

# **MSc in Clinical Epidemiology**

PROGRAMME BROCHURE

2015

Division of Community Health
Faculty of Medicine and Health Sciences
Stellenbosch University

www.sun.ac.za/clinepi

Clinical Epidemiology is the science of applying the best available research evidence to patient care. It uses the methods of epidemiology to find scientifically valid answers to questions concerning diagnosis, prevention, therapy, prognosis and aetiology, thus improving the evidence-base for the care of individual patients.

The course offers rigorous methodological training for those with a background or experience in a health-related discipline who wish to pursue a career in clinical research or evidence-based practice. The programme would be of interest to potential researchers who require robust training in research techniques, including advanced concepts and methods of epidemiology.

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# 1. OVERVIEW OF COURSE STRUCTURE

This is a 180 credit programme which consists of modules (120 credits) and a research project (60 credits).

| Types of learning activities | Credits             |
|------------------------------|---------------------|
|                              | 1 credit = 10 hours |
| Modules                      | 120                 |
| Research project             | 60                  |

# Nature and duration of programme

The programme is offered on a part-time basis over a minimum period of two years.

# Language specification

English

## **Modules**

Students need to do 10 modules, of which eight are compulsory and two elective.

## Compulsory modules

- Biostatistics I
- Biostatistics II
- · Diagnosis and Screening
- Fundamentals of Epidemiology
- Randomised controlled trials
- Research Proposal Writing and Grantsmanship
- Systematic Reviews and Meta-analysis
- Writing and Reviewing Scientific Papers

#### Elective modules (choose two)

- Clinical Guidelines
- Teaching evidence-based health care
- Infectious disease epidemiology
- Economic evaluation in health care
- · Health systems and services research
- Qualitative research methods for Health

**Duration of a module**: Semester (February – June or July – November)

When are core modules offered?

|        | Semester 1                              | Semester 2                                  |
|--------|---|---|
| Year 1 | Fundamentals of epidemiology            | Research proposal writing and grantsmanship |
| reari  | Biostatistics I                         | Systematic reviews and meta-analysis        |
| Voor 2 | Diagnosis and screening                 | Biostatistics II                            |
| Year 2 | Writing and reviewing scientific papers | Clinical trials                             |

When are elective modules offered?

| Semester 1 (year 2)                  | Semester 2 (year 1 and 2)               |
|--------------------------------------|---|
| Clinical guidelines                  | Qualitative research methods for health |
| Teaching Evidence-based health care  | Economic evaluation in health care      |
| Health systems and services research | Infectious disease epidemiology         |

#### Module structure

Modules are offered using a combination of face-to-face teaching and e-learning using Sun Learn, Stellenbosch University's online learning environment. Typically a module consists of

- 40 hours classroom time
- 80 hours self-study: reading / formal assignments / projects

#### Module assessment

50%: 2-3 formative assessments50%: summative assessment

Continuous and summative assessment of modules will be conducted through written examinations, oral presentations, written assignments and participation in discussions. A pass mark of 50% is required for each module, with a **45% sub-minimum** on formative and summative assessments. The student will be required to participate successfully and to integrate knowledge in projects, reports and assignments. An external examiner is appointed for every module. A candidate who fails any module may be denied the right to reregister for the programme.

Please note that we have to *enforce strict deadlines for all assignments*. Assignments handed in after the due date and time will not be marked. University guidelines related to *misconduct and dishonesty* will apply.

#### **Attendance**

Students should inform the module convener if they are going to be absent for more than one session in a block or in the semester.

- Students missing sessions must make their own arrangements to obtain material they have missed.
- Students should ensure that the examination weeks are kept free of any competing engagements.
- Semester timetables should be consulted well in advance.

#### Communication

Students should ensure that the programme administrator has all their contact details, including any change in email address. Communication will take place using Sun Learn and email.

#### **Short courses**

Some of the modules are available as short courses. Should a prospective full degree student have completed a short course offered by the programme, the student can apply for recognition of prior learning when entering the full degree programme.

# Research project

- Equal to one peer reviewed publication
- The completed research project must be submitted in the prescribed format and will be assessed by both internal and external examiners.
- Do familiarise yourself with the University Ethics and research integrity guidelines and procedures.

#### General:

All students should consult Part 1 of the University Calendar for general information related to studying with Stellenbosch University such as the code of conduct guiding the relationship between the supervisor and student, responsibilities of students, supervisors, etc.

http://www.sun.ac.za/university/yearbook/

# 2. ADMISSION REQUIREMENTS

To be eligible for application to the MSc (Clinical Epidemiology) programme

- The candidate shall hold an MB, ChB or equivalent degree; or a four-year professional bachelor's degree in a health-related discipline; or a BScHons degree in Medical Sciences of this University or another recognised university or an equivalent qualification approved by Senate.\*
- Mathematics at National Senior Certificate (NSC) level
- Computer literacy
- Fluency in written and spoken English
- Students will be selected on the basis of academic merit.
- \* Application by international students will be reviewed for equivalence of degree.

## **Application procedures:**

Full details of the application procedure is available on the programme website www.sun.ac.za.clinepi

Applications should include:

- Completed application form
- Letter of motivation
- Academic Record
- Proof of computer literacy
- Matric certificate

#### 3. STRUCTURED MODULES: OBJECTIVES AND CONTENTS

# i. Fundamentals of epidemiology

Conveners: Sade Adeniyi (Centre for Evidence-based Health Care) and Mark Engel

(University of Cape Town)

Requirements: Course entry requirements as outlined on page 6

#### **Objectives**

At the end of the course students will understand

- the history and development of clinical epidemiology
- how to frame research questions
- the principles, strengths and weaknesses of various study designs
- the different data sources
- measures of disease occurrence, measures of effect and association
- random error, bias, confounding and effect modification in epidemiological studies and how to deal with these issues
- how to determine causal links between exposure (treatment) and outcome
- epidemiological concepts related to Infectious diseases, occupational health and chronic diseases

- History and contribution of epidemiology
- Development of clinical epidemiology
- Framing research questions
- Strength and weaknesses of various study designs
- Data sources for clinical epidemiology
- Diagnosis and screening
- Measures of disease frequency/occurrence
- Measures of effect/association
- Random error
- Bias
- Confounding and effect modification
- External validity
- Causation
- Epidemiological concepts related to infectious diseases, occupational health and chronic diseases

#### ii. Biostatistics I

Convener: Tonya Esterhuizen (Centre for Evidence-based Health Care)

Requirements: Course entry requirements as outlined on page 6

## **Objectives**

At the end of this course students will be able to:

- Summarize statistical data using tables, graphs and appropriate summary statistics.
- Interpret significance tests and confidence intervals.
- Compare two samples using the student t test for continuous variables and the chisquared test for categorical data, in both paired and unpaired cases, calculate confidence intervals for the main results, and summarize the conclusions from such an analysis.
- Compare two samples using non-parametric tests, in both paired and unpaired cases, and summarize the conclusions from such an analysis.
- Use statistical software to present and analyze data.

- Descriptive statistics
- Probability and distributions
- Hypothesis testing, confidence intervals and non-parametric methods for:
  - One group
  - Two groups
- Implementing methods using statistical software

# iii. Research proposal writing and grantsmanship

Conveners: Tonya Esterhuizen (Centre for Evidence-based Health Care)

Requirements: Fundamentals of Epidemiology and Biostatistics I

# **Objectives**

By the end of the course students will be equipped with the tools needed to write and implement a protocol for a clinical research project.

#### Contents

The focus of this course will be on the principles of quantitative research methodology

- Select a topic and develop a well formulated research question
- Conduct a literature review including literature searching (different information sources, how to structure a database search, how to conduct a search effectively and efficiently)
- Reference management using for example Endnote
- Sampling techniques
- Sample size and power calculations
- Data collection strategies including questionnaire design and development
- Data analysis plan and data management
- Create a statistical analysis plan detailing the major steps in the statistical design and analysis of a study
- Ethics and preparing an application to research ethics committees
- Research integrity
- Appropriate funding bodies and procedures for grant applications and their assessment
- Grant proposal writing
- Grantsmanship
- · Compiling a biosketch

# iv. Systematic reviews and meta-analysis

Conveners: Taryn Young and Anel Schoonees (Centre for Evidence-based Health Care) and Tamara Kredo (SA Cochrane Centre, SA Medical research Council) Requirements: Fundamentals of Epidemiology and Biostatistics I

## **Objectives**

This module will enable students to understand the methods for conducting a systematic review to answer a clearly defined question about an intervention.

- Rationale for research synthesis
- Types of systematic reviews including Cochrane Reviews
- Accessing systematic reviews
- Formulating a review question
- Searching for evidence
- Study selection and data extraction
- Assessing risk of bias and quality of the evidence (GRADE)
- Synthesizing the evidence including narrative and quantitative methods
- Investigating publication bias
- Using systematic reviews Incorporating evidence into practice

#### v. Randomised controlled trials

Conveners: Hassan Mohamed (Community Health)

Requirements: Fundamentals of Epidemiology and Biostatistics I

## **Objectives**

To understand the design, conduct and practicalities of successful randomized controlled trials

#### Contents

Principles of comparative trials in investigating effectiveness, efficacy and safety of treatments

- Main features of different types of trials (strength and weakness of each design together with the implications for sample size requirements, analytic methods, interpretation and reporting)
- Ethics
- Good Clinical Practice and regulatory requirements
- Principles of trial conduct
- Reporting

Basic statistical methods used in randomized controlled trials

- How to select and apply appropriate statistical measures
- Presenting and interpreting results

#### **Practicalities**

- Recruitment strategies
- Data management
- Trial governance
- Quality assurance and control
- Participant retention

#### vi. Biostatistics II

Conveners: Tonya Esterhuizen (Centre for Evidence-based Health Care)

Requirements: Fundamentals of Epidemiology and Biostatistics I

## **Objectives**

At the end of this module, participants would be able to:

- Select and use appropriate statistical methods in the analysis of simple datasets and apply these methods by computer using a statistical package
- Present findings based on statistical analysis in clear, concise and understandable manner
- Understand and interpret output from statistical analyses carried out by computer, in relation to research and other questions being asked
  - Analysis of variance
  - linear regression
  - logistic regression
  - o survival analysis

- ANOVA
- Correlation
- Simple and multiple linear regression
- Logistic regression
- Survival analysis
- · Adjusting for confounding

# vii. Writing and reviewing scientific papers

Conveners: Charles Wiysonge and Taryn Young (Centre for Evidence-based Health Care) Requirements: Fundamentals of Epidemiology and Biostatistics I

#### **Objectives**

By the end of the module students would have

- a thorough grasp of the principles of critical appraisal as it applies to health care and the application and implementation of evidence in practice and policy.
- knowledge of the required structure, language and approach to writing a scientific paper or report.

- Phrasing answerable questions
- Critical appraisal of scientific papers covering the following research methodologies:
  - Randomized controlled trials (evaluating effects of treatment)
  - Cohort studies
  - Case control studies
  - Cross-sectional studies
  - Diagnostic studies
  - Systematic reviews
  - Economic evaluation of a health care intervention
- Writing a paper
  - Approaching a writing project
  - Structure of a paper
  - Effective presentation of data
  - Scientific language and style
  - Reviewing and improving your writing
  - Submitting the manuscript for publication
  - Other (dealing with editors and reviewers, plagiarism, correcting proofs, legal issues)

# viii. Diagnosis and screening

Conveners: Charles Okwundu (Centre for Evidence-based Health Care), Megan Rensburg

and A Zemlin (Chemical Pathology)

Requirements: Fundamentals of Epidemiology and Biostatistics I

## **Objectives**

At the end of the course students will understand

- · the principles and practice of disease screening
- the principles and practice of diagnostics

#### **Contents**

### Screening

- Validity of a test
- Receiver operator curves
- Reliability of test
- Likelihood ratios
- Predictive values
- Deciding on a screening programme (criteria of test, disease and screening programme)
- Implementing and evaluating screening programmes (special biases)
- Adverse effects of screening

## Diagnosis

- Test accuracy
- Multiple test
- Designing a diagnostic accuracy study
- Critical appraisal of diagnostic studies
- Systematic review of diagnostic studies

# ix. Clinical guidelines

Conveners: Tamara Kredo (SA Cochrane Centre, SA Medical research Council) and

Quinette Louw (Division of Physiotherapy)

Requirements: Fundamentals of Epidemiology and Biostatistics I

## **Objectives**

After completing the course, students will be able to

- describe the principles of development of evidence based guidelines
- outline the steps of guideline development
- describe the rationale for guideline adaptation
- outline the steps of guideline adaptation
- critically appraise guidelines
- describe the barriers and enablers of implementation strategies
- select appropriate interventions for an implementation plan
- select measures to use as audit tools to demonstrate practice change
- develop a guideline implementation plan

- Rationale for developing and using evidence informed guidelines
- Guideline adaptation and development
- · Decision analysis in guideline development
- Adapting and developing locally appropriate guidelines (community/hospital/private sector-based)
- Critical appraisal of guidelines
- Guideline implementation
- Evaluating the effectiveness of a guideline implementation plan by identifying and applying appropriate clinical audit measures

# x. Teaching Evidence-based Health Care

Conveners: Susan v Schalkwyk (Centre for Health Professions Education) and Taryn

Young (Centre for Evidence-based Health Care)

Requirements: Fundamentals of Epidemiology and Biostatistics I

#### **Objectives**

By the end of this course participants will:

- Be able to describe current concepts of how people learn
- Be able to write learning outcomes for teaching EBHC to a particular audience
- Be able to describe various teaching methods which promote active learning
- Have experienced some of the methods which promote active learning
- Have delivered and evaluated a teaching module in EBHC for a particular target audience and setting by:
  - Developing and selecting relevant teaching materials
  - Employing appropriate methods of teaching
  - Developing and using appropriate assessment and evaluation tools.

- How people learn
- Learning outcomes and how to write them
- Methods of instruction to facilitate learning
- Evaluating your teaching
- Presentation skills
  - Graphic presentation of data
  - Use of slides
  - Oral presentation skills
- Developing a teaching plan and delivering the lesson
  - o Select the EBHC topic (from one of the 5 A's) for your audience and setting
  - Plan the teaching interaction
  - Develop and select appropriate materials
  - Deliver the lesson(s)
  - Reflection, eliciting feedback and (summative) reporting.

# xi. Infectious disease epidemiology

Conveners: Jean Nachega (Centre Infectious Diseases) and Peter Nyasulu (Monash

South Africa)

Requirements: Fundamentals of Epidemiology and Biostatistics I

#### **Objectives**

After completion of the module the student will be able to:

- describe and understand the main epidemiological characteristics of the major infectious diseases
- describe how these epidemiological characteristics can be utilized to develop and evaluate strategies to prevent epidemics or endemic transmission of the major infections
- investigate an outbreak
- discuss transmission dynamics and mathematical modelling of epidemics
- discuss routine and sentinel surveillance
- · discuss the role of observational studies in infectious disease epidemiology
- discuss how experimental studies are used to evaluate efficacy and effectiveness of treatment and control measures

- definitions and nomenclature
- outbreak investigation
- transmission dynamics
- disease surveillance
- epidemiological studies and modelling
- vaccination efficacy and effectiveness
- epidemiology applied to HIV/AIDS, TB, STIs and other communicable diseases.

#### xii. Economic evaluation of heath care

Conveners: Lungiswa Nkonki (Community Health)

Requirements: Fundamentals of Epidemiology and Biostatistics I

#### **Objectives**

At the end of the module students will be able to understand and apply fundamental economic evaluation methods, in particular to

- to gain insights into theory and application of economic evaluation in health care;
- ii) to develop an understanding of economic evaluation techniques, their application and analysis;
- to develop skills in designing and conducting cost analysis, costeffectiveness analysis, cost-utility analysis and cost-benefit analyses with an aim of informing policy formulation and implementation process.

- Principles of economic evaluation
- Costing
- · Discounting, annualisation
- Cost benefit analysis
- Cost effectiveness analysis
- Cost utility analysis
- Uncertainty and sensitivity analysis
- Modelling in economic evaluation

# xiii. Health Systems and Services Research

Conveners: Lilian Dudley (Community Health)

Requirements: Course entry requirements as outlined on page 6

#### **Objectives**

After completion of the module the student will be able to

- Apply appropriate scientific principles and methods to the evaluation of health care;
- Evaluate dimensions of effectiveness, efficiency, humanity and equity of health services;
- Conduct a programme evaluation in health care;
- Assess the quality of health care;
- Conduct a health survey;
- Understand and interpret health systems and services research publications.

- Introduction to health care evaluation and health services research
- · Measurement of effectiveness, efficiency, equity and humanity in health care
- Health programme evaluation
- Measurement of quality of health care
- Health survey design

#### xiv. Qualitative Research Methods for Health

Conveners: Donald Skinner (Community Health)

Requirements: Course entry requirements as outlined on page 6

#### Objectives

After completion of the module the student will be able to

- Understand the role and philosophy of qualitative methods with the broader research framework
- Be able to write a qualitative protocol
- Be able do a qualitative interview, understand the running of focus groups and be able to observation research
- Be able to transcribe an interview and to prepare the material for analysis
- Be able to analyse qualitative data using a content analysis approach
- Be able to write a qualitative report
- Be able to critique a qualitative paper

#### **Contents**

The module is intended as an overview of qualitative methodology and to provide direct practical training in qualitative tools. As such the module will cover

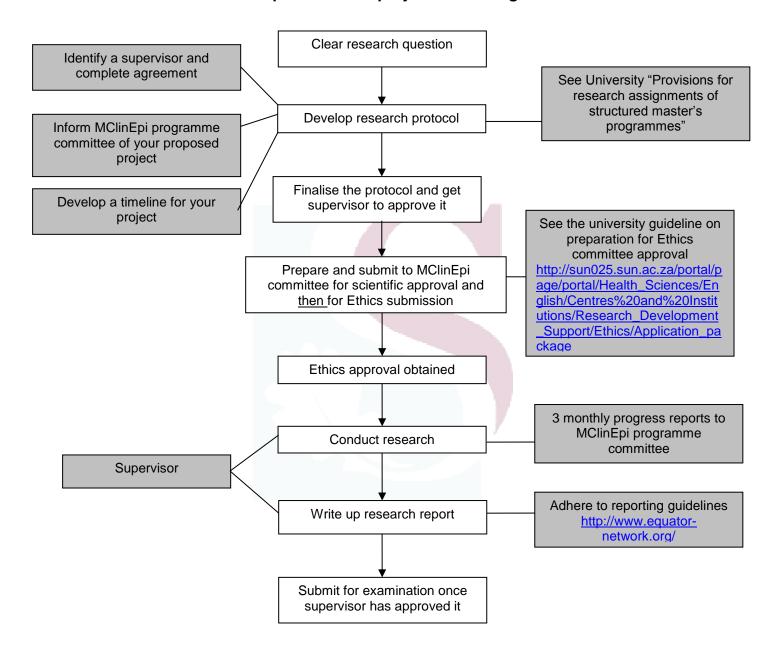
- the background and philosophy behind qualitative methods,
- an introduction and experience in the three major methods of data collection and analysis,
- other key methodological issues such as sampling and ethical issues

The assignments for the course take the participant through all phases of a very small qualitative study, including design of the study, data collection and analysis.

# 4. RESEARCH PROJECT (60 CREDITS)

The research project must be conducted on a relevant research question using a quantitative research design. Each student must have a supervisor who is affiliated with Stellenbosch University and can, in addition, have an external co-supervisor.

MClinEpi - Research project - flow diagram



The conduct of the research needs to adhere to research integrity and ethical principles of Stellenbosch University. Students are responsible to be familiar with these policies:

- SU Policy on Academic Integrity: The Prevention and Handling of Plagiarism
- Framework Policy for the Assurance and Promotion of Ethically Accountable Research at Stellenbosch University

#### Useful resources:

http://www.singaporestatement.org/

http://publicationethics.org/international-standards-editors-and-authors

The research project must be submitted as a completed manuscript for a (preferably subsidy-bearing) peer-reviewed scientific journal (i.e. that appears on the list of the approved scientific journals of the Department of Higher Education and Training) with the candidate as first author. This must comply with requirements as set out in the *Instructions for authors* of the relevant scientific journal including word count and referencing style and should align with good reporting guidelines <a href="http://www.equator-network.org/">http://www.equator-network.org/</a>.

The final submission should include the following:

#### **Declaration**

See "Provisions for research assignments of structured masters programmes" for the format.

## Part A: Completed manuscript

The completed manuscript must comply with requirements as set out in the *Instructions for authors* of the relevant scientific journal including word count and referencing style. The word count is typically 3000-4000. Supervisors will assist candidates to identify an appropriate journal. The article does *not* have to be submitted to the journal in order to meet academic requirements.

#### Part B: Appendices

These will vary with the study but should typically include:

- a. Relevant journal Instructions to Authors
- b. Questionnaire/data capture instrument(s) (as prepared originally for protocol)
- c. Ethics consent form(s) (as prepared originally for protocol)
- d. Selected tables or figures, with brief explanatory text, that would be useful for the examiner to see as part of the analyses, but which could not be included in the article due to word restrictions. This should not simply be a collection of analysis printouts but should be readable as an addendum with reference to the article.
- e. Any technical appendices needed for example, laboratory techniques, statistical formulae.
- f. Acknowledgements

#### **Submission process**

Two copies of the dissertation must be submitted, in temporary binding to the MSc Clinical Epidemiology Programme Coordinator. The submission deadline for December graduation is 1 September, and for March graduation it is 1 December.

*NOTE:* The programme coordinator must be informed 3 months in advance of the intention to hand in the research project.

We encourage MClinEpi students to submit their research projects for publication. In doing so, do be reminded that the Division of Community Health, Stellenbosch University, should be stated as an affiliation. If you have more than one affiliation, the Division of Community Health should be stated as a secondary affiliation.

Kindly also acknowledge MClinEpi as follows – This research project has been conducted as part of the academic requirements of the MSc in Clinical Epidemiology <a href="https://www.sun.ac.za/clinepi">www.sun.ac.za/clinepi</a>, Stellenbosch University.

The Faculty offers incentives to those who publish (for further info, Sasley Beukes can be contacted: sasleyb@sun.ac.za).

#### 5. BURSARIES

SURMEPI (Stellenbosch University Rural Medical Education Partnership Initiative) <a href="http://surmepi.sun.ac.za/">http://surmepi.sun.ac.za/</a> is offering bursaries for Masters and PhD students conducting research in rural or underserved areas, or on relevant aspects of healthcare in rural or underserved areas. Bursaries are allocated on a competitive basis, based on academic merit and financial need.

Novartis offers bursaries to students registered for full programme only i.e. students doing the components making up the 180 credits. Bursary funds can be used towards course related expenses such as class fees, textbooks, STATA software licenses and living expenses. For more information on the application procedure contact the MClinEpi administrator.

General bursaries: do look in the general University bursary booklet



# **SURMEPI**



Stellenbosch University Rural Medical Education Partnership Initiative

#### Aims:

- To increase the number and quality of health care workers in rural areas
- Retain health care workers over time and in areas where they are most needed
- Increase the capacity for regionally relevant research

Pioneering innovative medical education models to improve capacity, retention and recruitment of medical graduates in Sub-Saharan Africa

http://surmepi.sun.ac.za/

## 6. WHAT DO MSC CLINICAL EPIDEMIOLOGY STUDENTS SAY?

'Graduating with a M.-degree in Clinical Epidemiology defines a turning point in my career. While working as a doctor in primary health care I felt a strong need to learn more about practicing evidence-based medicine and understanding clinical research and literature. The course provided these vital skills but also gave trained me in planning and executing a study. Furthermore, the course provided a great framework for understanding biostatistics, taught me to write-up and present results and presented a wonderful opportunity to network with people who share my interest in research.'

'The MSc in Clinical Epidemiology has been a most enlightening and empowering experience. Enlightening as it revealed my glaring inadequacies in my understanding of evidence-based medicine and how to implement it and empowering as it has now provided me with the tools to evaluate scientific research and articles and critique them objectively. It has also allowed me to assist postgraduate students with developing and designing their research projects. I certainly would have liked to have followed this course many years ago.'

#### 7. CONTACT DETAILS

## Programme coordinator

**Prof Taryn Young** 

Faculty of Medicine and Health Sciences, Stellenbosch University

Tel: +27 21 938 9452/9157 Email: tyoung@sun.ac.za

#### **Programme administrator**

Division of Community Health

Faculty of Medicine and Health Sciences, Stellenbosch University

Tel: +27 21 938 9157 Fax: +27 21 938 9723

E-mail: mclinepi@sun.ac.za

#### International office

Co-ordinator: Postgraduate International Students

Mrs Rachel Pullen Tel: +27 21 938 9086 E-mail: crp@sun.ac.za

#### Postgraduate office

Coordinator: Postgraduate Studies

Ms Yolokazi Ntungwa Tel: +27 21 938 9811 Fax: +27 21 933 6330 E-mail: yolokazi@sun.ac.za