Introduction to Clinical Research: HIV-related Haematology and Transfusion Medicine

Protea Hotel Cape Town Mowbray
Liesbeek Ave, Observatory,
Cape Town, South Africa
April 23-27, 2018

Sponsored by:
U.S. National Institutes of Health (NIH),
Fogarty International Center
Grant # D43TW010345
Course Faculty:

**Edward Murphy MD, MPH** is an internist and epidemiologist with the specialty of viral epidemiology. He is Professor of Laboratory Medicine and Epidemiology/Biostatistics at the University of California San Francisco, and Senior Investigator at Blood Systems Research Institute (BSRI). Over the past 14 years, Dr Murphy has initiated a number of training programs for international transfusion safety, including overseas short courses and medium-term training in San Francisco. He is currently one of the three principal investigators for the NIH Fogarty International Center research training program in HIV related hematology and transfusion medicine in South Africa.

**Nareg Roubinian, MD, MPHTM** is a pulmonary, intensive care physician with training in epidemiology with research appointments at Blood Systems Research Institute, the Kaiser Permanente Division of Research, and the University of California in San Francisco. He is a co-investigator for the NIH funded REDS-III program in South Africa. His work focuses on predictive models and trends in blood utilization as well as clinical and laboratory factors in blood donors, components, and recipients relevant to the efficacy and potential harm of blood transfusion.

**Karin van den Berg, MBChB, MTM** is a Medical Doctor with the South African National Blood Service who completed her Master's in Medical Clinical Science in Transfusion Medicine at the University of the Free State. Her areas of interest includes the impact of HIV/AIDS on blood transfusion and blood donor safety. She is currently a co-investigator for the NHLBI funded Recipient Epidemiology and Donor Evaluation Study (REDS-III) in South Africa. She is a previous graduate of the 2008 TICR course in Durban, South Africa and recipient of the BSRI / Novartis research grant for TICR graduates.
**Estelle Verburgh MD, PhD** is a specialist physician and clinical haematologist in the Division of Clinical Haematology, Department of Medicine at the University of Cape Town. Dr Verburgh is passionate about clinical research that translates into patient benefit and is currently overseeing various projects that improve access to care and quality of diagnosis and treatment in HIV related haematology. She is one of the principal investigators for the NIH Fogarty International Center research training program in HIV related hematology and transfusion medicine in South Africa.

**Katherine Antel MBChB FCP (SA) Mmed Cert Clin Haem** is a specialist physician and clinical haematologist. She is currently working on her PhD project in the diagnosis of lymphoma, with particular emphasis on the complexities of diagnosis in HIV and in a TB-endemic area. She is funded by a Discovery Foundation Award, the Peter Jacobs Haematology Trust and a Fogarty Fellowship.

**HOST Organization:**

Dr. Estelle Verburgh and Prof. Vernon Louw, Division of Haematology, Department of Medicine at the Faculty of Medical Sciences, University of Cape Town. Dr. Verburgh is one of the three principal investigators for the NIH Fogarty HIV training grant under which this short course is given.

**Acknowledgements:**

We gratefully acknowledge **Dr. Steven Hulley** of UCSF who developed the original UCSF TICR course from which the current course has been developed, and who allow the use of syllabus and lecture materials from that course. We are also grateful to Dr. Greg Bellairs of the Western Province Blood Transfusion Service for his support of our research training activities over the years.

**Funding:** We gratefully acknowledge financial support for travel expenses, course logistics and teaching effort from: **The Fogarty International Center of the National Institutes of Health under Award Number D43-TW010345.**
SYLLABUS

Required Reading in the Textbook (before course begins):
(From Hulley SB et al Designing Clinical Research, 4th ed., 2013)

Chapter 1: The Anatomy and Physiology of Clinical Research
Chapter 2: Conceiving the Research Questions

Monday, April 23

8:30-10:30AM  Morning Lectures:
Welcome, Course Overview and Introduction to Clinical Research – Edward Murphy
Conceiving the Research Question – Karin vd Berg

11-12:30  Morning Small Groups:
Evaluate your Research Question (group participation)

12:30-1:30  Lunch

1:30-2:30PM: Demonstration:
How to use PubMed – Edward Murphy

2:30 PM- 4:30 PM  Afternoon Small Groups:
Write: 1) Protocol Outline; 2) Background & Significance section

Required Reading (for next day):
Chapter 4: Planning the Measurements: Precision and Accuracy
Chapter 7: Designing a Cohort Study
Chapter 8: Designing Cross-Sectional & Case-Control Studies
Chapter 10: Designing a Randomized Blinded Trial
(Optional reading Chapter 11: Alternative Clinical Trial Designs)
Tuesday, April 24

8:30 AM- 10:30 AM  Morning Lectures:
Observational Study Designs – Nareg Roubinian
Clinical Trials – Edward Murphy
Coffee break

11AM -12:30 PM  Morning Small Groups:
Write:
Finalize your research question
Study Design section

12:30-1:30 PM  Lunch

1:30-2:30PM  Lecture:
Outcome and Predictor Variables – Karin vd Berg

2:30 PM- 4:30 PM  Afternoon Small Groups:
Write:
Section on variables and measurement

Required Reading (for next day):
Chapter 5: Getting Ready to Estimate Sample Size: Hypotheses & Underlying Principles
Chapter 6: Estimating Sample Size & Power
Chapter 3: Choosing the Subjects: Specification, Sampling & Recruitment
(Optional Reading Chapter12: Designing Studies of Medical Tests)
Wednesday, April 25

8:30 AM-10:30 AM  Morning Lectures:
Introduction to Statistics – Nareg Roubinian
Sample Size and Statistical Power – Edward Murphy
Coffee break

11-12:30  Morning Small Groups:
Write:
Calculate (group activity) and then write sample size section

12:30-1:30 PM  Lunch

1:30-2:30 PM Lecture:
Choosing your Subjects: Sampling and Recruitment – Estelle Verburgh

2:30 PM- 4:30 PM  Afternoon Small Groups:
Write: Study population, sampling, inclusion and exclusion criteria

Required Reading (for next day):
Chapter 9: Enhancing Causal Inference in Observational Studies
Chapter 15: Designing Questionnaires and Interviews
Chapter 16: Data Management
Chapter 17: Implementing the Study: Pretesting, Quality Control & Protocol Revisions
(Optional Reading, Chapter 13: Utilizing Existing Databases)
Thursday, April 26

8:30 AM-10:30 AM Morning Lectures:
Cause and Effect, and Bias – Nareg Roubinian
Questionnaire Design and Data Collection – Katherine Antel
Coffee Break

11AM-12:30PM Morning Small Groups:
Write:
Bias and confounding in your study design; ways to address

12:30-1:30 PM Lunch

1:30-2:30PM Lecture:
Study Logistics, Quality Control and Budget – Karin vd Berg

2:30-4:30 PM Afternoon Small Groups:
Write:
Section on quality control and pre-testing

Required Reading (for next day):
Chapter 14: Addressing Ethical Issues

IMPORTANT: give your protocol to your designated peer reviewer by the end of today’s sessions so that he or she can read it overnight and then give you feedback during the peer review session on Friday.
8:30 AM-9:30 AM  Morning Lecture:
Human Subjects Considerations and Approvals – Estelle Verburgh

9:30 AM -12:30 PM  Morning Small Groups:
Peer review of research protocols (15 minutes each with coffee break in middle)

12:30-1:30 PM Closing session and farewell lunch

Required Reading:
None!
Title & your name

Research Question

Background and Significance (limit this to 1/2 page)

Study design
  what is your study design (e.g. cross-sectional, case-control)
  is it prospective or retrospective?
  nature of controls?

Study subjects
  selection criteria, target and accessible populations
  plans for sampling and for recruiting subjects

Measurements
  predictor variable(s) (intervention, if an experiment)
  outcome variable(s)
  potential confounding variables

Statistical issues
  Hypotheses, sample size estimates, analytic approach

Quality control and data management

Ethical considerations

References (not included in the 5-page limit)

Appendices (not included in the 5-page limit)
  Consent form
  Questionnaires and other data forms
  Budget: personnel and other expenses