Chapter 8
Research Principles and Evidence-Based Practice

Learning Objectives

• Explain the importance of EMS research.
• Distinguish between types of EMS research.
• Outline 10 steps to perform research identified in this chapter.
Learning Objectives

• Define evidence-based practice.
• Describe criteria to evaluate when reading a research paper.

EMS Research

• Essential to continued evolution
• Insight on intended effects, cost-effectiveness
  – 2001, national EMS research agenda
  – Ensure best possible care provided
  – Data based, lead to changes
  – Professional standards
  – Training
  – Equipment
  – Procedures
  – Improved patient care
  – Increases EMS professional respect

Types of Research

• Gathering research on which procedures, techniques, equipment are sound
• Gathering research to answer clinically valuable questions, find results, make system improvements
Standard Research Methods

- Descriptive
  - Events monitored, analyzed without attempt to manipulate/alter outcome
- Experimental
  - Intervention introduced, effects monitored for outcome
- Prospective
  - Specific question, hypothesis, data collection defined before study begins

Standard Research Methods

- Retrospective
  - Specific question, hypothesis, data collection defined after data already exists
- Cross-sectional
  - Group of subjects studied during specified period of time

Basic Principles of Research

- Research steps
  - Prepare question
  - Write hypothesis
  - Decide what to measure, best way to measure it
  - Define population
  - Identify study limitations
  - Seek study approval
  - Obtain informed consent
  - Gather data after conducting pilot trials
  - Analyze data with awareness of pitfalls in interpreting data
  - Determine what to do with research product
Prepare Question

• State specific problem, question
• Carry out standard research methods
• Examples
  – What factors predict student success on national registry of EMT's written examination?
  – Greater incidence of complications related to prehospital versus hospital peripheral vascular access
  – Does uniform influence patient’s satisfaction?

Write Hypothesis

• Relationship between two or more variables
  – Anything that varies in amount, type
• Major goal
  – Decide what to measure, how to measure it
Define Population

- Any group of persons
  - All patients with diastolic pressure greater than 100 mmHg
- Places
- Things

Identify Study Limitations

- Prevent selection bias
- Random sample
  - Equal chance being assigned to one group
  - Ensure through computer software programs, random digits, flip of coin
- Systemic sampling
  - Placed in groups in order encountered in prehospital setting

Identify Study Limitations

- Alternative time sampling
  - Assigns treatment group based on day, week, month patient is encountered in study
- Convenience sampling
  - Least preferred
  - Patients assigned to groups when particular person, crew is working
Identify Study Limitations

- Sampling errors
  - Best samples will not work perfectly to represent population
  - Chance inclusion of one person in study group rather than chance inclusion of someone else
- Bias may be the result of expectations of participants
  - Use blinding to decrease bias
- Single blind
  - One party unaware (blinded) of treatment at time given
  - Unaware of effect measured

Identify Study Limitations

- Double blind
  - Two parties blinded
- Triple blind
  - All parties blinded
- Unblinding
  - All parties are made aware of study, treatment, outcome to be measured

Seek Study Approval

- 1966, U.S. public health services mandate planning research
  - Institutional review board (IRB)
  - Independent ethics committee (IEC)
  - Ethical review board (ERB)
  - Required review by committee of institutional associates, federally funded research using human subjects
Seek Study Approval

- Regulations empowered IRBs to
  - Approve research
  - Require modifications in planned research prior to approval
  - Disapprove research
  - Perform critical oversight for research conducted on human subjects

Seek Study Approval

- Research requirements
  - Scientific
  - Ethical
  - Regulatory

Obtain Consent

- Informed consent
  - Subject voluntarily agrees to take part in research project
  - Has decisional capacity
  - Understands what is presented
Obtain Consent

- Consent at a distance
  - Base-station physician administers informed consent to subject via radio, telephone
- Consent by proxy
  - Paramedic administers informed consent to subject
- Stepped consent
  - Paramedic provides subject with brief overview of experimental therapy, full informed consent obtained at hospital

Obtain Consent

- Cohort consent
  - Permission is obtained to enter study at future time
- Deferred consent
  - Used during resuscitation
  - Subject stabilized, receives experimental therapy without permission
  - Family approached for traditional informed consent after

Obtain Consent

- Surrogate consent
  - Lay persons presented with experimental protocol, asked to rule if they feel treatment is appropriate
- Consent jury
  - Lay panel determines experimental protocol aspects, potential risks, complications that must be presented during request for consent
Gather and Analyze Data

- Use statistical methods
  - Numerical facts, data
  - Descriptive statistics
  - Inferential statistics

Descriptive Statistics

- Provides description of sample of objects, people being studied
- Does not infer anything from data, simply reports it
- Qualitative, quantitative

Descriptive Statistics

- Qualitative analysis
  - Nonnumerical
  - Organization, interpretation of observations
  - Sample size usually very small
  - Finds key underlying dimensions, patterns in group
  - Conclusions involve themes, trends, theories from interviews, discussion, and observation of population
### Descriptive Statistics

- **Quantitative analysis**
  - Mean, median, mode
  - Mean is arithmetic average of group
  - Median is arranging measurement according to size, smallest to largest, choose one in middle, or mean of two nearest middle
  - Median is 50th percentile, divides sample into two halves
  - Mode is number that occurs most often

### Inferential Statistics

- **Infers whether relationships are likely to occur in larger population**
- **Decides whether results support, contradict initial hypothesis**
  - Must assume opposite of what one may want to prove
  - Null hypothesis is default position or opposite of what is expected to prove
  - Research hypothesis is opposite of null hypothesis

### Inferential Statistics

- **Statistically significant**
  - Observed phenomenon represents significant departure from what might be expected by chance alone
Level of Significance

• Probability of type I error that investigator is willing to risk in rejecting the null hypothesis
• Probability of event occurring due to chance
• Acceptable risk of sampling errors, mathematic equation established

Level of Significance

• 0.05 (1 chance in 200) or 0.01 (1 chance in 100) that difference between two groups is greater than expected as a result of chance alone
• If lowered, probability of rejecting true hypothesis is decreased, probability of accepting false hypothesis is increased

Level of Significance

• Type II error
  – Investigator fails to accept alternative hypothesis when alternative hypothesis was true
  – Null hypothesis accepted when not true
• Must set before beginning research
Determine Result Actions

- Final step, several options
  - Publishing results
  - Presenting results
  - Performing follow-up studies

Scientific Literature Format

- Use format for writing manuscript for scientific literature
- Introduction
  - Brief, historical background
  - Relates previously published research
  - Provides rationale for study, research hypothesis

Scientific Literature Format

- Methods section
  - Describes how experiment is done so others can replicate it
  - Defines inclusion, exclusion criteria
  - Statistical methods used to analyze
- Results section
  - Answers to study questions, data (tables, figures)
  - Supports research findings
Scientific Literature Format

- Discussion section
  - Author interprets research findings
  - Limitations of project given
  - Suggestions for improving through follow-up research
- Conclusion
  - Brief, succinct summary of previous sections

Presenting Results

- Helps put research into practice
- Made to peers, professional organizations, higher education institutions
- Clinical studies can lead to improvements in patient outcomes

Follow-Up Studies

- Funding available for follow-up studies, done through collaborative efforts
  - Public agencies
  - Corporations
  - Foundations
  - State, federal government programs supporting research consortia
Evidence-Based Practice

- Traditional medical practice based on medical knowledge, intuition, judgment
  - Emphasis toward evidence-based practice
  - Guidelines for specific conditions
  - High-quality care focus on procedures proven useful in improving outcomes
  - Should participate in EMS research, data collection, sharing information
  - Helps design system-wide process for prehospital care, reflects current state of scientific evidence

Reviewing Research

- Read research critically, determine findings relevant to practice
- Population
  - Adequate, similar to practice
- Inclusion/exclusion criteria
  - Study of patients with chest pain did not include patients older than 65 years of age, eliminates key group at risk for heart disease, death
Reviewing Research

- Data collection
  - Anything could influence
  - Experimental study, how were groups randomized
  - Were methods clearly described?
  - Could method vary based on person delivering care?
  - Same conditions for control, experimental groups

Reviewing Research

- Results
  - Are numbers presented clearly?
  - When percentages are presented, are underlying numbers reported?
  - Statistically significant difference in outcome, is it also clinically significant?

Reviewing Research

- Discussion, conclusion
  - Conclusion consistent with results reported
  - Properly report correlations, relationships versus predictions
  - Link research to relevant literature
  - Limitations of study pointed out clearly
  - Make specific suggestions for future research
  - Identify any major flaws in the conclusion
Reviewing Research

• How does this relate to practice?
  – Suggest area of improvement for your system
  – Suggest area be monitored in QI program
  – Is there reason to seek more literature on the same subject to propose change in your system?

Summary

• Paramedic must be familiar with research principles to conduct research, collect research data, interpret published studies
• Research is essential to improve patient care
• Two main types of research methods are descriptive and experimental
  – Data are collected by various methods that may be prospective, retrospective, or cross-sectional

Summary

• Ten steps of EMS research
  – prepare question
  – write hypothesis
  – decide what to measure and how to measure it
  – define population
  – identify study limitations
  – seek IRB approval
  – obtain informed consent
  – gather data after conducting pilot trials
  – analyze data
  – present data
• Descriptive statistics do not try to infer anything about a subject that goes beyond data
Summary

- Qualitative analysis provides nonnumerical description of population
- Quantitative data analysis evaluates data using numbers
- Inferential statistics infers whether relationships seen in the sample are likely to occur in a larger population
  - Researchers develop null hypothesis

Summary

- EMS care should be evidence-based
  - Should be proof that interventions, procedures have benefit for the patient
- Paramedics should read research articles critically to determine whether they are relevant to practice

Questions?