Objectives

• Why is research important?
• Why should I do research?
• What are my research opportunities?
• Medical database research
• Questions and pitfalls of database research
Importance of Research

• Advancement of Medical Care
  – Contribution to your specific field
  – Improvement of patient care
  – Involves the core purpose of being a physician

– Contributions:
  • Diagnostic
  • Therapeutic
  • Invasive or Non-Invasive
  • MAY TAKE DECADES OR CENTURIES – CUMULATIVE
History of Wound Infections

- Edwin Smith Papyrus
  - Ancient Egypt (c 1600 BC)
  - Oldest known treatise
  - Scientific (not magic)
  - Trauma & Surgery
    - Wound Care
  - Thebes? Imhotep?
  - Edwin Smith & Mustafa Agha
    - 48 case histories
  - Observations & treatment
History of Wound Infections

• Hippocrates (460-377 BC)
  – Father of Medicine
  – Vinegar Irrigation & Dressings

• Galen (130-200 AD)
  – Roman Gladiatorial Surgeon
  – Pus Heralded Healing
    • Misguided – Poor Understanding

• Ambroise Paré (1510 – 1590)
  – French Military Surgeon
  – “I dressed the wound. God healed it.”
History of Wound Infections

• Robert Koch (1843-1910)
  – Berlin
  – Infection linked to Microbial Growth
  – Bacterial Plating Technique
  – Nobel Prize 1905 – TB

• Ignaz Semmelweis (1818-1865)
  – Austrian Obstetrician
  – Hand Washing
  – 5 fold decrease puerperal sepsis
History of Wound Infection

• Joseph Lister (1827-1912)
  – British Surgeon
  – Applied Louis Pasteur’s Principles
  – Antisepsis Prevents Infection
  – Carbolic Acid in Open Fractures
  – Carbolic Spray
    • Operating Room
    • Instruments
World War 1
World War I

- Antoine Depage (1862-1925)
  - Belgian Surgeon
  - Debridement
  - Delayed Closure
    - Microbiological Brushings

- Alexander Fleming (1881-1955)
  - British Microbiologist
  - Bacterial Studies – WWI
  - Nobel Prize 1945 – Penicillin
    - Howard Florey
    - Sir Ernst Boris Chain
History of Wound Infections

- John Eric Erichsen (1818-1896)
  - British Surgeon
  - University Hospital College – London
- Hospitalism
  - Sir James Simpson (Edinburgh)
  - Surgical Site Infection
    - Hospital Acquired
History of Wound Infections

• Hospitalism (1874)
  – 1870-1873
  – 36% Mortality – Amputations
    • Four Major London Hospitals
  – 30-50% Mortality
    • England/France/Germany/USA
  – Safer to be operated at home

• Closer Look at Works of:
  – Lister
  – Pasteur
  – Koch
Aseptic Surgery

• Began in 1880’s
  – Instrument Sterilization
    • Not routine
  – Gowns
  – Masks
  – Gloves
    • William Stewart Halsted (1852-1922)
    • Caroline Hampton Halsted
    • J Bloodgood
Importance of Research

• Advancement of Medical Care
  – Cumulative progression of findings
  – Built on previous works
  – Documentation of practice
  – Need volume of patients with disease
    • World Events – WWI and WWII
    • Hospital – specialties
    • Personal – interests
Importance of Research

• Evidence Based Medicine
  – "the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients."

• Guidelines
  – Research will establish guidelines of care
  – Combination of research and clinical judgment to individual patient needs

†Sackett DL et.al. BMJ 312 (7023): 71–2
Why Should I do Research?

• Analyze and Modify Clinical Outcomes
  – Should I change my practice?

• Improve Quality of Care
  – Practice
  – Hospital

• Personal Goals
  – Gratification
  – Academic Advancement
Clinical Outcomes

• Bariatric Surgery
  – High Risk Operations
  – High Risk Patient Population
  – RYGB or Sleeve Gastrectomy
  – Morbidity
    • Staple Line Leak
    • Anastomotic Leak
    • MI
    • PE/DVT
  – Smoking??
Clinical Outcomes

• Background Literature
  – Smoking is among preoperative factors
  – No data as independent risk factor for bariatrics

• Should I make my patient’s quit preop?
NSQIP

• National Surgical Quality Improvement Program
• American College of Surgeons
• Hospital based
  – Currently 461 hospitals in the U.S. (36 Int’l)
    • More complex than other systems
    • Requires commitment of resources by hospital
What does NSQIP do?

- Clinical dataset
  - Prospectively collected data from many institutions reduce selection bias
  - Data more reliable than traditional administrative data
- Large set of peri-operative variables
- 30-day follow up
- Very large volume of data readily available for QI analysis
  - Our hospital
  - National comparison
- Huge national database for research
## Smoking on All Bariatric Surgery

<table>
<thead>
<tr>
<th>Outcome (n = 41,445)</th>
<th>P</th>
<th>Odds Ratio (95% CI)</th>
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<tbody>
<tr>
<td>Superficial Infection</td>
<td>.16</td>
<td>1.15 (0.95 – 1.40)</td>
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<tr>
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<td>Prolonged Intubation</td>
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<tr>
<td>MI</td>
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<td>3.97 (0.54 – 29.27)</td>
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<tr>
<td>DVT</td>
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<tr>
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<tr>
<td>Cardiac Arrest Requiring CPR</td>
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<td>Bleed Requiring Transfusion</td>
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<tr>
<td>Sepsis</td>
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<td>1.49 (1.11 - 2.00)</td>
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<td>Shock</td>
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<td>1.78 (1.16 – 2.74)</td>
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<tr>
<td>LOS&gt;7 days</td>
<td>0.03</td>
<td>1.37 (1.12 – 1.67)</td>
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## Smoking on Open Bariatric Surgery

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<td>Deep Wound Infection</td>
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<td>0.63 (0.25 – 1.60)</td>
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<tr>
<td>Organ Space Infection</td>
<td>.03</td>
<td>1.79 (1.07 – 3.00)</td>
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<td>Dehiscence</td>
<td>.92</td>
<td>1.05 (0.47 – 2.35)</td>
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<tr>
<td>Pulmonary Embolism</td>
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<tr>
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<td>.97</td>
<td>N/A*</td>
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<td>DVT</td>
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<td>0.24 (0.10 – 1.76)</td>
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<tr>
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<td>Cardiac Arrest Requiring CPR</td>
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<td>0.58 (0.18 – 1.92)</td>
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<td>1.45 (0.82 – 2.57)</td>
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<tr>
<td>Shock</td>
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<td>1.59 (0.79 – 3.19)</td>
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<td>LOS&gt;7 days</td>
<td>.03</td>
<td>1.47 (1.04 – 2.08)</td>
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Smoking on Lap Bariatric Surgery

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<tr>
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<td>1.35 (0.94 – 1.92)</td>
</tr>
<tr>
<td>Dehiscence</td>
<td>.52</td>
<td>0.71 (0.25 – 2.00)</td>
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<td>Pulmonary Embolism</td>
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<td>0.79 (0.34 – 1.86)</td>
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<tr>
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<td>.32</td>
<td>2.77 (0.37 – 20.65)</td>
</tr>
<tr>
<td>DVT</td>
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<td>0.68 (0.33 – 1.40)</td>
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<td>Return to OR</td>
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<td>1.15 (0.95 – 1.40)</td>
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<tr>
<td>Pneumonia</td>
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<td>1.35 (0.91 – 2.00)</td>
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<tr>
<td>Reintubation</td>
<td>.04</td>
<td>1.61 (1.02 – 2.54)</td>
</tr>
<tr>
<td>Cardiac Arrest Requiring CPR</td>
<td>.58</td>
<td>1.35 (0.47 – 3.91)</td>
</tr>
<tr>
<td>Bleed Requiring Transfusion</td>
<td>.07</td>
<td>1.43 (0.98 – 2.10)</td>
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<tr>
<td>Sepsis</td>
<td>.04</td>
<td>1.44 (1.02 – 2.03)</td>
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<tr>
<td>Shock</td>
<td>.02</td>
<td>1.96 (1.14 – 3.36)</td>
</tr>
<tr>
<td>LOS &gt; 7 Days</td>
<td>.05</td>
<td>1.29 (1.00 – 1.66)</td>
</tr>
</tbody>
</table>
Why Should I do Research?

• Analyze and Modify Clinical Outcomes
  – Should I change my practice?

• Yes → Smoking is an independent risk factor
  – Improve my clinical outcomes for all bariatrics
  – Decrease hospital stay
    • Decrease Cost
    • Improve resource utilization etc.

• Leads to next question/project
  – Optimal duration of smoking cessation preop?
Why Should I do Research?

• Analyze and Modify Clinical Outcomes
  – Should I change my practice?

• Improve Quality of Care
  – Practice
  – Hospital

• Personal Goals
  – Gratification
  – Academic Advancement
Quality Improvement

• Why Is It Important?
  – Medical decision making
  – Evaluation of hospital performance
  – Reimbursement
  – Public reporting
    • Institutional
    • Individual physician
    • Group practices
Medical Decision Making

118 NSQIP Hospitals
- 66% Improved Mortality
- 82% Improved Complication Rates

Projections if all hospitals were NSQIP
- Save 100K lives
- Prevent 2.5M complications
- $25 Billion cost savings

Quality Improvement

• Why Is It Important?
  – Medical decision making
  – Evaluation of hospital performance
  – Reimbursement
  – Public reporting
    • Institutional
    • Individual physician
    • Group practices
Evaluation of Hospital Performance

• Centers for Medicare & Medicaid Services

• http://www.medicare.gov/hospitalcompare

• Surgical Outcomes Comparison
  – GW
  – Georgetown
  – Howard
Evaluation of Hospital Performance

Preoperative DVT Prophylaxis
Evaluation of Hospital Performance

Postoperative Glucose Control
Quality Improvement

• Why Is It Important?
  – Medical decision making
  – Evaluation of hospital performance
  – Reimbursement
  – Public reporting
    • Institutional
    • Individual physician
    • Group practices
Reimbursement

• Outcomes Data Used in Reimbursement
• CMS Hospital Value Based Purchasing
  – The Hospital Value-Based Purchasing (VBP) Program is a Centers for Medicare & Medicaid Services (CMS) initiative that rewards acute-care hospitals with incentive payments for the quality of care they provide to people with Medicare.

  – Hospital Inpatient Quality Reporting Program
Reimbursement

• CMS and ACS
  – Pilot Program
  – Voluntary Reporting of ACS NSQIP Hospitals to Hospital Compare Program of CMS
  – Interest in Other Registries
    • MBSAQIP
    • TQIP
    • STS

• This is just the beginning...
Quality Improvement

• Why Is It Important?
  – Medical decision making
  – Evaluation of hospital performance
  – Reimbursement
  – Public reporting
    • Institutional
    • Individual physician
    • Group practices
Public Reporting

www.medicare.gov/hospitalcompare/search.html
Public Reporting

Postoperative Glucose Control
Public Reporting

• CMS
  – Physician Compare
    • Individual Physicians & Groups
    • Currently List
    • 2015 – Data Outcomes to be included

• Questions??
  – Methodology of Different Reports
  – Validation of Data
  – NSQIP
Our Results

• Semiannual Report (SAR) – source of all data
  – Comparison to all NSQIP Hospitals
  – De-identified
  – Every 6 months
  – Limited by number of cases
    • One or two cases can cause a significant bias
    • Start Date – Feb 2012

• New Interim “Semiannual” Report quarterly
<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Observed</th>
<th>Pred**</th>
<th>Expected</th>
<th>Odds Ratio</th>
<th>C.I.***</th>
<th>Outlier Decile</th>
<th>Comment*</th>
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<tr>
<td>GV Mortality</td>
<td>1495</td>
<td>18</td>
<td>1.22%</td>
<td>1.12%</td>
<td>1.03%</td>
<td>1.12</td>
<td>0.74</td>
<td>1.68</td>
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<tr>
<td>GV Mortality</td>
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<td>119</td>
<td>7.66%</td>
<td>7.89%</td>
<td>7.39%</td>
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<td>13</td>
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<td>0.73%</td>
<td>0.60%</td>
<td>1.24</td>
<td>0.79</td>
<td>1.94</td>
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<td>20</td>
<td>1.34%</td>
<td>1.25%</td>
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<td>1.47</td>
<td>0.95</td>
<td>2.27</td>
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<td>GV Unplanned Implantation</td>
<td>1494</td>
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<td>0.80%</td>
<td>0.85%</td>
<td>0.92%</td>
<td>0.92</td>
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<td>GV Ventilator &gt; 48 hours</td>
<td>1339</td>
<td>25</td>
<td>1.87%</td>
<td>1.69%</td>
<td>1.06%</td>
<td>1.82</td>
<td>1.23</td>
<td>2.70</td>
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<tr>
<td>GV DVT/PE</td>
<td>1496</td>
<td>6</td>
<td>0.47%</td>
<td>0.53%</td>
<td>0.58%</td>
<td>0.91</td>
<td>0.56</td>
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<td>7</td>
<td>0.47%</td>
<td>0.59%</td>
<td>0.86%</td>
<td>0.68</td>
<td>0.40</td>
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<td>GV SSI</td>
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<td>42</td>
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<td>2.86%</td>
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<td>GV ROR</td>
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<td>48</td>
<td>3.21%</td>
<td>3.18%</td>
<td>3.07%</td>
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<td>0.79</td>
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<td>GEN Mortality</td>
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<td>0.88%</td>
<td>0.82%</td>
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<td>66</td>
<td>4.91%</td>
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<td>0.40%</td>
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<td>1.87%</td>
<td>1.57%</td>
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<td>0.52%</td>
<td>0.57%</td>
<td>0.64%</td>
<td>0.98</td>
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<td>0.50%</td>
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<td>1345</td>
<td>7</td>
<td>0.52%</td>
<td>0.62%</td>
<td>0.80%</td>
<td>0.76</td>
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<td>2.84%</td>
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<tr>
<td>GEN ROR</td>
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<td>2.53%</td>
<td>2.52%</td>
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<td>COLORECTAL Mortality</td>
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<td>22.94%</td>
<td>20.84%</td>
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<td>1.91</td>
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<td>COLORECTAL Length-of-Stay</td>
<td>84</td>
<td>11</td>
<td>13.10%</td>
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## General & Vascular Surgery

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<th>Expected Rate</th>
<th>Odds Ratio</th>
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<th>C.I.*** Upper</th>
<th>Outlier Decile</th>
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<tr>
<td>GV Mortality</td>
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<td>3.18%</td>
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## General Surgery

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<th>C.I.*** Upper</th>
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<td>0.74</td>
<td>1.38</td>
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Quality Improvement

• NSQIP
  – Identify Areas of Improvement
  – Identify Causative Factors
    • Institutional Data Review
• Quality & Process Improvement
  – Data Feedback
    • Hospital Committees
    • Physicians – all related specialties
    • Other Healthcare Providers – shared destiny
Why Should I do Research?

• Analyze and Modify Clinical Outcomes
  – Should I change my practice?

• Improve Quality of Care
  – Practice
  – Hospital

• Personal Goals
  – Gratification
  – Academic Advancement
Personal Goals

• How much research makes you happy?

• How much research do I have to do?
  – Residency
  – Attending
Residency

• Mandatory – *(my opinion)*
• Understanding of the process
  – Not necessarily in field of interest
• Ability to analyze and critique manuscripts
  • Accurate incorporation of data into your own practice
  • Not every manuscript published is useful
• National Exposure
  – Network of colleagues
  – Opportunities for collaboration
• Portfolio for Fellowship
Attending

• Mandatory – *(my opinion)*
• Answers Clinical Questions
  – Improves practice and patient care
• National Exposure
  – Network of colleagues
  – Opportunities for collaboration
Attending

- Academic Advancement
  - Clinical Contribution
  - Educational Contribution
  - Research Contribution
  - Community/National Contribution

- All are necessary

- Type of research contribution may vary upon practice
Research Opportunities?

• Clinical Research
  – Clinically heavy practice
  – Outcomes
    • Retrospective
    • Prospective
    • Database

• Basic Science Research
  – Bench research
  – Different time commitment
  – Almost impossible with clinically heavy practice

• Translational Research
  – Practical application of basic science findings
  – Most Impact
Research Opportunities?

• What is available to me?
  – Everything

• How do I get involved?
  – Find a faculty member with research in your field of interest
  – Have a research question or clinical question
Database Research

- Immediate access to large volume of patients
- Prospective or Retrospective
  - IRB Approval (relatively quick)
- Manageable time commitment
- NSQIP, TQIP, BQIP, NTDB
- NIS and others
Database Research

• Know your Database!!
  – Limitations of database = Limitations of Study
  – Type of database
    • Clinical vs. Administrative
  – Patient population
    • Representative sample?
    • Bias?
    • Are results generalizable?
  – Follow up?
    • How Long?
    • How is it obtained?
Database Research

• Know your Variables
  – Granularity is important
  – Limits ability for analysis
  – Limits ability to explode/narrow your focus

• NSQIP
  – Preop and Postop Variables (approx 170-200)
  – 30 day follow-up
  – Clinical database
**AMERICAN COLLEGE OF SURGEONS**  
**NATIONAL SURGICAL QUALITY IMPROVEMENT PROGRAM**  
**CLASSIC WORKSHEET**

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**DEMOGRAPHICS**

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**SURGICAL PROFILE**

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<th>January 1, 2011</th>
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### Operative Information

- **Highest Level of Resident (0-10):** N/A
- **Emergency Case:** NO
- **Wound Classification:** Clean
- **ASA Class (circle one):** 1
- **Surgery Start:** 12:00 PM
- **Patient Out Room:** 2:00 PM
- **Anesthesia Start:** 11:30 AM
- **Anesthesia Finish:** 1:30 PM

### Additional Operative Procedures

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<th>Other Procedure</th>
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<td>6.</td>
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<tr>
<td>7.</td>
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</table>

### Occurrences

**Intraoperative Occurrences:**
- Cardiac arrest requiring CPR
- Septic shock
- Other: ICD-9 Code:

**Postoperative Occurrences:**
- Pneumonia (Pnu)
- Unplanned intubation
- Other: ICD-9 Code:

### Discharge Information

- **Discharge Destination:** Home
- **Post-op ICD-9 Code:** 410.9
- **Diagnosis:** Stroke/CVA
- **Readmission:** NO
- **Information Source:** Medical Record
- **Was this readmission unplanned at the time of the procedure?** NO

### Occurrences Continued

- **CMS Occurrences:**
  - Stroke/CVA
  - Other:
- **Cardiac Occurrences:**
  - Cardiac arrest requiring CPR
  - Other:
- **Other Occurrences:**
  - Bleeding requiring transfusion
  - Other:
- **Medication:**
  - Tranquilizers
  - Other:

### Hospital Discharge Information

- **Readmission for any reason within 30 days of the principle procedure?** NO
- **Postop Death with 30 days:** NO
- **Hospital Discharge Date:** 01/01/2022
- **Date of death:** 01/01/2022
- **Other:**

### Notes

- If ICD-9 is unknown, describe the reason.
- **Was this readmission for a post-operative occurrence likely related to the principle surgical procedure?** NO
- **Still in hospital > 30 days:** NO
- **Postoperative Death:** NO
HOSPITAL DISCHARGE INFORMATION / READMISSIONS / MORTALITY / REOPERATIONS CONTINUED

Unplanned Reoperation:
Unplanned return to the operating room for a surgical procedure within 30 day postoperative period?  □ YES  □ NO

Was the return to the OR for a postoperative occurrence likely related to the principle procedure, or to any additional surgery performed under the same anesthetic as the principle procedure?  □ YES  □ NO

If yes, surgery date __/__/____  CPT code _____________  ICD9 code _____________  

Source (select one)  □ Medical Record  □ Patient/Family Report  □ Other

Notes: - If CPT code is not documented, describe the surgery.

Was there a SECOND unplanned reoperation within 30 days?  □ YES  □ NO

Was the second return to the OR for a postoperative occurrence that was likely related to the principle procedure, or to any additional surgery (i.e., 'other' or 'concurrent') performed under the same anesthetic as the principle procedure?  □ YES  □ NO

If yes:  Surgery date __/__/____  CPT code _____________  ICD9 code _____________  

Source (select one)  □ Medical Record  □ Patient/Family Report  □ Other

Notes: - If CPT code is not documented, describe the surgery.

Were there more than two unplanned reoperations for an adverse outcome related to the principal surgery within 30 days?  □ YES  □ NO

FOLLOW-UP

Follow-up within 30 Days:
Were you able to follow the case for the full 30 days?  □ YES  □ NO

(NOTE: Answer yes for death within 30 days)

If you were unable to obtain the 30-day follow up information:

A) How many days (0-29) were you able to follow this case?  _______

B) Which attempt methods were used for follow-up? (select all that apply)

Method  # of attempts  Method
□ Phone  ________  □ Documentation
□ Letter  ________  □ Other

Patient Contact Management:

Contact date: __/__/____  Contact action:  □ Phone  □ Letter  □ Document  □ Fax  □ E-mail  □ Other

Contact Results:
□ No Answer  □ Letter Received  □ Incorrect Number
□ Left Message  □ Tailed to Patient  □ Patient Refused
□ Letter Sent  □ Talk to Family

Contact Notes:

Revision: January 1, 2011
Pitfalls Database Research

• Usually a Result of Not Understanding Database
  – Clinical question cannot be answered by data
    • Lacks datapoints
    • Lacks granularity
    • Confounding variables
      – Not in database
      – Can not be controlled
  – Overstatement of Conclusions
    • Generalizability of results
    • Database sample (population based?, voluntary?, bias?)
Conclusions

• Research is a key component understanding and providing the best care to your patients
• Database research is an important and readily available tool to answer clinical questions and ensure quality of care when used appropriately
• Research opportunities are available here at GW in all disciplines
Testing whether laughter is the best medicine

“Yes ... I believe there’s a question in the back.”