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Essentials of good epidemiological practice

Written in good faith for the betterment of epidemiology in Switzerland

Given the importance of epidemiological work to policy and individual decisions in health care, the Epidemiology Group of the Swiss Society for Public Health decided to propose the following Essentials of Good Epidemiological Practice (EGEP). These recommendations are intended for all persons and institutions who are involved in commissioning, planning, preparation, conduct, analysis, assessment, review, valorisation or financial support of epidemiological studies.

We aimed to propose minimum standards for practices and procedures that should help to ensure good quality and integrity of epidemiological research, and to foster adequate reporting of the research results. The EGEP do not prescribe specific research methods, but state general and essential principles that provide

1. a standard reference to assist epidemiologists and allied scientists in public health research to adhere to good epidemiological practices,
2. a framework for the assessment of epidemiological work,
3. a structure to facilitate communication and collaboration among those involved in epidemiological studies, and
4. references for further information and consultation.

The intent was not to reformulate existing work (IEA 2004; IEA 1991; DAE 2004; ADELF et al. 1998; MRC 2000; American College of Epidemiology 2000; International Society for Pharmacoepidemiology 1996; Weiss 2000) nor to debate ethical principles of epidemiology. Instead, references have been made to previously published documents.

Epidemiology is a scientific discipline that studies the frequency, distribution, and determinants of diseases or health disorders in defined populations. Epidemiologists study conditions of good health, as well as the different factors influencing onset, course, and consequences of diseases and possible methods of prevention (Last 2001).

In epidemiology two main types of studies can be distinguished: observational studies and interventional studies. Ethical guidelines published for medical research (Good Clinical Practice (U.S. Food and Drug Administration 2000; European Union 2001; International Conference on Harmonisation of Technical Requirements 1996), Helsinki Declaration (World Medical Association 2004)) are primarily concerned with experimental designs in clinical research and do not cover many of the issues arising in observational studies often used in public health inquiry. The guidelines (IEA 2004) published by the European Epidemiology Federation was structured by four generally recognized ethical principles, which the EGEP also adopted as its ethical basis.

1. Autonomy *(Respect for individuals)*: Individuals have the right to choose and thus the right to know about the personal consequences of joining a study.
2. Beneficence *(Do good)*: Participants in research should be treated well. The research should aim at producing results beneficial for humankind
3. Non-maleficence (*Do no harm)*: Participants in research should not be subject to unjustified or avoidable burdens. Personal integrity should not be harmed. Misleading publications are unethical.
4. Justice: The same ethical standards apply for every subject and in every country. It is unacceptable to export risky research activities to disadvantaged countries and to carry out hazardous or burdensome research activities with vulnerable individuals to the benefit of others. Collegial behaviour should be fair and just.

Given constraints in resources, priorities should be set regarding the type and depth of epidemiological work or research to be conducted. Researchers should avoid working on research questions already definitely solved.

Soz.- Präventivmed. 50 (2005) 12 – 15
0303-8408/05/010012–4
DOI 10.1007/s00038-004-4008-8

Ideally a research project follows three phases: (1) the definition of the research question and the writing of the research protocol, (2) the realization of the study, and (3) the publication of the results. The following recommendations are presented according to these phases.

Study protocol

The study protocol compiles the essential elements of an epidemiological research project in written form. In it, the purpose of the study, the design, the target population, and the planned analyses are carefully described; administrative issues, potential problems and limitations are considered. Because the development of good protocols is a fundamental professional responsibility and ethical requirement, guidance should be sought from experienced epidemiologists and statisticians during the preparation phase of a study.

The study protocol should be comprised of:

1. Objective
1.1 Describe in the objective the kinds of knowledge or information to be gained from the study. The health related endpoint, the population under consideration, the kind of comparison (exposed vs unexposed) and the type of study should be stated.
1.2 State what the planned study can contribute to the existing level of knowledge, after referring to your core collection of relevant publications.
2. Hypothesis
State the hypotheses, and the means of operationalizing all hypotheses, before starting the study.
3. Population and sampling
3.1 Define the appropriate population to investigate.
3.2 Carefully select the sampling procedure. Plan measures to minimize sampling biases such as self-selection, loss of follow-up and the effect of non-response, and missing data. Try to minimize the sampling variance.
3.3 Estimate an appropriate sample size.
4. Data collection
4.1 Define what kind of data is needed to answer the research question, keeping in mind the potential strengths and weaknesses of the data that will be obtained.
4.2 Define the instruments or methods needed, giving preference to existing ones of good quality. Validate new instruments or methods. Be attentive when constructing variables; describe and document the process clearly.
4.3 Determine the explanatory and the main response variables and associate them with hypotheses.
4.4 Specify technical operating procedures and organizational measures for quality checks.
5. Statistical analysis
5.1 Develop a detailed plan for statistical analysis.
5.2 Propose and justify procedures for estimating effects and testing hypotheses.
5.3 Determine the possible confounders and effect modifiers. State how these can be dealt with in the statistical analyses.
5.4 Plan for an analysis that can handle eventual anomalies in your data.
6. Legal and ethical considerations
6.1 Verify the legal requirements for the conduct of your study.
6.2 Describe your methods for assuring data confidentiality.
6.3 If necessary, prepare to obtain informed consent.
6.4 Declare conflicts of interest.
6.5 Make reference to the standards of good epidemiological practice to be followed.
7. Quality
7.1 Plan a system of quality management for the study, including sufficient attention to proper measurement, data collection, coding, entry, cleaning, plausibility checks, and protection.
7.2 Plan to train collaborators.
8. Resources and requirements
8.1 Plan for the needed time, money, and personnel.
8.2 Plan sufficient resources for publications.
8.3 Delineate the responsibilities or obligations of the sponsors and of the principal investigator.
8.4 Develop mechanism should be in place for conflict resolution, e.g., with sponsors.
9. Early termination
9.1 Discuss what conditions or criteria would necessitate early termination of the study.
9.2 If necessary, establish in advance a panel to decide on early termination.

Study conduct

In this section, recommendations are proposed for the phase of a study during which the data collection and analysis take place.

1. Prerequisites and responsibilities
1.1 No study should be undertaken without a written study protocol. Discuss the completed plan with the entire research team including the statistician and/or some experienced external advisors.
1.2 The investigator is responsible for the day-to-day conduct of the study. If a team is at work, individual responsibilities should be defined, documented and adhered to.
2. Information management

2.1 Give all collaborators of the study all necessary information. If special skills are required, adequate training of collaborators should be provided.
2.2 Inform study subjects of all aspects of the study that are relevant to their decisions to participate, and obtain appropriate consent.
2.3. Regulate the flow of information, bearing in mind that privacy and confidentiality issues are primordial. Collaborators may need to be held to the code of confidentiality.
3. Data handling
3.1 Manage data collection, validation, and documentation as defined in the protocol. Consider keeping a study diary in which all major steps and events of the study are catalogued. If any amendments and changes to the protocol are necessary, they should be explicitly decided upon, noted, explained and dated. All study documents should be dated and archived in an accessible way.
3.2 Analyse the data according to the protocol, step by step, beginning with descriptive and proceeding to inferential statistics. Note any necessary modifications of the analytic plan in the study diary and give the reason for modifications. Look for qualified advice when needed.
4. Documentation
4.1 Create a structured database with documentation to be preserved as data archive, available for control and secondary use.
4.2 Prepare and archive documents relating to the analyses, including information on data set used, date of analysis, programmes, output and comments.
4.3 Keep up-to-date with the relevant literature, supplementing it with information from workshops, conferences, etc.

Publication of study results

The publication of study results is an essential part of the scientific process, providing the bridge between research and its application to everyday life. The following part of the EGEP aims to facilitate the process of reporting.

1. Publish research results without undue delay, disseminating them in good faith and with proper documentation. It can be helpful to prepare a preliminary report beforehand to be distributed to a select audience for comment and review. Studies which do not confirm the initial hypothesis should also be published.
2. Conform to such standard guidelines for publication as the Uniform Requirements for Biomedical Publications (International Committee of Medical Journal Editors 2004) and the CONSORT Statement (Moher et al. 2001). Authors of epidemiological papers are expected to submit their articles to the process of peer review.
3. Summarize completed studies in a final publication that accurately describes the study objectives, methods, results, and the principal investigator's interpretation of the findings. Select ways to convey the key information as clearly as possible.
4. At a minimum, the published paper shall include:

4.1 A descriptive title.
4.2 The names, titles, degrees, addresses and affiliations of the principal investigator and all co-investigators.
4.3 A structured and concise abstract. Be aware that MEDLINE stores a maximum of 250 words.
4.4 An introduction with background, purpose, and specific aims of the study. State the purpose and objectives of the research as it was stated in the protocol. Otherwise explain why the objectives were changed.
4.5 A description of the research methods, including:
   a. the selection of study subjects and controls,
   b. the data collection methods used, and the dates of initiation and completion of data collection,
   c. the statistical methods used in data analyses, including the transformations, calculations, or operations on the data made, and
   d. a description of the originally identified limitations of study approach and the methods used to address them (e.g. response rates or missing data). Describe any circumstances that may have affected the quality or integrity of the data.
4.6 A results section presenting a summary and analyses of the data. Include sufficient tables, graphs, and illustrations to present the pertinent data and to reflect the analyses performed.
4.7 A discussion including:
   a. a statement of the conclusions drawn from the analyses of the data,
   b. research cited in support of and/or differing from the present findings. Discuss possible biases and limitations in present research.
   c. consideration of the implications of study results.
4.8 Name(s) and address(es) of sponsor(s), if any. Disclose all possible conflicts of interests
4.9 References.

5. If a study cannot be published as a full report, try to publish the main result as a short report or as a letter to the editor.

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