SUMMER INSTITUTE 2020



Workshops In Quantitative Research Methodology

Department of Public Health Sciences Medical University of South Carolina Charleston, South Carolina May 4-14, 2020







The 2020 Summer Institute in the Department of Public Health Sciences at the Medical University of South Carolina (MUSC) offers several workshops that introduce current quantitative methods used in key areas of public health, population health, and biomedical and clinical research, and offer hands on experience with implementing these methods. The targeted audience includes public health professionals, biostatisticians, epidemiologists, biomedical and clinical researchers as well as residents, post docs, fellows and graduate students.

| May 4-5 | Longitudinal and Multilevel Data Analysis |
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| May 7-8 | Developing Your Clinical Trial Toolbox |
| May 11-12 | Fundamentals of Epidemiology: Population-Based Study Design & Analysis |
| May 13-14 | Analysis of Zero Inflated Count and Semi-continuous Data |

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Longitudinal and Multilevel Modeling (May 4-5)

Frequently in medical research, data are collected longitudinally and/or in clusters. This workshop will focus on familiarizing the participants with the appropriate analyses for such data. Linear Mixed Models ANOVA (including random effects, fixed effects, nesting, repeated measures, missing data), Generalized Linear Mixed Models for analyzing categorical data and introduction to growth models will be presented. The workshop will be divided into three modules. Module I - multilevel data, Module II - longitudinal data, Module III—SAS software and hands-on experience in using SAS for topics covered in Modules I&II. *Module III requires participants to have SAS installed on their laptops. The Modules I and II will be presented on Day I and the Module III will be presented on Day 2*.

Who Should Attend: Clinical researchers, biostatisticians and students who have not been exposed to these topics.



Sharon Yeatts is an Associate Professor of Biostatistics in the Department. She collaborates with clinicians at MUSC and around the country in several health related topics, with a focus on neurological trials. She oversees design and biostatistical analyses of several multicenter longitudinal studies. She teaches regression and factorial analyses in the graduate program.



V. Ramakrishnan (Ramesh) is a Professor of Biostatistics in the Department. He has extensive experience in Multilevel and Longitudinal data methods. He has authored or coauthored methodological articles in several areas of biostatistics, including missing data, genetic epidemiology, longitudinal growth models, mixture normal models. He has developed and taught graduate courses on several topics including a course in longitudinal and multilevel data analyses.



Developing Your Clinical Trial Toolbox (May 7-8)

This workshop provides two sessions per day (8-noon and 1-5 each day) on aspects of clinical trial development and implementation for randomized clinical trials, and hands-on experience with the latest developments. Attendees have the opportunity to bring their specific trial questions to the course for discussion and feedback. Fixed and Adaptive designs will be covered.

| Day I Session I: | Study Designs (aligning designs with objectives) |
|--------------------|---|
| Day I Session II: | Conducting Design Simulation Studies |
| Day 2 Session III: | Interim Analysis (Planning and Conduct) |
| Day 2 Session IV: | Practical Issues in Study Planning (budgets, form |
| | development. dissemination) |

Who Should Attend:

Clinical researchers, biostatisticians and students having an interest in clinical trial design and methodology.



Valerie Durkalski is Professor of Biostatistics and Director of The Data Coordination Unit (DCU), a statistical and data management center housed in the Department. The DCU specializes in the design of clinical trials and analysis of their data and in establishing, implementing and maintaining data and project management systems for multicenter clinical trials. Dr. Durkalski collaborates on several large multicenter clinical trials in various therapeutic areas, serves on several Data and Safety Monitoring Boards (DSMBs) and NIH peer-review panels. She publishes and presents on various topics related to the design and conduct of clinical trials and teaches 'Design & Conduct of Clinical Trials' to graduate students and healthcare professionals.



Caitlyn Ellerbe is an Assistant Professor of Biostatistics and Senior Biostatistician with the DCU, a statistical and data management center housed in the Department of Public Health Sciences. The DCU specializes in the design of clinical trials and analysis of their data and in establishing, implementing and maintaining data and project management systems for multicenter clinical trials. Dr. Ellerbe collaborates on the design and implementation of several large multicenter clinical trials with a focus on rare diseases, stroke, and other neurological emergencies. She publishes and presents on various topics related to the design and conduct of clinical trials, with a special emphasis on the design and conduct of adaptive clinical trials.



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Fundamentals of Epidemiology: Population-Based and Clinical Study Design and Analysis (May 11-12)

This two-day workshop includes six sessions (3 per day): (1) The rationale for specific study designs, their advantages and disadvantages for different research questions and populations under study, and practical methods and pitfalls in clinical and population-based studies. (2) Common sources of bias in observational research (selection bias, information bias, differential attrition, etc.), and strategies for minimizing bias. (3) Modern causal thinking, reviewing theory and methods for assessing causality in randomized or observational studies. (4) Understanding sources of confounding in observational research, and ways to assess and control confounding. (5) Theory and methods for assessing differential causal effects, interactions, and effect modification between causal factors. (6) An introduction to data analysis strategies and interpretation of results for different types of studies, including basic analyses as well as an introduction to different types of multivariable modeling. Throughout the workshop students will be presented with concrete examples of appropriate methods, pitfalls to avoid, and fundamentals of causal thinking and interpretation of findings when designing, conducting, or evaluating clinical or population-based research studies.

Who Should Attend:

Clinicians and students having an interest in clinic-based and population-based study design and analysis, public health, and interpreting published literature.



Jeffrey E. Korte is Associate Professor of Epidemiology, and Graduate Training Director for Epidemiology in the Department of Public Health Sciences at MUSC. Dr. Korte has particular research interests in HIV, substance abuse, and women's health, with over 20 years of experience conducting epidemiologic research and collaborating with clinical and population-based scientists. In addition, he has over 15 years of experience teaching epidemiologic research methods to PhD and masters students at MUSC. The contents of this workshop are informed both by his teaching experience and his research experience.



Analysis of Zero Inflated Count and Semi-continuous Data (May 13-14)

Day I AM—Continuous and Count Data

General linear models for continuous data (Gaussian, Gamma, log-normal) Examples- systolic blood pressure, medical cost, life data (in proc GENMOD)

General linear models for count data (Poisson, Negative Binomial) Overdispersion

Zero inflated data modeling using SAS

- Generalized Poisson model
- Two part or hurdle model (Poisson and negative binomial)
- Zero-inflated model (Poisson and negative binomial)

DAY I PM

Semi-continuous data modeling Two-part model Marginalized two-part model Data examples: blood alcohol level data

DAY 2 AM—Longitudinal Data

Longitudinal zero-inflated count data modeling

 Two-part and Zero inflated (ZI) (GLMM ZIP, GLMM ZINB, GLMM TPP, GLMM TPNB)

Longitudinal semi-continuous data modeling

- Two-part and Marginalized Two-part (mTP)
- GLMM TPGamma, MTPGamma

DAY 2 PM- Missing Data

Methods for analysis of missing data in cross -sectional studies

- Simple methods
- Multiple imputation

Methods for analysis of missing data in longitudinal studies

Sensitivity analysis for MNAR data



Dr. Gebregziabher is Professor of Biostatistics in DPHS and a coleader of the Biostatistics Core with the VA Health Services Research and Development funded Innovation Center for Health Equity and Rural Outreach. His research expertise is in longitudinal data, missing data, multiple outcomes research, and analysis of very large datasets. He collaborates in several areas of clinical & health services research related to T2DM, CKD, stroke, CVD, lung cancer and HIV/AIDS. He has over 100 peer-reviewed publications in top-tier biomedical journals and has developed/taught graduate courses on longitudinal data analysis, advanced regression, Bayesian analysis and Statistics in Epidemiology. He has served as President of Statistical Society of Ethiopians in North America, President of the South Carolina Chapter of the American Statistical Association and is currently Officer of the Statistics in Imaging Section.

VENUE

The courses will take place on the campus of the Medical University of South Carolina,

Recommended Area Accommodations:

Charleston Marriott Hotel 170 Lockwood Boulevard Charleston, SC 29403 (843)723-3000/(800)968-3569 www.marriott.com/chsmc Springhill Suites/Charleston Riverview 90 Ripley Point Drive Charleston, SC 29407 (843) 266-8081 www.marriot.com/chssh

| Comfort Inn | The Courtyard by Marriott |
|----------------------|---------------------------|
| 144 Bee Street | 35 Lockwood Drive |
| Charleston, SC 29401 | Charleston, SC 29401 |
| (843)577-2224 | (843) 722-7229 |
| www.choicehotels.com | www.marriott.com/chscy |

Inquire about an MUSC discount when making hotel reservations. Additional information on Charleston and area hotel accommodations may be found at <u>www.charlestoncvb.com</u>. Download a campus map at <u>www.musc.edu</u>.

General Daily Schedule:

Most classes start between 8:00 and 9:00am and end in the early evening between 4:00pm and 5:00pm

All classes will provide a catered box lunch. Please be sure to indicate on the registration form if you have any dietary restrictions.

Please contact the course director if a more specific scheduled is needed.

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| 2020 | Registration Form: |
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| Department of Public Health Sciences Medical University of South Carolina 135 Cannon St, Ste 303 MSC 835 Charleston, SC 29425-8350 Phone: 843-876-1578 Secure Fax: 843-792-6000 E-mail: talbotp@musc.edu Through Numbers to Knowledge Through Knowledge to Health | Last Name: Institution: |
| We're on the Web! www.musc.edu/phs | Longitudinal Analysis (May 4-5) Clinical Trials (May 7-8) Fundamentals in Epi (May 11-12) Zero-Inflated /Semi-Continuous Data (May 13-14) |
| Registration Deadline: April 15, 2020 Refund Policy: Requests for refunds must be made in writing. There will be a \$75 processing fee for cancellations made before April I, 2020. Following Apirl 1st, no refunds can be given. The department reserves the right to cancel a workshop in which case a full refund will be granted. | Total Amount: \$ Payment can be made by phone or mail. Contact information is on the top left corner of this page. Registration fees are payable in U.S. dollars only. Personal checks are acceptable if payable through a U.S. bank. Payment Method: o IIT (MUSC internal registrations only) o Check (make payable to MUSC, DPHS) o Visa o Mastercard o American Express Card #: Exp Date: |
| Please notify us about special ac- commodations or dietary re- strictions: | Name on Card: Authorized Signature: Cardholder address: |