Engaging Students with Biostatistics by Conducting Clinical Trials on The Island

Joint Statistical Meetings, Boston

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GAISE College Guidelines

1. Develop statistical thinking

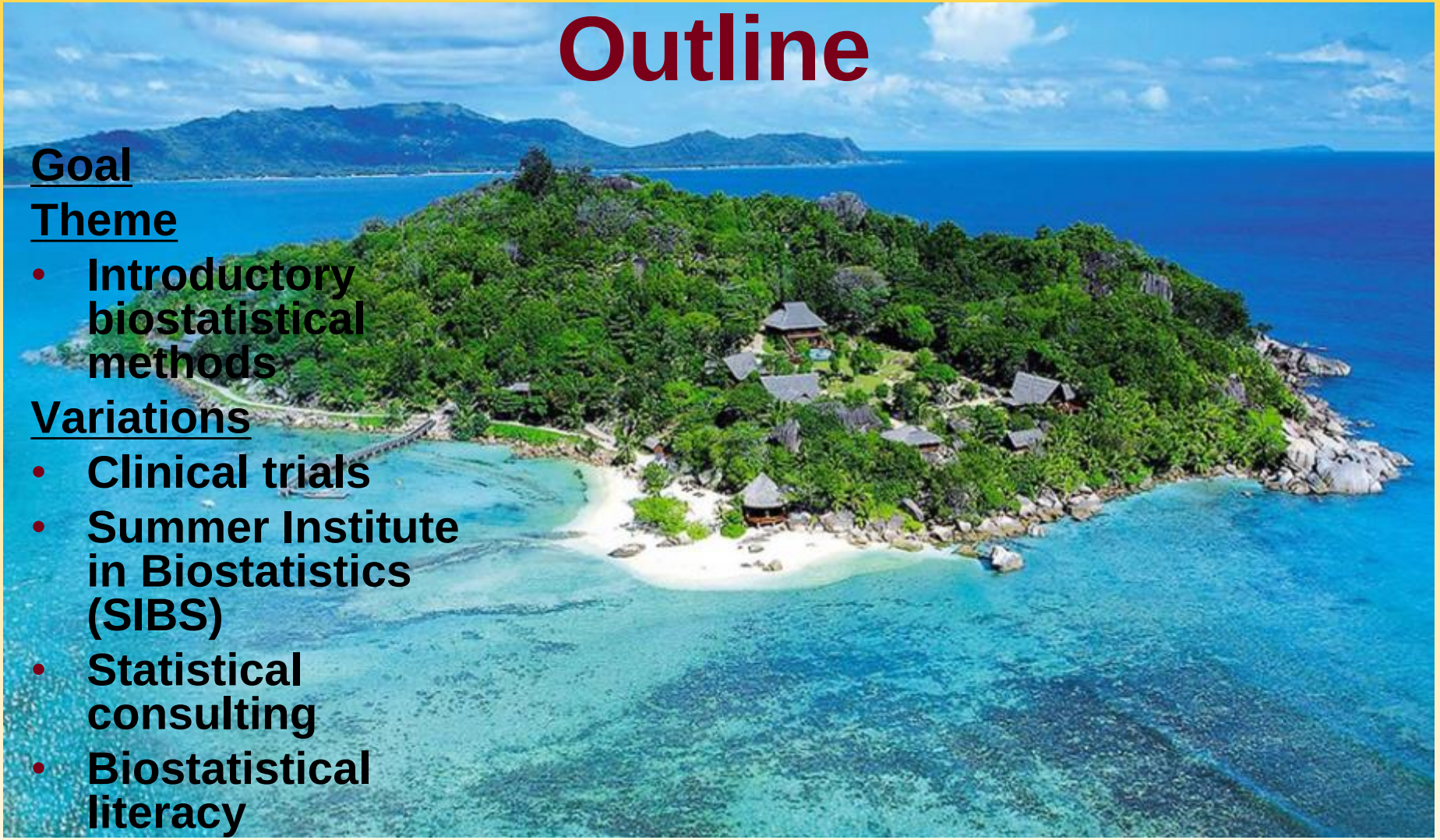
   "We should teach students that the practical operation of statistics is to collect and analyze data to answer questions."

2. Use real data

4. Foster active learning

5. Use technology (for developing concepts and analyzing data)…

Outline



Goal

Theme

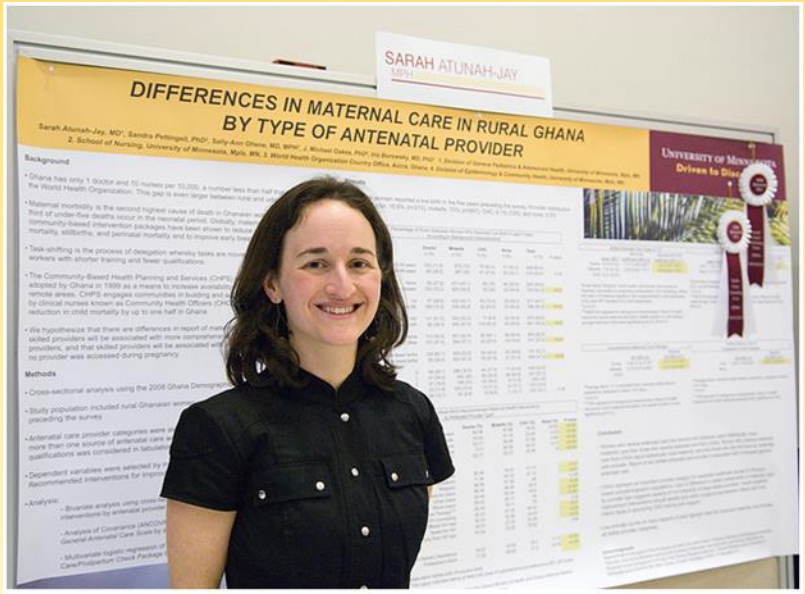
- **Introductory biostatistical methods**

Variations

- **Clinical trials**
- **Summer Institute in Biostatistics (SIBS)**
- **Statistical consulting**
- **Biostatistical literacy**

Theme
Introductory Biostatistical Methods

- PubH 6414
- Taught in fall, spring and summer terms
- Offered both in-person and online
- R Commander software
- Class size ~ 50 – 75 students, 3 TAs
- Varied backgrounds: physicians, dentists, nurses, veterinarians, pharmacists, public health graduate students and professionals, a few journalists, lawyers



Basic Island Project

Fall 2012+

- Students work in groups to design, conduct, and analyze results of a study using the Island
  - Groups of ~5 to 8 students
  - TAs serve as statistical consultants
- Students present their findings to the class at the end of the course
  - Talks (live or recorded)
  - Posters
  - Research papers
- CONSORT guidelines for reporting randomized controlled clinical trials are used
- Part of the grade is based on peer evaluations and on instructor-judged participation

Collaborating Online

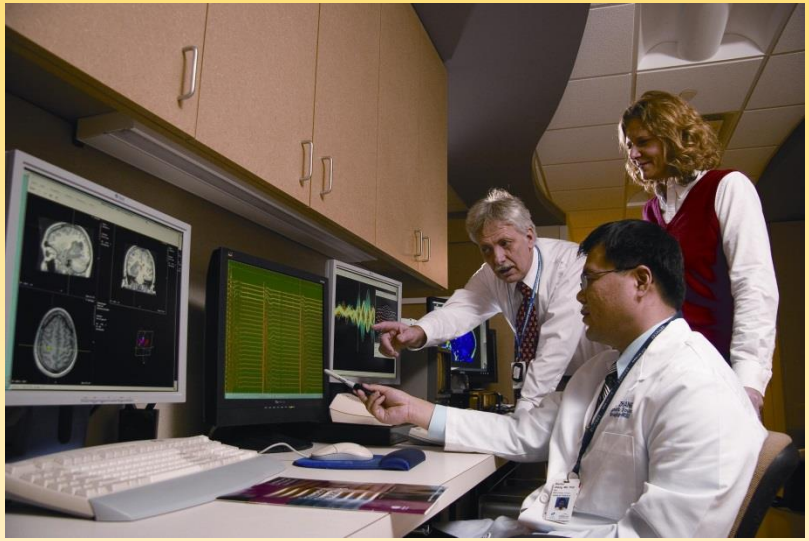
- Groups collaborate using various tools:
  - Google Hangouts, Skype, FaceTime, etc.
  - Google Drive, DropBox
  - Moodle chat rooms
  - phone, text, email
- Works best if groups meet weekly
  - as the in-person students do (in lab)

PubH 6414 Island Studies

Fall 2013 Online Class

- Effects of Methamphetamine on Cognitive Function in Young Adults
- **RE-WINE**: The Effect of Red Wine on Serotonin Release
- The Effect of Cannabis Tea on Short Term Memory Scores
- Effect of diabetes on the blood glucose level of "The Island" population after exercise
- **YIKES!** Youth Islander Knowledge Enhancement Study [Effect of Dextroamphetamine on Arithmetic Performance]
- Effects of Smoking on Pulmonary Functioning and Exercise Tolerance
- Effects of Music on Blood Pressure
- The **DREAM** Study: The Effect of Different Exercise Assignments on Melatonin

First Variation
Clinical Trials Course



- Taught fall and summer
- Online only
- Class size ~ 20 students, 1 TA
- Dual audience: undergraduates (public health minors) and graduate students (physicians, dentists, nurses, veterinarians, pharmacists, public health graduate students and professionals, a few journalists, lawyers)

Clinical Trials Projects

Fall 2013+

- Undergrads: Island project
  - Reviewed by a mock DSMB composed of the graduate students
    - Few adverse events
    - Limited ability to follow participants for long periods of time
- Grad students: Protocol project
  - Students write a complete study protocol
  - Reviewed by a mock IRB made up of the undergraduate students

Second Variation
Summer Institute in Biostatistics

- Six-week full-time in-person summer program
- SAS or R software
- Class size = 25 students, 2 TAs, 2 instructors
- Undergraduates, mostly juniors, potentially interested in careers in biostatistics

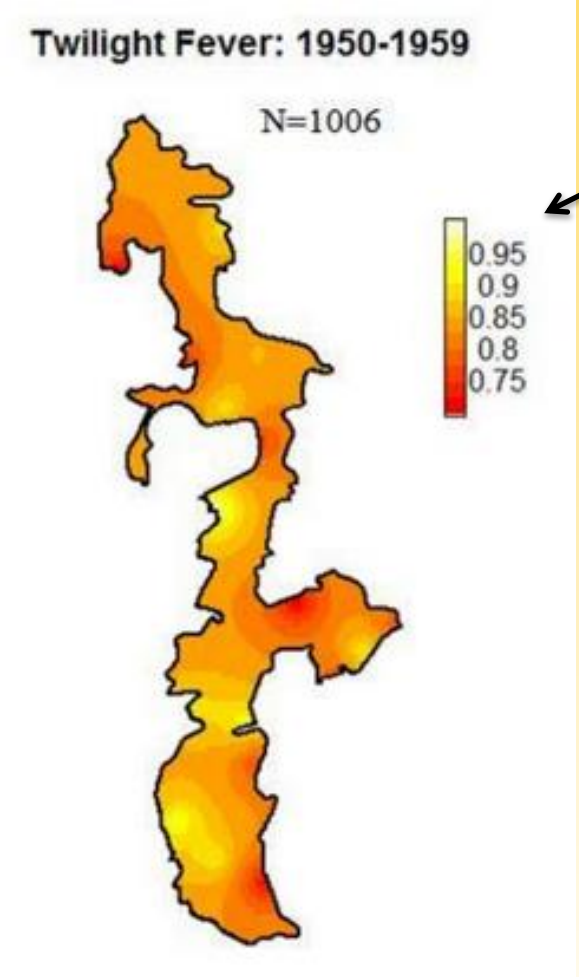
SIBS Island Projects

Summer 2013+

- Completed in much shorter time period, about three weeks.
- More complex, ambitious projects:
  - Observational studies, genomic studies, spatial statistics studies, epidemiologic studies, repeated measures, cross-over designs, factorial designs

SIBS Island Projects

Summer 2014 Class



- Genetic Analysis of Summer's Pain (GASP)
- Comprehensive Analysis of Twilight Fever in Island Towns (CATFIT)
- Can Altering Student's Testing Actions Work Across Youth (CASTAWAY)
- Analysis of the Short Term Effects of Caffeine on Hunger (ASTECH)
- Physical Ability from Coffee and Energy Drinks (PACED)
- Study and Analysis of Depression on Classical-Music Efficacy and Needle-Injected Serotonin (SAD OCEANS)

Third Variation

Statistical Consulting Course

- Collaboration between the Department of Statistics and the Division of Biostatistics
- Statistics 4893W (in-person):
  - Consulting / senior project / writing course
  - Senior undergraduate statistics majors
- PubH 6414 (online):
  - Graduate students: medical and public health professionals

Statistical Collaboration on the Island

Spring 2014+

- Teams of three senior statistics majors in Stat 4893W serve as statistical consultants for client teams of public health graduate students in PubH 6414 (one team to one team)
- Meet with clients via Google Hangouts or Skype
  - Help design study
  - Analyze pilot study data
  - Estimate main study sample size
- The statistics students' consulting report serves as one of their class assignments.

Formal Evaluation

- To assess and improve the collaboration
- Surveyed both ‘clients’ and ‘consultants’
  - Used Qualtrics online survey tool
- ‘Consultant’ comments:
  - “I had an interview at the Federal Reserve Board where I discussed my consulting experience. They seemed very impressed that I got such an experience.”
  - “I recently had an interview and they were interested in [my] interactions with the biostats students, the results that my group came up with and the Island program itself.”

Fourth Variation

Biostatistical Literacy Course

- New course in Fall 2014
- Focus is on understanding the medical/public health literature: t-tests through survival. No calculations.
- Will be taught fall, spring and summer
- Inverted classroom / active learning approach
- In-person and online
- Class size ~ 50 – 75 students, 3 TAs

Expanded Statistical Collaboration

Fall 2014+

- Literacy students will be the ‘investigators’
  - Choose the research question
  - Collaborate in designing the study
  - Carry out data collection
  - Write up and present the study results to their class
- Stat 4893W students will be the ‘consultants’ with an expanded role
  - Collaborate in designing the study
  - Estimate the sample size
  - **Analyze the study data**

Benefits for instructors

- Develops statistical thinking
- Uses real data
- Fosters active learning
  - Students collect and analyze their own real data to answer their own research question.
- Improves teaching
  - Brings out issues students are having difficulty with, e.g. random sampling vs. random assignment. Provides a built-in example to use in explanations.
- Makes instructor-student relationship more collegial
  - Instructors/TAs become statistical collaborators. (Instructor doesn't know 'the answer'!)
  - Vastly increases the amount of non-homework-, non-exam-related interaction with students.

Island Projects

Benefits for students

- **Application** – Students apply the concepts and methods they learn in class to a ‘real’ study
  - Study design, sampling methods
  - Collecting and organizing (and cleaning!) data
  - Analysis and interpretation

- **Collaboration** – Students learn the necessity of teamwork, across specialties, to carry out a research study. They learn what works well and what doesn’t for a cross-functional, often geographically dispersed team.

Island Projects
Benefits for students

- **Choice** - Students choose their study topic
- **Uniqueness** – No other group has carried out this particular study before
- **Context** - Students see where statistics fits in a research study
- **Communication** – Students gain experience presenting their work
- **Real** – Students sometimes forget that Islanders aren't real people and won't necessarily behave as suggested by the published literature!

  "The results from the pilot study indicated that the islanders did not behave like normal individuals. [Their behavior] disagreed with the literature."

Island 2.0

- Customized for teaching biostatistics and clinical trials
- Being developed by Susan Telke and team at Minnesota, in collaboration with the Island's creator, Michael Bulmer

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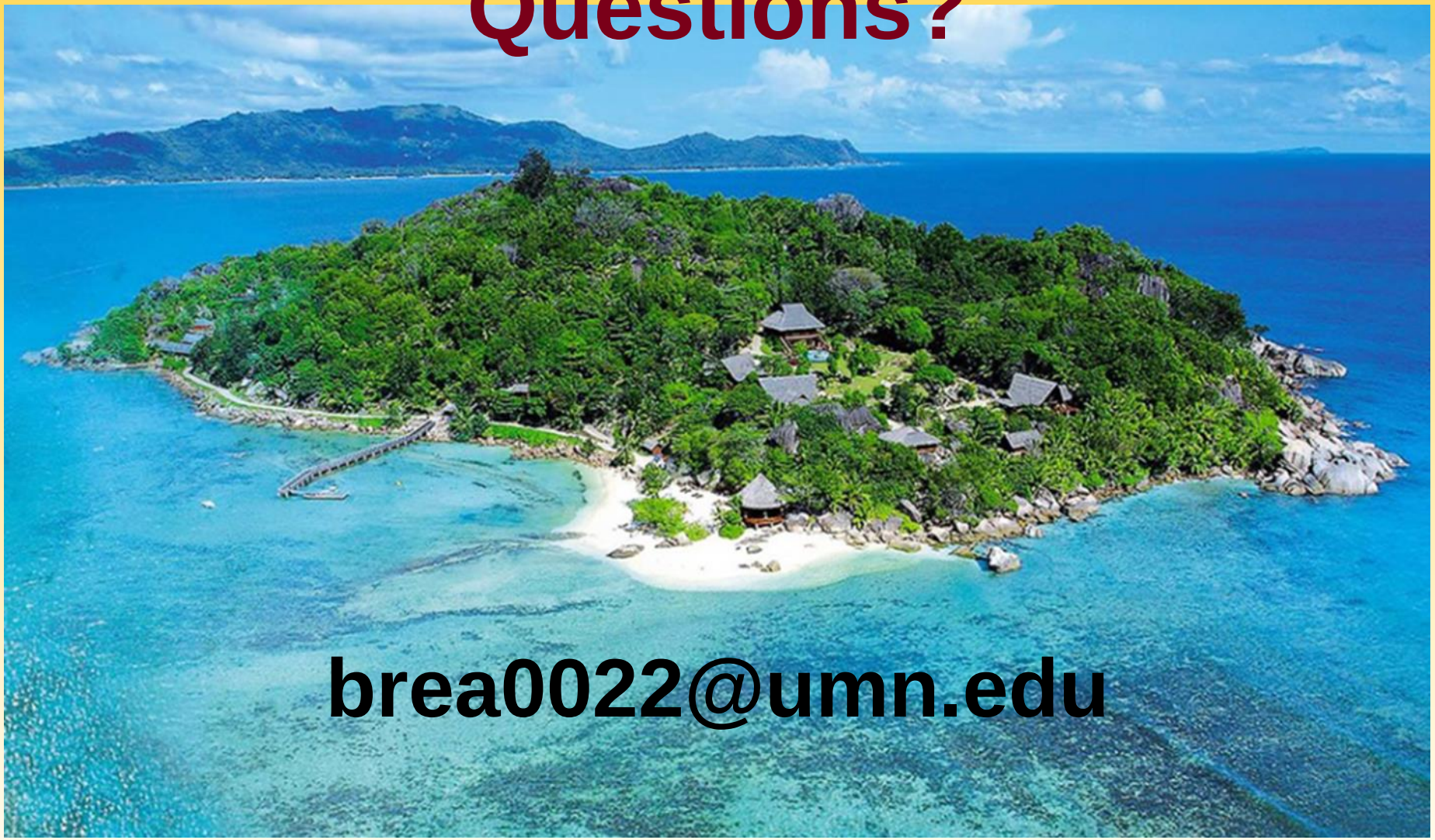
Questions?



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