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# Kurse Epidemiology & Public Health

## Coordinator:

Mrs. Catherine Mason

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## Quantitative Methods (6 ECTS)

This course gives insight into statistical principles and methods, with an emphasis on design and analysis of epidemiological research. The course consists of various elements including lectures, exercises, an R course with a data analysis project, as well as SAS courses and tutorials.

Its content covers the basic concepts of probability theory and statistical theory, methods of data description and estimation, tests to compare observations (for quantitative, nominal and non-normal outcomes), the issue of multiple testing, concept of sample size calculation, modelling associations using Linear Regression and Generalised Linear Models. A special focus is given to the practical application of these statistical methods for the participants' own statistical data analyses and to the presentation and interpretation of the results.

**ECTS:** 6

**Prerequisites:** Good knowledge of calculus and algebra

**Type of examination:** Written Exam

**Course coordinator:** Dr. Ursula Berger

**When:** Winter Semester (Oct - Dec)

**How to register?** Please contact the PhD program Office [phd@ibe.med.uni-muenchen.de](mailto:phd@ibe.med.uni-muenchen.de)

## Course Structure

**Lectures** – Students are provided with theoretical knowledge on the various statistical methods. Epidemiological examples are provided to illustrate their application and to allow for discussions about the theories learned.

**Exercises** – In the weekly exercises, students apply the methods they have learned in the lectures to practical examples. They are encouraged to present and discuss their solutions.

**Tutorials** – Students with little background in statistics are offered additional tutorials where they can profit from the experience and knowledge of their more advanced colleagues. In the tutorials the content of the actual lecture and exercise class is revised and additional exercises are discussed.

**R-course** – Students learn to perform their own statistical data analyses using the statistical software R.

**Data Project** - A data project offers students the possibility to address scientific questions by applying the learned statistical and epidemiological methods to real world data. They perform their analyses using R and present their results in form of a short report.

**SAS+ Course** – Students are offered an additional SAS course, where they have the opportunity to replicate the analyses of the data project using an alternative statistical software

## **Epidemiology I (12 ECTS)**

This module consists of "Advanced Methods in Epidemiology" in combination with three of four "Applied Epidemiology" courses. To take part in and successfully complete Epidemiology I, you need to cover the required course load and cannot choose only one part.

### **Advanced Methods in Epidemiology (6 ECTS)**

**Content:**

- Design and interpretation of cohort studies and case-based studies, missings
- Analyses of cohort studies using Poisson regression and survival analyses
- Methods for repeated measurements: Generalized estimating Equations and random effect models
- Methods for measurement error
- Methods for estimating non-linear exposure-response relationships

**Type of examination:**

Exercises and scientific protocol.

### **Applied Epidemiology - Epidemiology of Infectious Diseases (2 ECTS)**

**Content:**

- Infection and diseases: background
- Characteristics of the epidemiology of infections: origin, specifics
- Special methods of the epidemiology of infectious diseases (including, e.g. surveillance, methods to detect and differentiate infectious agents, measurements of effectiveness of vaccinations and modelling of epidemics)
- Descriptive epidemiology of infectious diseases (including, e.g. data sources and data collection in health reporting, regulations for the protection against infectious diseases, international reporting systems)
- Investigative and analytical epidemiology of infectious diseases (including, e.g. outbreak surveys, identification and classification of new agents)
- Interventions (including, e.g. exposure-prophylaxis, immune-prophylaxis, chemoprophylaxis, population-based protection against infections)
- Applied infectious disease epidemiology (infections during the life span, emerging and re-emerging infections: AIDS, TB, malaria, Bioterrorism)

### **Applied Epidemiology - Epidemiology of Cardiovascular Diseases (2 ECTS)**

**Content:**

- Pathophysiology, descriptive epidemiology (morbidity and mortality of key cardiovascular diseases)
- Hypertension and smoking (prevalence of hypertension and smoking, association between smoking and CVD, pathophysiological mechanisms, therapeutical studies)
- Lipids (prevalence dyslipoproteinemia, association between dyslipoproteinemia and CVD, pathophysiological mechanisms, therapeutical studies)
- Overweight, diabetes, insulin (prevalence of diabetes and overweight, associations between overweight, impaired glucose tolerance, diabetes and CVD, pathophysiological mechanisms)
- Psychosocial factors (relevance of psychosocial risk factors, association between psychosocial risk factors and CVDs, pathophysiological mechanisms)
- Nutrition (association between nutritional factors and CVD, pathophysiological mechanisms)

- Inflammation, haemostatis (association between haemostatic and inflammatory risk factors and CVDs, pathophysiological mechanisms)
- Gender differences, hormone therapy (differences in the relevance cardiovascular risk factors among men and women, gender differences in morbidity and mortality, influence of hormone therapy on the risk of CVD)
- Prevention and population-based intervention studies
- Genetic epidemiology (Genetic risk factors for CVD, gen-environment interactions)

### **Applied Epidemiology - Pharmacoepidemiology (2 ECTS)**

#### **Content:**

- Drug utilization research (DUR) (History, questions, achievements, relevance)
- Parameters, data sources (Defined Daily Dosis [DDD], Prescribed Daily Dose [PDD], critical appraisal, Annual Statistics for Prescription Drugs)
- Physicians' prescribing habits (case studies, measurement methods, behavioural changes of physicians' prescribing habits)
- Patient compliance (measurement methods, parameters, effects, case studies, potentials and possibilities for optimizing patient compliance)
- Quality assurance (structures, case studies)
- Adverse drug reactions (definitions, public health impact)
- Reporting systems (spontaneous reporting, systematic surveillance, registry)
- Pharmacovigilance (role of pharmacovigilance with case studies)
- Analysis of causality (criteria for an individual case and for epidemiological studies, principles of assessing risks and benefits)
- Legal framework (German Drug Law [Arzneimittelgesetz AMG], European Medicines Agency / International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use [EMA/ICH], Graduated Plan)
- International situation (data bases, PEMS)

### **Applied Epidemiology - Tumor Epidemiology (2 ECTS)**

#### **Content:**

- Descriptive epidemiology of cancer (from the incidence table to the world map of incidence and mortality)
- Cancer definitions, classifications (cancer as a genetic disease, histological classification, processes of molecular biology, disease models)
- Etiologic factors, primary prevention (known risk factors, smoking: an epidemic of the century, smoking prevention in Germany from 1933 – 1945).
- Early detection (screening, holistic appraisal, evidence of current screening programmes)
- Primary therapy in accordance to guidelines (guidelines, quality indicators, longterm results, presentation of data from the Tumour Registry of Munich [TRM] on the internet)
- Aftercare, tumour specific and final therapy (Setting goals in the levels of prevention, relevant criteria for goals, quality of life)
- Documentation, methods of work, tumour registry data, (transparency of the TMR, contents of documentation, data base handling, reporting, online access / documentation)
- Levels of analysis of cancer (example of describing the analysis: clinic-specific, tumour-specific, comparison of clinics, comparison of the literature, time trends, epidemiology)

## Epidemiology II (6 ECTS)

### Content:

- Presentation of advanced study designs including case-only studies, case-cohort, case-crossover and others
- Ecological study designs in various applications including spatial epidemiology
- Each study design will be presented both theoretically as well as illustrated by an example from the literature
- Sources of biases and potentials to control for bias and confounding by adequate designs will be discussed for each study type

### Type of examination:

Exercises.

## Clinical Epidemiology I (12 ECTS)

"Clinical Epidemiology I" consists of two parts, which must both be taken. The module ends with a written exam (60 - 90 minutes).

## Medical Informatics and Regulatory Issues in Clinical Research (6 ECTS)

### Content:

The course content is divided into two thematic units.

#### *Medical Informatics:*

- Basic information processing: historical overview, concept of data types, numerical data types, character sets, file formats, standardisation
- The Internet: historical overview, OSI reference model, Internet Protocol (IP), applications and application protocols, domain name system (DNS), organisational tasks and legal foundations
- Introduction to XML
- Database systems: data models, relational data model, normal forms, characteristics of database system, introduction to the Structured Query Language (SQL), combining Internet- and database technologies
- Overview of medical information systems
- Legal foundations of confidentiality and patient privacy
- Security of information systems: data encryption, authentication and authorisation, techniques for securing data networks
- Representation and standardisation of medical knowledge: medical coding systems, terminologies, special standards
- Development and implementation of information systems: development models, modelling data and processes, project management
- Specific requirements for information systems used in clinical research quality management

#### *Regulatory issues in clinical research:*

- Knowledge about relevant paragraphs of the AMG and MPG related to clinical studies: Introduction to important aspects of both laws (AMG: Law on Pharmaceutical Products, and MPG: Law on Medical Products), cover relevant examples in order to understand the distinction between both laws and the resulting consequences. Introduction to the legal notification procedures
- Knowledge about the GCP-ICH guidelines to implement clinical studies: Introduction to the key messages of the GCP-ICH regulation, depiction of the consequences of GCP-ICH. Relevant study documents

- Compilation of a study protocol: obligatory parts of study protocols, logistic outline
- Knowledge of ethical aspects of clinical studies: patient rights, benefit-risk assessment, patient education, Helsinki-declaration. Discussion of examples related to education and logistical aspects of patient education
- Knowledge of quality management of clinical studies: What are standard operating procedures (SOPs), how are they developed, structure of the quality management of a study, monitoring, audit, handling of relevant study documents
- Knowledge of the fundamentals of data management in clinical studies: Principles of configuring a case-report-form (CRF), connection between CRF and protocols, study data banks, plausibility check and construction of queries, cooperation between data management and monitors, database closure.
- Special aspects of prognosis and diagnosis studies: Differences in regulations and logistics
- Reporting standards for study results: CONSORT-Statement, Reports of diagnosis studies, reports of meta-analyses
- Aspects of pharmaceutical drug safety and pharmacoepidemiology: Gather information on and report about unwanted side effects, regulations and methods, fundamentals of pharmacoepidemiology

### **Advanced Methods in Clinical Epidemiology: Design, Evidence Synthesis, Safety and Quality (6 ECTS)**

#### **Content:**

The course is divided into 15 thematic blocks.

- Complex designs I: sequential studies
- Complex designs II: adaptive and flexible designs
- Practical and regulatory implications in studies with complex designs
- Advanced aspects of prognosis studies
- Advanced aspects of diagnosis studies
- Advanced aspects of studies in health economics
- Work strategy of IQWiG (“Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen”) and NICE („National Institute for Clinical Excellence“)
- Praxis and theory in the development of treatment guidelines
- Pharmaceutical safety (1)
- Pharmaceutical safety (2)
- Pharmaceutical safety (3)
- Quality assurance in the clinic: instruments and strategies (1)
- Quality assurance in the clinic: instruments and strategies (2)
- Quality assurance studies
- Quality of the provision of care: research

### **Clinical Epidemiology II (6 ECTS)**

Clinical Epidemiology II consists of two blocks, which must both be taken.

#### **Defining and Measuring Endpoints for Clinical Studies (3 ECTS)**

#### **Clinical Epidemiology: Advanced Statistical Methods (3 ECTS)**

### **Recent Development in Biostatistics (6 ECTS)**