Surgery Research Conference

Biostatistical Support for the Department of Surgery

To receive 1.0 credit for this session, text the SMS code: RULKOY to 414-206-1776. This code will expire in 5 days

ACCME Accreditation Statement: The Medical College of Wisconsin is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. AMA Credit Designation Statement: The Medical College of Wisconsin designates this live activity for a maximum of 1.0 AMA PRA Category 1 Credit™. Physicians should claim only the credit commensurate with the extent of their participation in the activity. Hours of Participation for Allied Health Care Professionals: The Medical College of Wisconsin designates this activity for up to 1.0 hours of participation for continuing education for allied health professionals.
Research Highlights
The Lennon Award is given annually to a full-time junior faculty member engaged in clinical practice who has demonstrated a proclivity for teaching at the Medical College of Wisconsin and who is committed to excellence in teaching or educational development. This award was specifically created by Dr. Lennon to recognize faculty who have clearly “made a difference” to the teaching programs at our institution.

The four recipients selected this year are:

- Erica Chou, MD
- Christopher Dodgion, MD, MSPH, MBA (Trauma & Critical Care Surgery)
- Theresa Maatman, MD
- Adrian Umpierrez de Reguero, MD
The Wisconsin Surgical Society

November 8-9, 2019
Kohler, WI

Submission Deadline: Thursday, August 22, 2019

15th Annual Academic Surgical Congress

February 4-6, 2020
Orlando, Florida

Submission Deadline: Friday, August 23, 2019
@ 11:59 PM EST
MCW Cancer Center presents

6th Annual Clinical Research Symposium

Elevating the Mission: Next Level Clinical Research Practice

Friday, October 4th, 2019
11:00am-4:00pm

Register HERE
Surgery Pre-Award Support Services

- **Identifying Funding Opportunities**
- **Proposal Initiation/Pre Award:**
  - Schedule initial meeting
  - Provide checklist and timeline for proposal
  - Proof all nonscientific documents
  - Project management support
  - Navigate internal/external submission processes
- **Proposal Development**
  - Interpret and ensure compliance with the RFA
  - Construct eBridge funding proposal
  - Collect & format biosketches, COIs, LOIs, etc.
  - Review and confirm budget and budget justification forms with Mary/Karen
- **Post Submission/Post Award**
  - GCO revisions

Click HERE: Intent to Submit Grant
Requirement for ORCID iDs for Individuals Supported by Research Training, Fellowship, Research Education, and Career Development

- National Institutes of Health (NIH)
- Agency for Healthcare Research and Quality (AHRQ)
- Centers for Disease Control and Prevention (CDC)

Awards Beginning in FY 2020 will be required to have ORCID (Open Researcher and Contributor Identifiers)

Notice Number: NOT-OD-19-109
What's ORCID iD?

ORCID iD endeavors to be a universal identifier for researchers. Your ORCID iD is made up of 16 letters and numbers. No two researchers can have the same ORCID iD.

ORCID is a hub connecting the research landscape

https://orcid.org
DISTINGUISH YOURSELF IN THREE EASY STEPS

ORCID provides a persistent digital identifier that distinguishes you from every other researcher and, through integration in key research workflows such as manuscript and grant submission, supports automated linkages between you and your professional activities ensuring that your work is recognized. Find out more

1. REGISTER  Get your unique ORCID Identifier. Register now! Registration takes 30 seconds.

2. ADD YOUR INFO  Enhance your ORCID record with your professional information and link to your other identifiers (such as Scopus or ResearcherID or LinkedIn).

3. USE YOUR ORCID ID  Include your ORCID identifier on your webpage, when you submit publications, apply for grants, and in any research workflow to ensure you get credit for your work.

https://orcid.org
**Publications**

**Research**

*ErbB3-binding protein 1 (EBP1) represses HNF4α-mediated transcription and insulin secretion in pancreatic β-cells.* *The Journal of Biological Chemistry.* (Han, EH, Singh P, Lee IK, Urrutia R, Chi YI)

**Pediatric Congenital Cardiac**


*Effect of endomyocardial biopsy on levels of donor-specific cell-free DNA.* *Journal of Heart and Lung Transplant.* (Zangwill SD, Stamm KD, Hidestrand M, Tomita-Mitchell A, Mitchell ME)

**Commentary: Cross my heart and stick a needle in it—I hope to live.** *Journal of Thoracic Cardiovascular Surgery.* (RK Woods)

**Commentary: Purulence in the heart of a child? This should not be.** *Journal of Thoracic Cardiovascular Surgery.* (RK Woods)

**Colorectal Surgery**

*Use of Neoadjuvant Chemotherapy in the Treatment of Locally Advanced Rectal Cancer.* *Journal of Surgical Research.* (Hu KY, Simpson MT, Blank JJ, Szabo A, Eastwood D, Ludwig KA, Peterson CY, Ridolfi TJ)

**Surgical Oncology**

*Breast Cancer in Women Aged 80 Years or Older: An Analysis of Treatment Patterns and Disease Outcomes.* *Clinical Breast Cancer.* (Ferrigni E, Bergom C, Yin Z, Szabo A, Kong AL)

**General Surgery**

*Salvage Options for Fundoplication Failure.* *Current Gastroenterology Reports.* (Munie S, Nasser H, Gould JC)

*Is that 'floppy' fundoplication tight enough?* *Surgical Endoscopy.* (Turner B, Helm M, Hetzel E, Gould JC)

**Cardiothoracic Surgery**

*Minimally invasive single-vessel left internal mammary to left anterior descending artery bypass grafting improves outcomes over conventional sternotomy: A single-institution retrospective cohort study.* *Journal of Cardiothoracic Surgery.* (Smith NJ, Miles B, Cain MT, Joyce LD, Pearson P, Joyce DL)

**Vascular/Cardiothoracic Surgery**

Dr. Grippo has focused on the design and utility of mouse models of cancer for over 20 years and continues to generate new mouse models, employing them in order to understand disease progression and the underlying molecular and cellular mechanisms of those events.

Dr. Grippo was actually one of the first to target mutant KRAS to mouse pancreas, demonstrating that KRAS expression in acinar cells results in acinar-to-ductal metaplasia together with pre-invasive lesions.

His laboratory research is focused on identifying defects in signal transduction pathways in GI cancers that affect mutant KRAS-induced neoplasia and cancer in genetically engineered mouse models with a particular focus on the effects of high fat diets on these KRAS-driven neoplasias.

Paul Grippo, PhD
Associate Professor, Gastroenterology and Hepatology, University of Illinois Cancer Center
Biostatistical support for the Department of Surgery

Aniko Szabo
Professor
Institute of Health and Equity, Division of Biostatistics
Director, Biostatistical Consulting Service
I used to think correlation implied causation.

Then I took a statistics class. Now I don't.

Sounds like the class helped.

Well, maybe.
Resources are available at multiple levels
MCW resources

- Limited free statistical resources
- Statistical software
  - SPSS – free
  - SAS, Matlab, GraphPad Prism – discounted license
Drop-in consulting

- Staffed by the Biostatistical Consulting Service analysts
- Monday 1 – 3PM
  - M3250 – walkway between HUB and MEB, 3rd floor
- Wednesday 10AM – noon
- Friday 1 – 3PM
  - Targeted at Cancer Center members
  - Currently in C5300 – CC administrative offices
CTSI resources

- Biostatistical consulting mini–grants
  - [https://ctsi.mcw.edu/investigator/services/ctsi-mini-grants/biostatistical-consultation/](https://ctsi.mcw.edu/investigator/services/ctsi-mini-grants/biostatistical-consultation/)

- Bioinformatics resources
  - Clinical Research Data Warehouse (CRDW)
    - Cohort discovery i2b2
    - Data extraction: Honest Broker or TriNetX
  - REDCap
  - Clinical Trials Office
Cancer Center

- Biostatistics Shared Resource
  - administered through the Biostatistics Consulting Service
- Focuses on cancer-related...
  - work that leads to grant applications
  - unfunded projects of Research and Research Associate members
Integration contract with Division of Biostatistics
- Started July 2017

Salary support of analyst and faculty (12.5%) time
- Aniko Szabo, PhD
- Ruta Brazauskas, PhD
- Rodney Sparapani, PhD
- Lisa Rein, MS
- Ruizhe (Rachel) Wu, MS
Projects since 7/2017

- Trauma And Acute Care Surgery
- Cardiothoracic Surgery
- Colorectal Surgery
- Surgical Oncology
- Pediatric Surgery
- Vascular And Endovascular Surgery
- General Surgery
- Congenital Heart Surgery
- Transplant Surgery

Total: 119
Tonight: Are millennials killing the joint replacement industry?

<table>
<thead>
<tr>
<th>Operation Rate per 100,000</th>
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<tbody>
<tr>
<td><strong>Baby boomers</strong></td>
</tr>
<tr>
<td>Knee</td>
</tr>
<tr>
<td>720</td>
</tr>
</tbody>
</table>

Stats pet peeve: People mixing up cohort effects and age effects.

http://xkcd.com/2080/
Collaboration

- Planning
- Data collection
- Advice, help with analyses
- Statistical analysis
- Reporting

COME EARLY!
Planning

- **Design**
  - brainstorm and choose an experimental design
  - clinical trials, observational studies, surveys, ...

- **Sample size determination**
  - too much or too little data is a waste of resources
  - help you plan how much data you need to collect so that your study can evaluate your hypothesis

- **Grants, IRB proposal preparation**
  - write the sections on the statistical analysis plan and sample size considerations
Study design examples

- Dr Amy Wagner: GOOD study
  - Randomized multi-site trial
  - Interim analysis plan
  - Weighted composite endpoint
- Dr Terri deRoon-Cassini / Colleen Trevino
  - NIH and local grant applications
    - Trauma quality of life clinic
    - Chronic pain
- Dr Panna Codner
  - Microbiome studies
Data collection

- Randomization
  - develop and implement randomization scheme

- Analytic dataset creation
  - National databases: STS, NSQIP, NIS, NCDB, ...
  - Clinical Research Data Warehouse
  - Merging data from different sources

- Data management
  - advice on database design, and set-up
  - work with REDCap, OnCore, Excel
Clinical Research Data Warehouse

- Cohort definition
  - i2b2

- Data extraction
  - Honest Broker, TriNetX
  - Gives all available data about the subjects

- Analytic data set
  - Define events of interest
  - Extract covariates
  - Merge with internal datasets (if MRN identified)
Analytic data set creation

Dr Jon Gould
- MarketScan: anti-coagulation drugs by codes
- Calculate travel distance/time from patient’s home to Froedtert

Dr David Joyce
- UNOS transplant data
  - Identify listing history to find double listings
  - Track lung allocation score over time
I don't trust linear regressions when it's harder to guess the direction of the correlation from the scatter plot than to find new constellations on it.
Data management

- Well organized data enables good research
  - Complex studies require careful organization
  - Simple studies benefit from good organization
- Database vs spreadsheet
  - Spreadsheets have few or no rules
  - Databases have strict rules
    - Enforce data types: numbers, dates, ...
    - Enforce set of possible values
  - Rules make spreadsheets more like a database
<table>
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<th>Age</th>
<th>Race</th>
<th>ANGIO read #1</th>
<th>Location of stenosis</th>
<th>ANGIO read #2</th>
<th>Location of stenosis</th>
<th>QUALITY</th>
</tr>
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<tbody>
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<td>white non-hispanic</td>
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<td>4/19/2002 3 CTA Head</td>
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<td>2/19/2002 3 CTA Head</td>
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</table>
How to frustrate the analyst

- More than one piece of information in a single cell
- Mixed characters and numbers
- Merged cells
- **Color coding**
- UPPERCASE and lower case text (NO, No, no!)
- Confused coding or formats
- “Prettifying”
- Identifying information
### Better now?

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<th>QUALITY angio 1</th>
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<th>Location Angio 2</th>
<th>QUALITY Angio 2</th>
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</table>
Variables

- Short yet meaningful names
  - Top row of spreadsheet

- Create a “key” to formatted values
  - 0=‘no’, 1=‘yes’, 9=‘n/a’
  - M=‘male’, F=‘female’

- Data dictionary
  - Longer description of the variables, units
  - Key for formatted values
## Post-surgery events

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<th>ID</th>
<th>Date of surgery</th>
<th>Re-operation</th>
<th>Date of reop</th>
<th>Date of last followup</th>
<th>Date of reop or LFU</th>
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Alternative way
More date troubles

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The SAS System

Date

42995
43268
42851
43221
  2/10/2018
  43270
    7/10/2017
  42874
  43341
    7/31/2017
        1/11/2018
  42842
  42872
Sample Units & Observations

- Depends on Study Design
- Usually one row of data per sample unit
  - ie: one row per patient
  - “wide” layout
  - side-to-side scrolling problems
- Sometimes one row per observation
  - “long” layout
  - wasted space with demographics
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<td>DBP</td>
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## Demographics and Clinical Data with linking index variable

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<th>DBP</th>
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<td>82</td>
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<td>130</td>
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<td>76</td>
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<td>120</td>
<td>84</td>
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<td>140</td>
<td>78</td>
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<td>3</td>
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<td>1</td>
<td>126</td>
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<tr>
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<td>124</td>
<td>80</td>
</tr>
<tr>
<td>5</td>
<td>3</td>
<td>134</td>
<td>n/a</td>
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</table>
Analysis

- Statistical modeling, data analysis
  ◦ choose the appropriate analysis methods
  ◦ perform the analyses
  ◦ large projects might need to get additional funding support

- Interpretation
  ◦ interpret the results in the context of your research
<table>
<thead>
<tr>
<th>P-VALUE</th>
<th>INTERPRETATION</th>
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<td>0.001</td>
<td>HIGHLY SIGNIFICANT</td>
</tr>
<tr>
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<tr>
<td>0.02</td>
<td></td>
</tr>
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<td>0.03</td>
<td></td>
</tr>
<tr>
<td>0.04</td>
<td>SIGNIFICANT</td>
</tr>
<tr>
<td>0.049</td>
<td>OH CRAP. REDO CALCULATIONS.</td>
</tr>
<tr>
<td>0.050</td>
<td>ON THE EDGE OF SIGNIFICANCE</td>
</tr>
<tr>
<td>0.051</td>
<td></td>
</tr>
<tr>
<td>0.06</td>
<td></td>
</tr>
<tr>
<td>0.07</td>
<td>HIGHLY SUGGESTIVE, SIGNIFICANT AT THE</td>
</tr>
<tr>
<td>0.08</td>
<td>P&lt;0.10 LEVEL</td>
</tr>
<tr>
<td>0.09</td>
<td></td>
</tr>
<tr>
<td>0.099</td>
<td>HEY, LOOK AT THIS INTERESTING SUBGROUP ANALYSIS</td>
</tr>
<tr>
<td>≥0.1</td>
<td></td>
</tr>
</tbody>
</table>

http://xkcd.com/1478/
Reporting

- Reports
  - ready-to-publish description of the statistical methods used, prepare summary tables
  - review manuscript

- Plots
  - design and produce publication quality plots that communicate your message effectively
Example: mapping

Dr David Joyce – seasonality in heart donations

by Lisa Rein
Example: SEM

Dr Terri deRoon-Cassini – post-traumatic chronic pain

Baseline

- $\log_{10} 2-\text{AG}$
- $\log_{10} \text{Cortisol}$
- $-1.11$
- Pain severity

6-months

- $\log_{10} 2-\text{AG}$
- $\log_{10} \text{Cortisol}$
- $-1.11$
- Pain severity

ISS

Female Gender

0.78

0.02

0.02

0.21

0.17

0.22

1.02

0.29

0.78

0.79
Example: propensity scores

Dr Michael Cain – STS sternotomy study

by Alexis Visotcky
Example: cumulative incidence

Dr David Joyce – management of RV failure

by Lisa Rein
Example: interactive model

Dr Chris Dodgion – SSI risk prediction

by Anjishnu Banerjee and Joy Liu
Example: interactive model

Dr Chris Dodgion – SSI risk prediction

by Anjishnu Banerjee and Joy Liu
## Example: meta-analysis

### Dr Amy Wagner – delivery timing in gastroschisis

#### Days to First Enteral Feeding (FF)

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Patients</th>
<th>Control</th>
<th>Days Preterm</th>
<th>Control</th>
<th>Weight</th>
<th>Mean difference, days [95% CI]</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Group 1</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Al-Kaff 2015</td>
<td>193</td>
<td>69</td>
<td>13.7</td>
<td>14.7</td>
<td>34.7%</td>
<td>-1.00 [-2.98, 0.98]</td>
</tr>
<tr>
<td>Baud 2013</td>
<td>77</td>
<td>131</td>
<td>23.8</td>
<td>29.2</td>
<td>24.2%</td>
<td>-5.40 [-12.90, 2.10]</td>
</tr>
<tr>
<td>Serra 2008</td>
<td>13</td>
<td>10</td>
<td>4.6</td>
<td>12.7</td>
<td>31.5%</td>
<td>-8.10 [-12.10, -4.10]</td>
</tr>
<tr>
<td>Sakala 1993</td>
<td>10</td>
<td>12</td>
<td>13.0</td>
<td>42.0</td>
<td>9.6%</td>
<td>-29.00 [-46.87, -11.13]</td>
</tr>
<tr>
<td><strong>Group 1 Summary</strong></td>
<td>293</td>
<td>222</td>
<td></td>
<td></td>
<td></td>
<td>-6.99 [-13.47, -0.52]</td>
</tr>
<tr>
<td>Heterogeneity: I² = 63.9%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect: p=0.034</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| **Group 2**           |          |         |              |         |        |                                 |
| Charlesworth 2007     | 33       | 59      | 17.8         | 15.0    | 44.6%  | 2.75 [-0.62, 6.12]              |
| Huang 2002            | 25       | 21      | 23.4         | 13.0    | 25.1%  | 10.40 [2.46, 18.34]             |
| Pulligandia 2004      | 76       | 37      | 27.9         | 18.4    | 30.3%  | 9.50 [2.95, 16.05]              |
| **Group 2 Summary**   | 134      | 117     |              |         |        | 6.71 [1.27, 12.15]              |
| Heterogeneity: I² = 62.3% |
| Test for overall effect: p=0.016 |

| **Overall Summary**   | 427      | 339     |              |         |        | -0.71 [-5.74, 4.31]             |
| Heterogeneity: I² = 66.7% |
| Test for overall effect: p=0.781 |

by Ziyan Yin
Requesting services

- DOS support:
  - Submit request form to Krissa Packard

- General consulting:
  - iLab
    - [https://mcw.ilab.agilent.com/service_center/show_external/4696](https://mcw.ilab.agilent.com/service_center/show_external/4696)

- Timing:
  - At least 2 weeks
  - Preferably 4+ weeks, especially if popular deadline
CURVE-FITTING METHODS
AND THE MESSAGES THEY SEND

**LINEAR**
"Hey, I did a regression."

**QUADRATIC**
"I wanted a curved line, so I made one with math."

**LOGARITHMIC**
"Look, it's tapering off."

**EXPONENTIAL**
"Look, it's growing uncontrollably!"

**LOESS**
"I'm sophisticated; not like those bumbling polynomial people."

**LINEAR, NO SLOPE**
"I'm making a scatter plot but I don't want to."

**LOGISTIC**
"I need to connect these two lines, but my first idea didn't have enough math."

**CONFIDENCE INTERVAL**
"Listen, science is hard but I'm a serious person doing my best."

**PIECEWISE**
"I have a theory, and this is the only data I could find."

**CONNECTING LINES**
"I clicked 'smooth lines' in Excel."

**AD-HOC FILTER**
"I had an idea for how to clean up the data, what do you think?"

**HOUSE OF CARDS**
"As you can see, this model smoothly fits the data and I don't extend it ahhhhhh!"

http://xkcd.com/2048/