Medical College of Georgia

Department of Emergency Medicine

Center for Operational Medicine

Prehospital Disaster and Operational Medicine

International Research Fellowship

Duration: 6 months (5 months online/self-study + 1 month live "observership" in augusta)

Methods: Online Self Study, mentorship and a live 1-month practicum in Augusta GA, USA

Cost: TBD

Course Director: Amado Alejandro Baez, MD, PhD, MSc, MPH, FAAEM, FCCM abaez@augusta.edu

Introduction

Research is an important component to the development of Emergency Care globally. Many international emergency medicine clinicians engaged in research may not be aware of some fundamental principles of conducting and disseminating medical research. Ignorance of these fundamentals can lead to investigator frustration, disorganized researcher efforts, and ultimately a reduction in the emergency care researcher pool. The field of emergency medicine now has experienced and funded emergency care researchers who can highlight key points to finding mentors, obtaining extramural funding, designing research proposals, initiating research, and disseminating research results. Some of this information has been presented in lectures, discussed at national meetings, printed piecemeal in review articles, and published in lengthy books. However, a pithy, consolidated, and accessible guide focused on the junior, novice, or evolving emergency care investigator has not been available. The MCG COM International Research Fellowship will offer participants intellectual resources and direct faculty mentorship to successfully understand principles of generating quality research in emergency medicine, areas covered will include public health, epidemiology, economics, informatics, database management, primary data collection, project administration, and IRB issues applied to Prehospital Disaster and Operational Medicine.

Historically and presently, Latinos are underrepresented in clinical research. Researchers want diversity in clinical trials so Latinos and other underrepresented groups benefit from new treatments. This International Research Fellowship will specifically be directed at talented Latin American physicians interested in further developing their research skills. The online format facilitates participation and the live teleconference modules will be delivered in Spanish by MCG faculty members.

Augusta University and The Medical College of Georgia DEM

The Department of Emergency Medicine at the Medical College of Georgia at Augusta University is comprised of Adult and Pediatric Emergency facilities and a Level-1 Trauma center. We service the CSRA in Emergency Medicine and service the surrounding 13 counties in Trauma care. Providing care for over 85,000 patients and 1,500 trauma patients.

Our department serves the State of Georgia and the nation through the education of students, residents, and post-graduate fellows through clinical research in Emergency Medicine. We strive to produce highly educated emergency physicians in the areas of patient care, medical knowledge, practice-based learning, communication, professionalism, and compassionate care.

The Center of Operational Medicine (COM) is a major division of the Department of Emergency Medicine at the Medical College of Georgia at Augusta University. The mission of the COM is to promote excellence in emergency medical care in prehospital, austere, and unconventional environments through education, training, research, and operational support.

About the Georgia CTSA

https://georgiactsa.org/about/what-we-do/index.html

The institutions of the Georgia Clinical & Translational Science Alliance leverage their complementary strengths to accelerate clinical & translational education, research, & community engagement to impact health.

Areas to be developed by the International Research Fellowship Include:

1. Identification of Area of Focus within Emergency Care Research 2. Hypothesis Generation; 3. Research Design; 4. Data Collection Methods; 5. Data Monitoring and Interim Data Analysis; 6. Data Analysis; 7. Presentation of Research; 8. Manuscript Preparation, Submission, and Revision; 9. Grant Preparation, Submission, and Revision; 10. Project Management; 11. Ethical Aspects of Medical Research; 12. Regulatory Requirements; 13. Informatics; 14. Teaching Skills; 15. Career Development.

International Research Fellowship Goal:

To offer a hybrid/ blended, comprehensive study format program for LATINAMERICAN residents, research staff and faculty members that are interested in furthering their research knowledge and skills.

Program Objectives:

1. Learn various statistical analysis techniques
2. Understand different methods of hypothesis development and testing.
3. Understand various types of study design and methodology.
4. Understand the methods for obtaining patient/subject consent.
5. Understand basic statistical methods and their appropriate application.
6. Understand ethical considerations and implications in research.
7. Learn the skills necessary a manuscript that is acceptable for publication in a peer review journal.
8. Understand the modalities of research funding.
9. Learn how to write grants.

Format

The International Fellowship is designed to match the research-specific educational goals of the Society for Academic Emergency Medicine Model Curriculum for Emergency Medicine Residency training.

The program will integrate 3 teaching elements:

1- An Online- Self Study Program 2- Preparation of a research proposal (Based on the NEMSIS data base) 3- A 1 month practicum at MCG (learner covers living costs in Augusta)

EDUCATIONAL MODULES

INITIAL MODULES

1- **CTSI Clinical Study Design Types**

https://twd.ce.emorynursingexperience.com/courses/ctsi-clinical-study-design-types

2- **Basic Statistical Principles: Validity and Sample Size**

https://twd.ce.emorynursingexperience.com/courses/basic-statistical-principles

3- **Privacy and HIPAA: Concerns in Global Clinical Trials**

https://twd.ce.emorynursingexperience.com/courses/privacy-and-hipaa

4- **The National Emergency Medical Services Information System (NEMSIS)**

https://nemsis.org/what-is-nemsis/#:~:text=The%20National%20Emergency%20Medical%20Services,prehospital%20EMS%20activations%20is%20documented

ONLINE PROGRAM

Introduction to Clinical and Translational Research An Online Exploration

https://georgiactsa.org/training/clinical-translational-research.html

Supplemental advanced lectures have been included in this course as additional reading.

Electronic documents of several basic research design and methodology publications as well as established module specific-links to the American College of Emergency Physicians Basics of Research Video Series by Dr Ed Panachek, as well as link to the UM CITI Program.

Monthly live teleconference sessions (in Spanish) will be help to improve coordination of educational objectives.

OPEN SOURCE RESOURCES

ACEP: Emergency Care Research A Primer. (Important Chapters 7-10)

https://www.acep.org/globalassets/sites/acep/media/sections-documents/em-research/acep-research-primer-book-pdf.pdf

BMJ Epidemiology for the Uninitiated: https://www.bmj.com/about-bmj/resources-readers/publications/epidemiology-uninitiated/

ACEP Emergency Medicine Research Webminars

https://www.acep.org/embrswebinars

Complete Idiots Guide to Statistics (Full text PDF) : https://archive.org/details/CompleteIdiotsGuideStatistics2nd/page/n2

OPENEPI: Open Source Epidemiologic Statistics for Public Health

http://www.openepi.com/Menu/OE_Menu.htm

Statistics at Square One

https://www.bmj.com/about-bmj/resources-readers/publications/statistics-square-one

The CDC EPI Info and STAT Calc

https://www.cdc.gov/epiinfo/user-guide/statcalc/statcalcintro.html

Ethics and IRB

History of Ethics in Medical Research: https://binged.it/2LgiuMC

Basics of Research Ethics: https://binged.it/2LfwF4T

Collaborative Institutional Training Initiative (CITI) Program (Optional):

https://about.citiprogram.org/en/courses/

- Human Subjects Research
- Responsible Conduct Research

Evaluating the Literature

How to read a paper: Assessing the methodological quality of published papers

https://www.bmj.com/content/315/7103/305.full

APPLICATION

A letter of interest and current Curriculum Vitae in English. The letter should state your intent, such as to broaden academic experience. It should also state your plans program completion and your current level of education/experience.

Required documents include:

•Copy of Medical School Diploma

•At least two letters of recommendation

•FULL comprehension of the English language, both written and oral

•Medical Certificate attesting to your good state of health

Please include in your email 1) a current and complete mailing address, 2) the length of fellowship you are requesting, and 3) the month/year you wish to start.

Before applying, please take a look at additional program requirements to ensure that all requirements can be met.

After application gets approved, the students will complete our online research program, with direct faculty mentorship online. After completion of the online modules, students are expected to complete a research proposal based on ongoing research programs and faculty interests.

FULL GA CTSA MODULES DESCRIPTIONS

Basic Statistical Principles: Validity and Sample Size

https://twd.ce.emorynursingexperience.com/courses/basic-statistical-principles

Self-paced
1 credit

Program Description:

The fundamental principles of statistics, including hypothesis testing, power, multiplicity, mathematical and data adjustments, and statistical confidence will be discussed. These principles applied to study design inform clinical endpoints, sample size, biases, validity, and missing data. At the end of this program the learner will:

- Understand basic statistical principles relate to clinical research and how they affect clinical trial practices and study design
- Differentiate between statistical and clinical significance.
- Evaluate different types of endpoints, e.g., continuous, ordinal, binary, survival, composite, surrogate)
- Identify factors leading to missing data and biases and statistical techniques utilized to manage these factors.

Course Topics:

1. Statistical Inference
2. Hypothesis Testing
3. Statistical Significance and Clinical Significance
4. Power and Sample Size
5. Randomization and Blinding
6. Estimates and Confidence Intervals
7. Multiplicity and Approaches for Multiplicity Adjustments
8. Regulatory Claims
9. Multiple Endpoints vs. Co-Primary Endpoints
10. Different Types of Endpoints
11. Clinical and Surrogate Endpoints
12. Missing Data and Bias

Speaker: Steve Snapinn, PhD, is a managing expert at Advarra. Dr. Snapinn holds a PhD in Biostatistics from the University of North Carolina at Chapel Hill, MS in Bioengineering from Columbia University in the City of New York, and BS in Engineering Science from the University of Virginia. He has over 30 years of experience as a biostatistician in the pharmaceutical industry. Formerly, he was a consultant at Seattle-Quilcene Biostatistics LLC, the Senior Vice President of Biometrics at Alder Biopharmaceuticals Inc., the Vice President of Global Biostatistical Science at Amgen, and the Senior Director of Biostatistics at Merck. He is also the former editor of Statistics in Biopharmaceutical Research and is a fellow of the American

Statistical Association. He has shared his expertise about the essential role of statistics in the medical product development process with numerous graduate and doctoral students at USC for 4 years as a guest lecturer. snapinns@gmail.com

CTSI Clinical Study Design Types

https://twd.ce.emorynursingexperience.com/courses/ctsi-clinical-study-design-types

Self-paced
1 credit

The Georgia Clinical & Translational Science Alliance - Georgia CTSA and Southern California Clinical and Translational Science Institute -SC-CTSI collaborate to provide free, high quality educational programs for clinical research professionals at novice to expert levels of experience. At the completion of each course or program, participants earn contact hours recognized by a certificate and/or badge.

Course Description:

This course provides an in-depth exploration of various clinical trial design types (i.e., cohort, case-study, quasi-experimental, etc.) along with the statistical methods often used respective to each type (i.e., Chi-square test, T-test, non-parametric Wilcox logistic regression, etc.). Other topics discussed include development of a testable research question using PICOT criteria, data collection, and brief explanations on the advantages and disadvantages of each trial design type.

Learner Objectives:

- At the end of this course, the learner will be able to:
- Define different clinical trial study designs (i.e., descriptive, analytic, observational, cohort, case-control, quasi-experimental, crossover, cluster randomized, non-inferiority trials).
- Formulate a research question using PICOT criteria.
- Understand how study designs should align with the research question, data collection, and statistical analyses.
- Define different types of data (i.e., continuous, dichotomous, ordinal categorial, nominal, count, and survival).

Course Topics:

1. Clinical trial study designs and the associated statistical methods used
2. PICOT criteria to develop the research question
3. Statistical analysis plan
4. Testing differences among groups
5. Types of data
6. Regression models

Speaker:

Wendy Mack, PhD, is the Director of the Biostatistics, Epidemiology, and Research (BERD) Core at the Southern California Clinical and Translational Science Institute (SC-CTSI) and a Professor in the Department of Preventative Medicine, Division of Biostatistics in the Keck School of Medicine at USC. She received her doctorate in Biometry from USC. She has over 25 years of experience in directing biostatistical and data coordination activities for multiple single-centered and multi-centered clinical trials and observational studies. She has directed the biostatistical and data coordination activities of randomized clinical trials (the majority being NIH- or PCORI-funded), as well as NIH-funded program projects, and has a wealth of experience and expertise in analysis of longitudinal clinical trial outcomes.With over 30 years of teaching USC students, Wendy remains deeply committed to training the next generation of clinical investigators and biostatisticians. As the former director of the MS programs in Biostatistics and Epidemiology in the Department of Preventive Medicine, she has mentored numerous K-awardees, junior faculty, and graduate students (MS and PhD).

Privacy and HIPAA: Concerns in Global Clinical Trials

https://twd.ce.emorynursingexperience.com/courses/privacy-and-hipaa

Self-paced
1.5 credits

Full course description
The Georgia Clinical & Translational Science Alliance- Georgia CTSA and Southern California Clinical and Translational Science Institute -SC-CTSI have collaborated to provide free, high quality educational programs for clinical research professionals at novice to expert levels of experience. At the completion of each course or program, participants earn contact hours recognized by a certificate and/or badge.

Description

This explores core concepts of privacy in clinical research including similarities and differences between the U.S. and E.U. Privacy protections under the U.S. Health Insurance Portability and Accountability Act (HIPAA) and the European Union General Data Protection Requirements (GDPR) will be discussed. Additional complex considerations such as privacy breaches, disclosure obligations, penalties for non-compliance, state-specific laws, and the impact from Brexit will be examined.

Topics:

1. Key concepts around privacy
2. Global privacy
3. United States: Health Insurance Portability and Accountability Act (HIPAA)
    - Covered entities vs business associates
    - Accessing personal health information (PHI) for clinical research
    - De-identified data standards
4. United States: State Laws
    - California Consumer Protection Act (CPPA)
    - Children's Online Privacy Protection Act (COPPA)
5. Patient/Subject Protections under General Data Protection Regulation (GDPR)
6. GDPR basics

    - Reporting a data breach or loss
    - Penalties
7. Personal identifying information under GDPR
8. Brexit impact to EU clinical trials
9. Clinical trials: Privacy pitfalls
    - Breach, disclosure obligations
    - If there is a breach, what next?
    - Potential damages

Speaker:

Terence J. Hogan, Esq. Partner is subject matter expert within RGP's Healthcare practice, with extensive background and expertise in Legal, Regulatory and Compliance matters. Terence has 20+ years of experience both within industry, leading functional business performance improvement projects related to the acquisition and development of regulated drug and device products, audit and inspection of GMP facilities, litigation support for product liability, transactional services, and data protection in the US, EU and Asia. Terence has experience developing tailored client solutions and implementing transformative initiatives with clients across many industry sectors. Terence served as executive-level in-house counsel for several Fortune 500 companies. In these roles, he has provided counsel on ANDA patent litigation, R&D regulation and compliance, import/export regulation and compliance, and privacy breaches of varying sizes. Terence also has a strong background in transactional support, as well as intellectual property prosecution and litigation. Terence began his consulting career with RGP in 2015. He has spoken internationally at various industry & professional events, on various topics pertaining to healthcare and life sciences, and currently resides in Orange County, California. terence.hogan@rgp.com

Georgia Clinical & Translational Science Alliance

Introduction to Clinical and Translational Research An Online Exploration

https://georgiactsa.org/training/clinical-translational-research.html

This exploration is organized into 4 parts that will each take 1-2 hours to complete:

Part 1: Understanding the Translational Science Research Ecosystem

Part 2: Basic Concepts Defining the Analytic Approach to Research

Part 3: Elements of Clinical and Translational Research Studies

Part 4: Clinical and Translational Research Study Design Types

At the end of each part is a 10-question multiple choice assessment meant to reinforce the learning objectives and provide some real world examples of the concepts in the CTR literature.

Development of this program was supported by the National Center for Advancing Translational Sciences of the National Institutes of Health under Award number UL1TR002378.

The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Learner Objectives:

- Identify the features that characterize translational research ecosystems: translational stages, developmental phase, clinical application, data types and collection methods, unit of analysis, and epistemological objectives.
- Define the fundamental concepts of precision, accuracy, validity, causality, and types of associations.
- Identify the steps from defining a target population to selecting a study sample.
- Identify the processes of developing minimal important difference when defining study measures in causal inference CTR.
- Describe the reasons for conducting power and sample size calculations in CTR study design.
- Recognize the purpose, features, strengths, weaknesses, and optimization of observational study design, and its most commonly utilized styles.
- Recognize the purpose, features, strengths, weaknesses, and optimization of experimental study design, and its most commonly utilized styles.

Program Developer:

Dr. Jordan A. Kempker is an Assistant Professor of Medicine at the Emory University in the Division of Pulmonary, Allergy, Critical Care and Sleep Medicine. He received his Bachelor of Arts in Religious Studies in 2003, followed by his Doctor of Medicine in 2007; both from the University of Florida. He then completed his Internship and Residency at Emory and then served as served for one year as a Chief Resident at Grady Memorial Hospital. To develop his professional capacity as a Clinical-Translational scientist, Dr. Kempker then completed a Masters in Science and Clinical Research through the Georgia Clinical & Translational Science Alliance and the Emory Laney Graduate School. He completed his Fellowship training in Pulmonary and Critical Care Medicine at Emory University before transitioning to a faculty position in 2015. Dr. Kempker has conducted research exploring the roles of vitamin D deficiency in the risk for serious infections. His current research interests are in spheres of epidemiology, health services research, social disparities, and Critical Care Medicine; primarily exploring the health disparities and longitudinal risk factors for important critical illnesses such as sepsis and Acute Respiratory Distress Syndrome.

Basics of Research Self Study Program PRE-TEST

(Based on the ACEP EMBRS Ed Panacek Research Video Series)

Research Basics

1. What is the validated way to properly perform research? What is it called and how is it done?

 Answer: the scientific method This should be described as starting with a research question or hypothesis, designing an experiment, conducting the experiment and collecting data, analyzing that data and seeing whether it answers the question or supports the hypothesis.

2. When a study is analyzed, the degree to which the actual study measurements (data) support the conclusions of the study is called which of following:

A. Reliability B. Internal validity C. External validity D. Interrater reliability E. Concordance

3.

Random errors are simple mistakes or sloppiness that could occur in any direction, i.e. randomly. Systematic error is also referred to as "bias" and is a pattern of errors that are relatively consistent in terms of the direction and/or magnitude of the measurement error.

Research Questions

1. List the four elements generally required for properly formatted research questions:

Answer: PICO i. namely patients, intervention (or independent variable), comparison, outcome (dependent or outcome variable)

2. What is the null hypothesis? Define it.

Answer: That there is no difference between the two study groups. i. Namely that the results from arm A (data set A), when subtracted from the results of arm B (data set B), result in a "null" or empty set of data.

3. What is the alternative hypothesis? Define it.

Answer: That there is a difference between the two study groups o namely that data A minus data set B results in some leftover number that is not equal to zero.

4. When reporting data analysis with statistical comparisons, "p" values are routinely reported. What does "p" mean?

Answer: P is simply an abbreviation of the word probability. o It's designed to quantify the effects of random chance on data sets and help the investigator understand whether differences observed could have happened by random chance alone.

Principles of Research Study Design

1. There are numerous different study designs available. There also are multiple different classification systems to help understand the different designs. List and describe some different classifications systems in common use:

Answer: o i. Descriptive vs analytic o ii. Interventional versus observational o iii. Classification by time frame Retrospective, cross-sectional, prospective o iv. Classification by degree of scientific rigor True experimental, quasi-experimental, non-experimental

2. In research questions in study designs, it is important to understand the main research variables. Define and provide an example of an independent variable and a dependent variable:

The independent variable (IV) is that parameter that generally varies between the two groups and is the primary interest of the study. It's also often referred to as the predictive variable or the intervention variable or the exposure variable. In therapy studies, it's therapy A vs therapy B. The dependent variable (DV)is the outcome of interest and sometimes referred to as the outcome variable. It, generally, is what is used to see whether the independent variable has an effect or makes a difference. Examples would be death rates, hospital admission rates, improvement in pain scores, etc.

3. Study designs vary in terms of their general level of scientific validity or the "strength of evidence" that they provide to support their conclusions. Organize the following study designs

from highest level of scientific validity to lowest, in order: cross-sectional, cohort, case control, randomized clinical trial, retrospective case series.

Answer: 1. RCT, 2. prospective cohort study, 3. case control, 4. cross-sectional, 5. retrospective case series (depending upon other study design elements, prospective cross-sectional studies might be considered to have a higher level of validity and an entirely retrospective case control study, in some situations).

True Experimental Study Designs

1. Which of the following study design elements are not required in a "true experimental" design?

A. Randomization B. Blinding C. Manipulation D. Control

2. All of the following are true experimental study designs except:

A. Randomized clinical trials B. Cross-over studies C. Factorial studies D. Prospective cohort studies E. Group sequential

3. All of the following are disadvantages of true experimental study designs, except:

A. Impractical for common clinical conditions B. Require patient consent C. Require randomization D. Are resource expensive

Cohort Studies

1. Define the term cohort and what it means in terms of clinical study design:

Answer: It comes from the Latin term cohorts and refers to a set group of soldiers who are all of the same type.

In research it means a group of individuals who all share some trait and then are followed together through time making observations looking for the outcome of interest.

2. All of the following are examples of cohorts, except:

A. A group of individuals all born during the same time period or generation B. Individuals who all share the same outcome, e.g. died from lung cancer C. Group of individuals all living in the same city, all working at the same location D. Group of individuals sharing a common exposure, e.g. to cigarette smoke or radiation

3. All of the following are advantages to cohort studies, except:

A. Do not need to randomize B. Can study multiple outcomes for each exposure of interest C. Ideal for studying rare outcome D. Prospective design allows precise measurement of exposures and outcome E. Generally less expensive than randomized clinical trials

Case Control Studies

1. In terms of research design classification, case control studies fit into which of the following categories based on degree of scientific validity:

A. True experimental B. Quasi-experimental C. Non-experimental D. None of the above

2. Which of the following statements best describes the "case-control" study design?

A. Subjects selected based upon exposure, but studied retrospectively B. Subjects selected based upon exposure, but studied prospectively C. Subjects selected based upon outcome and studied retrospectively D. Subjects selected based upon outcome and studied prospectively

3. All of the following are advantages of case-control study designs except:

A. Ideal for studying rare outcomes B. Can be performed entirely retrospectively C. Ideal for studying rare exposures (cohort studies are best for this) D. Less expensive to perform than randomized trials or cohort studies

Cross Sectional Studies

1. In terms of the time frame perspective, cross sectional studies should classically be considered:

A. Prospective B. Retrospective C. Neither D. Both

2. Cross sectional studies are best and most commonly used to:

A. Establish cause/effect relationships B. Establish dose response curves C. Establish prevalence rates D. Establish incidence rates E. Prove associations

3. Regarding cross sectional studies, which of the following statements is not true:

A. Each subject should be studied or measured only once B. All observations have to occur at the same time C. The denominator is directly measured at the same time as the numerator, making for accurate prevalence calculations D. Each subject must be studied at the equivalent time or milestone

Other Research Study Designs

1. All of the following are examples of "descriptive" study designs except:

A. Case reports B. Ecologic studies C. Case series D. Descriptive epidemiology

2. Regarding "before-end-after" studies, which of the following statements is not true:

A. Can be performed entirely retrospectively B. Can be performed entirely prospectively C. Is a term used to refer to changes in the environment that are under the investigator's control D. Can be performed ambispective, that is both retrospectively and prospectively E. Are best performed with multiple measurement periods, both during the before portion, as well as during the after portion

3. Within the spectrum of study designs, "case series" are most appropriately used to:

A. Demonstrate cause-effect relationships B. Compare differences between groups C. Systematically describe new or rare medical experiences D. Calculate prevalence or incidence rates

Elements of a Study Protocol

1. In selecting study subjects, using "convenience sampling" should be considered in which of the following:

A. True probability sample B. Non-probability sample C. Proven representative sample D. Random sample

2. Which of the following would be an example of an "effectiveness analysis" as opposed to an efficacy analysis:

A. Evaluation under "ideal" conditions B. An industry sponsored Phase III clinical trial C. A case control study D. A multi-center study in "real world" conditions

3. In establishing the "validity" or accuracy of a study measurement, which of the following is not an accepted approach:

A. Content validity B. Interrater validity (this is used for reliability, not validity) C. Criterion validity D. Predictive validity

Sample Size and Power

1. Identify (circle) each of the following parameters that are always included in performing sample size calculations:

A. Alpha level B. Beta level C. Effect size

D. 95% confidence interval E. Type of study outcome data (dependent variable)

2. In calculating a sample size, in general, if the investigator is looking to be able to detect a 50% smaller effect size (e.g. detecting a 10% instead of a 20% difference in outcome between groups), the change in required sample size would be about:

A. Twice as many subjects B. Four times as many subjects C. The same number of subjects D. One-half the number of subjects E. One-fourth the number of subjects

3. Which of the following changes will not require a larger sample size:

A. Decreasing the Beta level from 0.2 to 0.1 B. Decreasing the Alpha level from 0.05 to 0.25 C. Studying an outcome (dependent) variable that is more common D. Trying to detect a smaller effect size or difference between groups