Commentary I
Essentials of good epidemiological practice: are guidelines following guidelines?

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Pilots are trained to fly aeroplanes, surgeons are trained to operate on patients, but who is trained to conduct epidemiological research? The first two statements are platitudes, the third is a question of genuine concern. Much, if not most, epidemiological research is done by colleagues with little or no formal training in epidemiology. This may be particularly true for Switzerland. Our country, thanks to Bernoulli, may have been ahead of modern epidemiology in the 18th century (Dietz & Heesterbeek 2000) but since then the road has been largely downhill, and neither clinical nor population-based epidemiological research have a strong tradition in Switzerland. Indeed, the poor quality of applied clinical research in Switzerland is a matter of current debate (Schweizerischer Wissenschafts- und Technologierat 2002). Against this background, recommendations on essential principles of good epidemiological practice (Altpeter et al. 2004), "written in good faith for the betterment of epidemiology in Switzerland" by the Epidemiology Group of the Swiss Society for Public Health are surely welcome. Or are they?

What audience, what purpose, what methodology?

Recommendations and guidelines are "systematically developed statements" and several bodies have formulated methods for developing scientifically sound guidelines (Shaneyfelt 1999). In this commentary we examine to what extent the EGEP guidelines follow guidelines on how to develop guidelines. Table 1 lists eight accepted methodological standards. These were developed in the context of clinical practice guidelines, but are equally helpful when examining methodological and reporting guidelines.

Table 1 Methodological standards on guideline development

Standard
1. Purpose of the guideline is specified
2. Rationale and importance of the guideline are explained
3. The participants in the guideline development process and their areas of expertise are specified
4. Intended audience or users of the guideline are specified
5. Method of identifying scientific evidence is specified
6. The evidence used is identified by citation and referenced
7. The method by which the guideline underwent external review is specified
8. An expiry date or date of scheduled review is specified

Adapted from Shaneyfelt et al. (1999)

What is the purpose and intended audience of the EGEP guideline? We do not think that this is well defined at present. Should these recommendations mainly be used by researchers from other disciplines who lack training in epidemiology? In this case, recommendations that essentially consist of a check list ("describe, define, select, … publish"), with little explanation of the whys and why nots, or on the hows and how nots will be of limited use. For example, the recommendation to analyse the data "beginning with descriptive and proceeding to inferential statistics" and to "determine the possible confounders and effect modifiers" will be of little help to those not familiar with these terms. On the other hand, recommendations such as "define what kind of data are needed to answer the research question" or "plan for the needed time, money, and personnel" are stating the obvious. Other statements are ambiguous to any audience, for example "plan for an analysis

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that can handle eventual anomalies in your data". This statement could easily be misunderstood and the EGEP recommendation might be inappropriate, depending on what exactly is meant by "anomalous data".

What can be learned from earlier initiatives? In the case of the Consolidated standards on the reporting of clinical trials (CONSORT) (Moher et al. 2001), the working group not only published the result of its work (i.e., the guidelines), but also an explanatory document (Altman et al. 2001) giving the rationale, background information and relevant examples for each item of the statement. This additional article aimed to make the process of guidelines development more transparent and helped to increase the acceptance of the proposed guidelines. The recent initiative to develop standards of reporting in diagnostic research (STARD) followed a similar strategy (Bossuyt et al. 2003a; 2003b). Unfortunately, the methods of guidelines development are not explained in the case of EGEP. For instance, it remains unclear how the items were selected and what empirical evidence or theoretical considerations underpin that selection.

In addition to a transparent methodological approach to guideline development, it is essential to subject the draft recommendations to review by the epidemiological community, including review by future users. Wide circulation among opinion leaders and intended users, followed by revisions taking comments into account, will improve quality, publicise the effort and broaden ownership. This, and other commentaries accompanying the publication of the EGEP recommendations can be seen as a form of peer review, but this is post-hoc and therefore unsatisfactory.

What about implementation?

The development of recommendations should be linked to a thoughtful implementation strategy – one of the most consistent findings in research of health services is the gap between evidence and practice (Grol & Grimshaw 2003). Indeed, publishing the EGEP recommendations in an English-language specialist journal will have limited impact. If the authors are serious about the "betterment of epidemiology in Switzerland" then considerable efforts will be needed to explain, promote and implement the EGEP guideline. These efforts should reach beyond the narrow Swiss epidemiological community.

Setting up a dedicated website has been useful for disseminating reporting guidelines (see www.consort-statement.org). Experience with clinical practice guidelines demonstrates that changing professional behaviour is difficult, but not impossible (Grimshaw et al. 2004). Various strategies targeting obstacles at different levels are required, and education needs to be interactive and continuous and include discussion of the relevant evidence. Some barriers to change will be associated with the organisation of the research process, resources, leadership and the political environment, and difficult to tackle in the short term.

Conclusions

The publication of recommendations for good epidemiological practice is a welcome initiative. The current version of this guideline should, however, be seen as a living document, which will evolve over time in order to contribute to improving epidemiological research in Switzerland.

Erik von Elm and Matthias Egger

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Commentary II
Swiss epidemiology needs Swiss epidemiologists

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Epidemiological research has a limited tradition in Switzerland: it was only with the introduction of social and preventive medicine into the medical curricula in 1962 (see Jeanneret 1994), that it got an academic home. Postgraduate teaching in epidemiology was delayed for another 30 years when it became possible to get a MPH-degree in Switzerland; and a School of Public Health has yet to be created. However epidemiology is one of the basic tools in public health and it is therefore, very appropriate that the epidemiologic group of the Swiss Society for Public Health has formulated recommendations for "essentials of good epidemiological practice" (Altpeter et al. 2005). This is certainly a valuable task to undertake and the group is to be credited for this. Personally, I would like to comment on the recommendations on two different levels: First, I would like to have a short look at the general use of such a document in Switzerland and secondly, I would like to give some thoughts to its contents.

The first question is: Who is this document meant for?

Are Swiss epidemiologists an international species? The aim of the recommendations is to assist all persons and institutions that are involved in "commissioning, planning, preparation, conduct, analysis, assessment, review, valorisation or financial support of epidemiological studies" and it is written for "the betterment of epidemiology in Switzerland".

This subtitle already illustrates a basic problem we are confronted with when planning and reviewing epidemiological projects in our country: it is the language problem. If we write for Switzerland why write in a language, which is not our mother tongue? Why not formulate recommendations in German and French?* There are members in the group who formulated the recommendations who are from French or German language regions in Switzerland and certainly the document is not written for native English language speakers. The "minimum standards" should be easily and completely understood by medical students, MPH-trainees and persons in federal and cantonal offices. We know by experience, that these groups would prefer to read a document in their own language. Epidemiological research should have a primordial place in the improvement of public health in Switzerland. The main responsibility for health and health care remains in the cantonal health departments where the mastery of foreign languages is sometimes limited. Mastery of foreign languages is better in academic researchers – but do we really want to limit communication within Switzerland of a document designed for Switzerland?

Epidemiological concepts and requirements are summarized in a "cookbook" or "check list" fashion. This can be useful at many different levels, but care should be taken to avoid the illusion, that by using a "check list" an epidemiologist is created. I do not have the slightest doubt that the document has already had as effect by bringing together a group of Swiss epidemiologists and drawing together a consensus on what constitutes good epidemiological practice – the process in itself has a value for Switzerland quite apart from its product.

Some thoughts on the content

The document has four chapters: introduction, study protocols, study conduct, and publication of results. These three steps (apart from the introduction) in the course of a study are certainly important. When planning a study the timing is crucial. Recommendation in this part reads "plan for needed time ..." and later on "... plan for sufficient resources for publication". While in reviewing studies I usually find suffi-

* Note from the editors: We followed this recommendation and provided a translation of the guidelines into German, French, and Italian in this issue.

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cient resources planned for conducting the study and mainly for the data collection, there is a general tendency to grossly underestimate the time and resources needed for data cleaning and analysis. This part might have deserved an own section in the document and could have replaced the part of the "publication" chapter.

A further comment is of more general nature. The recommendations insist on hypothesis formulation. For many years, I have tried to avoid formulating hypotheses, which only point in one particular direction. However, it has become a general requirement for protocols to formulate explicit hypotheses and in this context the documents follows the established rules. But in my experience of reviewing numberless protocols and reports, I have become suspicious about this requirement: it directs the mind of the researcher to follow one particular path and to ignore different aspects. To look at data with a very open mind is often called "fishing" and has been criticized in many textbooks and documents relating to epidemiologic research. But to follow only one particular line of hypotheses limits the freedom of the researcher and causes him or her to sometimes ignore differences or heterogeneity in the data. Reviewers have a tendency to refer back to original hypotheses when reports point out results due to risk factors not originally identified. Stratification has become a neglected tool in epidemiologic analysis because so-called confounders can be easily "adjusted for". In fact, in many instances, gender differences have been overlooked because they were not formulated in the original hypothesis and adjustment for the influence of the variable was conducted without full consideration of its impact. Some caution on hypotheses formulation and relaxation in following the line of hypotheses might be recommended in the document: the sentence in the publication section "studies, which do not confirm the initial hypothesis should also be published" is misleading in this context. The aim of the study ought to be formulated in more neutral terms, for instance "to investigate whether x influences y" and it should be remembered that statistical testing always refers to the null-hypothesis.

Conclusion

The document will certainly be a great help to the uninitiated; the standards it proposes are high and therefore to be welcomed. Fulfillment of its recommendation would be demanding for even a most experienced epidemiologist. But basically, I wish the document one specific thing: translation into French and German in order that it have an optimum reception in medical students, MPH-students and Cantonal Health Departments.

Ursula Ackermann-Liebrich

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Commentary III
Towards good epidemiological practice in Switzerland

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A hearty welcome to "Good epidemiological practice!" The initiative of enhancing epidemiology as one of the solid scientific bases of public health is greatly appreciated. The burden of disease and its determinants, properly assessed by observational studies and surveillance, but also communicated in a timely fashion, are at the root of policy making, of interventions, and of their evaluation. Valid data and sensible conclusions serve as the basis for resource allocation. Proper randomized trials are crucial to assess the effectiveness of these allocations. The framework addresses these aspects.

Public health sciences only make progress if rational theory development is combined with empirical confirmation. Consistent theories are put to the test in daily life. In science, daily life requires that the theories allow for deriving and formulating – always theoretically refutable, according to Karl Popper – hypotheses that can be tested by observational or experimental studies.

Proper development and formulation of the hypothesis are crucial before it can be tested. For instance, as one is unable to check on all stones existing on earth to see whether one of them could float in the air, you might choose to reformulate the hypothesis to "all stones float in the air". Trying to make one of them float, you could refute the hypothesis.

Once we are happy with the hypothesis, we plan and select the appropriate study design. As in life, there are things that are grossly inappropriate, such as exposing healthy men aged 20 years to a pathogenic agent for 30 minutes under ideal laboratory conditions and then extrapolating the health effects that they experience as a result to sick women aged 60 years.

As in life, there is not only design but also conduct. If we fail to properly design a study, it is meaningless to interpret its results. Foul data are the main cause of faulty results and can only lead to faulty conclusions. However, even if trials are valid and repeatable, it is not guaranteed that valid conclusions are drawn from them. While this is most important to public health decision makers, humans tend to generalize where they should not.

The present paper constitutes a valuable basis for studies that are both relevant to public health and proper science. As a check list, its use may not be limited to beginners. Its content should be incorporated into the core curriculum of any scientist. In public health, we want to do the right thing rightly and at the right time. The public also rightly expects this from us. Let's use the "essentials" and do it essentially right.

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Commentary IV
Good epidemiological practice: ethical review is essential

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The Swiss society for public health publishes very useful guidelines for good epidemiological practice, prepared for "the betterment of epidemiology in Switzerland". Unfortunately a crucial point is omitted in the text: research protocols should undergo ethical reviews. This is however a general and universal obligation to investigators and institutions, for any research on human subjects (Levine 1996). The international guidelines, such as the Helsinki declaration (World Medical Association 2000), the guidelines from CIOMS (1991; 2002) and from WHO (2000) are very clear, as are the Swiss guidelines for medical research (SAMW 1997). The same principles strictly apply to research carried out in developing countries (CIOMS 1991; WHO 2000; Nuffield Council on Bioethics 2002).

Our experience during the past 12 years at the research ethics committee for epidemiology and public health is that some investigators still don't respect this rule. Some examples are national studies on health and behaviours, or some projects by students. Other projects have been submitted after completion of the study, because ethical review was requested by the editors. This of course was not acceptable to the committee. Even projects by health authorities are not systematically reviewed. In one occasion, we were told that a project was ethical, since it was requested by the government… .

Ethical reviews often contribute favourably to the quality of projects. Firstly, submitting a project obliges investigators to write a formal protocol. Surprisingly, a number of projects are carried out without this fundamental element. Secondly, in most cases corrections are requested and recommendations are made. The main issues are about information of participants, confidentiality of data and formulation of questions in questionnaires. Quite frequently the ethical review helps the investigators overcome ethical and legal obstacles to the study. For instance, a study on child sexual abuse prevalence, research in genetic epidemiology or projects involving participation through the Internet could hardly be carried out without the approval of the committee.

Compared with clinical research, epidemiology is often considered to involve relatively minor risks. However, when small risks are applied to many persons, the damage can be very significant. The study of healthy people also raises specific ethical issues.

In general, epidemiologists have good, even excellent intentions. However, the issues at stakes in medical research are very complex and sometimes unidentified by the researchers. Any research project can involve significant risks and can raise complex ethical and legal questions. It is crucial that all projects in epidemiology and public health are reviewed by ethics committee in order to safeguard the rights and welfare of research subjects and to improve the quality of research.

Paul Bouvier

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Commentary V
Wie kann eine hochqualifizierte Wissenschaft zur Förderung der Public Health garantiert werden?

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Ausgangslage

Die Entwicklung des schweizerischen Gesundheitswesens wird zunehmend von einem politischen Spannungsfeld beeinflusst, das längerfristige Planung schwierig macht.

Akteure mit höchst unterschiedlichen Werthaltungen und Interessen bemühen sich, ihre eigenen Standpunkte und Strategien als die für die Bevölkerungsgesundheit besten, gerechtesten oder wirksamsten darzustellen. Generell sind in unserer hochentwickelten, demokratischen Informations- und Wissensgesellschaft unterschiedliche, ja gegensätzliche Expertenmeinungen und Gutachten häufig.

Wie soll in einer solchen Situation eine Regierung handeln, die ihre beschränkten Ressourcen optimal für ein gutes, effizientes Gesundheitswesen und zur Förderung der Public Health einsetzen will? Eine Regierung benötigt zuverlässige, vollständige oder repräsentative Daten und Informationen sowie eine sorgfältige, genaue, kompetente und unabhängige Analyse dieser Daten, damit sie zweckmässige, wirksame und wirtschaftliche Massnahmen beschliessen und deren Durchführung evaluieren kann.

Wertvoller Beitrag der „Essentials of good epidemiological practice"...

In dieser Situation können die „Essentials of good epidemiological practice" einen wertvollen Beitrag liefern für die Qualitätssicherung des Forschungsprozesses in der Gesundheitsforschung. Die „Essentials" enthalten präzise Richtlinien für einen transparenten, methodisch guten, genauen und ethisch verantwortbaren Forschungsprozess. Das schweizerische Bundesamt für Statistik unterstützt solche Richtlinien und fordert seine Mitarbeitenden sowie die Scientific Community auf, sie konsequent zu befolgen.

Die „Essentials" sind in sich schlüssig, vollständig, gut verständlich und können damit breit angewendet werden.

... aber nur partielle Garantie für „gute" Forschung

Allerdings bieten die „Essentials" nur eine partielle Garantie für eine Wissenschaft und Forschung zur Förderung der Public Health, da sie nur den Forschungsprozess im engeren Sinne betreffen. Der Entstehungszusammenhang und der Verwertungszusammenhang von Forschungsprojekten wird nicht thematisiert. Dies kann auch nicht die Aufgabe solcher Richtlinien sein. Forschende könnten aber meinen, dass die Befolgung der „Essential" bereits eine hinreichende Garantie für ein „gute" Forschung sei. Aus unserer Perspektive, der Perspektive des Service Public und des öffentlichen Interesses, heisst „gute" Forschung und Wissenschaft aber nicht nur ein qualitativ guter Forschungsprozess, sondern auch ein Entstehungs- und Verwertungszusammenhang von Gesundheitsforschung, der zu einem erheblichen Teil eine nachhaltige Verbesserung der Bevölkerungsgesundheit bezweckt. Dies ist heute zunehmend in Frage gestellt.

Die Festlegung von Fragestellungen und die Ressourcenallokation in Wissenschaft und Forschung waren zwar schon immer durch unterschiedliche Interessen geprägt. In Zeiten von stagnierender Wirtschaftsentwicklung, Spardruck und zunehmendem Konkurrenzkampf innerhalb der Scientific Community werden aber die Akteure noch mehr gezwungen, mit kurzfristiger Perspektive ihre eigenen Interessen zu verfolgen. Dass die Privatwirtschaft, z.B. die Pharmaindustrie, Forschung finanziert, die ihren wirtschaftlichen Interessen dient, ist naheliegend und soll hier nicht weiter diskutiert werden.

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Zu wenig Anreiz für Public-Health-Forschung

Wir diskutieren hier vielmehr die Verwendung öffentlicher Mittel. Problematisch sind nicht nur Kürzungen der öffentlichen Forschungsmittel, sondern auch eine für die Public Health bedenkliche Dynamik innerhalb der Universitäten. Wer Ruhm und Karriere machen oder auch nur überleben will, muss die persönliche Profilierung optimieren. Wegen den in den Universitäten vorherrschenden Qualitäts- und Produktivitätskriterien muss er möglichst viel publizieren in möglichst hochrangigen Zeitschriften, d.h. in Zeitschriften mit einem hohen Impact Factor, der durch die globale, angelsächsisch dominierte Zitierungshäufigkeit berechnet wird.

Für die Erforschung der Public Health in der Schweiz gibt es in den Universitäten aus zwei Gründen wenig Anreiz: Zum einen sind die spezifischen Gesundheitsprobleme der Schweiz als Forschungsgegenstand global gesehen nur bedingt und meist nur in Europa von Interesse, also finden entsprechende Forschungsergebnisse wenig Eingang in höchstrangige amerikanische Zeitschriften – auch wenn sie z.B. die „Essentials" bestens befolgen. Zum anderen gibt es in der Public-Health-bezogenen Forschung keinen entscheidenden, durch die naturwissenschaftlich-technisch Entwicklung bedingten Fortschritt. Dieser Forschungsbereich ist deshalb innerhalb der Medizin noch marginaler geworden als er schon immer war.

Neben Kriterien des qualitativ guten Forschungsprozesses, wie sie von den „Essentials" formuliert werden, braucht es deshalb Kriterien und Strategien, wie Ressourcen in angewandte, für die Public Health der Schweiz relevante Forschung gelenkt werden können. Konkret heisst das zum Beispiel, dass in der Abteilung für angewandte Forschung des Schweizerischen Nationalfonds weiterhin Public-Health-relevante Programme und Kompetenzzentren gefördert werden, und dass den Bundesämtern hinreichende Mittel für angewandte Forschung zur Verfügung stehen. Innerhalb der Universitäten sollte die praktische Relevanz ein zusätzliches Erfolgskriterium von Forschungsergebnissen werden, das bei der Ressourcenverteilung, bei Beförderungen und bei Berufungen berücksichtigt wird. Dazu braucht es einerseits den Willen der Politik und ein deutlich artikuliertes Interesse der Akteure des Gesundheitswesens, insbesondere der Versicherer und der Leistungserbringer, andererseits aber auch ein kritisches Bewusstsein und eine soziale Verantwortung der Forschenden.

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