1st year:	**Module 2**
Module Title:	**Epidemiology and Evidence Based Practice: designs**
Number of Credits:	**12 EC**
Module leaders:	**G.S. de Wolf, MSc**
Lecturers:	**E. Bakker, PhD / M. Leeflang, PhD / B. Snoeker, MSc**

Aim of the module

During this module students learn the basic principles and research methods around two essential themes: 1) research aimed at evaluating causality (e.g. risk factors of developing disease, or (side)effects of intervention) and 2) research aimed at evaluating probability (e.g. chances of correct diagnosis, or chances of outcome of disease (prognosis)). In addition, students learn how to critically appraise a reported study around these themes, and train their skill in scientific writing.

Overall synopsis

With an experimental study design (RCT) as a working example, basic principals of research into causal relationships are introduced. Students are given a historic overview of the philosophy of causality and its modern principals. Using these, the concept of confounding and methods for correction in observational study designs (cohort and case-control design) are introduced. Students are trained to recognize the aforementioned in published research and are stimulated to design original studies in this manner. Principals of research into diagnostic accuracy are introduced as an example of probabilistic research. Different calculations of diagnostic accuracy are introduced as measures of probability. Sources of bias and variation in these calculations are reviewed. Students are introduced into the methods and considerations of sudies into patient prognosis and how to combine different prognostic factors into one coherent predictive model.

Learning outcomes as a whole

- The student knows the methodological benefits and drawbacks of different types of (pre)experimental designs, as well as their ethical boundaries.
- The student is able to select an appropriate design to study a given clinical question.
- The student is able to predict and avoid different sources of bias in research.
- The student can identify strengths and weaknesses in evidence around the two essential themes of causation and probability
- The student is able to calculate and to interpret frequently used statistical measures fluently. (OR, RR, NNT, NNH, sensitivity, specificity, likelihood ratio, DOR, survivaltime analysis)
- The students has knowledge of ethical considerations in medical research

Assessment strategy

Knowledge of clinical epidemiology will be tested via an exam with open-ended questions.

Notes:

Final mark for this module will only be granted when a peer-reviewed “Letter to the editor” is turned in.

Session 1: Lecture – Causal research I - Philosophy of Causation
Student understands benefits of RCT; knows of problems of executing RCT & knows of problems analyzing RCT.

Session 2: Lecture – Causal research II - Studying Intervention
Students can apply the three scientific views on causality when critically appraising a report aimed at establishing causality.

Session 3: Lecture – Causal research III - Observational Studies - Design
Student can name limitations of RCT to identify Risks; Student has knowledge of different designs for observational studies; Student can discuss benefits and limitations of each design; Student can recognize threats to internal validity in observational studies; Student can apply techniques to counter these threats.

Session 4: Lecture – Causal research IV – Observational Studies - Analysis
Student can apply different stratergies to counter (or correct for) a major source of bias caused by confounding by indication.

Session 5: Tutorial - Critical Appraisal Causal Research
Student can differentiate between reasons for critical appraisal; Student can appraise the internal validity of an individual study; Student can rate the limitations to validity as minor or as impairing (red flags); Student can reason on shifts in final results, due to minor problems in validity; Student can reason on applying the results to individual patients or on generalizing to groups of patients

Session 6: Lecture – Probabilistic Research III - Studying Diagnosis
Student can describe and explain the parameters for analysis of research studying diagnosis; Student can describe the basic cross-sectional research design for studying diagnosis; Student can name the main methodological issues concerning internal and external validity in cross-sectional designs for studying diagnosis

Session 7: Lecture – Probabilistic Research I - Probability and Prognosis
Student can describe and explain the design and analysis of research studying prognosis; Student can name methodological issues concerning internal and external validity in research studying prognosis

Session 8: Lecture – Probabilistic Research II - Modelling Prediction
Student can name, describe, and explain the phases of derivation, validation, and impact analysis of prediction models; Student can name and explain the four levels of evidence for prediction models

Session 9: Lecture – Probabilistic Research IV - Critical Appraisal Probability
Student can name, describe, and explain the main methodological issues concerning internal and external validity in prognosis studies; Student can name, describe, and explain the various sources of bias and variation in diagnostic accuracy research; Student can explain the consequences of bias and variation for parameters of diagnostic accuracy

Session 10: Lecture – Putting it all Together
This lecture will recapture the highlights of previous lectures. Four research proposals (of actual studies) will be presented; an intervention study, an ethiological study, a diagnostic study and a prognostic study. During the presentations issues of study design will be highlighted and discussed.