LMU LUDWIG-MAXIMILIANS-UNIVERSITÄT MÜNCHEN

How to write a protocol

Scentific Skills Course
WS 08/09

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What is a protocol?

A protocol is a document that describes the objective(s), design, methodology, statistical considerations and organization of a study.

With other words:

A protocol is a document which (ideally) answers all questions about the planned study as well as about all aspects potentially arising during the study.

→ cornerstone of any epidemiological research project

General aspects

The primary objective of a protocol is …

- to justify the relevance of the hypothesis and the need of the study
- to demonstrate the appropriateness of the proposed methods for testing the stated hypothesis
- to demonstrate the feasibility of the proposed study in the specific time and with available resources

Additionally …

- Prevents failure to collect crucial information
- Lays down the rules for all partners
- To obtain approval of ethical committees
- Application for funds

Guidelines

Clinical Trials:

Chapter 6 of GCP ICH Topic E 6 (R1) Guideline for Good Clinical Practice (CPMP/ICH/135/95)

Epidemiological research:

no standard structure for a protocol

→ Good Epidemiologocal Practise (GEP) - Guidelines

Guidelines: Clinical Practise

Chapter 6 of GCP ICH Topic E 6 (R1) Guideline for Good Clinical Practice (CPMP/ICH/135/95)

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Guidelines: GEP

GOOD EPIDEMIOLOGICAL PRACTICE (GEP)

IEA GUIDELINES FOR PROPER CONDUCT OF EPIDEMIOLOGICAL RESEARCH

SUMMARY

In these guidelines, we begin by outlining the background to epidemiological research and the role of ethics committees. We then summarise the four general ethical principles for research and the important concept of informed consent. The second section provides suggested rules for good research behaviour under the headings of working with personal data, data documentation, publication, and exercise of judgment with a final note on scientific misconduct. It is our intention that these guidelines will be kept under regular review as new problems and opportunities emerge.

http://www.dundee.ac.uk/iea/GoodPract.htm

Leitlinien und Empfehlungen zur Sicherung von

Guter Epidemiologischer Praxis (GEP)

Langversion

Arbeitsgruppe Epidemiologische Methoden der Deutschen Arbeitsgemeinschaft für Epidemiologie (DAE)

In Zusammenarbeit mit der

Deutschen Gesellschaft für Medizinische Informatik, Biometrie und Epidemiologie (GMDS),

Deutschen Gesellschaft für Sozialmedizin und Prävention (DGSMP)

Deutschen Region der Internationalen Biometrischen Gesellschaft (DR-IBS)

http://www.dgepi.de/infoboard/stellungnahmen.htm

Guidelines: GEP

Good Epidemiological Practice – proposal for a protocol
(adapted from London School of Hygiene and Tropical Medicine, MSc in Epi)

Structure:

1. Background (reasons for study)
2. Overview of study design
3. Methods (detailed design)
4. Logistics
5. Pilot studies
6. Data procession and analysis
7. Reporting
8. Long-term plans
9. Ethical considerations
10. Timing
11. Staff
12. Finances
13. Supplements

Protocol:
1. Background

- what is already known ?
  (review literature)
- why is it necessary to conduct the study ?
  (importance of subject area)
- how this will add to existing knowledge ?
  (what is unknown)
- what are the objectives / hypotheses tested ?
- what are the long term goals ?
  (influence on future action/research; how will study results be used)

→ many studies have been conducted that should never have been started!

Protocol:
2. Overview of study design

1. detailed specification of aims, objectives and specific hypotheses

   SMART-rule:
   - Specific – 'not focus on…'
   - Measure something
   - Action orientated – 'in order to…'
   - Relevant
   - Time specified

   main objective dictates design and methods
2. type of study

   (with brief justification)
3. population under study
4. outline of data to be collected

Excursus: Accuracy of hypotheses I

Example I:

To detect an incidence of meningoencephalitis associated with MMR vaccines that would be considered of public health importance subsequent to the introduction of a new MMR vaccine in Germany.

Excursus: Accuracy of hypotheses II

Example II:

Hypothesen :

1. Die Effizienz der Versorgung am Unfallort und in der frühen klinischen Phase (z.B. notfallmed. Maßnahmen) beeinflußt das Outcome 12 Monate nach Unfall.
2. Eine Verschlechterung der Prognose (Outcome 12 Monate nach Unfall) kann erwartet werden:

- wenn ein Patient vom Unfallort nicht direkt in eine neurotraumatologische Einrichtung, sondern erst nach Aufnahme in eine allgemeine Unfallklinik zuverlegt wird.
- wenn Verzögerungen der präklinischen und klinischen Versorgung auftreten.

3. Die Qualität der Versorgung ist regional, Tages-, Wochen- und jahreszeitlich unterschiedlich.

Excursus: Accuracy of hypotheses III

Example III:

Primary objectives:

To test the influence of the protein content of the infant formula fed during the first year of life on growth until the age of two years (main outcome measures: length and weight velocity).

Statistical analysis

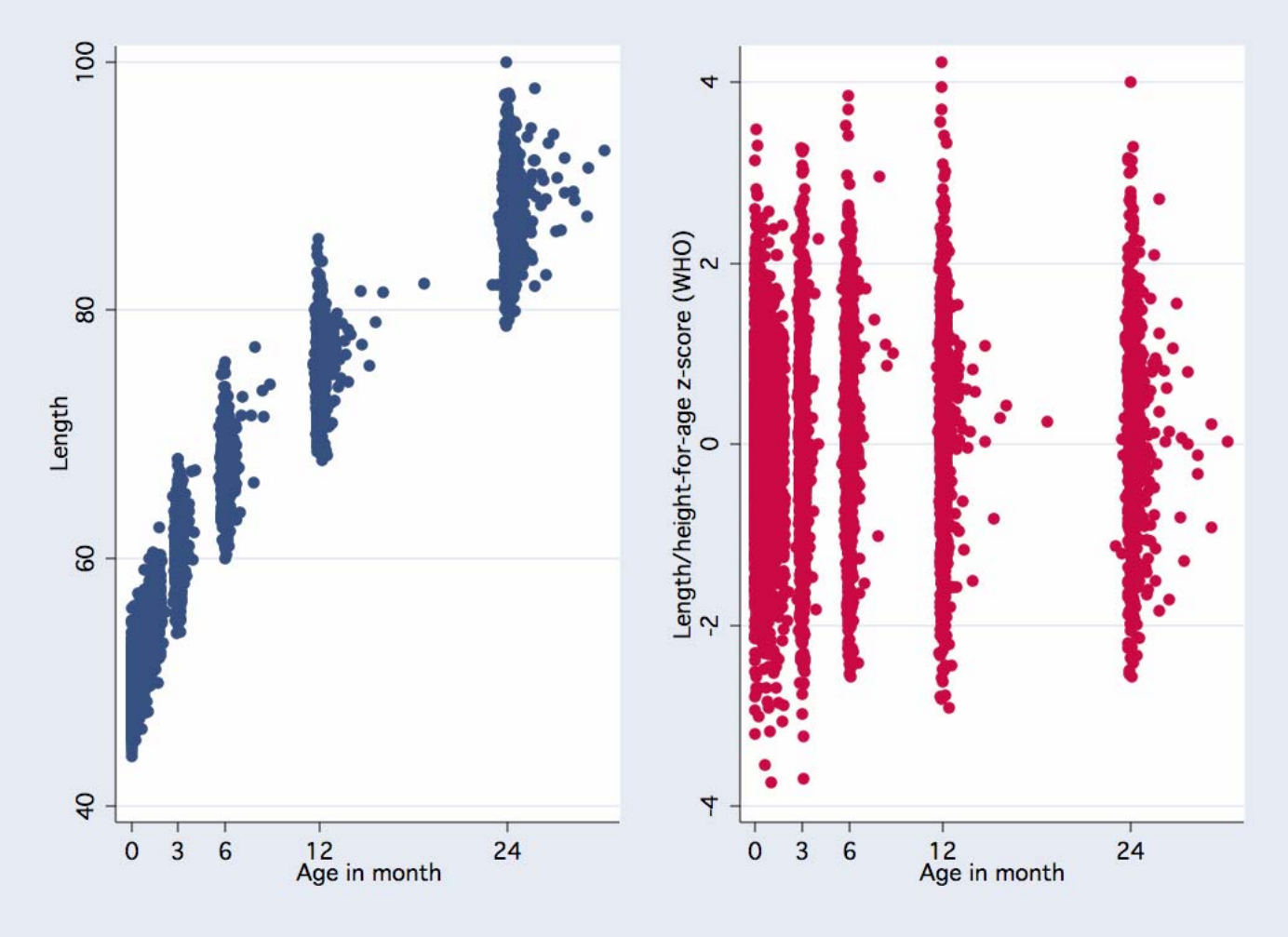
The following primary hypothesis will be considered, using ANOVA-techniques:

H1: There is a difference in length velocity until age of 2 years between the two intervention groups

H2: There is a difference in weight velocity until age of 2 years between the two intervention groups.

Excursus: Accuracy of hypotheses III

This is how it was done:



Excursus: Accuracy of hypotheses III

This is how it was done:

"The primary endpoints were length and weight at 24 months, which were expressed as standard deviation scores (z-score) of length-for-age and weight-for-length. Weight-for-length shows less variation than weight-for-age and is a better descriptor of body composition in children then weight. We applied z-score outcomes, because they make the data more comparable to other studies, standardize for gender, and take into account the true age at the measurement. Growth up to 24 months of age was analysed by adjusting the respective anthropometric measurement for its baseline measurement as recommended. (…) Anthropometric results were expressed as z-scores relative to the growth standards of the World Health Organization for breastfed children "

Excursus: Accuracy of hypotheses IV

Example IV:

2. To describe the incidence of invasive *H. influenzae* and Hib disease in Germany 2001 through 2007 in the context of historical rates observed prior to licensure of hexavalent vaccines (generated by ESPED surveillance data 1998-2000).

3. To estimate the effectiveness of hexavalent vaccines with a follow-up up to six years:

   a. after incomplete primary series;
   b. after a complete primary series;
   c. after receiving a booster / 2nd year dose after the age of 11 months following no or incomplete priming;
   d. after a complete primary series followed by a booster dose at the age of 11 months or later ('fully immunised');

   e. after any number of vaccinations but not according to the recommended schedule.
   f. after an immunisation according to the recommended schedule.

   For definitions see section 4.3.

Protocol:
3. Methods (detailed design)

1. population to be studied
2. sampling
3. data requirements
4. sample size
5. data collection methods (for quantitative data)
6. sources of bias
7. definitions

Protocol:
3. Methods (detailed design)

1. population to be studied

appropriateness for study objectives
background information
representativeness (generalisability of findings)
expected problems:
cooperation / availability of support / stability (e.g. follow-up)

2. sampling
3. data requirements
4. sample size
5. data collection methods (for quantitative data)
6. sources of bias
7. definitions

Protocol:
3. Methods (detailed design)

1. population to be studied

2. sampling

sampling units (persons, households, …)
sampling methods/frame (random / cluster / stratified, …)
(cases and controls)
precise exclusion and inclusion criteria
action in event of refusal or non-response
if relevant: instructions to persons selecting sample
randomisation procedures

v1

3. data requirements
4. sample size
5. data collection methods (for quantitative data)
6. sources of bias
7. definitions

v1 würde ich streichen

v.grote; 28.11.2008

Protocol:
3. Methods (detailed design)

1. population to be studied
2. sampling

3. data requirements

what items will be measured?
How are they measured? (continuous, categorical, …)

CAVE:
don’t overload study
accuracy vs. practicability
implications of errors and variation

4. sample size
5. data collection methods (for quantitative data)
6. sources of bias
7. definition

Protocol:
3. Methods (detailed design)

1. population to be studied
2. sampling
3. data requirements

4. sample size

- what level of precision is required for estimates?
- what is the expected size of differences to be measured?
- what is the minimum difference we wish to be able to detect?
- what is the expected variance of data?
- what power is required?

5. data collection methods (for quantitative data)
6. sources of bias
7. definition

Protocol:
3. Methods (detailed design)

1. population to be studied
2. sampling
3. data requirements
4. sample size

5. data collection methods

design of questionnaires
recording materials (forms, cards, …)
instructions to interviewers/field workers
- variation between interviewers
- number of interviews per day
- handling of specimens / storage and transport
- labeling and recording
- …

method specification of measurements (e.g. blood pressure)
(double) blind?
identity of individuals in case of follow-up
flow chart for data collection in the field
quality control – initially, during survey

6. sources of bias
7. definition

excursus: Design of questionnaires

1 – Which family member smokes?

	yes, smokes	no, does not smoke	unknown
father/mother's partner	☐	☐	☐
mother/father's partner	☐	☐	☐
childs sibling	☐	☐	☐
grandfather	☐	☐	☐
grandmother	☐	☐	☐
others	☐	☐	☐

excursus: Design of questionnaires

2 - Does any of the parents or grandparents suffer from CVD – cardiovascular disease (stroke, angina, heart attack) or hypertension?

	CVD	hypertension	unknown
father	☐	☐	☐
mother	☐	☐	☐
grandfather	☐	☐	☐
grandmother	☐	☐	☐

excursus: Design of questionnaires

QUESTIONNAIRE OF FOOD HABITS AND PARENTAL ATTITUDES TO CHILD FEEDING

1. Does your child get any supplements on a regular basis (3 or more times a week)?
   Please tell us what kind of supplements your child gets, the name and the manufacturer of the preparation as well as the dose/amount your child takes per day!

   ☐ no
   ☐ yes → which: *(see table)*

	Name and manufacturer of the preparation	Quantity a day (drops, teaspoons, tablespoons, …)
vitamins (like Vit. D, C)		
minerals (like Iodine, Calcium)		
vitamins + minerals combined		
others, please specify:		

excursus: Design of questionnaires

Erinnern Sie sich nun bitte an die ersten drei Lebensmonate Ihres Kindes.

1a. Hat Ihr Kind damals mehr als drei Stunden täglich gequengelt oder geschrieen?

☐ Ja
☐ Nein *=> weiter mit nächstem Fragenblock*

1b. Trat dieser Zustand mindestens an 3 Tagen in der Woche auf?

☐ Ja
☐ Nein *=> weiter mit nächstem Fragenblock*

1c. Hat dieser Zustand länger als drei Wochen angehalten?

☐ Ja
☐ Nein *=> weiter mit nächstem Fragenblock*

Protocol:
3. Methods (detailed design)

1. population to be studied
2. sampling
3. data requirements
4. sample size
5. data collection methods (for quantitative data)

6. sources of bias

- non-response – substitutions do not remove bias
- selection bias
- interviewer variation
- measurement errors
- information bias
- non ‘blind’ examination
- confounding – variables to include

7. Definition

Protocol:
3. Methods (detailed design)

1. population to be studied
2. sampling
3. data requirements
4. sample size
5. data collection methods (for quantitative data)
6. sources of bias

7. Definition

   outcome variable
   exposure variables
   confounders
   effect modifiers

   → be clear and precise!

Excursus: Definitions I

Example I:

4 DEFINITIONS

4.1 Haemophilus influenzae cases

A case of invasive *Haemophilus influenzae* infection will be defined as any hospitalisation due to a systemic infection clinically compatible with an invasive *H. influenzae* disease (e.g., meningitis, pneumonia, epiglottitis, septicaemia, cellulitis, arthritis) and isolation of *H. influenzae* from a normally sterile body site such as blood or cerebrospinal fluid. All cases occurring in children less than 10 years of age are to be reported.

Excursus: Definitions II

Example II:

4.3 Categories of Vaccination status

According to the recommended German vaccination schedule the following two vaccination categories were defined:

Completeness of vaccination schedule

- Incomplete primary series: after receiving 1-2 doses in the first year of life.
- Complete primary series: after receiving at least three doses of DTaP-containing Hib combination vaccines in the first year of life.
- Boosted or 2nd year dose: after receiving a booster dose at the age of 11 months or later following full priming, or any dose in the second year of life regardless of priming
- A specification of the latter category is:
  Full immunisation: after receiving a booster dose at the age of 11 months or later following full priming.

Protocol:
4. Logistics

- participating institutes
- responsibilities and tasks of each partner
- adequate staff with appropriate skills and time available
- equipment checklists
- data ownership / transmission of data
- flow charts and time charts

→ anticipate action in event of illness, vehicle breakdown etc.

Protocol:
5. Pilot studies

- what aspects need pilot investigation?

→ anticipate design changes as result of pilot study

→ do not rush into main study too soon

Protocol:
6. Data processing and analysis

- processing of forms and questionnaires -
  where to store? who for data entry? double data entry? ...
- coding – how? who? where? when? what categories?
- validation and 'data cleaning' (DVP)
- Statistics (SAP)
  descriptives (mean / median?; min-max / percentiles?)
  what p-value, CI, …
  consideration of confounding
    - stratification
    - multivariable analysis
  type of statistic (Chi-Square, Cox regression, …)

Protocol: 7. Reporting

- report: when due? what extend? (interim, end, exact date)
- planned publications:
  topic, time plan, authors, authors order
- role of the sponsor / supporter:
  right to participate in writing, embargo period
- information of participants
- information of the public / politicians
- when to inform whom?

→ It is an ethical requirement to publish the results of a trial

→ Principal investigators (PI) should have full rights to publish and should be responsible for interpretation of results

→ PIs should feel responsible to inform the public if the study results indicate action (recommendations)

Protocol: 7. Reporting

STROBE Statement (http://www.strobe-statement.org/):
checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of

Excursus: Role of the sponsor

Example:

… the university and its employees shall keep in confidence the results of the project or any other know-how, data processes, or other information marked as confidential by the Sponsor, as far as this is of justified interest of the Sponsor.

… We agree that you shall have the right to publish or permit the publication of any information or material relating to or arising out of the work after prior submission to the Sponsor. Any proposed publication / presentation for submission to a journal or scientific meeting should be sent to the Sponsor who will undertake to comment on such documents within four weeks. The Sponsor will not refuse publications without substantial reasons.

Excursus: Role of the sponsor

Example:

… The Investigators have the right to publish or permit the publication of the results or any information or material relating to or arising out of the Project. Any proposed publication / presentation for submission to a journal or scientific meeting will be sent to the Sponsor who will undertake to comment on such documents within 30 days. The Investigators commit themselves to take into account reasonable remark raised by the Sponsor. …

Protocol:
8. Long-term plans

- storage of questionnaires and data recording forms
- storage of specimens
- possible follow-up investigations

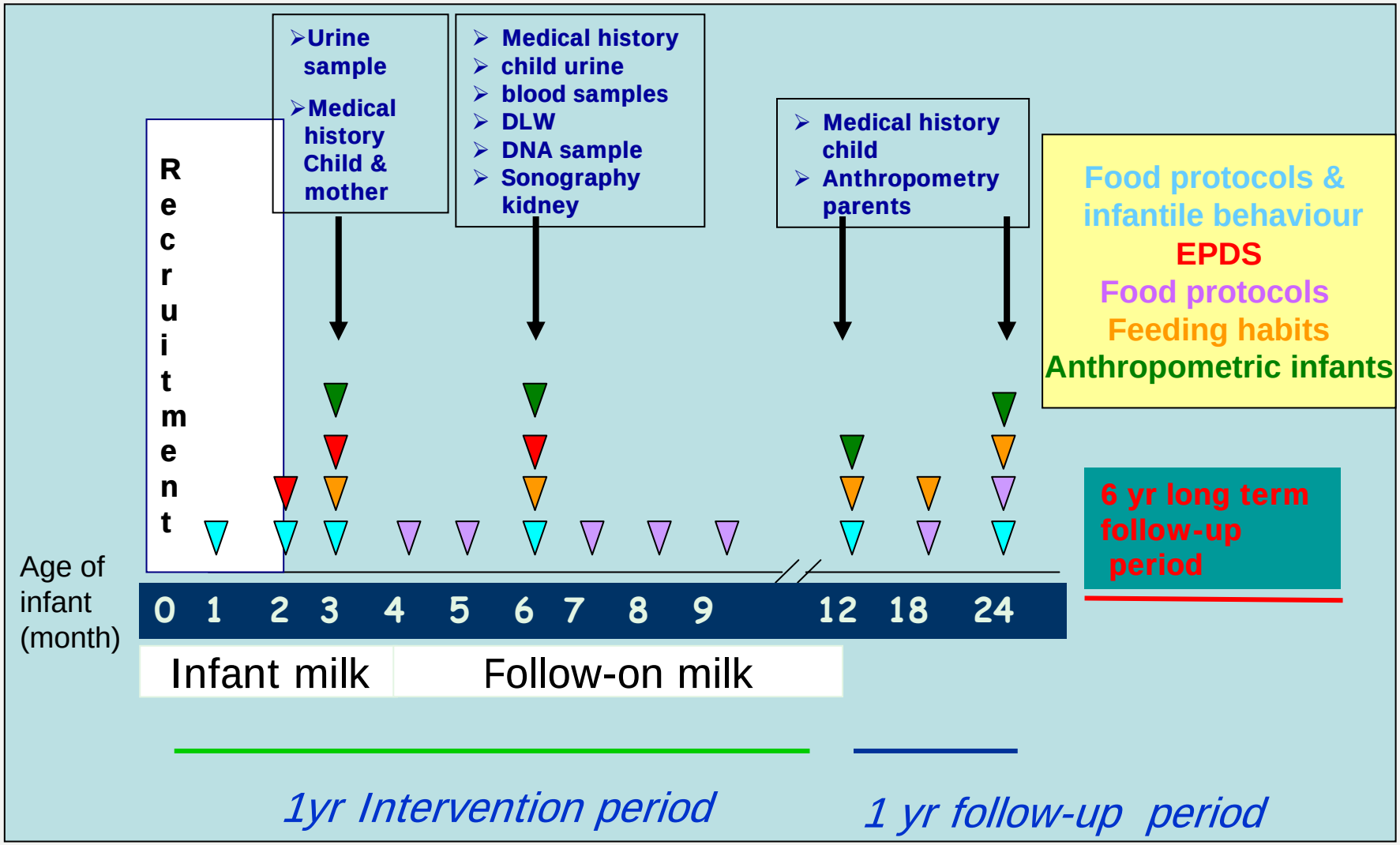
Protocol:
9. Ethical considerations

1. ethical committee review (Declaration of Helsinki)
2. informed consent
3. individual vs. community considerations
4. confidentiality – record anonymity / data storage
5. political, social, economic considerations

Excursus
Ethics + data protection: example

- Intervention study + observational birth cohort (breastfed children)
- Intervention: two formula of lower and higher protein content randomized to children exclusively formula fed
- Objective: Does the protein content (in the range of allowance) of formula influence growth (and the later risk of obesity)?

Excursus
Ethics + data protection: example



Excursus
Ethics + data protection: example

- What ethical issues arise in this type of study?

Excursus
Ethics + data protection: example

- Cohort study → personal data needed for contact of a longer period
- Intervention: specific recommendations of the conduct of the study, including safety
- Invasive procedures: risks
- Diagnostic procedures: what happens with pathologic values/results
- Children: cannot give consent → specific care has to be taken
- Insurance: intervention, invasive procedures, travel
- Breastfeeding is the standard feeding method → do not intervene by study design
- Strenuous protocol with a lot of measurements → good reasoning

Excursus
Ethics + data protection:
Helsinki declaration

WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI
Ethical Principles for Medical Research Involving Human Subjects

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended by the:
29th WMA General Assembly, Tokyo, Japan, October 1975
35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September 1989
48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
52nd WMA General Assembly, Edinburgh, Scotland, October 2000
53th WMA General Assembly, Washington 2002 (Note of Clarification on paragraph 29 added)
55th WMA General Assembly, Tokyo 2004 (Note of Clarification on Paragraph 30 added)
59th WMA General Assembly, Seoul, October 2008

Excursus
Ethics + data protection: Helsinki declaration

A. INTRODUCTION

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects**,** including research on identifiable human material and data.
The Declaration is **intended to be read as a whole** and each of its constituent paragraphs should not be applied without consideration of all other relevant paragraphs.
(...)
9. Medical research is subject to **ethical standards that promote respect for all human subjects** and protect their health and rights. Some research populations are particularly vulnerable and need special protection. These include those who cannot give or refuse consent for themselves and those who may be vulnerable to coercion or undue influence.
(...)

B. PRINCIPLES FOR ALL MEDICAL RESEARCH

11. It is the duty of physicians who participate in medical research to protect the (…) **right to self-determination, privacy, and confidentiality** of personal information of research subjects.
12. Medical research involving human subjects must **conform to generally accepted scientific principles**, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory (…).
(...)
14. The design and performance of each research study involving human subjects must be clearly described in a research protocol. The protocol should indicate (…) how the principles in this Declaration have been addressed. The protocol should declare (...) **potential conflicts of interest** (...).
15. The research protocol must be **submitted** (...) to a research ethics committee **before the study begins** (...). No change to the protocol may be made without consideration and approval by the committee.

CHECKLISTE ZUR ETHISCHEN BEGUTACHTUNG EPIDEMIOLOGISCHER STUDIEN	
Fragestellung der Studie	vgl. Anmerkung
• Fragestellungen und Ziele der geplanten Studie	3.1
• Relevanz der Studie für die epidemiologische Forschung	3.1
• Formulierung von Forschungshypothesen	3.2
Studienplanung und Studiendesign	
• Art der Studie (z.B. Kohortenstudie, Fall-Kontroll-Studie)	2.1, 2.2
• Fallzahlabschätzung	3.3
• Auswahl der Studienteilnehmer	3.4
• Statistische Methoden	3.2
Erhebungsinstrumente	4
• Darstellung der verwendeten Erhebungsverfahren	
• Invasivität	
• Unmittelbare und mittelbare Risiken	
Probanden-Information und Einverständniserklärung	
• Information der Probanden über Ziele und Ablauf der Studie	5
• Einverständniserklärung (Form, Reichweite)	5, 5.3
• Ausnahmeregelungen zum Einholen des Einverständnisses	5.1
• Erweiterung der Fragestellung	5.2
Vertrauliche Behandlung der Daten	
• Art und Umfang der Anonymisierung	6.1, 6.2
• Regularien der Weitergabe von Daten/ der Kooperation mit anderen Wissenschaftlern	6.3
Rechtliche Beziehungen	7
• Wegeversicherung und zusätzliche Probandenversicherung	
• Probanden-Honorar	
Biologische Materialien/genetische Marker	
• Art der gewonnenen Materialien (gering-, hochinformative Marker)	8
• Einverständniserklärung	8.1
• Spätere Erweiterung der Fragestellung und Rückgriff auf vorhandene Materialien/Befunde	
– gering-informative Marker	8.2
– hoch-informative Marker	8.3
Kommunikation der Ergebnisse	9.1, 9.2
• Wissenschaftliche Publikation	
• Information von Probanden, Angehörigen, Hausärzten	
• Mitteilung an Entscheidungsträger, allgemeine Öffentlichkeit	

aus:

Entwurf einer Checkliste zur ethischen Begutachtung epidemiologischer Studien

Deutsche Arbeitsgemeinschaft für Epidemiologie
(Entwurf Wichmann HE, Jöckel KH, Raspe HH, Kohlmann T (federführend)

http://www.daepi.de

Excursus
Ethics + data protection: legislative basis

§ 3 Bundesdatenschutzgesetz:

(1) Personenbezogene Daten sind Einzelangaben über persönliche oder sachliche Verhältnisse einer bestimmten oder bestimmbaren natürlichen Person (Betroffener).

Excursus
Ethics + data protection: anonymisation

Anonymised data (§ 3 Abs. 6 BDSG)

- Absolute anonymisation: no relation to subjects possible
  → legislation for data protection do not apply

Is this generally valid for a dataset with ICD10-discharge diagnosis routinely produced in hospitals when leaving only ICD10 diagnosis, year of stay, length of stay, and age in years (months for the first year of life) and sex in the dataset?

Anonymised data (§ 3 Abs. 6 BDSG)

- Absolute anonymisation: no relation to subjects possible → legislation for data protection do not apply

- factual anonymisation:
  relation to a subject is only possible with disproportional effort (time, cost and workforce)

  here, individual rights/risks and scientific needs have to be balanced; depending on the evaluating person, Bundesland, organisation different solution could be archived; → this needs some efforts of reasoning in the protocol
  (at least in the ethical application!)

- pseudonymization:
  all person-related data within a data record is replaced by one artificial identifier

Excursus
Ethics + data protection: categories of high relevance

Specific types of person-related data (§ 3 Abs. 9 BDSG)

Data on

- race and ethnic background
- political position/attitudes
- religious and philosophical beliefs
- affiliation to trade unions
- health
- sexuality

Excursus
Ethics + data protection: attainment of study aims

- Data collection has to be indispensible for attainement of the study aims
- No stockpiling of data
- Personal data can only be used for the purpose they were collected for (appropriation).

→ Study aims can be fomulated in a way that makes post-hoc changes possible!

e.g. new scientific evidence / new hypothesis or new candidate genes

Excursus
Ethics + data protection: logistics

- Collection, processing and use of personal data is to be protected by technical and organisational measures

- e.g.
  - Storage of names, addresses in a place physically separated from other collected data
  - access authorisation procedures
  - use of a trustee (notary or similar)
  - telematic and encryption technology

Excursus
Ethics + data protection:
Consent form - requirements

- Information
  - Who is responsible?
  - What data are processed?
  - Who is processing?
  - What is the aim of storage?
  - Where and for what time what data are stored?
  - Who has access to the data?
- Voluntariness
  - Ban on tie-ins („Lockvogelangebote“)
  - Economic dependency
- Formularities
  - accentuate consent
  - written
  - Possibility to withdraw consent

Excursus
Ethics + data protection

- Please see also:

http://www.dgepi.de/infoboard/stellungnahmen.htm

Protocol:
10. Timing

- planning / organisation
  - **design forms/questionnaires**
  - **recruitment and training of staff**
  - **obtain equipment (vehivles, drugs, printed questionnaires, …)**
  - **get permissions**
  - **get ethical**
  - **local and/or national administration**
  - **get informed consent**

- pilot study
  - **train stuff**
  - **test methods**
    - **– e.g. validate questionnaire**
  - **adjust procedures for final study**

→ Visualize time tables

- final study
  - **complete preparations**
  - **fieldwork and data collection**
  - **follow-up**
  - **consider possible ‘disasters’ (e.g. sickness)**
  - **analysis (data preparation, computing)**
  - **write up**
  - **publication lag**
  - **travel time, time for holidays and congresses**
  - **overall timing**

Protocol: 11. Staff

1. definition of jobs
   - number required – field, laboratory, office
   - age, experience, qualifications
   - salary
2. recruiting and selection
   - personal contacts
   - advertising
   - interview and other selection methods
3. training
4. duration of employment – careers structure
5. consultants and advisors

Protocol:
12. Finances

1. Source of funds
2. Complete budget – capital and recurrent costs

   salaries, travel, equipment, petrol, printing, stationary, postage, telephone

   fees for services – consultants, laboratory tests

   computing

   flexibility for unexpected costs

   contingency (if allowed)

1. Inflation, devaluation
2. Role of the sponsor / supporter

Excursus: Funding opportunities

http://www.uni-muenchen.de/forschung/forschungsfoerderung/index.html
LMU Munich
http://www.dfg.de/forschungsfoerderung/foerderung_uebersicht.html
Deutsche Forschungsgemeinschaft (DFG)
http://cordis.europa.eu/fp7/home_en.html
Community research and development information service
Forschungs- und Entwicklungsinformationsdienst der EU
http://cordis.europa.eu/fp7/ict/
ICT auf CORDIS
www.nks-lebenswissenschaften.de
national contact point life sciences, Germany
Nationale Kontaktstelle Lebenswissenschaften
www.nks-ist.de
national contact point ICT, Germany
Nationale Kontaktstelle ICT
www.kowi.de
Koordinierungsstelle der EU Wissenschaftsorganisationen

Protocol: 12. Finances

Personal-durchschnittssätze der DFG für das Jahr 2008

Entgeltgruppe nach TV-L	Vergütungs-/ Besoldungsgruppe	West 2008 Euro/Jahr	Ost 2008 Euro/Jahr
	C4, W3	94.800	90.000
E 15Ü	BAT I (A16, C3, W2)	81.600	76.800
E 15	BAT Ia (A15, C2)	72.000	67.200
E 14	BAT Ib (A14, C1, W1)	66.000	62.400
E 13	BAT IIa (A13)	58.800	55.200
E 12	BAT III	54.000	50.400
E 11	BAT IVa	50.400	46.800
E 10	BAT IVb	45.600	43.200
E 9	BAT Va/b	42.000	39.600
E 8	BAT Vc	36.000	33.600
E 7	---	34.800	32.400
E 6	BAT VIb	33.600	31.200
E 5	BAT VII (MTArb)	31.200	30.000
E 4	---	31.200	28.800
E 3	BAT VIII	30.000	27.600
E 2	BAT IXb, Ixa	28.800	26.400
E 1	---	26.600	25.200
	Wissenschaftliche Hilfskraft (mit Abschluss)	18.000	16.800
	Studentische Hilfskraft	12.000	10.800

Protocol:
13. Supplements

- (Methodological appendices)
- References (or separate point)
- Questionnaires
- Variable list with definitions
- Introductory letter to study participants
- Forms for informed consent
- Amendments which describe changes in the study structures not considered in the protocol

Protocol: Common problems

- Too ambitious: too many questions
- Insufficient attention to previous literature
- Poor justification
  why is it important to answer this question?
  what impact does it have on public health?
- Poorly formulated objectives! Unspecific
- Inappropriate analysis
- Inadequate description
- Absence of pilot or test