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Intervention Research

Academic year 2013-14

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29-8-2013 1:30

Period
Period 1  Startdate: 09-Sep-13  Enddate: 27-Sep-13

Code
EPI4901

ECTS credits
4.0

Organisational unit
Fac. Health, Medicine and Life Sciences

Coordinator
C.J.A.W. van Gool - de Vrede

Description
If an observational study reveals an association between two states or events A and B, this association may be interpreted as follows: 1. B is caused by A. 2. A is caused by B. 3. Both A and B are caused by a third factor. 4. The association between A and B is merely a chance phenomenon. In order to prove causality an intervention trial design may be applied. The umbrella term intervention study refers to those study designs in which the investigator manipulates one or more independent variables, whereas the other independent variables are kept constant or controlled at the same time. This approach is regarded the most powerful study design for discovering causal relationships. Within the health sciences domain two types of experiments can be distinguished: laboratory experiments and experiments that are conducted outside the laboratory (field experiments). Furthermore a distinction can be made between experiments in humans and experiments in (laboratory) animals or animal products. This unit will focus on experimental research in human beings outside the laboratory. Clinical trial is a common name to indicate this type of experiments. In general control over the non-manipulated independent variables is pursued by means of a random allocation procedure. Therefore randomized controlled trial is often used as an alternative term. According to the type of independent factor to be manipulated, clinical trials can be classified again into preventive trial, management trial, and intervention trial. Preventive trials aim at the introduction of a protective factor under controlled circumstances. Management trials are conducted to highlight the role of treatment strategies and health care services. Often the focus of the evaluation is on the process of health care provision as such, and less on the outcome of this process. In intervention trials the efficacy of the treatment is the major object of interest. Just like in preventive trials, changes in health measures that are considered the most relevant outcome parameters, are the primary concern. A sharp demarcation between these three types of experimental studies does not exist, some overlap is possible. In the lab the experiment is the prevailing type of study. This predominance is that strong, that some biomedical researchers hardly seem to realize that alternative study designs can be chosen as well. Outside the laboratory the situation is totally
different. This is partly due to the fact that ethical objections can be put forward against the deliberate exposure of people to health-threatening conditions. This may urge the researcher to rely on an observational study design. Giving up the rigorous control over external determinants may lead to biased results and a reduced internal validity of the study. Although a randomised controlled trial is not always feasible, such a trial remains the paradigm of cause-effect research. This means that one should try to imitate the experimental design as much as possible, even when designing an observational study. The term ‘paradigm’ in its current meaning was introduced by the scientific philosopher Thomas Kuhn. According to Kuhn the scientific process consists of solving puzzles guided by a standard example, a model, most of the times. In that sense the randomised clinical trial currently can be regarded a paradigm for health (care) research. Therefore, it is important to be familiar with the various aspects of intervention studies, also for scientists who are not involved in experimental research themselves.

**Goals**

After completing this unit the participants should have a sufficient level of knowledge and insight regarding the various aspects of the design, conduct and analysis of intervention studies, more in particular with regard to: . The classification of intervention studies, e.g., pre-experimental, quasi-experimental, and true experimental designs; phase I, II, III, IV trials. Rationale of and prerequirements for experimental intervention studies (feasibility, justification, clinical trials and evidence-based health care). Historical development of clinical trials. The core elements of the ‘classic’ experimental study design (parallel, placebo-controlled, double-blind, randomized clinical trial): choice of study subjects (inclusion-end exclusion criteria, study size), choice of outcome measures, choice of intervention strategies, informed consent procedure, prognostic factors, randomisation, prestratification, blinded outcome measurement, dealing with protocol deviations (drop-outs, non-compliance, missing values). Alternative experimental study designs: cross-over trial, factorial design, Latin square design, prerandomization design (Zelen design), sequential analysis design. Methods of random allocation (randomization list, simple randomization, replacement randomization, random permuted blocks, biased coin method, stratified randomization, minimization, balancing, unequal randomization, computer-assisted randomization, administrative aspects) Design/choice of study population: inclusion and exclusion criteria, eligibility, source for selection, recruitment, patient registration. Design/choice of intervention: treatment schedule (route of administration, amount and frequency of dosage, duration of therapy, etc.), intervention contrast (placebo, usual care), co-interventions. Design/choice of outcome measurement: primary vs secondary outcome measures, timing of measurements, quality of outcome measures (validity, reliability, sensitivity-to-change, intended vs unintended effects. The role of the run-in period (qualification period). The powerful placebo. Statistical analysis of intervention trial results: intention-to-treat analysis vs per-protocol analysis (valid cases analysis). Dealing with (potential) protocol deviations: ineligible patients, missing values (incomplete evaluation, promoting and evaluating treatment compliance, avoiding and evaluating study subject attrition (withdrawals), violations of timing of outcome measures). Evaluation of unintended outcomes (adverse events (AE), serious adverse events (SAE)). Planning, organization of trials, and administrative aspects of clinical trials (documentation, design of forms, standard operating procedures (SOP's), data management, audit procedures, multi centre trials). Ethical and legislative aspects of intervention trials (METC, WMO, GCP, harmonization at the European level). Practical aspects of intervention trials. Requirements for an intervention trial protocol and an intervention trial report.

**Instruction language**

EN

**Prerequisites**

**Recommended literature**

**Teaching methods**

PBL
LECTURE(S)
TRAINING(S)

**Assessment methods**

WRITTEN EXAM
FINAL PAPER

**Key words**
Observational Research

Date last modified
29-8-2013 1:30

Period
Period 1 Startdate: 30-Sep-13  Enddate: 25-Oct-13

Code
EPI4902

ECTS credits
6.0

Organisational unit
Fac. Health, Medicine and Life Sciences

Coordinator
P.A. van den Brandt

Description
Health sciences research can be divided into observational and experimental studies. As far as observational study designs are concerned, information regarding specific characteristics – e.g. exposure and outcome phenomena in cause-effect research – is collected in one or more groups of individuals, but the investigator does not affect the individuals to be observed. The experimental study design is regarded to be the paradigm of scientific health sciences research. Since this type of research is not always feasible in human populations, however – due to objections related to ethical considerations, blinding of study subjects, compliance, budget constraints, etc. – often an observational study design has to be chosen. In that case the intention is to mimic the principles and conditions that apply to experimental research as closely as possible. This simplifies the (causal) interpretation of the results of observational study results. When designing and conducting observational research that intends to simulate the results of experimental research, the comparability of the subgroups of individuals under study is being pursued for this reason, as well as comparable methods for measuring exposure information and related outcomes. If a sufficient level of comparability is not obtained, various types of bias may occur – a rough classification distinguishes selection bias, information bias, and confounding) – that may harm the internal validity of the study and give rise to spurious results. Within the domain of analytical epidemiology a distinction can be made between correlation studies, with observations at the population level (often termed ecological studies: geographical correlations, time series analyses), and studies with observations at the individual level. The second type can be split up further into cross-sectional studies and longitudinal studies (cohort studies, case-control studies). During this unit the major archetypes of observational research will be elaborated in detail. Much attention will be paid to the design, conduct, analysis and interpretation of these studies. As for the statistical analyses, this unit will not yet cover the application of multivariate analysis techniques. These will be the focus of the unit Advanced statistical analysis techniques for epidemiology.
Goals
After completing this unit the participants are supposed to have sufficient knowledge and understanding regarding to the following subjects: Observational study designs and their advantages and disadvantages: ecological study, case series, cross-sectional study, case-control study, prospective and retrospective (historical) cohort studies, hybrid designs (nested designs). Classification of study designs according to epidemiological and the social sciences tradition. Application of measures of disease frequency and measures of determinant-disease association in various study designs. Choice of study populations and sampling strategies. Sampling as part of various designs. Criteria for the assessment of the methodological quality of research: validity, precision, statistical efficiency. Sources of bias in various designs: selection bias, confounding, information bias. Illustrations and possibilities for quantification of these concepts in various designs. Measures to prevent or combat bias: restriction, matching, stratification, standardization. Effect modification (interaction) and procedures to reveal this phenomenon. Principles of causal reasoning. Principles and steps of an outbreak investigation. Simple statistical analysis techniques in observational research: analysis of 2 x 2 tables, 2 x k tables, chi square tests, tests for trend; stratified analysis, matched analysis. Application of statistical analysis techniques in various observational study designs. Exposure measurement in the context of observational research, with attention to aspects of data collection and processing (coding, data entry, cleaning, quality control, etc.).

Instruction language
EN

Prerequisites

Recommended literature

Teaching methods
PBL
LECTURE(S)
TRAINING(S)

Assessment methods
WRITTEN EXAM

Key words
Health Measurement

Academic year 2013-14

Date last modified
11-1-2014 1:30

Period

Code
EPI4903

ECTS credits
3.0

Organisational unit
Fac. Health, Medicine and Life Sciences

Coordinator
C.H.G. Heuts - Bastiaenen

Description
The central variable in epidemiology and in epidemiological research is always health. Epidemiologists are interested in the frequency of occurrence of health problems in the population. Especially if a health phenomenon is measured in an epidemiological context with the intention to analyze its relationships with other characteristics, it is necessary to delineate this phenomenon as accurately and precisely as possible, since it is imaginable that the nature and the strength of the relationships of interest are typical for different definitions or aspects of the (stage of) disease under study. Moreover, the health problem of interest may not always be a disease process or the outcomes of such a process; sometimes it may concern a handicap, or a trauma injury caused by an accident. Since there is no term available which covers all these aspects, disease will be used in general. This unit deals with the principles and methods of operationalizing and measuring the various aspects of health and disease. Without much effort one can identify a large number of different definitions of health in the literature. Probably the most well known one originates from the World Health Organization (WHO), which describes health as a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. A remarkable characteristic of this and other definitions of the health concept is the tendency to regard health and well-being as equivalent terms, and to define health in a positive sense. Health is more than just the absence of disease is the underlying motto. Another feature of many definitions of health is that they stress its dynamic, process-like character. This means that health is regarded the successful response of the individual to varying challenges from the environment. In this view, ill-health and disease are caused by exceeding the individual capacity for adaptation. This may be the consequence of either an excessive load or a reduced load-bearing capacity. It is common practice to distinguish the concept of health into somatic, psychical, and social components. Such descriptions of the health concept give little hold for epidemiological research, which focus on the measurement of a specific aspect of health or disease in individual population members. Almost all concrete operationalizations of the health concept focus on what the more abstract description was detested for: the presence or absence of disease. Dependent on the
underlying motive for the investigation, the research question, and the practical circumstances one will choose an objective, a subjective, or a social dimension. An 'objective' approach implies that ill health is considered at the organic level ('disease'), as far as this can be observed from the outside. At the forefront is the diagnosis to be made by a qualified specialist (physician, physical therapist, psychiatrist, clinical psychologist). A 'subject' approach means that ill health is considered at the individual level ('illness'). Now the focus is on the personal perception of one's health, the self-perceived health state, which strongly contributes to the quality of life. The third approach looks at ill health at the social level ('sickness'), as is reflected by health-related behaviour like disease absenteeism (sickness absence from work), bed rest, and consumption of health care services. To be clear, one universal health measure that covers all dimensions does not exist. Sickness absence, medical consumption and perceived health as a rating based on just a few written questions, are examples of health measures that may be acceptable at the aggregated (population) level, but that can hardly be interpreted at the individual level without additional information. The operationalization of a particular health dimension or a specific aspect of such a dimension is termed a health indicator. It is apparent from the foregoing that a large number of health indicators can be conceived. At first glance the objective dimension of health seems hardly be open to discussion and criticism, since a specific disorder or defect is either present or absent. However, the occurrence of disease phenomena can often not be captured by a simple dichotomous variable, due to a lack of sharp borders between diseased and non-diseased states. Being ill is often reflected by a complex pattern of signs and symptoms that show a changing composition and appearance over time. These time-related changes in the clinical picture of a disease are referred to as the (natural) course of the disease. Actually, one has to deal with a situation in which a large number of symptoms and phenomena manifest themselves in different patients to a different extent. Therefore, diagnostic testing rests upon a far-reaching simplification of the complex phenomena that are present in reality, and is far less objective than sometimes is assumed. International standardization and operationalization of diagnostic criteria is urgently needed, in order to enable unambiguous measurement of disease and counting of disease occurrence. Within this context, the International Classification of Diseases (ICD), which has advanced to its 10th version, has an important role to play. The same holds for other internationally accepted disease classification systems, like ICIDH, ICPC, and ICF. Epidemiological researchers cannot do without an thorough description of employed diagnostic criteria, which preferably should be based on the international standards mentioned before. Attempts to make a correct estimation of the occurrence of a certain disorder or defect in a population at a given point in time are affected by the variety of both the type of manifestation and the severity of that defect. This is caused by the fact that diseased people may display a different course of the disease, and, moreover, may have arrived at a different stage of the disease development process. Health indicators that represent the objective dimension of health, such as mortality and morbidity measures, are frequently applied in epidemiological research. However, indicators of subjective health and sickness behaviour enjoy a growing popularity. The measurement of disability and functional (in)capacity, in particular, makes sense in epidemiological research, not only to quantify the seriousness of chronic disorders, but also to evaluate the outcome of interventions in physical therapy, rehabilitation medicine, or other medical fields. For this purpose an impressive number of standardized health measurement rating scales have been developed, in the form of structured interviews, questionnaires, and observation scales. Measurement scales that focus on the individual perception of functional disability are frequently applied in quality of life investigations. Many instruments have been developed to assess the health-related quality of life, either generic, domain-specific, or disease-specific QoL measures. The subjective dimension of health emphasizes self-assessment. Measuring subjective health can be conducted very straightforward, by means of inquiring directly about felt complaints. Most indicators of the social dimension of health do refer to medical consumption. The underlying idea is that, at least at the population level, a relatively poor health status will be accompanied by an increased use of health services. Medical consumption can be expressed either in frequency of use or in financial expenses. An alternative indicator of health is the registered level of absence through illness from work. Roughly speaking the reasoning behind this is: the higher the absenteeism, the higher the level of ill-health. Basically this
association may apply to both individual employees and, for instance, a category of workers in a certain branch of industry. Nevertheless, absence from work remains a poorly interpretable and probably less valid indicator of health.

**Goals**

After completing this unit the participants are supposed to have sufficient knowledge and understanding of the following subjects: . The various dimensions of health and the use of health and vital indicators in public health planning and evaluation. The principles of classifying health and disease phenomena, and the use of health classification systems. Health registries and health surveillance systems. The various types of health measurement scales. The theory of health and exposure measurement (clinometrics), and the major parameters of the quality of a health measurement scale (validity, reliability, sensitivity to change, etc.). The step-wise process of the development of a health outcome measurement scale. The main principles of diagnostic testing and diagnostic strategies. The main principles of population screening of health and disease problems and risk factors, and the evaluation of screening activities.

**Instruction language**

EN

**Prerequisites**

**Recommended literature**


**Teaching methods**

PBL
LECTURE(S)
TRAINING(S)
Assessment methods
WRITTEN EXAM

Key words
Applied Epidemiology

Academic year 2013-14

Date last modified
11-1-2014 1:30

Period

Code
EPI4905

ECTS credits
3.0

Organisational unit
Fac. Health, Medicine and Life Sciences

Coordinator
B.A.J. Verhage

Description
The first four weeks of this unit will focus on the current state of knowledge regarding the epidemiology of some commonly occurring diseases and disease processes. For each of the diseases the main results from both descriptive and analytic epidemiological studies will be highlighted: frequency of occurrence (prevalence, incidence, case- fatality ratio, etc) in general, and related to some relevant characteristics of person (risk groups), place (geographical distribution), and time (e.g., time trends); natural course of the disease, major etiologic risk factor, main prognostic risk factors, efficacy of preventive measures and therapeutic treatments. For the time being only a provisional choice has been made for the diseases that will be discussed during this unit: Cancer cardiovascular disease Low back pain and other musculoskeletal disorders.

Goals
After completing this unit the students are supposed to have sufficient knowledge and skills regarding . The epidemiological aspects of some common diseases in human beings, in particular cardiovascular diseases, low back pain, and cancer: frequency of occurrence, risk groups, etiologic factors, prognostic factors, efficacy of preventive measures and therapeutic treatments.

Instruction language
EN

Prerequisites

Recommended literature

**Teaching methods**

LECTURE(S)
PBL

**Assessment methods**

WRITTEN EXAM

**Key words**

No key words available,
Intervention Mapping

Academic year 2013-14

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29-8-2013 1:30

Period

Code
GZW4006

ECTS credits
6.0

Organisational unit
Fac. Health, Medicine and Life Sciences

Coordinator
R.M.M. Crutzen

Description
Position within the full curriculum. This unit uses and extends knowledge and skills acquired during preceding modules. An introductory overview of Intervention Mapping will be given in the first week, after which the course is an extended training familiarizing students with planning, needs assessment, theory in Health Promotion, the use of different media, and other intervention strategies. In the preceding units, students have acquired the necessary knowledge for a needs assessment; here they translate results into health promotion program objectives. In the present unit this knowledge and experience is further deepened by designing interventions in terms of detailed descriptions of objectives, theoretical foundation, empirical evidence, production plans, pilot testing, implementation plans, and process and effect evaluation. Central theme. The Intervention Mapping protocol is the central theme of the unit. In applying this planning model, theory about determinants of health behaviour and more specifically cardiovascular risk behaviour is studied and relevant interventions are evaluated. Organization of the unit. The unit is divided in 6 parts: needs assessment, program objectives, methods and strategies, program design and production, diffusion and implementation, and evaluation. Needs assessment: In the first phase of the unit, students analyse case descriptions of needs assessments concerning nutrition, physical activity and cardiovascular problems, if needed completed with additional literature review. Using this, students define health promotion goals and objectives and specify (intermediary and end) target groups. Program objectives: In the second phase health promotion goals are specified in program objectives on different ecological levels (individual, interpersonal, group, community, environment, policy). This results in matrices of objectives and levels. Methods and strategies: In phase three, students identify relevant methods for attaining the objectives through brainstorm and literature review. If needed they identify evidence gaps, and specify the need for additional research. Finally, potentially effective methods are translated or operationalised in practical health promotion strategies. Program design, pretest and production: In phase four the individual strategies are combined and integrated in one coherent program. The scope of the program is defined as well as the order of program elements and activities. An implementation
protocol for the program is developed. Plans are made for pretesting, and for the production of the program. Diffusion and implementation. In phase five a linkage group is defined. Students design a theory- and evidence-based plan for effective diffusion, adoption, implementation and sustainability of the program. Evaluation. In the final, sixth phase of the unit students write a plan for process and effect evaluation. They define indicators for effectiveness, research designs and procedures. Success criteria are defined on the basis of program objectives and needs.

**Goals**

Knowledge and understanding. After the unit, students can describe the Intervention Mapping protocol. Students can develop a theory-based health promotion program using the Intervention Mapping protocol. They can use the Intervention Mapping tools: brainstorm, literature and new evidence. Students can describe the relation between physical activity, nutrition and cardiovascular disease. Students can describe state-of-the-art health promotion programs for nutrition and physical activity. Students can integrate policy, environmental, and individual level explanations and theories. Students know the most important organisations and stakeholders in the field of cardiovascular disease, physical activity and nutrition. Application of knowledge and understanding. Students can integrate their knowledge of theory and evidence concerning nutrition and physical activity in the Intervention Mapping protocol. Students can translate general health promotion goals into specific program objectives. Ideas, theory and evidence can be integrated in a new, realistic and promising health promotion program. Methodological and research knowledge are translated in efficient and sound formative and evaluation research plans. Making judgements. Students acknowledge the utility and necessity of using a planned development protocol like Intervention Mapping for the development of theory- and evidence-based health promotion programs. Communication. Students can communicate own opinions and ideas. Students can critically discuss their own and other’s ideas, opinions, theories, work. Learning skills. After the unit students have demonstrated to be able to effectively cooperate in small groups with persons of different background and initial level. Students can apply the Intervention Mapping protocol to other fields and topics.

**Instruction language**

EN

**Prerequisites**

**Recommended literature**


**Teaching methods**

LECTURE(S)

ASSIGNMENT(S)

**Assessment methods**

FINAL PAPER

WRITTEN EXAM

**Key words**
Systematic Literature Review

Academic year 2013-14

Date last modified
17-1-2014 1:28

Period
Period 2  Startdate: 25-Nov-13  Enddate: 20-Dec-13

Code
EPI4904

ECTS credits
3.0

Organisational unit
Fac. Health, Medicine and Life Sciences

Coordinator
M.C.J.M. van Dongen

Description
Systematic reviewing and critical appraisal of the scientific literature can be considered essential elements of an evidence-based health care approach. The following topics will be dealt with during the module: . Various types of literature review (narrative review, systematic review, meta-analysis based on statistical pooling of individual study results). Advantages and disadvantages of the systematic type of review (ãblindedãE reviews based on methodological quality assessment of the component studies) compared with the classical, narrative review. Domains of systematic reviews: randomized clinical trials, observational studies, and diagnostic studies. The consecutive steps in the process of systematic reviewing: identification of eligible research articles, extraction of the relevant information from the studies included, statistical analyses in order to attain to a summary assessment of therapeutic efficacy, diagnostic accuracy, or etiologic importance. Or, more specifically: formulation of the research question, identification of component studies, definition of in- and exclusion criteria, blinding of publications, extraction of study characteristics, extraction of study results, estimation of publication bias, statistical analysis / pooling, estimation of heterogeneity, exploratory statistical analysis, interpretation and publication. Considerations regarding the delineation of the research question underlying the systematic literature review. Search strategies and procedures to identify studies through electronic bibliographies and other sources. Principles underlying the inclusion of papers into the review databases. Procedures of literature management. Aspects of data extraction from the included studies (extraction of qualitative data, extraction of quantitative data, estimation of publication bias). The application of criteria for blinded quality assessment of component studies (comparison of various criteria lists). Calculation and utilization of quality scores. Methods of quantitative data extraction for statistical pooling: choice of effect measures (association measures) for binary outcome data (RR, RD, OR, diagnostic OR, RRR, NNT, etc.), and continuous outcome data (WMD, SMD), respectively; calculation of dispersion measures (SE) in addition to measures of central tendency. Prevention and diagnosis of bias in systematic reviews: bias in the location of studies, publication bias (sources of publication bias, estimation of publication bias based
on eye-ball detection (Funnel plot) or statistical testing). Dealing with methodological quality differences and sources of heterogeneity (patients, reference groups, interventions, outcome measures) in meta-analyses. Further statistical analysis of meta-analysis results: semi-quantitative pooling methods (vote-counting methods, Fisher’s method), quantitative pooling methods (fixed effects pooling, random effects pooling, sensitivity analysis), meta-regression analysis, exploratory analysis. Guidelines for the presentation and publication of meta-analyses of experimental and non-experimental studies (QUOROM, MOOSE, etc.). Suitable software for performing meta-analysis, in particular the statistical pooling process (e.g., Stata, Review Manager). Practical applications of the results of systematic reviews: at the patient’s bedside, in clinical guideline development, in evidence-based policy making, in economic evaluation. The global organization of the systematic reviewing process: the role of the Cochrane Collaboration and other bodies involved in performing meta-analyses and disseminating the results of meta-analyses.

Goals
After completing this unit the participants should have a sufficient level of knowledge and insight regarding the various aspects of systematic reviewing the literature, more in particular as to: The various types of literature review: narrative review, systematic review, meta-analysis. Advantages and disadvantages of systematic reviews. Various domains of application of systematic reviews: experimental studies, observational studies, and diagnostic studies. The steps of a systematic literature review: from research question and review protocol, via methodological quality assessment and statistical pooling of individual study results, towards interpretation and conclusions regarding the level of evidence. Literature search strategies to identify relevant component studies to be included in the literature review. Principles and procedures of efficient literature management. Criteria for blinded quality assessment of component studies in a systematic review. Quantitative data extraction and calculation of summary measures of effect: methods and measures for statistical pooling. Prevention and diagnosis of bias in systematic literature reviews, with special attention to the identification of publication bias. Principles and methods of dealing with sources of heterogeneity regarding type of study subjects, type of intervention / exposure measurements, type of outcome measures within the context of systematic reviewing the literature. Statistical software dedicated to the performance of statistical pooling within the context of systematic literature review. The organization and logistics of a worldwide concerted effort to perform systematic reviews of the efficacy of health (care) interventions: the Cochrane Collaboration.

Instruction language
EN

Prerequisites

Recommended literature

**Teaching methods**

PBL

**Assessment methods**

FINAL PAPER

PRESENTATION

**Key words**
Advanced Statistical Analysis Techniques

Academic year 2013-14

Date last modified
11-1-2014 1:30

Period
Period 3 Startdate: 06-Jan-14 Enddate: 28-Feb-14

Code
EPI4906

ECTS credits
6.0

Organisational unit
Fac. Health, Medicine and Life Sciences

Coordinator
S. Vanbelle

Description
This unit deals with the design, conduct and interpretation of multivariable epidemiological data analysis. The focus will be on the following statistical techniques and procedures: analysis of variance and covariance, multiple linear regression analysis, logistic regression analysis, survival analysis, analysis of repeated measurements, sample size and power estimations. Analysis of variance and covariance Based on pre-existing knowledge regarding ANOVA, several relevant aspects of this technique will be elaborated more in depth during the current unit. In particular the unbalanced design concept and its consequences for data analysis will be highlighted. ANCOVA can be regarded a useful extension of ANOVA, which enables to involve also continuous independent variables in the data analysis, in addition to categorical variables. Attention will be paid to the assumptions for ANCOVA and how these can be checked. Which are the assumptions underlying multway ANOVA? What is the meaning of confounding and effect modification? How can multiway ANOVA help to manage potential confounders? Which profit can be made by expanding from ANOVA to ANCOVA? Which additional assumptions apply to ANCOVA, and how can these assumption be checked? What is meant by an unbalanced design?, and what does such a design imply for AN(C)OVA? These and related questions will be addressed by various paper-and-pencil and computer exercises. Linear regression analysis The principles of (multivariable) regression analysis will be dealt with into more depth. The mutual relationship between AN(C)OVA and regression analysis will be highlighted. Special attention will be paid to the diagnosis and the treatment of confounding and effect modification (interaction), the role of the hierarchy principle in dealing with confounding and interaction, the diagnosis and treatment of collinearity of various predictors of the outcome variable in regression analysis, the role of outliers among the observed values, the check for the assumptions underlying regression analysis, and the principle of dummy coding for binary and polytomous independent variables. Logistic regression analysis The theory and practice of (multiple) logistic regression analysis will be studied. The focus will be on the potentials of this technique to analyse and control for confounding and interaction. As such logistic regression analysis can be considered a logical, multivariate extension of the
method of stratified analysis. The relationship between logistic regression analysis and alternative strategies to deal with
the association between a dichotomous outcome variable and multiple predictor variables, like loglinear regression
analysis and discriminant analysis will be clarified. Attention will be paid to the prerequisites and limitations of this
technique, model specifications, analysis of collinearity, etc. . . Survival analysis in health sciences research there is a
frequently felt need to gain insight into the development over time of the chance of occurrence of relatively rare events,
and how these chances are affected by various risk factors. In such situations study subjects have to be followed during a
certain period of time, the transitions of one state into another have to be registered, and both the waiting times until a
new state occurs and the length of stay in the original and newly acquired states have to be registered. Moreover, the
status of one or more time- dependent personal characteristics and other risk factors that are supposed to be related to
the length of stay in a particular vital state. Nowadays it has become widely accepted to use survival functions and
hazard rates as statistical analysis techniques, instead of the classical regression methods. The hazard rate is a
function of time, which gives at any time point the instantaneous rate of occurrence of a specific event, provided that
this event has not occurred previously. The survival function describes for any point of time the chance that a specific
event will occur after that time-point. Mean and median length of stay in a particular state can be calculated from the
hazard rate and the survival function. In general groups can be compared by calculating the ratio of hazard rates (relative
or multiplicative rate analysis) and graphical plotting of the results (Kaplan-Meier survival curve, cumulative hazard
rates). In order to analyse how length of stay is influenced by personal and environmental risk factors methods of relative
rate regression analysis can be applied, Cox regression being a well-known example. The current popularity of hazard
rate and survival function analyses is mainly due to the way these techniques can account for censored data. By means of
both paper-and-pencil and computer exercises attention will be paid to the various aspects of the methods and

techniques of advanced event- history analysis: the concepts of hazard rate, survival curve, hazard ratio, relative rate
regression analysis, mean and median length of stay; concepts like starting time, censoring, and competing risks;
calculation, testing (e.g. logrank test) and interpretation of hazard rates, survival curves, and hazard ratios; calculation
of confidence limits; construction of survival curves (Kaplan-Meier method); detection of prognostic factors through Cox
regression; assumptions for Cox regression, and differences between Cox regression and alternative regression
techniques, like Weibull regression and Gompertz regression. . . Repeated measurements analysis Some (epidemiological)
study designs are characterized by the fact that the same outcome phenomenon has to be measured repeatedly in the
same study subjects. An advantage of such repeated measurement designs is that, in general, smaller sample sizes are
required to attain the same level of discriminatory power than for ‘regular’ designs, and that effect estimations are more
precise. However, because of the repetition of the measurements one should be aware of the occurrence of spurious
effects, e.g. testing effects, effects caused by fatigue, and carry-over effects, and try to control for these effects by
means of design adaptations. Moreover, correlations between repeated measurements should be taken into account
during data analysis. If the correlations do not fulfil certain criteria, various alternative analytical approaches can be
applied, ranging from simple adjustments of the results of a standard analysis of variance (univariate approach) to a more
complex solution in which the repeated measurements are considered separate dependent variables (multivariate
approach). The most straightforward design includes one single factor that has to be assessed repeatedly (e.g.,
measurements of blood pressure at different points of time during the day). In such a design only an intra-subject factor
can be distinguished (time of the day). The split-plot design and the crossover trial are examples of more complex designs
in which inter-subject factors are involved as well, in addition to intra-subject factors. The split-plot design combines
parsimony with the opportunity to prevent differential carry-over effects. The crossover design is frequently used when
the outcome phenomenon shows a natural course (regression or progression) over time, which may interfere with the
diagnosis of a treatment effect. Each design has specific advantages, but is associated with specific requirements as to
the data analysis at the same time. The case and the exercises will address the various types of repeated measurement
designs, the assumptions to be made when analysing repeated measurement data, concepts like compound symmetry and
puerility, the distinction between main effects and interaction effects, and statistical testing in case of repeated measurements. Research design: choice of statistical techniques and sample size Each scientific investigation can be split up into three phases: design and planning; conduct; analysis and reporting. During the first stage all activities that are part of the second and third stages should be planned and recorded as thoroughly and detailed as possible, in order to prevent disappointments and frustrations during the phase of data analysis. As a final activity of this unit, the students will have to develop the design for a study, starting from a self-selected research question, with special emphasis on the statistical section of the research protocol (choice of strategy for statistical analysis, consecutive tests and procedures to be conducted, estimation of sample size requirements, etc.). Preparations will commence already during the first week of the unit.

**Goals**

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: . Analysis of variance and covariance (elaboration of the previous introduction at bachelor level, e.g. covariates and interaction, estimation and testing, sample size considerations, power, missing values, outliers) Linear regression analysis techniques (elaboration of previous introduction at bachelor level, e.g. covariates and interaction, dummy coding, estimation and testing, sample size considerations, power, missing values, outliers, AN(C)OVA as a linear regression model) Logistic regression analysis for binary outcome variables Analysis of survival data (event-history analysis) Analysis of repeated measurements Choice of appropriate statistical analysis strategy and techniques, given a specific epidemiological research question and study design Appropriate dealing with power and sample size requirements for a given epidemiological research question and study design.

**Instruction language**

EN

**Prerequisites**

**Recommended literature**


**Teaching methods**

PBL
LECTURE(S)
TRAINING(S)

Assessment methods
WRITTEN EXAM

Key words
Trial-based Economic Evaluations

Academic year 2013-14

Date last modified
29-8-2013 1:30

Period
Period 3 Startdate: 06-Jan-14 Enddate: 28-Feb-14

Code
RHS4002

ECTS credits
6.0

Organisational unit
Fac. Health, Medicine and Life Sciences

Coordinator
S.M.A.A. Evers

Description
This unit is structured according to the basic steps (problem 1), which are considered in a trial-based economic
evaluation. Every trial starts with the systematic gathering of the available information using various sources and several
search strategies (problem 1). The core business of trial based economic evaluation is that both costs (problem 2 and 3)
and consequences (problem 4 and 5) are identified, measured and valued. A next step is that all future costs and
consequences should be stated in terms of their òpresent valueò (discounting problem 6). Furthermore estimates of costs
and consequences that are obtained in trial-based economic evaluation are subject for uncertainty for several reasons. In
sensitivity analysis (problem 6) the impact of uncertainty on trial- based economic evaluations is assessed. Economic
evaluations have generated new analytic challenges (problem 7) such as how to incorporate economic evaluations in
sample size calculations, the occurrence of skewed distribution, and censored costs and consequence data. In the final
problem (problem 8) attention is paid to a sound scientific presentation and use of trial-based economic evaluations.
This leads to the following structure of tasks: . Problem 1 Preplanning: basic elements of trial-based economic
evaluations and systematic information gathering. This problem provides an introduction to issues in the design and
analysis of economic assessments conducted in trial based economic evaluation. These relate to the quantifying costs and
outcomes up till the presentation and use of economic evaluation results. Basic knowledge of these issues is necessary for
the critical appraisal of published literate which is point of departure for every trial based economic evaluation. As a
result, this problem furthermore highlights how to identify relevant literature in the field of economic evaluations by
using both general (such as Medline) as well as HTA specific sources (such as the NHS EED). Finally students have to
undertake a critical appraisal of a published trial-based economic evaluation in practice. . Problem 2 and 3 Cost measures
and valuation Several issues surrounding costing been issued in 2.1 Health Technology Assessment. This problem provides
a more in-depth analysis of issues relating to the measurement and valuation of costs (problem 2). Next to that three
particularly thorny issues, the treatment of overhead costs (techniques for allocating shared overhead costs to individual
projects), the role and estimations of productivity costs and, the costing of informal care will be discussed in problem 3. . Problem 4 and 5 Output measures and valuation Economic evaluation is basically on deploying the resources to the intervention with the greatest benefit. In economic evaluation several methods are used for outcome measurements and valuations. In the earlier course attention was be paid to the more traditional methods, which relate mortality, clinically focussed measures and Health Related Quality of Life (HRQoL). Next to a more thorough approach to these methods, attention will be paid to the validity and reliability of the different methods to measure utilities, both at a patient level as well as on a societal level (problem 4). In problem 5 attention will be drawn on alternatives to these traditional methods such as contingent valuation and the conjoint analysis. . Problem 6 Discounting and handling uncertainty Problem 6 will focus on variability and uncertainty. Uncertainty in trial-based economic evaluations is pervasive, entering the evaluation process in every stage. The aim of this problem is to get student acquainted with the state of the art of methods for handling uncertainty in trial-based economic evaluations. In HTA a distinction is often made between deterministic (discussed in HTA1) and stochastic uncertainty analysis. In this module the emphasis is on stochastic analyses, which are relevant in trial-based economic evaluations. In this problem the several types and methods of handling uncertainty in stochastic analysis will be discussed. . Problem 7 Statistical consideration Besides an application of the basic statistics in trial based economic evaluations some typical situation occur in these studies. In this problem we highlight three statistical issues, sample size calculation, skewed distribution, and censored costs and consequence data. As part of a prospective trial, economic evaluators have to consider and justify what sample size in required to conduct a trial-based economic evaluation. Furthermore, the overall picture is that in these studies few patients incur rare but highly expensive costs, while many patients have no or a few costs. This induces a skewed distribution. One of the solutions to trigger this problem is to look how alternative results influence the CE plane and CE acceptability curve. Another issue is that due to the long-term follow-up, the complexity of the instruments or due to the disease and its treatment patients may drop-out of the analysis resulting incomplete data. Several methods for dealing with incomplete data will be discussed in problem 7. . Problem 8 Presenting and using economic evaluation results The objective of trial-based economic evaluations is to improve decisions about the allocation of health care resources. To get insight into the validity and usefulness of a trial-based economic evaluation for allocation of these decisions, the reporting of the results has to be done in a transparent matter. Attention will be paid in this problem to transparent reporting frameworks. Furthermore in using trial-based economic evaluations one has to regard the applicability of these studies. This final problem will also focus on the transferability of trial-based economic evaluations from setting to setting, and from country to country.

**Goals**

Applying knowledge and insight At the end of the module students: . Can apply the theoretical framework of trial-based evaluations to scientific research; Can apply in a sound scientific way the insight and knowledge regarding trial-based evaluations in scientific research; Can see the relationship between the knowledge and insight gained in the earlier module „Health Technology Assessment„, and the current module on HTA. Judgement of: At the end of the module students: . Can judge and interpret the value of trial-based evaluations published in the literature; Can judge, based on their knowledge in this module, the quality, strengths and weaknesses of new developments of trial-based evaluations. Communication At the end of the module students: . Can articulate their opinions regarding trial-based evaluations; Can discuss the value of trial-based evaluations published in the literature; Can discuss the quality, strengths and weaknesses of new developments of trial-based evaluations. Can express, both verbally and written, information regarding trial-based evaluations; Can give presentation regarding the results of trial-based evaluations; Can, in a scientifically sound way, write reports and articles regarding trial-based evaluations. Skills for further teaching At the end of the module students: . Will have the ability to work with colleagues in a multi-disciplinary team which performs trial-based evaluations; Will have the ability to design, develop, analyse, interpret and report trial-based evaluations.
Instruction language
EN

Prerequisites

Recommended literature

Teaching methods
PBL
LECTURE(S)
ASSIGNMENT(S)

Assessment methods
WRITTEN EXAM
ASSIGNMENT

Key words
Advanced HTA Methods

Academic year 2013-14

Date last modified
14-5-2013 1:27

Period
Period 6  Startdate: 02-Jun-14  Enddate: 27-Jun-14

Code
RHS4001

ECTS credits
5.0

Organisational unit
Fac. Health, Medicine and Life Sciences

Coordinator
C.D. Dirksen

Description
Goals
Instruction language
EN

Prerequisites
Recommended literature

Teaching methods
PBL
LECTURE(S)

Assessment methods
WRITTEN EXAM
ASSIGNMENT

Key words
Introduction to Epidemiology

Academic year 2013-14

**Date last modified**
21-2-2014 1:29

**Period**
Period 1  Startdate: 02-Sep-13  Enddate: 06-Sep-13

**Code**
EPI4900

**ECTS credits**
2.0

**Organisational unit**
Fac. Health, Medicine and Life Sciences

**Coordinator**
B.A.J. Verhage

**Description**
The course Introduction to epidemiology is the first unit in the Master of Epidemiology and the Health Science Research Master (HRSM) and will take place within 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 (clinimetrics), basic health measurement, 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 introductory 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 Introduction to epidemiology will be attended by students of the Master of Epidemiology and the HRSM. Besides these students, the course will be available as a stand-alone course for anyone who wants to become acquainted with basic epidemiological methods. The audiences that will be targeted for the course are - PhD students or postdoctoral fellows in the fields of public health, medicine, statistics, and biology; - Medical doctors; and - Health professionals.

**Goals**
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 (confounding, information bias, selection bias) 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 knowledge and understanding of the principles of causality and causal reasoning, and be able to distinguish between various criteria that can be used to assess a causal relationship between exposure and health outcome. - 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 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 research paper)

**Instruction language**
EN

**Prerequisites**

**Recommended literature**
For this introductory course in epidemiology use will be made of the basic epidemiology book Webb P, Bain C. Essential Epidemiology: An Introduction For Students And Health Professionals. Cambridge: Cambridge University Press; 2011. Additional literature will be provided during the course.

**Teaching methods**
PBL
PRESENTATION(S)
SKILLS
TRAINING(S)

**Assessment methods**
ATTENDANCE

**Key words**
Writing a Research Proposal

Academic year 2013-14

Date last modified
21-2-2014 1:29

Period
Period 6   Startdate: 02-Sep-13   Enddate: 04-Jul-14

Code
RHS4101

ECTS credits
0.0

Organisational unit
Fac. Health, Medicine and Life Sciences

Coordinator
C.J.A.W. van Gool - de Vrede

Description

Goals

Instruction language
EN

Prerequisites

Recommended literature

Teaching methods

Assessment methods

Key words
Scientific English

Academic year 2013-14

Date last modified
21-2-2014 1:29

Period
Period 6  Startdate: 02-Sep-13  Enddate: 04-Jul-14

Code
RHS4102

ECTS credits
0.0

Organisational unit
Fac. Health, Medicine and Life Sciences

Coordinator
C.J.A.W. van Gool - de Vrede

Description

Goals

Instruction language
EN

Prerequisites

Recommended literature

Teaching methods

Assessment methods

Key words
Intervention Development

Academic year 2013-14

Date last modified
25-9-2013 1:30

Period

Code
HEP4213

ECTS credits
6.0

Organisational unit
Fac. Health, Medicine and Life Sciences

Coordinator
R.M.M. Crutzen

Description
The focus of this module is on Intervention Mapping (IM), which is a protocol for developing theory- and evidence-based health promotion interventions. IM can guide health promoters through programme development, demystifying and monitoring the development process and eliminating mistakes identified by previous teams. IM describes the process of programme development in six steps: 1) needs assessment, 2) specifying change objectives, 3) selecting theory-based intervention methods and practical applications, 4) designing and organizing of the program, 6) specifying adoption and implementation plans, and 6) generating an evaluation plan. Besides IM, attention will also be paid to effectively cooperating in small groups with persons of different background and initial level, as this is a skill that students will also need in other modules and in their future working environment. The module will be assessed with an individual exam and a group paper.

Goals
The general aim of the present module is to understand and apply steps and principles of the Intervention Mapping Protocol in the development, implementation and evaluation of interventions. Furthermore, the module aims at improving working in teams, as this is part of our curriculum, but also in professional life.

Instruction language
EN

Prerequisites

Recommended literature
S. Parcel, Gerjo Kok, Nell H. Gottlieb, Maria E. Fernández. Students need to search for additional literature (using e.g., PubMed, PsycINFO, and Google Scholar) regarding the specific health problem they target.

**Teaching methods**

- ASSIGNMENT(S)
- WORK IN SUBGROUPS
- LECTURE(S)
- PAPER(S)
- PBL
- TRAINING(S)

**Assessment methods**

- ASSIGNMENT
- FINAL PAPER
- WRITTEN EXAM

**Key words**

- Intervention development
- Intervention Mapping
- Needs assessment
- Selecting theory-based intervention methods and practical applications
- Adoption and implementation plan
- Program objectives
- Evaluation
Molecular and Genetic Epidemiology

Academic year 2013-14

Date last modified
21-2-2014 1:29

Period
Period 2  Startdate: 25-Nov-13  Enddate: 20-Dec-13

Code
EPI4910

ECTS credits
3.0

Organisational unit
Fac. Health, Medicine and Life Sciences

Coordinator
I. Arts

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 high-throughput 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 pro’s and con’s of different study designs used in molecular and genetic epidemiology. 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.

Goals
1. 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: 1. Basic concepts of genetics. 2. Concepts, principles and designs of studies to investigate hereditary disorders characterized by low gene frequency and high gene penetrance. 3. Concepts, principles and designs of population/association studies to investigate hereditary disorders characterized by low gene penetrance. 4. Gene-environment interactions. 2. Applying knowledge and understanding - Ability to read and interpret scientific articles on molecular and genetic epidemiology. 3. Apply the knowledge on sources of variation in molecular and genetic epidemiological studies to optimize the design of such studies. 4. Making judgments - Ability to judge the applicability of principles and methods of molecular and genetic epidemiology to new research themes and questions. 4. Communication - On the design, methodological intricacies and outcomes of epidemiological studies involving genetic and molecular biomarkers. 5. 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.

**Instruction language**

EN

**Prerequisites**

**Recommended literature**

**Teaching methods**

ASSIGNMENT(S)
WORK IN SUBGROUPS
LECTURE(S)
TRAINING(S)

**Assessment methods**

WRITTEN EXAM

**Key words**
Basic Ethics of Health Care Research

Academic year 2013-14

Date last modified
29-8-2013 1:30

Period
Period 4  Startdate: 10-Mar-14   Enddate: 02-May-14

Code
RHS4004

ECTS credits
5.0

Organisational unit
Fac. Health, Medicine and Life Sciences

Coordinator

Description
The unit starts with an introduction into the historical background of research ethics and the development of codes (Neurenberg, Helsinki). Next central concepts are discussed (autonomy, balance between burden for the patient and prospect of result). Attention is payed to the way in which these concepts are laid down in law and function in review boards. A third issue is the tension between methodology and ethics. How to inform the patient without endangering the design? How to ensure that enough patients participate? What to do when one of the alternatives in a randomised trial is unattractive to patients?

Goals
Knowledge and insight The student has knowledge of and insight in: . the historical background of (research)ethics central concepts in research ethics (respect for autonomy, burden of the research) the tension between research ethics and methodology (informed consent, inclusion of subjects, randomisation) Application of knowledge and insight . The student is able to apply knowledge and insight mentioned above to the field of healthcare research Judgment . The student is able to develop a balanced view on basic ethical problems in research with patients Communication . The student is able to communicate conclusions to colleagues in the tutor group Learning abilities . The student is able to study and understand conceptual aspects of basic research ethics

Instruction language
EN

Prerequisites

Recommended literature
. The teaching method in this unit is Problem based learning. The training is based upon role-play. There will be 4 lectures.
Teaching methods

PBL
LECTURE(S)
TRAINING(S)

Assessment methods

WRITTEN EXAM

Key words
Qualitative Research

Academic year 2013-14

Date last modified
11-1-2014 1:30

Period
Period 4 Startdate: 10-Mar-14 Enddate: 02-May-14

Code
RHS4005

ECTS credits
5.0

Organisational unit
Fac. Health, Medicine and Life Sciences

Coordinator
J.S.M. Krumiech

Description

Goals

Instruction language
EN

Prerequisites

Recommended literature

Teaching methods
PBL
LECTURE(S)
ASSIGNMENT(S)
TRAINING(S)

Assessment methods
WRITTEN EXAM

Key words
Cost-effectiveness Modelling Methods

Academic year 2013-14

Date last modified
29-8-2013 1:30

Period
Period 5   Startdate: 05-May-14   Enddate: 30-May-14

Code
RHS4007

ECTS credits
6.0

Organisational unit
Fac. Health, Medicine and Life Sciences

Coordinator
M.A. Joore

Description
This unit is structured according to the PROACTIVE approach to decision analytic modelling as an instrument for health care decision-making. This approach is characterised by 3 major steps, each consisting of three sub steps. Although all these sub steps seem to be a logical sequence of procedures in modelling, iteration through some steps will be necessary. Step 1 of PROactive, PRO is focussing on addressing the right problem (P) and the possible consequences (Reframing the problem) that should be achieved by the decision analytic modelling (Objectives). The second step of proACTive, ACT aims to design and develop the structure of the decision analytic model, by defining Alternatives for handling the medical problem, to model the Consequences of each of the alternatives and to define the Trade-offs by valuing the consequences of the alternative courses of action. The third and final step of proactIVE, IVE concentrates on the calculations that are an important part of decision analytic modelling. First, evidence and values have to be integrated of the different medical options that are to be evaluated. This will result in a Value estimate of the effectiveness and cost-effectiveness of each of the alternative in order to be able to choose on either criterion the one that is to be preferred. Finally, a decision analytic model makes it possible to Explore assumptions and uncertainty explicitly. . This leads to the following structure of tasks: . STEP 1: General introduction to decision analytic modelling and PROactive (1 week) Problem 1 Principles, proÆEs and conÆEs of modelling in economic evaluation Cost-effectiveness models are often positioned as an opponent to trial based economic evaluations, however models serve a different purpose. Several reasons exist for using models instead of empirical research. The aim of models is to synthesize available information about the effectiveness and costs of alternative ways of screening, diagnosing, treating, and rehabilitating patients. In this part of the model questions are studied such as what is a decision analytic model; why model at all; strengths and weaknesses of models; a populationÆ of a tree; the contrast to individual patient decision-making; the contrast and complement to trials . STEP 2: proACTive (2 weeks) Problem 2 Structuring and analysing the decision problem as a tree A decision tree is a graphical presentation of a choice between two or more health technologies that are considered
alternatives for specific patient population. Each alternative is characterised by events that occur by chance: a patient might be treated successfully or experience side effects; a patient might die immediately or live a long live in perfect or imperfect health. These events are called clinical pathways that have to be defined explicitly in a decision model. Topics are: how to define the structure of a tree; what probabilities are relevant in a tree and how can they be defined; which costs have to be estimated; how can health outcomes be defined in a model; what does it mean rolling back a tree and what probability calculations are performed; what are clinical pathway probabilities. Individual learning and individual modelling-task (12 hours). Problem 3 Structuring the decision problem as a Markov model The most important limitation of decision trees is that these models are inefficient or even not useful for health technologies that influence a health state of a patient temporarily. The same is true for disease that are characterised by episodes of different disease stages. Health state transition models or Markov models are suited for these situations. In this part of the module the focus will be on how to structure a Markov model; the meaning and definition of transition probabilities; how to define time dependent transition probabilities; how life expectancy can be used as an outcome of a health state transition model; and how such a model can be used for QALY estimations. . STEP 3: proactIV (4 weeks) Problem 4 Analysing the decision problem as a Markov model After having defined and build a health state transition model, the model has to be populated with data. Of course these data should reflect the real world in order to be able to define the value (utility) of state rewards or to value the transition of one health state to another (transition rewards). Once the values in the models are defined, analysing the model is possible. For that reason a choice has to be made whether a total patient population is basis for the calculation or whether individual patients should be simulated through the model in a so called micro simulation. . Problem 5 Making models probabilistic In principle model calculations can be very precise. One-way sensitivity analyses (discussed in HTA1) are used to show the impact of an uncertain value of a model parameters on the outcome of the model in order to test the robustness of the research conclusions. However, the uncertainty of a model is additionally dependent of the complexity of data used. Probabilistic sensitivity analysis (2nd order Monte Carlo simulation) uses the probability distribution of the parameters that are used in the model in order to assess the multivariable uncertainy in modelling. . Problem 6 Analysing cost-effectiveness and presenting uncertainty There is always a probability that the decision, based on these techniques, turns out to be wrong. Of course risk adverse or risk neutral decision makers want to know what the probability is and what the (financial-) consequences are from making the wrong decision or what the financial consequences and the health gain are for patients. In cost-effectiveness modelling the uncertainty of a cost-effectiveness estimate is explicitly assessed and represented in for instance the cost-effectiveness plane, confidence intervals for ICERs or cost- effectiveness acceptability curves. Net benefit calculations make it possible to estimate the potential gain or loss of a decision in monetary values. . Problem 7 Policy decision-making and the value of information Of course, the incremental cost-effectiveness of a health programme over the comparator is not the only (scientific) information that is taken into account by a decision maker. Sometimes it is worthwhile to postpone a decision to wait for further evidence, which can be assessed by using the expected value of perfect information and expected value of sample information calculations. And besides the cost-effectiveness on a patient level, patient population characteristics are important in order to be able to asses not only the willingness to pay for a health technology but also the ability to pay. These aspects will be studied in the final part of this module.

Goals

Global objective: To learn about the in and outs of decision analytic modelling methods in health economic evaluation. This unit combines a deepening of understanding of the theoretical concepts with a hands-on training of the basic elements of a decision analytic cost-effectiveness model. . Knowledge and insight. Motivation for and principles and methods of cost-effectiveness modelling techniques (decision trees and health state transition models) Recurring events in modelling (cohort simulations vs. 1st order Monte Carlo simulations) Handling uncertainty in cost-effectiveness models (probabilistic sensitivity analysis and 2nd order Monte Carlo simulations, monetary net benefit, and cost-effectiveness
expected Value of Information analysis (International) transferability of cost-effectiveness results
Applying knowledge and insight. Ability to motivate the design of a model Ability to build, analyse, and interpret a
cost-effectiveness model Ability to explore the uncertainty of the results of a model Ability to assess and prioritise
aspects of the model for further research Judgement. Awareness of the quality, strengths and weaknesses of own cost-
effectiveness models and models from other students and researchers. Communication. Ability to discuss and report the
methods and results of a cost-effectiveness model in a group of students, both in written and verbally. Ability to report
the methods and results of a cost-effectiveness model in detail in a technical report. Skills. Ability to work with
colleagues in a multi-disciplinary team Ability to design, develop, analyse, interpret and report a cost-effectiveness
model.

Instruction language
EN

Prerequisites

Recommended literature
Briggs AH, Sculpher M, Claxton K. Modelling methods for health economic evaluation (to be published end of 2005!)
Hunink M, Glasziou P. Decision-making in health and medicine (chapters 1 and 12) Kuntz KM and Weinstein MC. Modelling
Chapter 7, pp 141-171. Briggs AH. Handling uncertainty in economic evaluation and presenting the results. In: Drummond
care; merging theory with practice. Chapter 10, pp 256-276.

Teaching methods
PBL
LECTURE(S)
ASSIGNMENT(S)
TRAINING(S)

Assessment methods
WRITTEN EXAM
FINAL PAPER

Key words
Complex Health Interventions: Evaluation

Academic year 2013-14

Date last modified
26-3-2014 1:26

Period
Period 6  Startdate: 02-Jun-14  Enddate: 27-Jun-14

Code
RHS4015

ECTS credits
5.0

Organisational unit
Fac. Health, Medicine and Life Sciences

Coordinator
E.P.E. Mesters

Description
planning. Although intervention mapping is a framework for planning, implementation and evaluation of interventions, during the intervention mapping course students were merely acquainted with making effective decisions at each step of the program. Intervention Mapping. This course of the Social Science profile of the Health Science Research Master is closely related to the earlier (around November) provided course on. Process evaluation is an essential component of any program evaluation or intervention research effort, but is especially indispensable when dealing with complex interventions. Process evaluation may focus on the extent to which an intervention is implemented with respect to its originally planned content, its accuracy, coverage, and quality. In process evaluations we may also learn about the social relations among program stakeholders, which will at least in part co-constitute the effectiveness of the program. Process Evaluation will be the main focus of interest, in particular evaluation During this course. While conducting process evaluation - often starting at the same moment as the beginning of the intervention/program development- we learn to understand the multiple causes for the intervention results achieved. In addition the process evaluation may help to improve the quality of the program, as the evaluation provides insights in the experienced problems that arise when implementing the program. The diversity of determinants of health (for example at the individual, family, organization, community and policy level) and the comprehensive approaches to public health interventions necessitates the use of multiple conceptual and methodological approaches for carrying out process evaluation. There is no one set of process evaluation questions or evaluation methods (multiple or mixed) that is going to be the most appropriate for all situations. Process evaluations can be conducted formatively (as part of the development of an intervention or may refer to program assessment early in the implementation of the program and used to make changes to the program to make sure the intervention can be implemented as intended) or summatively (done at the end of a program to examine the extent to which an intervention was implemented as it as intended, and the extent to which expected outputs were produced). Firstly, this course will focus on the definitions, aims, relevance, theoretical and methodological underpinnings
concerning process evaluation. Secondly, while developing a process evaluation plan you will learn to apply theoretical insights into practice. In Week 2, we provide a project which students may choose as an example for developing a process evaluation plan. Students may also take their own research project as an example. In week three a implementation training is planned and a site visit to a project management center will be part of the program. This 4-week module entails two 1½-hour meetings per week (except for the last week which has one meeting). Meetings may be preceded by lectures (duration 1½ hours). Meetings and lectures are open for external participants as well (e.g., PhD students). In week 3 one of the meetings is extended and used to provide a training workshop on program implementation. This day is open for external participants as well. This process will be supervised and guided by regular consultation. From week 2, students will individually work on an assignment concerning the development of a process evaluation plan for a project. The report will serve as the exam for this unit.

**Goals**
Affective After this course the student has insight in: 1. The importance of planned and systematic process evaluation; 2. The importance of developing a process evaluation plan of a health promotion intervention. Regulative After the course the students have the skills: 1. To develop a process evaluation plan using mixed methods for a health promoting intervention; 2. To select and apply gathered information during the development of a process evaluation instrument; 3. To elaborate methods of program implementation; 4. To manage a project by working individually.
Social-communicative: After the course the students have the skills: 1. To report on the development of the process evaluation plan in a final paper.

**Instruction language**
EN

**Prerequisites**

**Recommended literature**

**Teaching methods**
WORK IN SUBGROUPS
LECTURE(S)
PAPER(S)
PBL
PRESENTATION(S)
TRAINING(S)

**Assessment methods**
ASSIGNMENT
PRESENTATION

**Key words**
process evaluation, mixed methods, stakeholders, logic model, program, theory, interventions, health,
Acquiring Advanced Professional Skills

Academic year 2013-14

Date last modified
29-8-2013 1:30

Period
Period 6  Startdate: 30-Jun-14  Enddate: 04-Jul-14

Code
RHS4011

ECTS credits
3.0

Organisational unit
Fac. Health, Medicine and Life Sciences

Coordinator
C.J.A.W. van Gool - de Vrede

Description
In this course students experience the writing of a research proposal / grant application. This is an important skill because of the growing importance of acquiring grants. For a grant application to be successful, a number of elements are required. First of all it is necessary to have an original, innovative and scientifically well-founded research question. Furthermore, it is increasingly important to build on to existing expertise and past performance of successful research. A grant application should be technically very well written: it needs a crystal clear structure (problem, objectives, time schedule etc.) Finally, know-how of the strategies of specific funds is increasingly important. Sometimes good applications are not rewarded because they do not fit the funds strategies. During the course students learn about the ins and outs of the main Dutch funds, and students write their own research proposal / grant application

Goals
The objective of this unit is to prepare students thoroughly for their thesis research project and to assist them in developing skills that are considered essential for being a successful health sciences researcher. The modules and their specific objectives and time-schedules are described in Module 1, Module 2 and Module 3. The main objective of this course is to learn how to write a grant application. To facilitate this there are the following objectives: . Knowledge and insight: . Students learn about the contents of the various elements of a grant application; Students learn about the various funds, their strategies and procedures, their focus, their rules. Applying knowledge and insight: Students learn how to write and submit a grant application. Students learn where to find and how to approach various funds. Judgement of: . Students learn the pitfalls and conditions for success in obtaining grants. Communication: . Students learn how to apply for funding of research projects. Students present their research project for an audience of teachers and students. Skills for further teaching: Students can apply the learnt skills in a future research environment.
**Instruction language**
EN

**Prerequisites**

**Recommended literature**

**Teaching methods**
LECTURE(S)
TRAINING(S)

**Assessment methods**
WRITTEN EXAM
FINAL PAPER
PRESENTATION

**Key words**
Internship and Thesis

Academic year 2013-14

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Period
Year  Startdate: 01-Sep-13  Enddate: 31-Aug-14

Code
RHS4013

ECTS credits
60.0

Organisational unit
Fac. Health, Medicine and Life Sciences

Coordinator
R.A. de Ble

Description

Goals

Instruction language
EN

Prerequisites

Recommended literature

Teaching methods

Assessment methods

Key words