guidelines Strategy



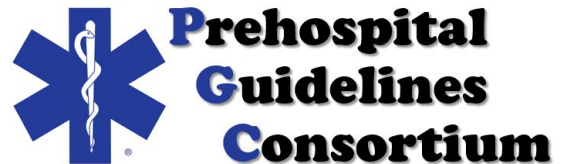
Mission: Engage EMS stakeholder organizations, institutions, agencies, and leaders in a **sustainable process** that promotes the **development, implementation, and evaluation** of prehospital evidence-based guidelines.

1. **Create a Consortium** of national organizations and Federal entities that can improve communication and collaboration among EMS stakeholders in EBG-related projects;
2. **Promote research** supporting prehospital EBGs;
3. **Promote development** of prehospital EBGs;
4. **Improve education** related to prehospital EBGs;
5. **Facilitate the implementation** of prehospital EBGs;
6. **Establish standardized evaluation methods** for prehospital EBGs; and
7. **Promote funding** for the development, implementation, and evaluation of prehospital EBGs.

PGC was Formed as Action #1 of the National Prehospital EBG Strategy

Mission:

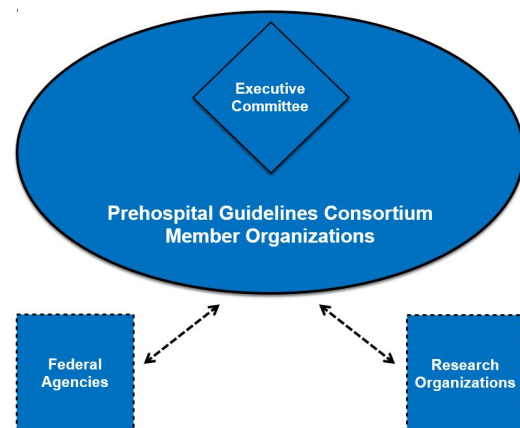
To engage EMS stakeholder organizations, institutions, agencies and leaders in a sustainable process that promotes the development, implementation and evaluation of evidence-based guidelines for prehospital care



Comprised of Member Organizations and Liaisons with Federal and Research Entities

- ▶ 35 member organizations
 - ▷ 11 Executive Committee organizations

- ▶ Liaisons with 7 Federal agencies and research organizations



Completed Projects

- ▶ Online repository of existing prehospital EBGs and related resources
 - ▷ Available at prehospitaguidelines.org
- ▶ Educational module for EMS educators on evidenced-based medicine and EBGs
 - ▷ Covers required content for NREMT recertification (EMT and Paramedic)
 - ▷ Freely available at prehospitalguidelines.org
- ▶ Systematic review of literature on implementation of EMS EBGs
 - ▷ Fische et al. Prehosp Emerg Care 2018;22:511-519
- ▶ Educational articles related to evidence-based medicine and EBGs for EMS personnel

Ongoing Projects

- ▶ Systematic review of all existing EMS evidence-based guidelines
 - ▷ Classification by AGREE II and IOM criteria for clinical guidelines
- ▶ Update the NASEMSO Statewide EBG Implementation Toolkit
 - ▷ National implementation
 - ▷ Educational module for implementing new EBGs
- ▶ Gap analysis for new or revised EMS EBGs using Delphi process
 - ▷ Using stakeholder group from within the PGC
- ▶ Piloting a dissemination plan for new EBGs through PGC member organizations
- ▶ Collaboration with NEMSQA linking EBGs to performance measures
- ▶ **5th Annual Meeting of PGC in San Diego on January 10, 2020**

Questions?

Please submit questions through the webinar platform

Get Involved and Learn More

- ▶ Get involved with the AHRQ Effective Health care Program:
 - ▷ effectivehealthcare.ahrq.gov/get-involved
- ▶ Find out more about prehospital EBGs and available resources:
 - ▷ prehospitalguidelines.org
 - ▷ ems.gov/projects/evidence-based-guidelines.html
- ▶ View the naloxone EBG and related resources:
 - ▷ nasemso.org/projects/naloxone-evidence-based-guidelines/
- ▶ Speakers' contact info
 - ▷ Dr. Christian Martin-Gill: maringillc2@upmc.edu
 - ▷ Dr. David Niebuhr: david.niebuhr@ahrq.hhs.gov
 - ▷ Dr. Ken Williams: kwilliamsMD@gmail.com
 - ▷ Max Severeid: max.severeid@dot.gov

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