Master's Programme

Master Epidemiology

Fac. Health, Medicine and Life Sciences

Introduction to Epidemiology

Full course description

The course is the first module in the Epidemiology and Health Sciences Research master's programmes and will take place during a 5-day period in which the participants will be acquainted with the basic principles of epidemiological research. These include measures of disease frequency and exposure measurement, basic health measurement (clinimetrics), basic study design (including randomized controlled trials, cohort studies, case control studies, and cross-sectional studies), measures of association, validity and bias in epidemiological research, and a brief introduction of systematic literature review/meta-analysis.

The main aims of the course are to enable the participants to appreciate the basic concepts of epidemiology and critically assess epidemiological studies (e.g., research papers or research protocols). For this, use will be made of lectures, group discussions, and small practical individual or group assignments (e.g., questions or calculations related to the topic of the preceding lecture).

The course will be attended by students of the Epidemiology and Health Sciences Research master's programmes. Besides these students, the course will be available as a stand-alone course for anyone who wants to become acquainted with basic epidemiological methods.

Course objectives

Knowledge and understanding

The course participant:

- Is able to distinguish between various measures of frequency of health outcomes (i.e. cumulative incidence, incidence density, point prevalence, period prevalence, life-time prevalence)
- Has basic knowledge of and insight into the principles of classifying health and disease outcomes
- Is able to distinguish between the various types of health measurement scales and the relevant aspects of the quality of a health measurement scale (i.e. validity, reliability, sensitivity-to-change)
- Is able to distinguish between various measures that quantify the strength of association between determinants and health outcomes (i.e. risk difference, risk ratio, rate ratio, attributable proportion)
- Is able to distinguish between various study designs in epidemiology (i.e. ecological studies, cross-sectional studies, cohort studies, case-control studies, and randomized controlled trials)
- Has knowledge of and insight into relevant aspects of the design/choice of the study

population (e.g., inclusion and exclusion criteria, eligibility considerations, source for selection, recruitment procedures).

- Is able to identify the major advantages and disadvantages of the different epidemiological study designs
- Knows the difference between internal validity and external validity of epidemiological studies
- Appreciates the potential threat of bias (selection bias, information bias, confounding) to the internal validity of an epidemiological study.
- Appreciates the difference between confounding and effect modification (interaction).
- Appreciates various design measures to prevent bias or to adjust for bias in observational research (restriction, matching, standardization, stratified analysis, blinded measurement, use of independent data sources)
- Has basic knowledge of and insight into the main principles and procedures of diagnostic test (strategy) development and evaluation
- Is able to distinguish between the various types of literature review (e.g., narrative review, systematic review, meta-analysis) and to identify the advantages and disadvantages of these types of literature review
- Is able to identify the subsequent steps of a systematic literature review.

Making judgments

• The course participant is able to recognize and assess the general quality of an epidemiological study (e.g., a research protocol or a research paper)

Recommended reading

Basic literature For this introductory course in epidemiology use will be made of basic epidemiology book: - Webb P, Bain C. Essential Epidemiology: An Introduction For Students And Health Professionals. Cambridge: Cambridge University Press; 2016. Advised literature for students without SPSS experience: - Field A. Discovering statistics using IBM SPSS statistics; 5th ed. London: Sage Publications Ltd, 2017.

EPI4920 Period 1 30 Aug 2021 3 Sep 2021 Print course description ECTS credits: 1.0 Instruction language: English Coordinator:

• <u>B.A.J. Verhage</u>

Teaching methods: Work in subgroups, Lecture(s), PBL Assessment methods: Attendance Fac. Health, Medicine and Life Sciences

Observational Research

Full course description

Observational research is aimed at studying the occurrence of phenomena that are "naturally" present in the population or society, and characteristics that are associated with these phenomena. Because experimental (intervention) research is not feasible for many relevant health issues, observational research is often needed to answer these questions. This can concern research on cause and effect aimed at (genetic and environmental) factors influencing the etiology or prognosis of diseases, factors that can explain specific behaviour, or descriptive research. Observational research forms the cornerstone of epidemiological research.

This module elaborates theoretical and practical aspects of observational research. Moreover, quantification of a number of methodological phenomena, such as confounding and effect modification will take place. Students will learn to evaluate various observational designs regarding strengths and weaknesses, depending on the setting where these designs are being applied. By means of lectures, exercises and skills training sessions attention will be paid to the following aspects: Observational research designs and their advantages and disadvantages: case-control studies, cohort studies, nested case-control and case-cohort designs, correlation study, crosssectional research; Choosing among designs; Exposure measurement in observational research and potential misclassification; Sources of bias in various designs: selection bias, confounding and information bias. Illustration and quantification of these terms in different designs, and ways to deal with bias; Stratified and matched analyses; Effect modification and statistical analysis procedures; Causal reasoning and causal diagrams; Application of these analysis techniques in different observational research designs; Reporting guidelines for observational research. Students who register are requested to work on practical assignments regarding statistical analyses using existing datasets, in addition to intensive course participation. The course will be concluded with a written test.

Course objectives

- Principles and practice of observational studies
- Designs for etiologic and prognostic epidemiologic research
- Hybrid designs: Nested case-control studies + case-cohort studies
- Selection bias, information bias (misclassification) and confounding
- Matching, stratified analysis, Mantel-Haenszel testing, standardization
- Evaluation of effect modification (interaction)
- Causal inference, causal diagrams, principles of causal reasoning
- Reporting of observational studies in epidemiology: STROBE

Prerequisites

Basic Textbook: Szklo M, Nieto J. Epidemiology Beyond the Basics. Jones and Bartlett Learning, 2019 (fourth edition). Other literature from scientific journals will be made available through the Reference List in the Student Portal > My Courses

EPI4921 Period 1 6 Sep 2021 22 Oct 2021

Print course description

ECTS credits: 6.0 Instruction language: English Coordinator:

• P.A. van den Brandt

Teaching methods: Assignment(s), Work in subgroups, Lecture(s), Paper(s), PBL, Training(s) Assessment methods: Assignment, Attendance, Written exam Keywords: Cohort study Case-control study Nested case-control study Case-cohort study Selection bias Confounding Interaction Matching Stratified analysis Causal diagrams Fac. Health, Medicine and Life Sciences

Intervention Research in Health Care

Full course description

There are various aspects to take into consideration when constructing an RCT and many of the issues involved will be discussed in lectures, through practical and discussion groups: design options, issues in good clinical practice such as informed consent, blinding, process evaluation, power calculation and randomization, missing values and data-analyses in general.

As there are many potential errors associated with health services research, this module will focus on various key features of RCT design, with particular emphasis on design, validity and dataanalysis.

A well-designed, methodologically sound RCT evaluating an intervention can provide strong evidence of a cause-effect relation if one exists. These studies are often used to chance practice and taken up in guidelines, being the ultimate goal of research on therapeutic effectiveness. On the other hand, poorly designed studies are dangerous because of their potential to influence practice based on flawed methodology.

The umbrella term 'intervention study' refers to those study designs in which one or more independent variables are manipulated by the investigator, whereas the other independent variables are kept constant or controlled at the same time. This 'experimental' approach is regarded the most powerful study design for discovering causal relationships and can be the sturdiest ways of doing research, however, has many ethical and design issues to be taken into account. This module will focus on experimental research in human beings outside the laboratory. 'Clinical trial' is a common name to indicate this type of experiments especially as it is often used to assess the efficacy and effectiveness of a new treatment for patients.

Course objectives

Knowledge and understanding

Ability to distinguish between various classes of intervention studies (e.g. pre-experimental, quasiexperimental and true experimental designs; parallel group designs, cross-over designs, N-of-1 design, non-inferiority trials etc). 1.

Knowledge of and insight into the rationale of and prerequisites for experimental intervention research. 2.

Knowledge of the historical development of intervention trials. 3.

Ability to identify the core elements of the 'classic' intervention study design (RCT = parallel, placebo-controlled, double-blind, randomized trial): choice of study subjects (in- and exclusion criteria, study size), choice of outcome measures and follow-up time (PICOT). Ability to choose intervention strategies and contrasts, informed consent procedure, randomization, prestratification, blinding, dealing with protocol deviations (drop-outs, non-compliance, missing values), registration of (serious) adverse events. 4.

Ability to distinguish between various alternative intervention study designs (e.g., cross-over design, factorial design, Latin square design, prerandomization design (Zelen design), sequential analysis approaches, N of 1 trial designs, group-randomized trial design). 5.

Ability to distinguish between alternative methods of random allocation of trial participants: adaptive vs. fixed allocation randomization procedures (e.g., simple randomization, stratified randomization, block randomization, response randomization, replacement randomization, biased coin method, minimization, balancing, unequal randomization). 6.

Knowledge of and insight into relevant aspects of the design/choice of the study population (e.g., inclusion and exclusion criteria, eligibility considerations, source for selection, recruitment procedures, patient registration). 7.

Knowledge of and insight into relevant aspects of the design/choice of the intervention (e.g., treatment schedule (route of administration, dosage, duration), intervention contrast (placebo, usual care), dealing with co-interventions). 8.

Knowledge of and insight into relevant aspects of the design/choice of outcome measurement (e.g., primary vs. secondary outcome measures, timing of measurements, quality aspects (validity, reliability, sensitivity-to-change / responsiveness), intended vs. unintended effects). 9.

Ability to identify pros and cons of a run-in period (qualification period). 10.

Knowledge of and insight into the role of placebo intervention within the context of a randomized trial. 11.

Knowledge and insight into the characteristics and differences between pragmatic and explanatory designs regarding designing, performing and interpreting the results of such trials 12.

Knowledge and understanding of the so-called mixed methods designs. Designs were a combination of quantitative and qualitative research methods are used 13.

Knowledge, understanding and skills regarding procedures that deal with protocol violations. 14.

Knowledge of and insight into strategies and procedures of statistical analysis of intervention trial results (e.g., intention-to-treat vs. per-protocol (valid cases) analysis, appropriate statistical techniques). 15.

Knowledge, understanding and skills regarding procedures for sample size and power calculation in intervention trials and more in general. 16.

Ability to interpret the results of an intervention trial and to draw balanced conclusions with respect to the effectiveness of an intervention. 17.

Knowledge of and insight into the requirements for intervention trial protocols and reports. 18.

Knowledge of and insight into planning, organizational, administrative and other practical aspects of intervention trials (e.g., documentation, design of forms, standard operating procedures (SOPs), data management, audits, multicentre trials). 19.

Knowledge of and insight into the ethical and legislative aspects of intervention trials (e.g., METC-procedures, WMO, GCP, international harmonization, requirements). 20.

Recommended reading

Basic literature - Friedman LM, Furberg CD, DeMets DL, Reboussin DM, Granger CB. Fundamentals of clinical trials; 5th ed. New York: Springer, 2015. (eBook or hardcover). Suggestions for further reading - Meinert CL. Clinical trials; design, conduct and analysis; 2nd ed. New York: Oxford University Press, 2012. (Also available as eBook). - Pocock SJ. Clinical trials: a practical approach. Chichester: John Wiley & Sons, 1983. - Fleiss JL. The design and analysis of clinical experiments. New York: John Wiley & Sons, 1986 (new edition: 1999). Published online: 28-1-2011 (Wiley Online Library). - Weiss NS. Clinical epidemiology: the study of the outcome of illness. New York: Oxford University Press, 1998. - CONSORT group. The CONSORT (Consolidated Standards of Reporting Trials) website. CONSORT documents: http://www.consort-statement.org/. - ICH Expert Working Group. ICH Harmonised Tripartite Guideline: Guideline for Good Clinical Practice E6(R1). Geneva: ICH, 1996.

EPI4922 Period 1 6 Sep 2021 22 Oct 2021 Print course description ECTS credits: 5.0 Instruction language: English Coordinator:

• <u>C.H.G. Heuts - Bastiaenen</u>

Teaching methods: Assignment(s), Lecture(s), Work in subgroups, PBL, Skills, Paper(s) Assessment methods: Assignment, Attendance, Written exam Keywords: Randomized controlled trials, Pragmatic versus Explanatory trials, experiment, Randomisation, bias Fac. Health, Medicine and Life Sciences

Advanced Statistical Analysis Techniques

Full course description

The major objective of this course is to prepare students optimally for the use of statistics in their practical work and the period after. The student is taught to apply the most commonly used statistical analysis techniques in a responsible way. Also should he be better able to judge the statistical facets of research as carried out by others.

The training aims at applying advanced statistical techniques in a responsible way. The emphasis will be on concepts underlying the statistical techniques and on interpreting the results, with the mathematics being kept to a minimum. The course material is primarily based on SPSS software. The use of R and STATA will only be briefly approached.

The following techniques will be treated

Analysis of variance and (co)variance

- 1. Linear regression
- 2. Logistic regression
- 3. Analysis of survival times
- 4. Analysis of repeated measures (linear multilevel models)

For each topic there are two lectures and two tutorials. During the first tutorial, theoretical issues are discussed while emphasis on the interpretation of results obtained with SPSS on real data sets is given in the second tutorial. Concerning the lectures, the first one is more theoretical and involves the presentation of the method and the assumptions behind. In particular, the consequences of violating the assumptions are investigated. The practical interpretation of software outputs is also of great interest. In the second part, we analyze a real dataset together and debate over the best choices to make to analyze the data. Then, we discuss how the results can be summarized to be presented to an audience with minimal statistical knowledge.

Course objectives

After completing this unit the participants should have acquired the knowledge and skills required for the independent use and critical assessment of various (multivariable) statistical analysis concepts, procedures and techniques which are prominent in epidemiological research:

- 1. Analysis of variance and covariance.
- 2. Linear regression analysis techniques
- 3. Logistic regression analysis for binary outcome variables
- 4. Analysis of survival data
- 5. Analysis of repeated measurements (linear multilevel models)

For each of this statistical technique, the participant should be able to deal with confounding, interaction and outliers, be aware of the assumptions underlying the use of the technique, know some advantages and disadvantages of the technique, interpret results and use dummy coding. The participant should also be able to choose an appropriate statistical analysis strategy, given a specific epidemiological research question and study design.

Recommended reading

Basic literature - Field A. Discovering statistics using IBM SPSS statistics (4th ed). London: Sage

Publications Ltd, 2013.

EPI4923 Period 2 25 Oct 2021 17 Dec 2021 Print course description ECTS credits: 6.0 Instruction language: English Coordinator:

• <u>S. Vanbelle</u>

Teaching methods: Lecture(s), PBL, Training(s) Assessment methods: Written exam Keywords: Analysis of (co)variance, Linear regression, logistic regression, Survival analysis, Analysis of repeated measures Fac. Health, Medicine and Life Sciences

Clinimetrics

Full course description

The course 'Clinimetrics' (EPI4924) is scheduled during period two of the Master of Epidemiology. This 8-week course runs parallel with the courses 'Writing a research question and outline proposal' (EPI4930) and 'Advanced Statistical Analysis Techniques' (EPI4923).

Clinimetrics can be broadly defined as the science of (clinical) measurements. The field of clinimetrics is devoted to the development and assessment of measures of health-related phenomena in clinical practice and health research. As a methodological discipline focused on the concepts, quality and interpretation of measurements, it encompasses the various aspects and theories of health and exposure measurement. It is therefore of great importance within epidemiological research, which most often is focused on health or a health-related phenomenon as the main outcome (dependent) variable and a certain health determinant as the exposure (independent) variable of interest.

Topics include:

- concepts of health and functioning and various dimensions of these concepts;
- types of measures and methods for health and exposure measurement;
- steps in the development, testing, and evaluation of measures;
- principles of measurement theory underpinning health and exposure measurement;
- quality indicators of measures, including reliability, validity, and responsiveness;
- aspects related to the interpretability of health and exposure measurements;
- main principles of diagnostic testing and diagnostic research;
- biomarkers within the context of health and exposure measurement roles of.

This course is based on the principles of problem-based learning (PBL). Various topics are introduced in lectures and further discussed in tutorial group meetings. A number of practicals are also scheduled throughout the course to practice with the theoretical concepts through assignments and presentations. The mixture of lectures, tasks, practicals, assignments, and presentations creates an optimal learning environment for mastering the topics of this course.

Course objectives

Knowledge and understanding

Students know and understand:

- principles of classifying health and disease, and the use of health classification systems;
- various types of measures and measurement methods;
- theory of health and exposure measurement (clinimetrics);
- relevant aspects of the quality of measures and measurement methods (validity, reliability, responsiveness);
- steps required for the development and evaluation of a measure or measurement scale;
- steps and skills required for the critical evaluation of measures and methods for health and exposure measurement;
- main principles of diagnostic research and indicators and evaluation of the quality of diagnostic tests and strategies;
- roles of biological markers (biomarkers) within the context of health and exposure measurement and monitoring.

Applying knowledge and understanding

Students are able to:

- perform a critical assessment of the design and results of already published clinimetric or diagnostic studies;
- apply the main principles and techniques of health measurement scale development and evaluation, including diagnostic tests, to assess the appropriateness of (existing) scales and test strategies regarding validity, reliability, responsiveness, and interpretability, or to develop a new measurement scale / diagnostic test (strategy).

Making judgments

Students are able to:

• form a balanced judgment on the application of a broad range of health measurement scales, diagnostic test procedures and strategies within the context of both health sciences research and practice.

Communication

Students are able to:

• -communicate with experts and non-experts, both by means of written reports / comments and oral presentations, on the design, methodological issues, results and conclusions of a broad range of clinimetric studies and diagnostic research.

Recommended reading

Basic textbooks on measurement theory and concepts: • Measurement in Medicine. HCW de Vet, CB Terwee, LB Mokkink, DL Knol. Cambridge University Press (2011, 1st edition) • Health Measurement Scales: a practical guide to their development and use. DL Streiner, GR Norman, J Cairney. Oxford University Press (2014, 5th edition) Basic statistics book: • Discovering statistics using IBM SPSS Statistics. A Field. Sage Publications Ltd (2018, 5th edition) Recommended textbooks: • Epidemiology. L Gordis. Elsevier Saunders (2014, 5th edition) • Clinical Epidemiology. The Essentials. RH Fletcher, SW Fletcher, GS Fletcher. Lippincott Williams & Wilkins (2014, 5th edition) • Measurement and the measurement of change. DF Polit, FM Yang. Wolters Kluwer (2016, 1st edition)

EPI4924 Period 2 25 Oct 2021 17 Dec 2021 Print course description ECTS credits: 5.0 Instruction language: English Coordinator:

• M.J.L. Bours

Teaching methods: Assignment(s), Lecture(s), Work in subgroups, Presentations, Skills, PBL, Training(s) Assessment methods: Assignment, Attendance, Presentation, Written exam Keywords: validity, reliability, validity to change, responsiveness, Diagnostics, prognosis, evaluation, biomarkers, quality of life Fac. Health, Medicine and Life Sciences

Writing a Research Question and Outline

Full course description

The outline written during the current module is the outline for the research protocol that is to be written later on this year (EPI4927 in period 4) and will guide you during your thesis period. Essentially, therefore, you start working on your thesis from the current module onwards. The knowledge gained in the master program so far should enable you to formulate a clear research question, write an introduction on your study topic that logically leads up to the research question, and give an outline for the methodology needed to investigate the research question. The reason for starting with this early on in the program and separating this from the module 'Writing a Research Protocol' (EPI4927 in period 4) is that it takes time to formulate a good research question and to familiarize yourself with the research setting within which your internship will take place. The research protocol will be worked out in full using this outline during the module 'Writing a Research Protocol'.

Note: for HSRM students, this module is linked to the module RHS4020 'Acquiring advanced

professional skills' which also includes the part of 'Writing a Research Protocol' as a preparation for the thesis period. The part 'Writing a Research Protocol' will be offered to Health Sciences Research master students from periods 4 through 6.

Course objectives

By the end of this module, you should have attained the following learning goals:

Knowledge and understanding:

knowledge on and insight into how to formulate a research question; and basic knowledge of and insight into the outline of a(n epidemiological) research protocol.

Applying knowledge and understanding:

ability to formulate a research question; and ability to understand the basic principles of writing an outline for a research protocol

Making judgements: ability to form a balanced judgement on the quality of a research question

Recommended reading

Campbell JD. Formulating the research question. Dept. Family and Community Medicine, University of Missouri, 2004. Creswell JW. Research design. Los Angeles: Sage, 2009; Ch7: Research Questions and Hypothesis. Dos Santos Silva I. Cancer Epidemiology: Principles and Methods. Lyon: IARC publications, 1999. Ch18: Designing, planning and conducting epidemiological research. Haynes RB (2006). Forming research questions. Journal of Clinical Epidemiology 59, 881-886. Polit DF, Beck CT. Nursing research; principles and methods; 7th ed. Part 6: Communicating research. Chapter 25: Writing a research proposal; pp. 629-650. Philadelphia: Lippincott Williams Wilkins, 2004. In addition, you will find the literature covered in the modules so far relevant to this module. You are also encouraged to find other general literature on protocol writing and will need to find literature relevant to your specific thesis subject.

EPI4930 Period 2 25 Oct 2021 17 Dec 2021 Print course description ECTS credits: 1.0 Instruction language: English Coordinator:

• <u>C.C.J.M. Simons</u>

Teaching methods: Assignment(s), Lecture(s) Assessment methods: Final paper Keywords: research protocol formulating a research aim formulating a research question formulating a hypothesis study methodology academic writing thesis period Fac. Health, Medicine and Life Sciences

Molecular & Genetic Epidemiology

Full course description

Molecular and genetic epidemiology are emerging innovative fields of research in which molecular, genetic and biochemical concepts and techniques are incorporated into epidemiologic studies focusing on complex diseases. This is made possible by recent rapid technological advances in highthroughput laboratory assays that measure biomarkers in biological samples. Biomarker profiles that can be used in molecular epidemiology can range from just a few targeted markers to a whole metabolome, and may include the measurement of (epi)genetic variation, gene expression, proteins, small molecules, and functional assays. Epidemiology has been proven valuable to identify associations between exposure and disease, in particular because it enables us to study long-term effects of 'normal' variation in exposure in populations. However, traditional epidemiology does so without obtaining information of the biological processes that underlie these associations. Molecular and genetic epidemiology have the power to open up this 'black box'. It will not only enhance the measurement of exposure, effect, and susceptibility, it will also give insight in complex biological mechanisms, and generate novel hypotheses about disease mechanisms. This knowledge will lead to the identification of early etiologic, diagnostic, and prognostic markers of disease, it will allow us to better target preventive strategies, and will yield new leads for treatment. In this module, students will be familiarized with the different types of molecular biomarkers that can be used in epidemiological studies, including those measured with novel high-throughput -omics technologies. They will learn the pros and cons of different study designs used in molecular and genetic epidemiology, including Mendelian randomization. Students will be introduced to the knowledge that can be generated through molecular and genetic epidemiology. This course is an introductory course to a complex, but promising field of research.

Course objectives

Knowledge and understanding

Elementary knowledge of and insight into molecular epidemiology:

- Basic concepts of molecular biology
- Concepts, principles and designs of studies using molecular biomarkers
- Application of -omics in molecular epidemiology

Elementary knowledge of and insight into genetics and genetic epidemiology:

- Basic concepts of genetics
- Concepts, principles and designs of studies to investigate hereditary disorders characterized by low gene frequency and high gene penetrance
- Concepts, principles and designs of population/association studies to investigate hereditary disorders characterized by low gene penetrance
- Gene-environment interactions

Applying knowledge and understanding

- Ability to read and interpret scientific articles on molecular and genetic epidemiology
- Apply the knowledge on sources of variation in molecular and genetic epidemiological studies to optimize the design of such studies

Making judgments

• Ability to judge the applicability of principles and methods of molecular and genetic epidemiology to new research themes and questions

Communication

• On the design, methodological intricacies and outcomes of epidemiological studies involving genetic and molecular biomarkers

Learning skills

• Ability to proceed to an advanced level of studying the principles of molecular and genetic epidemiology, either by means of courses or by autonomous investment

EPI4925 Period 3 3 Jan 2022 28 Jan 2022 <u>Print course description</u> ECTS credits: 3.0 Instruction language: English Coordinator:

• M.P. Weijenberg

Teaching methods: Lecture(s), Patientcontact, Training(s) Assessment methods: Participation, Written exam Keywords: molecular-epidemiology; genetic-epidemiology; biomarkers; omics; mendelian randomization; GWAS; big data; Fac. Health, Medicine and Life Sciences

Meta-analysis

Full course description

In many healthcare domains, there is an abundance of literature on the same topics. When multiple studies have been published with a similar research question, e.g., estimating the efficacy of a specific intervention compared to placeno, they are unlikely to report exactly the same effect size. Effect sizes may differ in order of magnitude, in whether they are significantly different from zero, or may even differ in sign. Those differences in results between studies can arise due to differences in source population, study methods, and sampling variance, amongst others. Both for researchers and for professionals who are expected to interpret and apply the results of scientific research, it is

vital to be able to summarize and review all relevant literature in one's own domain of interest in a systematic and reproducible way. Nowadays, a systematic literature review is the point of departure of almost every new research initiative, and upon completion the study results will often be incorporated in an updated version of the review. Systematic reviews are at the heart of evidence-based medicine and public health. In this module, students will learn to apply meta analysis techniques in the context of systematic literature reviews.

Course objectives

- Knowledge and understanding of the place of the systematic literature review and metaanalysis in the hierarchy of empirical evidence
- Knowledge and understanding of the steps of a systematic literature review
- Knowledge and understanding of guidelines for review protocol writing of systematic reviews (e.g., PROSPERO)
- Ability to identify and construct the relevant elements of a research question for a systematic literature review (PICO[T])
- Knowledge and understanding of literature search strategies and identification of relevant databases (e.g., the use of MeSH-terms)
- Knowledge and understanding of methodological quality assessment tools for selected studies based on study design (e.g. ROBINS-II)
- Ability to distinguish between and mention the advantages and disadvantages of the various types of literature review
- Ability to tailor the principles of systematic literature review to the requirements of different research questions (e.g., overall effect, subgroup effects)
- Acquaintance of software that can be used to perform a meta-analysis (i.e., R)
- Knowledge and understanding of different sources of between-study heterogeneity within the context of systematic literature review (e.g., clinical, methodological, effect measure, and sampling variance)
- Knowledge and understanding of various methods to quantify between-study heterogeneity
- Knowledge and understanding of meta-analysis techniques for effect measures of continuous outcome variables
- Knowledge and understanding of meta-analysis techniques for effect measures of binary outcome variables
- Knowledge and understanding of different sources of bias (e.g., publication bias, reporting bias and citation bias) within the context of a systematic literature review, and ability to identify evidence of publication bias (e.g., funnel plot)
- Knowledge and understanding of accepted standards and guidelines for the reporting of systematic literature reviews (e.g., PRISMA)

Recommended reading

Basic literature - Borenstein M, Hedges LV, Higgins JPT, Rothstein HR. Introduction to Meta-Analysis; 1st ed. Chistester: John Wiley & Sons, 2009. - Shwarzer G, Carpenter JR, Rücker G. Meta-Analysis with R; 1st ed. Heidelberg: Springer, 205. Suggestions for further reading - Egger M, Davey-Smith G, Altman D. Systematic Reviews in Health Care: Meta-Analysis in Context; 2nd ed. -Higgins JPT, Green S. Cochrane Handbook for Systematic Reviews of Interventions; 1st ed.

EPI4931 Period 3 3 Jan 2022 Master Epidemiology 28 Jan 2022 Print course description ECTS credits: 3.0 Instruction language: English Coordinator:

• S.M.J. van Kuijk

Teaching methods: Assignment(s), Lecture(s), Work in subgroups, Research, Skills, Training(s) Assessment methods: Attendance, Final paper Keywords: Systematic literature revieuw; Meta-analysis; pooling; heterogeneity; random-effects; fixed-effect Fac. Health, Medicine and Life Sciences

Writing a Research Protocol

Full course description

Students will learn how to write a research proposal for their thesis topic in Epidemiology. The main activity is to write their proposal supported by active discussions of different sections of their protocol by peers and teaching staff. These activities will additionally be supported by lectures. Three lectures will elaborate on each of the sections of the protocol: 1) the background leading up to the main aim of the study, the specific research guestions and hypotheses, 2) the study design, and 3) and the statistics and power calculations. There will also be a working lecture on power and sample size calculation during which students will compute the required sample size or the power of the study. In addition, there is a lecture at the beginning of the module on scientific writing in English which will be provided by the language centre. In addition, there will be a lecture on how to make a scientific poster and a question hour. The module runs in parallel to the module on "Systematic Literature Review and Meta-analysis", during which students start learning how to critically and systematically assess literature. Throughout the module attention will be given to research ethics and research integrity. Last but not least, students will learn hStudents will learn how to write a research proposal for their thesis topic in Epidemiology, as a preparation for their thesis period which follows directly after this module. The main activity is to write their proposal supported by active discussions of different sections of their protocol by peers and teaching staff. These activities will additionally be supported by lectures. Three lectures will elaborate on each of the sections of the protocol: 1) the background leading up to the main aim of the study, the specific research questions and hypotheses, 2) the study design and population, and measurement instruments, and 3) and the statistics and power calculations, and a data analysis plan. There will also be two trainings on power and sample size calculation during which students will practise with these calculations and compute the required sample size or the power of the study. In addition, there is a lecture at the beginning of the module on scientific writing in English which will be provided by the language centre. In addition, there will be a lecture on how to make a scientific poster and a question hour. The module runs in parallel to the module on "Systematic Literature Review and Meta-analysis", during which students start learning how to critically and systematically assess literature. Throughout the module attention will be given to research ethics and research integrity (supported by a lecture). Last but not least, students will learn how to make a time-line, which they will use on a weekly basis during their entire internship period. At the end of the module

each student will present and defend his/her research protocol through a poster presentation during a plenary session in front of a 'review committee' consisting of peer students and staff members from the Department of Epidemiology.

Course objectives

Knowledge and understanding

- Knowledge of and insight into the basic outline of an epidemiological research protocol
- Knowledge of and insight into the requirements regarding the various components of a scientific research protocol (e.g., title of the research project, abstract, background, aim of the study, research question(s), hypotheses, study design, choice of study population including inand exclusion criteria, describing measurement instruments for main outcome variables, determinants / interventions, confounders and effect modifiers, sources of bias, proposed statistical analyses, power calculations, ethical considerations, timeline, bibliographic references, and a statistical analysis plan)
- Knowledge of the guidelines for writing a research protocol

Applying knowledge and understanding

- Ability to write an epidemiological research proposal independently in scientific English
- Ability to review and assess the quality of research protocols written by peers

Making judgments

• Ability to form a balanced judgment on the quality and relevance of research proposals in the field of epidemiology ("responsible epidemiological research practice"), also in a comparative sense.

Communication

• Ability to communicate with experts and non-experts, both by means of written report / comment and oral presentation on the contents, the strengths and the weaknesses of (epidemiological) research proposals, conceived by him- or herself or by other investigators.

Learning skills

- Ability to proceed to a higher level of scientific writing, for instance writing a proposal for a larger and more complex research project, or writing skills which can be applied during the writing of the thesis in the form of a scientific article.
- Skills to present and defend the final version of a study protocol in front of a scientific committee.

Recommended reading

Apart from the literature covered in the previous modules of the Master, recommended literature for this module includes: - Polit DF, Beck CT. Nursing research; principles and methods; 7th ed. Part 6: Communicating research. Chapter 25: Writing a research proposal; pp. 629-650. Philadelphia: Lippincott Williams Wilkins, 2004. - Dos Santos Silva I. Cancer Epidemiology: Principles and Methods. Lyon: IARC publications, 1999. Ch18: Designing, planning and conducting epidemiological research.

http://publications.iarc.fr/Non-Series-Publications/Other-Non-Series-Publications/Cancer-Epidemiolo gy-Principles-And-Methods-1999 - Written series of 12 one-pagers on effective writing and publishing scientific papers by Daniel Kotz and Jochen Cals in the Journal of Clinical Epidemiology. Available online: http://www.scientificwritingtips.com/ - Campbell JD. Formulating the research question. Dept. Family and Community Medicine, University of Missouri, 2004. Available online: https://www.atsu.edu/research/pdfs/campbell_syllabus.pdf - Creswell JW. Research design. Los Angeles: Sage, 2009; Ch7: Research Questions and Hypothesis. Available online: https://www.sagepub.com/sites/default/files/upm-binaries/22782_Chapter_7.pdf - Haynes RB (2006). Forming research questions. Journal of Clinical Epidemiology 59, 881-886. Available online: https://www.jclinepi.com/article/S0895-4356(06)00233-2/abstract.

EPI4927 Period 4 1 Feb 2022 1 Apr 2022 Print course description ECTS credits: 6.0 Instruction language: English Coordinator:

• <u>M.P. Weijenberg</u>

Teaching methods: Lecture(s), Work in subgroups, Paper(s), Presentations, Training(s), PBL Assessment methods: Final paper, Presentation Keywords: Research question Hypothesis Study design Operationalization Measurement instruments Statistical analysis Power analysis Sample size calculation Research integrity Ethical considerations Fac. Health, Medicine and Life Sciences

Topics in Epidemiology

Full course description

In this eight-week course, students can choose two topics (out of four) to study in more depth. The topics are specialisations within epidemiology or related to epidemiology.

In a topic, an expert in the field will introduce students to the topic using lectures, practicals, journal clubs, et cetera. A topic will be offered on three consecutive Fridays. The topics are Epidemiology of Infectious Diseases, Clinical Data Science, HTA/Health Economic Evaluation and Clinical Prediction Models.

Furthermore, attention will be given to the professional development of the master students. This will include discussions with senior epidemiologists (willing to reflect on their career), alumni and of contributions by UM Career Services.

Course objectives

Besides these general objectives of the course, the individual topics have more detailed objectives

Knowledge and understanding

- Understand the relation between epidemiology and the topics of the selected topics;
- Knowledge of and insight into the concepts, principles and practical steps of the topics of the selected topics for research projects;

Applying knowledge and understanding

- ability to apply the knowledge and understanding of the selected topics to scientific research;
- ability to perform simple analyses and interpret the results of research in the domain of the selected topics;
- ability to explain the importance of self-awareness in making study and career choices;

Making judgments

- is able to critically judge the methodological quality of research in the selected topics;
- is able to explain the importance of self-awareness in making study and career choices;

Communication

- ability to communicate with experts and non-experts on the selected topics;
- talk to others about their own professional interests, qualities and needs;

Learning skills

- identify and discuss useful online and offline networking practices for exploring and identifying career opportunities;
- find and use vacancy websites effectively.

Recommended reading

The literature is topic-specific

EPI4932 Period 4 1 Feb 2022 1 Apr 2022 Print course description ECTS credits: 6.0 Instruction language: English Coordinator:

• <u>L.J. Schouten</u>

Teaching methods: Assignment(s), Work in subgroups, Lecture(s), Paper(s), Presentation(s), Research, Skills, Training(s)

Keywords: infectious diseases, data science, prediction analysis, health economics/HTA, professional development Fac. Health, Medicine and Life Sciences

Placement and Thesis

Full course description

The placement period is the ultimate chance for a student to apply the knowledge he/she has gained in the previous year with regards to study methodology and epidemiology, to develop their competencies as a researcher, and to be able to make a start on their scientific CV. The thesis duration is 12 weeks, and 18 weeks when also including the credits for the preparation of the thesis through writing an outline and research question (EPI4930) and finally a full research proposal (EPI4927).

Course objectives

Knowledge and understanding

- In-depth knowledge and understanding of the subject matter of the master research & thesis
- Skills that are acquired in the subsequent phases of the research project: defining a research question; developing study design; collection and balancing of relevant information; data collection, analysis and interpretation, drawing conclusions; for instance, data collection skills, measurement skills, organizational skills, communication skills, statistical skills, analytical skills, etc.
- Skills that are required to prepare the master thesis, based on the research project (e.g., writing skills).

Communication

• Ability to communicate with experts and non-experts, both by means of written report (journal article) and oral presentation on the background and aim, theoretical framework, research question, design, methodological issues (choice of study population, choice of determinants / interventions and outcome measures, choice of measurement tools, choice of statistical analysis techniques), results, remaining uncertainties and conclusions of his/her own master research.

Learning skills

• Development of learning capacities that are required to be able to operate more independently in a more complex research environment in the near future.

Recommended reading

Literature included in previous modules, including literature on writing as part of the modules EPI4930 "Writing a Research Question and Outline" and EPI4927 "Writing a Research Protocol". Further, additional literature will need to be used depending on the thesis topic.

EPI4929

Master Epidemiology Year 1 Sep 2021 31 Aug 2022 Print course description ECTS credits: 18.0 Instruction language: English Coordinator:

• <u>C.C.J.M. Simons</u>

Teaching methods: Paper(s), Presentations, Research Assessment methods: Final paper Keywords: Research question Study design Statistical analysis Results Discussion Bias Research integrity Ethical considerations Time plan Professional behavior