

**International Course in Health Research Methodology
Zevenwacht, South Africa
January 28th to February 1st, 2010**

International Faculty

Bosch, Jackie
Devereaux, PJ
Furberg, Curt
Pogue, Janice
Probstfield, Jeff
Wittes, Janet
Yusuf, Salim

African Faculty

Levitt, D
Mayosi, B
MBewu, A.
Ntsekhe, M
Siegfried, N
Steyn, K
Tollman, S
Volmink, J

Arrival (28th January)

17:30-19:30 Faculty meeting to review content and structure of the course

19:30-22:00 Faculty dinner

Day 1 (29th January)

8:00-8:30 Why do we do clinical research and what are the approaches? S. Yusuf
Talk: 30 min

8:30-9:15 RCT presentation 1: P.J. Devereaux
Overview

1. What is an RCT?
2. Key aspects of RCT design
3. Applying the appropriate design to the appropriate phase
4. Parallel design trials
5. Large trials

Talk: 30 min, Discussion: 15 min

9:15-10:00 General presentation 1: C. Furberg
1. Study question
i. Components of a good study question
ii. Primary versus secondary questions

iii. Explanatory versus pragmatic questions

Talk: 30 min, Discussion: 15 min

10:00-10:30 Break

10:30- 11:15 General presentation 2: J. Volmink

2. Study population

- i. Wide versus narrow eligibility criteria
- ii. Generalizability

Talk: 30 min, Discussion: 15 min

11:15-12:40 General presentation 3: J. Bosch

Overview of the study intervention and outcomes

1. Study intervention

- i. Practical versus intensive interventions
- ii. Placebo or active controls
- iii. Approaches to enhancing compliance

Talk: 25 min, Discussion: 15 min

2. Study outcome:

J. Probstfield

- i. Primary versus secondary outcomes
- ii. Potential benefits and limitations of composite outcomes
- iii. Surrogate outcomes
- iv. Safety versus efficacy
- v. Different measures of efficacy (relative risk, absolute risk reduction, NNT, etc.)

Talk: 30 min, Discussion: 15 min

12:40-14:00 'Lunch with the media': International Press Conference organised by the MRC and addressed by the Minister of Health

14:00-14:40 RCT presentation 2: J. Pogue

Methodological issues

- 1. Concealment of randomization
- 2. Blinding
- 3. Analytic approaches - intention to treat principle, per protocol principle, as treated principle

Talk: 25 min, Discussion: 15 min

14:40-16:10 **Statistics for Trials:** J. Wittes

1. How big should my study be? Key judgments, components and approaches to sample size and other relevant aspects of study design

Talk: 30 min, Discussion: 15 min

2. The reliability and unreliability of subgroup analyses J. Probstfield

Talk: 30 min, Discussion: 15 min

16:10 – 16:55 RCT presentation 3:

Statistics

1. How do I analyze the results of my RCT? J. Pogue
2. Noninferiority trials

Talk: 30 min, Discussion: 15 min

16:55- 17:15 First day wrap-up, overview of next three days S. Yusuf

18:30-20:00 Reception

20:00 Dinner

Day 2 (30th January)

8:00-8:50 Assessing causality: The role of different methodological approaches
S. Yusuf

Talk: 30 min, Discussion: 20 min

8:50-9:40 Observational studies presentation 1: S. Tollman

1. Types of observational studies
 - i. Analytic studies
 - A. cohort studies
 - B. case-control studies
 - C. cross-sectional studies
 - D. surveys
 - E. Ecological studies
 - ii. Descriptive studies
 - A. case report
 - B. case series

Talk: 30 min, Discussion: 20 min

9:40: 10:40 Observational studies presentation 2: J. Wittes

Statistics for observational studies

1. Analytical Approaches for Observational Studies

Talk: 35 min, Discussion: 25 min

10:40-11:10 Break

11:45-12:35 General presentation 4: P.J. Devereaux
Key Aspects of Evaluating Diagnostic Tests

Talk: 30 min, Discussion: 20 min

12:35-12:45 Wrap-Up Day 2

12:45-14:00 Lunch

18:30-19:30 Reception

19:30-20:30 Discussion Groups

Is there a role for cohort studies in addressing CVD and Metabolic Disease research questions in South Africa?

Potential Discussion Group Leaders:

Baigent, C	Mayosi, B
Bosch, J	Siegfried, N
Devereaux PJ	Tollman, S
Furberg, C	Mbewu, A
Volmink, J	Opie, L
Wittes, J	Probstfield, J
Yusuf, S	

Day 3 (31st January)

- 8:00-8:20** Applicability of clinical trial results to clinical practice D. Levitt
- 8:20-9:20 RCT presentation 4: Journal Club
- Article 1: The POISE trial. (Lancet 2008;371:1839-47) (
- Study Presenter: M Ntsekhe
Facilitator: P.J. Devereaux
(Presentation: 10 min, Discussion: 30 min)
- 09:20-10:00** Observational studies presentation 3: Journal Club
- Article 2: The Argincourt study (Tollman S et al. Lancet 2008;372:893-901
- Study Presenter: L. Ntyintyane
Facilitator: S. Tollman
(Presentation: 10 min, Discussion: 30 min)
- 10:00-10:30** Break
- 10:30-11:20** Meta-analysis presentation 1: J. Pogue
Clinical Trials
- Talk: 30 min, Discussion: 20 min
- 11:20-12:00** Meta-analysis presentation 2: Journal Club
- Bongani –We thought a meta-analysis related to HIV would be appropriate hear.
Can you suggest an appropriate article? (N. Siegfried to suggest suitable article)
- Study Presenter: M. Engel
Facilitator: N. Siegfried
(Presentation: 10 min, Discussion: 30 min)
- 12:00-12:50** Meta-analysis presentation 3: P.J. Devereaux
Observational studies
- Talk: 30 min, Discussion: 20 min
- 12:50-13:00** Wrap-Up Day 3

13:00-14:30 Lunch

14:30-17:30 Investigators Meetings (HOPE3, PURE, IMPI)

18:30-19:30 Reception

19:30-20:30 Discussion Groups

Is there a role for new cohort studies in addressing CVD and Metabolic Disease research questions in South Africa?

Potential Discussion Group Leaders:

Bosch, J
Devereaux PJ

Furberg, C
Mayosi, B
Mbewu, A

Pogue, J
Siegfried, N
Tollman, S
Volmink, J
Wittes, J
Yusuf, S

Day 4 (1st February)

8:00-9:00 RCT & Observational presentation: Journal Club

Observational study

Grodstein F, Manson JE, Colditz GA, Willet WC, Speizer FE, Stampfer MJ. A prospective observational study of postmenopausal hormone therapy and primary prevention of cardiovascular disease. *Ann Intern Med* 2000;13 (12): 933-41.

Study Presenter: L Zuhlke

(Presentation: 10 min)

RCT

Writing Group for the Women's Health Initiative Investigators. Risks and benefits of estrogen plus progestin in healthy postmenopausal women. Principal results from the Women's Health Initiative randomized control trial. *JAMA*

2002;288(3):321-33

Study Presenter: K Steyn

(Presentation: 10 min)

Facilitators: S. Yusuf/J. Wittes

(Combined Discussion: 40 min)

9:00-9:40 General presentation 5: C. Furberg
Monitoring the Interim Results of Clinical Trials
Talk: 25 min, Discussion: 15 min

9:40-10:10 Long-term Participant Follow-up, Particularly in Trials with Mixed Results
J. Probstfield

10:10-10:25 Break

10:25-13:00 **Challenges in Conducting Research & Being a Researcher**

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| 1. Ensuring you have the right training and skills | P.J. Devereaux |
| 2. How to get trained as a researcher in South Africa | B. Mayosi |
| 3. Special challenges of becoming a researcher
and doing research in South Africa | D. Levitt |
| 4. Building a research program | C. Furberg |
| 5. Collaboration & team building | S. Yusuf |

Each presentation will be 15 minutes, followed by a 10-minute discussion.

There will be a final fifteen minute period at the end to have a general discussion.

13:00-13:30 Course Wrap-Up & Awards

13:30 Lunch and completion of course