Research and Evidence-Based Guidelines in EMS
Goals

Upon completion of this session, the participant will be able to:

◦ Describe evidence base medicine (EBM) or evidence based practice (EBP)
◦ Explain the value of research in EMS
◦ Explain the value and use of evidence-based guidelines (EBG)
◦ Describe the steps for creating an EBG
◦ Correctly incorporate EBGs into prehospital care
Knowledge of research and evidence-based medicine has become part of the National Registry’s Core Competency Program.
Knowledge of research and evidence-based medicine has become part of the National Registry’s Core Competency Program.
Pages on evidence based guidelines from the NCCP guidelines

Images used with permission from NREMT
What is evidence-based medicine?
Consider how many of our early practices have changed...

Compressions to ventilations ratio in CPR:
- 15:2
- 30:2
- Continuous

Tourniquets
- In favor → Out of favor → In favor

Military anti-shock trousers

Medications no longer used in cardiac arrest
- Atropine
- Bretyllium
What truths were these practices based on?

Has practice changed over the years?

Were there good things that changed?

How did these changes come about?
Usually someone asked...

“Why do we do it this way?”

“Is there a better way to do this?”

“What would happen if...?”

“How come...?”

“I saw this new product, should I...?”
Then the group kept doing what they had been doing, or.....

They tried something new
Changed their practice
Shared their “findings”
Convinced others to change

Some individuals have changed practice based on the success of a single study. Others changed their practice based on an aggregate of available evidence.
What is current EMS care is based on?

EMS protocols
- Developed locally, regionally, or statewide

EMS guidelines
- Evidence-based guidelines
- Expert or consensus-based guidelines

Position statements of national organizations
- Usually address individual topics, often related to potential controversy or differing opinion

NASEMSO’s National Model EMS Clinical Guidelines
These are mostly expert consensus-based
Statewide EMS Protocols & Guidelines

<table>
<thead>
<tr>
<th>Type of Protocols or Guidelines</th>
<th>No. States</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mandatory Statewide Protocols</td>
<td>21 (42%)</td>
</tr>
<tr>
<td>Optional Model Guidelines</td>
<td>17 (34%)</td>
</tr>
<tr>
<td>No Statewide Protocols/ Guidelines</td>
<td>12 (24%)</td>
</tr>
</tbody>
</table>

Where did protocols or guidelines come from? Was there any “science” behind them?

Protocols and guidelines may be based on:

◦ Expert opinion

◦ Stakeholder consensus

◦ Review of research studies

◦ Evidence-based guidelines
# Evidence-Based Guidelines for EMS

**What is the issue?**
- Wide variability in EMS care
- Challenge of incorporating evidence into practice
- Lack of uniform measurements to assess the quality of prehospital care

**How do EBGs help?**
- Uniform recommendations leading to consistent prehospital care
- Synthesize available evidence to advance quality of EMS
- Facilitate creation of standards for measuring quality of prehospital care

*Only limited evidence-based guidelines exist for EMS*
Evidence Based Guidelines...

...thoughtfully integrate best available research findings

...consider clinical expertise and judgement

...consider the values and preferences of patients and clinicians

...are NOT based solely on personal experience, anecdote, or “how we (always) do it”
Evidence-Based Guidelines aim to

Improve medical decisions and **quality** of care

Improve **clinical outcomes** for patients

Improve **satisfaction** of clinicians as they deliver care to patients

Provide **consistency** of care across clinicians and healthcare systems
Examples of Prehospital Evidence-Based Guidelines
Examples of Prehospital Evidence-Based Guidelines

An Evidence-Based Prehospital Guideline for External Hemorrhage Control: American College of Surgeons Committee on Trauma

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

An Evidence-Based Guideline for the Air Medical Transport of Prehospital Trauma Patients
The Need for More Evidence-Based Medicine in EMS
NEMSAC Recommendations (2012)

1. Form relationships among stakeholders
2. **Incorporate EBGs into EMS education**
3. Develop strategies for defining outcomes, training EMS researchers, and creating funding sources
4. Create center(s) of excellence for EMS EBG development
5. Create a registry of current EBG efforts
6. Sustain the National EBG Model Process into Federal grant guidance language
7. Sponsor EBG scientific assemblies and workshops

National EMS Advisory Council: The Next Steps for Prehospital Care Evidence-Based Guidelines, 2012
FICEMS Strategic Plan (2013)

Goal 2: Data-driven and evidence-based EMS systems that promote improved patient care quality

- Objective 2.1: Support the development, implementation, and evaluation of evidence-based guidelines (EBGs) according to the National Prehospital EBG Model Process

- Objective 2.3: Develop relationships with Federal and non-Federal stakeholders to support the development of scientific evidence for prehospital care
Research and EMS Care
Impact of Research on EMS Care

Resuscitation Outcomes Consortium
- Impact of CPR fraction
- 15:2 vs 30:2 for CPR
- Shock first vs CPR first
- Amiodarone, lidocaine, or placebo
- Hypertonic saline for traumatic shock and traumatic brain injury

Neurological Emergencies Treatment Trials (NETT)
- IV lorazepam vs IM midazolam for seizures
Impact of Research on EMS Care

Table of Contents

Acute Pain
- Angina

Advanced Airway Management
- Airway Confirmation
- Intubation
- Medication for Airway Management

Airway Emergency
- Foreign Body Obstruction/Complete/Partial
- Near Hanging

Allergic Reaction
- Anaphylaxis
- Mild Allergic Reaction

Altered Mental State-Dec. LOC
- Altered Mental Status (NYD)
- Hypoglycemia
- Hypoglycemia
- Seizure (Adult)

Burns
- Burns (fire/flash)
- Chemical/Scald/Scrub
- Electrocut/Electrical Burns
- Possible Airway Burns

Cardiac Arrest
- General Cardiac Arrest Care
- PEA/Asystole
- Post-Cardiac Arrest Care
- Traumatic Arrest
- VFA/T-Pulseless (Shock Advised)

Cardiac Arrhythmia
- Bradycardia
- Stable Narrow Complex Tachycardia
- Stable Wide Complex Tachycardia

https://emspep.cdha.nshealth.ca/TOC.aspx
Impact of Research on EMS Care

Dalhousie University

Spinal Injury
Last Reviewed: Jun 15, 2016

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>SUPPORTIVE (Green)</th>
<th>NEUTRAL (Yellow)</th>
<th>AGAINST (Red)</th>
<th>NOT YET GRADED (White)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (strong evidence exists)</td>
<td>In-Line stabilization for intubation</td>
<td>Steroid</td>
<td>Cervical Collar</td>
<td>Hypertone Saline</td>
</tr>
<tr>
<td>2 (fair evidence exists)</td>
<td>C-Spine Clearance</td>
<td>Scoop stretcher</td>
<td>Long Spinal Immobilization Devices</td>
<td></td>
</tr>
<tr>
<td>3 (weak evidence exists)</td>
<td>Leave Helmet In Place</td>
<td>Spinal Precautions</td>
<td>Immobilization in Penetrating Trauma</td>
<td></td>
</tr>
</tbody>
</table>

Interventions

Cervical Collar

<table>
<thead>
<tr>
<th>Level</th>
<th>Direction</th>
<th>Primary Outcome</th>
<th>Reference</th>
</tr>
</thead>
</table>

https://emspep.cdha.nshealth.ca/LOE.aspx?VProtStr=Spinal%20Injury&VProtID=2
Impact of Research on EMS Care

Many other studies that have impacted our care:

- Trauma triage
- Bystander CPR & Resuscitation
- Use of tourniquets
- Prehospital activation of the cath lab
Performing Research

Scientific Method

◦ Ask a question
◦ Conduct literature review to seek answers
◦ Determine a hypothesis based on literature review
◦ Test the hypothesis
◦ Analyze the data to prove or disprove hypothesis
◦ Report findings, discuss limitations
◦ Refine hypothesis or adjust process and begin again
Quantitative Research

Uses the **scientific method**

Involves collecting **measurable data** with **statistical analysis**

**Tests variables** that may impact an outcome

May be:

- **Prospective** (e.g. randomized trials)
- **Retrospective** (i.e. using existing data)

Used to develop **evidence-based guidelines**
Qualitative Research

Often *observational*

Data are more *descriptive* instead of measurable

Best for *generating questions* and *explaining concepts* where there is no measurable data
  
e.g. Why do EMS providers choose to do things a certain way?
Types of research studies

**Case Studies**
I did something and it worked – or didn’t

**Case Series**
I did something several times and it worked – or didn’t

**Cohort Studies**
study cases with common characteristics to identify factors related to developing a disease or outcome

**Case Control Studies**
study cases with an outcome or intervention and compare to controls

**Randomized Controlled Trials**
study the random administration of an intervention or control
Types of research studies

Least certain

Case Studies
I did something and it worked – or didn’t

Case Series
I did something several times and it worked – or didn’t

Cohort Studies
study cases with common characteristics to identify factors related to developing a disease or outcome

Case Control Studies
study cases with an outcome or intervention and compare to controls

More certain

Randomized Controlled Trials
study the random administration of an intervention or control
Randomized Controlled Trials

The highest quality clinical study to test an intervention

Patients selected who meet specific criteria

Patients randomly assigned to either an intervention or a “control” group

Administer the intervention (and possibly a placebo)

Assess for difference in the outcome
Limitations of Randomized Controlled Trials

Sometimes we can’t randomize to an intervention

Very costly

Time consuming

Requires large numbers of patients

May be unfeasible due to setting/environment

Requires more statistical analysis
Ethics in Research

History of unethical experimentation
- Nazi medical experimentation (1930s)
- Milgram experiments (1960s)
- Tuskegee syphilis study (1930-1972)

National Research Act (1974)
- Development of federal regulations for human subjects research
- Need for informed consent and IRBs

Belmont Report (1979) - Ethical standards for federal research
- Respect for persons
- Beneficence
- Justice
Informed Consent
- Process of gaining permission from a subject for participation in research
- Difficult in the prehospital setting
- Waiver of informed consent possible for minimal risk studies

Exception From Informed Consent (EFIC)
- Allows interventional research without a waiver of consent
- Must be for a life threatening condition
- Consent must not feasible due to subject’s medical condition
- Risk/benefit must be reasonable
- Requires community consultation and public disclosure
Challenges of EMS Research

Impediments to informed consent process
Randomization of interventions
Buy-in from EMS providers
Logistics
Continuity of medical records
Variability in documentation
Using Evidence-Based Guidelines
Evidence-Based Guidelines

Developed based on systematic review of all the available medical literature

Assist EMS systems, medical directors, and field personnel in making decisions about patient care

Address specific clinical questions

Ensure high quality patient management
What if we just read all of the published research and keep our practice current with the evidence?

Keeping track of all new evidence is almost impossible with the amount of literature being published!

A 2010 study indicated over 75 clinical trials and 11 systematic reviews were published every day in medicine

Even if one could read and digest each article in 10 minutes – that’s over 14 hours a day*

Evidence-based guidelines help to:

1. Decrease the amount of work that each individual must do to be knowledgeable of all of the available medical evidence, including:
   - Prior guidelines
   - Systemic literature reviews
   - EBP summaries
   - Individual peer-reviewed research
Evidence-based guidelines help to:

2. Determine if something is worth incorporating into your practice, based on:
   ◦ Critical look at currently available evidence
   ◦ Feasibility of implementation
Evidence-based guidelines help to:

3. Review medical evidence to **answer questions that can directly improve patient outcomes**
Evidence-based guidelines help to:

4. Identify evidence-based **recommendations** that help improve patient care

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Evidence-Based Guidelines are useful

EBGs are promoted by:
- National organizations
- Insurers
- Accreditation bodies
- Others
How is an evidence-based guideline created and used?
From Evidence to Guidelines

Performing scientific studies
- Develop a research question
- Identify the patient population to study
- Carry out the study and data analysis
- Appropriately interpret the research findings

Synthesizing evidence from multiple studies

Developing recommendations
- Based on the best available scientific evidence
- Incorporating clinical judgement of experts
- Considering the values and preferences of the patients and clinicians

All of this takes a lot of resources, time, and effort
Multiple groups are engaged in creating evidence-based guidelines for EMS

Primary researchers in prehospital care
- Perform research that guidelines are based on

Evidence-based practice centers
- Synthesize the literature used by experts to create guidelines

Guideline development groups
- Often led by national organizations with broad stakeholder participation
Creating an evidence-based guideline begins with research that...

Must ask the right question(s)
Must involve the right population
Must analyze data accurately and without bias
Must allow conclusions that appropriately inform future practice
Creating an Evidence-Based Guideline

A National Model for Developing, Implementing, and Evaluating Evidence-based Guidelines for Prehospital Care

Eddy S. Lang, MD, CCFP(EM), Daniel W. Spaite, MD, Zoe J. Oliver, MD, Catherine S. Gotschall, ScD, Robert A. Swor, DO, Drew E. Dawson, and Richard C. Hunt, MD

1. External Inputs
2. Guideline Initiation and Evidence Review
3. Evidence Appraisal
4. Guideline Development
5. Model EMS Protocol Development
6. Guideline/Protocol Dissemination
7. Implementation
8. Evaluation of Effectiveness, Outcomes, Clinical Research, QI Evaluations
Step 1: External Inputs

Identify what evidence already exists
- Existing prehospital guidelines
- Existing prehospital protocols
- Prehospital components of multidisciplinary guidelines

EMS scope of practice and educational standards

Input from EMS researchers and professionals
Step 2: Guideline Initiation and Evidence Review

Develop the question you are trying to answer

- Review of the existing literature will be guided by this question
- How you ask this question is of key importance

Examples of clinical questions:

- Should we use tourniquets to control hemorrhage?
- Should we administer aspirin to patients with chest pain?

Perform a review of the evidence based on your clinical questions
PICO questions focus your search

P  Patient or problem
I  Intervention or indication
C  Comparison or control
O  Outcome
Questions may be about:

- Intervention or therapy
- Diagnostic test or screening method
- Prognosis
- Risk factors
Clarifying the PICO Question

Patient
◦ Age, sex, conditions, numbers, etc.

Intervention/indication
◦ Clear description of what you are doing

Comparison or control
◦ What happens when you DO NOT do the action

Outcomes
◦ The impact you are trying to measure
Questions may address...

Interventions or therapies
  ◦ Best evaluated with randomized, controlled trials

Diagnostic tests
  ◦ Identify the ability of a tool to identify a disease
    e.g. Prehospital 12-lead

Risk factors for specific illness
  ◦ May identify the likelihood that a patient has serious illness
    e.g. trauma or stroke triage tools
Example PICO Questions

In prehospital patients age >35 years with chest pain,

does administration of aspirin versus no aspirin reduce mortality?
Example PICO Questions

**P**
In prehospital patients age >18 years with potential spinal injury,

**I**
does placement of a cervical collar versus no cervical collar

**C**
reduce long term neurological deficits from spinal injuries
Performing a literature review

There are multiple resources for conducting a literature review:
Existing research databases:

- PubMed.gov
- Google Scholar
- EBSCO Health CINAHL Complete
Performing a literature review

Peer-reviewed literature

Trade publications
Step 3: Evaluating the Evidence

Must assess the quality of the evidence
- Study design
- Risk of bias
- Does it address your population?
- Are the results consistent?

Using a systematic method of evidence appraisal is key
- E.g. the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) system
Summary OF GRADE Methodology

Formulate question
Select outcomes
Rate importance
Outcomes across studies
Create evidence profile
with GRADEpro
Rate quality of evidence for each outcome

Randomization increases initial quality
1. Risk of bias
2. Inconsistency
3. Indirectness
4. Imprecision
5. Publication bias

Grade up
1. Large effect
2. Dose response
3. Confounders

Grade overall quality of evidence across outcomes based on lowest quality of critical outcomes

Summary of findings & estimate of effect for each outcome

Ongoing Efforts to Promote Evidence-Based Practice

Systematic review

Guideline development

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

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

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

Grade 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..."
Step 4: Guideline Development

Usually involves a diverse expert panel involving input from multiple stakeholders, such as:

- EMS medical directors
- EMS professionals
- EMS administrators
- Patient representatives

Must weight the risks and benefits of interventions
Must account for the values and preferences of the population
Must put in the context of real-life EMS care
Step 5: Model EMS Protocols

Often created as part of the guideline development process
Facilitate easier implementation in EMS systems
May not be a one-size fits all
  ◦ Maybe one-size fits most?
May be used as a template that can be adapted to local practices
  ◦ Scope of practice
  ◦ Availability of personnel, medications and equipment
  ◦ Education and training needs
Step 6: Guideline Dissemination

Guidelines often published in peer-reviewed journals
◦ May not be read by the general EMS community
◦ Often not easily accessible to the general community

Stakeholder organizations help dissemination
◦ Education through standardized courses
◦ E.g. Advanced Cardiac Life Support, International Trauma Life Support
Step 7: Guideline Implementation

One of the greatest challenges to use of guidelines

Must consider:
- Buy-in or support from end-users
- Education and training
- New medications or equipment
- Funding for new initiatives
Implementing EBGs in EMS is Challenging!

Very challenging to change engrained practice
May implement something without changing practice
Equipment issues may be limiting
Funding may be limited or non-existent
Buy-in can’t be bought
May not have a mechanism to evaluate the impact of implementation
Remember when Implementing Change

EMS agencies require on average over 1 year to implement national guidelines such as cardiac arrest guidelines*

It may take up to 17 years for clinical research to make it into everyday practice**

*Good evidence for the change can reduce resistance and decrease the time needed for full implementation*


Implementation Toolkits Can Help

Statewide Implementation of an Evidence-Based Guideline

General Toolkit V2.1

[This Toolkit contains resources developed for State EMS Offices participating in the NASEMSO Statewide Implementation of a Prehospital Care Guideline Project.]
Step 8: Evaluation

A critical component of the guideline process should evaluate whether a guideline:

- Was truly implemented (i.e. is it being used how it was intended)
- Is effective at positively impacting outcomes
- Is cost effective
National EMS Information System (NEMSIS)

National database used to store EMS data from the U.S.
Universal standard for patient care information from 911 responses
Funded through the National Highway Traffic Safety Administration (NHTSA)
Serves as a tool to facilitate evaluation of evidence-based guidelines

Powered by NHTSA’s Office of EMS
Cardiac Arrest Registry to Enhance Survival (CARES)

Program for standardized data collection for out-of-hospital cardiac arrest (OHCA)

Aims to help communities determine standardized outcome measures for OHCA

Can facilitate evaluation of implementation of guidelines related to OHCA
Ongoing Efforts to Promote Evidence-Based Practice
National Highway Traffic Safety Administration (NHTSA)

Supporting efforts to increase evidence-based medicine in EMS care

- Development of EMS evidence-based guidelines (EBGs)
- Implementation projects for prehospital EBGs
- National Prehospital Evidence-Based Guidelines Strategy
Many national organizations are engaged in developing and implementing prehospital EBGs.
Where do I find more information on prehospital guidelines?

www.prehospitalguidelines.org