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:
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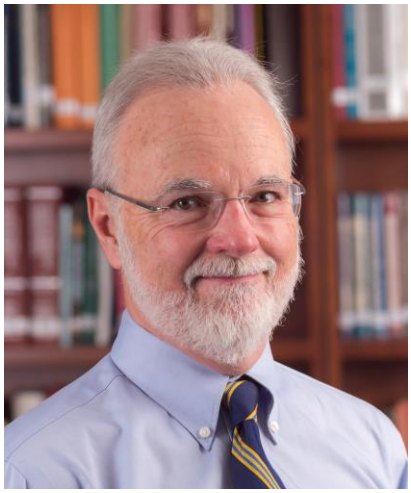
Course Faculty:



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:

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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

1:30-2:30PM 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.

Friday, April 27

8:30 AM-9:30 AM Morning Lecture:

Human Subjects Considerations and Approvals – Estelle Verburgh

9:30AM -12:30PM 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!

5 Page Protocol
Suggested Outline

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