HOW TO DEVELOP A RESEARCH PROTOCOL
The conscientious, explicit, and judicious use of current best evidence in making decisions about the care of the individual patient

It means integrating individual clinical expertise with the best available external clinical evidence from systematic research

Dr. David Sackett, 1996
Evidence-Based Medicine

Clinical Expertise

Patient Care

Patient Values

Best Evidence

American College of Foot and Ankle Surgeons
Research and Evidence-Based Medicine Committee: 2007
ACFAS.org
FootPhysicians.com
Fundamental Principles

✓ Evidence is never enough
✓ Hierarchy within EBM
Steps In EBM Process

✓ Clinical Problem
✓ Question
✓ Resource
✓ Evaluation
✓ Patient
Asking the Question

Foreground Question

Background Question

Novice  Expert

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“P.I.C.O.”

- Patient + Problem
- Intervention
- Comparison
- Outcome
Levels of Evidence

✓ January 2003
  • Journal of Bone and Joint Surgery American

✓ February 2005
  • American Academy of Orthopaedic Surgeons
JBJS Am Levels of Evidence

✓ I, II, III, IV, V based on design

✓ Types

• Therapeutic
• Prognostic
• Economic
• Decision Analysis
Randomized Control Trial
• Level I or II

Cohort
• Level II or III

Case Control
• Level III

Case Series
• Level IV

Expert Opinions
• Level V
Grades of Recommendation

✓ **Grade A**
  • Treatment options supported by strong evidence
  • Level I or II studies

✓ **Grade B**
  • Treatment options supported by fair evidence
  • Level II or III studies

✓ **Grade C**
  • Treatment options supported by either conflicting or poor quality evidence
  • Level III or IV studies

✓ **Grade I**
  • Insufficient evidence exists to make recommendation
Levels of Evidence in Orthopaedic Journals

- Journal of Bone and Joint Surgery Am + Br
- Journal of Orthopaedic Trauma
- Journal of Shoulder and Elbow Surgery
- American Journal of Sports Medicine
- Journal of Prosthetics and Orthotics
- Foot and Ankle International
- Journal Hand Surgery
- Journal of Arthroplasty

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JBJS 87A(12), 2005
Levels of Evidence

Level I

Level II

Level III

Level IV

JBJS 87A(12), 2005
Evaluation of the Foot and Ankle Literature

✓ Journal Foot and Ankle Surgery
✓ Foot and Ankle International
Evaluation of the Literature


• 334 Articles
• 7 RCT
Evaluation of the Literature

Jan 2005 – Nov 2008

- 810 Articles
- 10 RCT

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“Target your reading to particular issues related to the patient”
EBM Literature Sources

✓ Cochrane Database
✓ Medline
✓ UpToDate
✓ Best Evidence
✓ OVID

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AGAINST ↔ FOR

✓ “Old Hat”
✓ Cook Book Medicine
✓ Population Studies
✓ Lack of Gold Standard
✓ Access Difficulty

✓ Strong Evidence
✓ One Part
✓ Patient Decision
✓ Evidence Pyramid
✓ Trained Professionals
How to Develop a Research Protocol

✓ Checklist:

• Determine research question
• Perform literature search
• Justify proposed research
• Determine research design
• Select measurable data points
• Determine method of statistical analysis
• Create Budget
• Write protocol
Example:

In the treatment of calcaneal fractures, does open reduction with internal fixation (ORIF) or closed reduction with casting provide better functional results?
Perform Literature Search

☑ Comprehensive search of multiple databases including:
  • PubMed
  • Ovid
  • CINAHL
  • Cochrane Database of Systematic Reviews
  • Cochrane Central Register of Controlled Trials
  • EMBASE
  • Bibliographies of selected articles
  • Etc.
Justification for Proposed Research

Example:

- The literature is currently inconclusive as to whether operative or non-operative treatment of calcaneal fractures provides better outcomes
- Wide variation in the severity of fractures treated operatively vs. non-operatively in the studies reviewed
- Prospective trials included surgeons of varying experience employing different surgical procedures/techniques
- Significant differences in the rates of post-operative complications among studies
- Few randomized controlled trials have been done comparing operative to non-operative management
Example:

- Patients with Sanders Type II and III calcaneal fractures treated with ORIF by a single, experienced surgeon will have better functional results when compared with a similar group of patients treated non-operatively.
Example:

- Use sample size calculator found on the internet to determine appropriate sample size to reach statistical significance
- Will require averaging of results from previous similar studies (if available) to use as sample percentages for the calculation
- A confidence interval of 95% (alpha of 5%) and a statistical power (1-Beta) of 90% or greater should be utilized if possible
Define Study Population

Example:

- Closed Sanders Type II and III calcaneal fractures in patients aged 18 to 50 years presenting to our hospital for treatment without major co-morbidities as defined in inclusion and exclusion criteria.
Example:

- The subjects will be selected from those patients presenting to our hospital ER or clinic with closed Sanders Type II and III calcaneal fractures who meet the inclusion criteria for the study and agree to participate after a full explanation of the protocol.
Determine Inclusion Criteria

✅ Example:

- Closed Sanders Type II and III calcaneal fractures
- Unilateral lower extremity injury
- Male and Female patients
- Age 18 to 50 years
Determine Exclusion Criteria

✓ Example:

- Open calcaneal fractures
- Sanders Type I or IV calcaneal fractures
- Peripheral arterial disease defined as ABI <0.8
- Patients with Diabetes Mellitus
- Patients on Corticosteroids
- Previous rearfoot/ankle surgery on affected side
- Bilateral lower extremity injury
Example:

• Prospective
• Randomized
• Controlled Trial
Example:

• Once a subject is identified and agrees to enter the study, they will randomly be placed into either an operative or non-operative treatment group using a predetermined table of randomization.

• Random number table generators are available on the internet.
Select Measurable Data Points

✓ Example:

- **Function after return to weight bearing (WB):**
  - ACFAS Rearfoot Scoring Scale *(compare to pre-injury)*
  - AOFAS Hindfoot Scale *(compare to pre-injury)*
  - Computerized Gait Analysis
  - Return to work/pre-injury activities?

- **Pain Level after return to WB:**
  - Visual Analog Pain Scale
  - Narcotic/NSAID use

- **Fracture reduction:**
  - CT evaluation at time of injury *(Sanders Classification)*
  - X-ray evaluation at time of injury and periodically throughout healing *(Essex/Lopresti Classification/Gissane’s angle, etc.)*
Using all the information collected to this point, write a detailed description of how study will be conducted and what procedures will be performed at each study visit.
Determine Method of Statistical Analysis

✅ See ACFAS Research/EBM Committee module presentation:

• “Choosing the Appropriate Statistical Analysis Tool”
Determine Time Frame for Study Completion

☑ Example:

• Dependent upon:
  ✔ Number of calcaneal fractures treated at the facility per year
  ✔ Sample size required for statistical significance
  ✔ Number of study visits/data collection points required for completion
Identify Limitations of Study

Example:

Sources of Bias:

- Unable to blind subject to type of treatment provided
- Difficult to blind investigator to type of treatment provided
- Those evaluating radiographs will also be aware of treatment utilized
Identify Limitations of Study

Example:

- Limits to Generalizability
  - Previous studies have shown tendencies for worse post-operative outcomes in patients with worker’s compensation claims, people over 50 years of age, and male patients in general ⇒ We will exclude patients over 50, but must include males and will need to include patients with on the job injuries, as we will be unable to reach our sample size if we exclude these patients
  - A high learning curve has been reported for surgeons performing ORIF of calcaneal fractures which translates to worse outcomes for patients operated on by inexperienced surgeons ⇒ This could equate to an inability to reproduce results by surgeons with less experience
  - Patients over age 50 or with multiple co-morbidities may not have similar results with either operative or non-operative intervention, as those included in this study
Example:

- Will utilize standard ACFAS Rearfoot scoring scale, AOFAS Ankle-Hindfoot Scale, and VAS Pain Scale
- Will develop a History and Physical form including demographic data for patients and code form to make it easy for data entry (i.e., male = 1; female = 2)
Determine Your Budget

Example:

- Consultant: Statistician ($50 to $100/hr)
- Equipment: Computerized Gait Analysis Program ($8,000)
- Printing: Consent forms, Data collection forms, VAS scales, AOFAS scoring sheets, ACFAS scoring sheets, etc. ($200)
- Clerical: Data Entry ($12/hr)
✓ Write a consent form for the study following the guidelines set by your Investigational Review Board

✓ Include all potential risks of participation in the study
Protocol Submission

Example:

- Type protocol in format required by the Investigational Review Board and/or funding agency you wish to apply to
- Be sure to complete all portions of the application in order for your submission to be considered for approval/funding
Where Does EBM Fit with Foot and Ankle Surgery??
Where Does EBM Fit?

✓ ACFAS
✓ Research
✓ EBM ONLY??
✓ Your Step

“The surgery went well - we were able to save the foot after all.”