How to Start a Research Program

Frederick B. Rogers, MS, MD, FACS
Director of Trauma
Lancaster General Hospital
Outline

• The Vision
• The Reality
• Types of Research
• Crucial Elements
• Research Design (PICO)
• Abstract Preparation
• Practical Tips
• Conclusion
The Vision

LGH Hospital Level II
- LGH trauma center is best in Lancaster County
- Lancaster County is the best county in PA
- PA is the best state in the U.S.
- U.S. is the best country in the world
- The World is the best planet in the universe

Guthrie’s RPH Level II
- Guthrie’s RPH trauma center is best in Bradford County
- Bradford County is the best county in PA
- PA is the best state in the U.S.
- U.S. is the best country in the world
- The World is the best planet in the universe

LGH trauma center is the best trauma center in the universe!!!

Guthrie’s RPH trauma center is the best trauma center in the universe!!!
The Vision

Corollary: B/c we are proud to work in two of the finest trauma centers, we have a moral imperative to share our expertise with the rest of the trauma community.
The Reality

Newton’s First Law of Inertia
The Reality

Chief of Trauma @ UCSD:
Steve Shackford, MD, FACS
Chief of Surgery, UVM College of Medicine 1989-2008
Board of Directors of EAST- 1993-95
President of Western Trauma Association- 2001
President AAST- 2005

“Fred, taking care of patients is the easy part of trauma surgery- the hard part is doing research, writing papers, and presenting them.”
Types of Research

1. Basic Science
   a. Level I University Trauma Centers
   b. Gov’t Grants (NIH, DOD, NSF)
   c. Protected Time
   d. Long Process - careers
   e. Specific Facilities (animal labs)
   f. $$$$$$$
Types of Research

2. Translational Research
   a. MD/PhD Partnership
   b. Hybrid Model
   c. Level I University Trauma Centers
   d. Goal: Is to translate the findings in basic science research more quickly and efficiently into medical practice
   e. New and rapidly evolving domains (centers of excellence) - lots of funding
Types of Research

3. Clinical Research
   a. Prospective or Retrospective
   b. Cheap
   c. Practical - relevant to everyday trauma care
   d. The hospital and trauma service are a veritable, verdant laboratory of clinical research
   e. Immediately relevant and beneficial to trauma patients
   f. Level I, II, or III
Levels of Evidence for Health/Medical Research

- Systematic Reviews/Meta-Analysis
- Randomized Controlled Trials
- Cohort Studies
- Case-Control Studies
- Case Series, Case Reports
- Editorials, Expert Opinion
Types of Studies

• **Cohort Studies**
  – Follow patients who have a specific condition or treatment
  – Compare them with another group that has not been affected by the condition or treatment
  – Observational
  – Two groups may differ in ways other than in the variable under study

• **Case Control Studies**
  – Patients who already have a specific condition
  – Compared with people who do not
  – They often rely on medical records and patient recall for data collection
  – A statistical relationship does not mean than one factor necessarily caused the other.

• **Case series and Case reports**
  – Collections of reports on the treatment of individual patients or single patient
  – No statistical validity
## Best Study Design

<table>
<thead>
<tr>
<th>Type of Question</th>
<th>Suggested best type of Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapy</td>
<td>RCT &gt; cohort &gt; case control &gt; case series</td>
</tr>
<tr>
<td>Diagnosis</td>
<td>prospective, blind comparison to a gold standard</td>
</tr>
<tr>
<td>Etiology/Harm</td>
<td>RCT &gt; cohort &gt; case control &gt; case series</td>
</tr>
<tr>
<td>Prognosis</td>
<td>cohort study &gt; case control &gt; case series</td>
</tr>
<tr>
<td>Prevention</td>
<td>RCT &gt; cohort study &gt; case control &gt; case series</td>
</tr>
<tr>
<td>Clinical Exam</td>
<td>prospective, blind comparison to gold standard</td>
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</table>
Crucial Elements - Mandatory

In Order of importance:
• Zealot!!!
• Institutional Commitment and Support
• Statistician:
  – When I ask what time it is, don’t tell me how to build a clock
• Registry Access- home grown, PTSF, NTDB, TQIP, AAST/EAST Multi-institutional trials
  – Begin networking with other hospitals- develop local consortiums (Level II)
Crucial Elements- Ideal

- Grant Writer
- Research Savvy Secretarial Support- abstracts, power points, manuscript preparation
- Research Institute with Seed Money
- Research Coordinator
Research Sequence

- Literature Review → Study Design → Data Collection
- Analysis → Abstract
- Abstract → Manuscript → Review Article
PICO Strategy

• Evidence-Based Medicine
  – “conscious, explicit, and sensate use of the best evidence available in decision-making about patient care”
  • SACKET (Canada), et al:
  – Identification of best scientific evidence to support clinical decision making
  – PICO is used to identify best evidence in the construction of a research question
## Description of the PICO Strategy

<table>
<thead>
<tr>
<th>ACRONYM</th>
<th>DEFINITION</th>
<th>DESCRIPTION</th>
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<tbody>
<tr>
<td>P</td>
<td>Patient or Problem</td>
<td>Can be only one patient, a group of patients with a particular condition or a health problem</td>
</tr>
<tr>
<td>I</td>
<td>Intervention</td>
<td>Intervention of interest. Can be therapeutic, preventive, diagnostic, prognostic, administrative or related to economic issues</td>
</tr>
<tr>
<td>C</td>
<td>Control or Comparison</td>
<td>Standard intervention, the most used intervention or no intervention (placebo)</td>
</tr>
<tr>
<td>O</td>
<td>Outcome</td>
<td>Expected Result (Primary and Secondary)</td>
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Abstract Preparation

Step 1: *Most Important* HAVE A GREAT IDEA

a. Novel
b. Entertaining
c. Controversial

Small trauma centers must think outside the box
e.g. Press-Ganey; Filter Registry (Follow-up advantage)
Abstract Preparation

Step 2: Follow directions and adhere to deadline

a. Specific Font
b. Line Spacing
c. ± Tables
d. Intro, Methods, Results, Conclusion
Abstract Preparation

Step 3: Always state your hypothesis

Hypothesis = a statement of expectation(s) which are used to explain a scientific phenomena

a. Goes in the introduction
b. Many program committees will reject an abstract unless it has an explicitly stated hypothesis
Abstract Preparation

Step 4: Make sure your study is designed to answer your hypothesis

a. Make your results simple; easy to understand (WHAT MAY SEEM INTUITIVELY OBVIOUS TO YOU, MAY BE QUITE COMPLICATED TO SOMEONE NOT INVOLVED WITH YOUR RESEARCH)

b. Field test your abstracts with people unfamiliar with your work
Step 5: CONCLUSION

a. Is hypothesis accepted or rejected?

b. What are the implications of your study on trauma care?

c. Last sentence needs to be a ZINGER!!!
Practical Tips

1. Start with monthly research meeting and take minutes with an agenda
   a. Invite everyone to participate (MDs, Pas, residents, nurses, NPs, pharmacists, PT/OT, med students)
   b. Have an agenda for the meeting
      i. Update on presentations/publications
      ii. Individual presents his/her idea for the group
      iii. PICO format
      iv. New Ideas
      v. Deadlines
      vi. Future Agenda- who is to present
Meeting Minutes

Research Meeting/Trauma Service
June 9, 2009
Trauma Office

Attendance:
Frederick Rogers, MD, MS, FACS
John Lee, MD
Tracy Evans, MD
Jennifer Costello, Pharm.D.
Lanyce Horn, BSN, RN
Jill Rebuck, Pharm.D
Sheri Edgar, PM&R
Jennifer Lambert, PM&R
Lisa Hershiser, RN
Brandy Lykens, PA

Minutes

<table>
<thead>
<tr>
<th>ISSUE/TOPIC</th>
<th>DISCUSSION/ANALYSIS</th>
<th>ACTIONS/FOLLOW-UP</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. Updates</td>
<td>ICU – John Lee, MD</td>
<td>Dr. Rogers and Dr. Lee will meet this week to put the project together</td>
</tr>
<tr>
<td></td>
<td>• AAST Mtg. is in Pittsburgh on 10/1</td>
<td></td>
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<tr>
<td></td>
<td>• Paper is due 9/15</td>
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<tr>
<td></td>
<td>• Premise was to state that having intensivists here has decreased LOS in the ICU, as well as the ventilator days; however, it became interesting to see that our raw mortality rate did not decrease.</td>
<td></td>
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</tbody>
</table>
• Why did some indicators change, while some did not?
• Maybe we are actually approaching patients much earlier to do comfort measures.
• There is more information to be looked at.

**VAP – Lanyce Horn, BSN, RN**
• Mike Horst, Lanyce and Dr. Rogers looked at the VAP scoring system and made their final selection on the methodology.
• Mike is doing some final validation on the scoring system.
• Apply VAP score potentially to patients who may not even be ventilated at the time, but could be at risk for ventilation.

**Women in Trauma – Dr. Evans and Brandy Lykens, PA**
• Questionnaire will be multiple choice
• Jill Rebuck helped with ways to interpret answers
• Focus on why women go into trauma
• Should we include all women general surgeons or just trauma?
• Timeline will depend on the target audience
• Better to go through EAST than AAST – there are members of EAST who are not members of AAST
• Military personnel will be included
• Lit search revealed almost no information on women & surgery, and nothing on women & trauma
• Cost: none if done electronically; minimal if paper (100-200)

• Lanyce will write the abstract, then start working on the article

• Brandy waiting for feedback from Dr. Evans r/t questions
• Brandy, Jill and Dr. Evans will meet
• Get survey to EAST by 8/1?
<table>
<thead>
<tr>
<th><strong>PT – Sheri Edgar and Jennifer Lambert</strong></th>
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<tbody>
<tr>
<td>• Training the trainer program</td>
</tr>
<tr>
<td>• Competency training – goal is 80% of their staff</td>
</tr>
<tr>
<td>• Main objective is to not have a weekend where staff doesn’t know how to work around vents, lines, etc.</td>
</tr>
<tr>
<td>• Potential for research</td>
</tr>
<tr>
<td>• Needs to be put into a process where it can be analyzed objectively – could potentially be published</td>
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<table>
<thead>
<tr>
<th><strong>II. Other Topics</strong></th>
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<tbody>
<tr>
<td><strong>DVT – Dr. Rogers</strong></td>
</tr>
<tr>
<td>• Requested data on whether or not prolonged entrapment is a setup for developing DVT later on in the hospital</td>
</tr>
<tr>
<td>• Compare 2 populations – entrapment vs. no entrapment</td>
</tr>
<tr>
<td>• Should be enough data to write an abstract</td>
</tr>
<tr>
<td>• Need to set up a definition for entrapment</td>
</tr>
<tr>
<td>• Check with Registry for data availability</td>
</tr>
<tr>
<td><strong>Abstract Deadlines</strong></td>
</tr>
<tr>
<td>• July 1st is the deadline for EAST abstracts</td>
</tr>
<tr>
<td><strong>Geriatric Bundles</strong></td>
</tr>
<tr>
<td>• Pre-geriatric bundle data vs. after geriatric bundle?</td>
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<tr>
<td><strong>Aortic Dissection Paper</strong></td>
</tr>
<tr>
<td>• Brandy and Dr. Evans need to meet</td>
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<tr>
<th><strong>III. Next Meeting</strong></th>
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<tbody>
<tr>
<td>• The next meeting will be held on October 16th @ 2 p.m. in the Trauma Office</td>
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Frederick Rogers, MD, MS, FACS
Trauma Program Medical Director
Lancaster General Hospital
Trauma Service
Research Meeting

Agenda

10/16/09
2-3 p.m.
Trauma Office

1. Introduction of new members and new Director of Research
2. Congratulations to John Lee for AAST presentation, and congratulations to Lanyce, Sally, Jo Ann and Kat for abstracts accepted to SCCM
3. PICO format for Research and Ethics in Research-Presentation by Lois Sakorafas
4. Present to Publish – Meeting Abstract Deadlines
5. Publish to Florish – Journal Options: NEJM
6. Put LGH Trauma/Surgical Critical Care program on the National map
7. Lancaster General Hospital Journal
8. LGH Trauma/Research website
9. Other items
Practical Tips

2. Develop a wall of fame
   a. Bulletin board with copies of all recent publications by group
   b. Display all posters presented around office

3. Printout schedule for meetings and abstract deadlines and place in sign-out area

<table>
<thead>
<tr>
<th>Meeting</th>
<th>Abstract Deadline</th>
<th>Date</th>
<th>Place</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAST</td>
<td>Closed</td>
<td>9/12-9/15/2012</td>
<td>Kauai, HI</td>
</tr>
<tr>
<td>EAST</td>
<td>7/1/2012</td>
<td>1/15-1/19/2013</td>
<td>Scottsdale, AZ</td>
</tr>
<tr>
<td>SESC</td>
<td>7/12/2012</td>
<td>2/9 - 2/12/2013</td>
<td>Jacksonville, FL</td>
</tr>
<tr>
<td>SCCM</td>
<td>9/5/2012</td>
<td>1/19 - 1/23/2013</td>
<td>San Juan, Puerto Rico</td>
</tr>
<tr>
<td>Western Trauma</td>
<td>10/1/2012</td>
<td>3/3 - 3/8/2013</td>
<td>Aspen, CO</td>
</tr>
<tr>
<td>Southwestern</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Surgical</td>
<td>10/19/2012</td>
<td>3/24 - 3/29/2013</td>
<td>Santa Barbara, CA</td>
</tr>
<tr>
<td>ESTES</td>
<td>11/5/2012</td>
<td>5/4 - 5/7/2013</td>
<td>Lyon, France</td>
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</tbody>
</table>
Wall of Fame
Practical Tips

4. Success in Numbers!!!
   a. The more abstracts you submit the greater probability of success

5. “Never, never, never give up!” –Winston Churchill
   a. “There is a journal for every article” –Fred Rogers, 2012
   b. Be persistent, do not accept “reject”
   c. Get the reviewer’s comments
   d. Resubmit
   e. Impact Factor= frequency “average article” in a journal has been cited in a year
      - Injury: 2.336
      - J. of Trauma: 3.129
      - Critical Care Medicine: 6.254
      - NEJM: 53.298
Conclusion

• Research is a lot of hard (extra) work
• Intellectually Stimulating
• Extremely Satisfying
• Increase footprint in academic trauma community
• Essential PTSF Level I Criteria
Pennsylvania Trauma Systems Foundation
2012 Standards for Trauma Center Accreditation

General Standards

<table>
<thead>
<tr>
<th>Standard XXXIV—Trauma Research Program</th>
<th>Level I</th>
<th>Level II</th>
<th>Level III</th>
</tr>
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<tbody>
<tr>
<td>A. The institution will have a designated trauma research director (Trauma Program Medical Director or one of the trauma surgeons, who remains clinical active in trauma care and demonstrate current (two years) involvement in and commitment to research in trauma care.</td>
<td>E</td>
<td>D</td>
<td>_</td>
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<tr>
<td>B. The institution must have formal regularly scheduled trauma research meetings.</td>
<td>E</td>
<td>D</td>
<td>_</td>
</tr>
<tr>
<td>C. The institution must have an identifiable Institutional Review Board process, active research protocols, physicians and allied health professionals involved in extramural educational presentations, and an adequate number of peer-reviewed scientific publications.</td>
<td>E</td>
<td>D</td>
<td>_</td>
</tr>
<tr>
<td>D. Four (4) extramural educational presentations are required each year. These must be presented outside the institution.</td>
<td>E</td>
<td>D</td>
<td>_</td>
</tr>
<tr>
<td>E. Methods of demonstrating the trauma center/system involvement and commitment to research will include, but not be limited to:</td>
<td>E</td>
<td>D</td>
<td>_</td>
</tr>
<tr>
<td>1. Publications must appear in peer-reviewed journals included in Index Medicus. In a three-year cycle, the minimum acceptable number is twenty (20) trauma related publications. This must include a minimal activity of one trauma or trauma related publication from members of the general surgery trauma team and one from each of the three (3) of nine (9) disciplines listed: neurosurgery, emergency medicine, orthopedic surgery, radiology, anesthesia, critical care medicine, pre-hospital, burns and rehabilitation. Other surgical, non-surgical, nursing or allied health professional or work done in collaboration with other trauma centers and participation in multi-center investigations may be included in the peer review publications and can contribute to the minimal acceptable number of publications.</td>
<td>E</td>
<td>D</td>
<td>_</td>
</tr>
</tbody>
</table>
Conclusion

“Research is to see what everybody else has seen, and think what nobody else has thought”

-Albert Szent-Györgyi,

Hungarian Biochemist
Winner of 1937 Nobel Prize
Discovered Vitamin C

“Somewhere, something incredible is waiting to be known”

- Dr. Carl Sagan, 1934-1996