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Embarking on Unethical and Phony Research Activity

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Abstract

Ethics is the cornerstone for any research. Researchers face an array of ethical requirements. They must meet professional, institutional and national standards for conducting research with human participants in addition to being responsible for the ethical conduct of students supervised. Hence, it is the opinion of the authors that research should be an activity devoted to exploration of the law of nature which is compelled by a desire to know the truth.

Embarking on Unethical and Phony Research Activity

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, consequences of diseases, and possible methods of prevention (Last, 2001).

Ethics is the cornerstone for any research. Researchers face an array of ethical requirements. They must meet professional, institutional and national standards for conducting research with human participants in addition to being responsible for the ethical conduct of students supervised. Hence, it is the opinion of the authors that research should be an activity devoted to exploration of the law of nature which is compelled by a desire to know the truth. Sadly, in the real world, other factors often interfere with this ideal aspiration. It is unfortunate that there are instances, although rare, wherein researchers have violated important ethical standards (Good Epidemiological Practice, 2007).

Ethical Issues in a National Oral Health Survey (2010-2011)

Any large-scale study provides ample opportunity for manipulation and interpretation of data. The following represents the procedure and findings of a national oral health survey conducted 2010 – 2011, in an unnamed county as reported to the authors. In the opinion of the authors, the survey violated the standards of any research or epidemiological practice. For example, epidemiologists were requested to examine people with used unsterilized instruments due to lack of available sterilized instruments. Were that not egregious enough, it was reported that researchers were requested not to examine the children and to record all children as caries free. Many researchers refused to succumb to these unethical practices. To further compound the

atrocities, the surveying team did not visit half of the selected sites for the state; although data were reported for the entire state. The overarching question is: who orchestrated these manipulations? Who was going to benefit, or was there a benefit by this misrepresentation of findings regarding the oral health of this population to the rest of the world? These questions beg to be answered.

Impact of unethical research practices on general public

What good would this conduct of research be to the general public or to policy makers? Based on this manufactured research, the policy makers were left to frame future oral health goals for the county. Clearly, the above described procedure violates the four general ethical principles of research: autonomy, beneficence, non-maleficence and justice.

Combating unethical research practices

Good Epidemiological Practice

Good epidemiological practice (GEP) guidelines (recommended by scientific organizations) cannot prevent the previously described problems, but are intended to promote discussion and to inform and educate epidemiologists, other researchers, and the general public. We not only need a code of practice in research but also need to implement it in our research activities. We must also be sure to obtain a reasonable balance between ethical constraints and the opportunities for legitimate research of importance to public health (World Medical Association, 2004).

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.

**The guidelines and recommendations to assure good epidemiological practice (GEP)
(German society for epidemiology, 2008)**

Guideline 1 (Ethics)

Epidemiological research must be conducted in accordance with ethical principles and must respect human dignity as well as human rights

Ethical principles arise from national and international law governing human and civil rights as well as the rights of patients, research subjects and investigators. These ethical principles are also to be applied in epidemiological research even in the absence of an explicit legal obligation.

Guideline 2 (Research Question)

The planning of every epidemiological study requires explicit and operationalizable research questions that are to be formulated as specifically and precisely as possible. The selection of the study population must be justified on the basis of the main research question.

The research question is indispensable, as it forms the basis upon which the potential use of an epidemiological study can be identified. Based on the research question, it must be obvious if and to what extent the research project seeks to serve medical, scientific, disease prevention, health promotion, socio-political or other comparable social or corporate interests. The explicit formulation of the research question is a fundamental pre-requisite for the planning and evaluation not only of the study design and instruments, but also of the timeline and budget of the planned research. The operationalizability of the research question enables the selection, design, and application of the most suitable methodological elements for a given epidemiological study (selection of the research sample, survey instrument, estimate of sample size given a predefined level of precision, etc.). The specification and focusing of the research question requires the existing scientific evidence for being amassed and evaluated at the beginning of a research project. Therefore it helps to avoid the use of obsolete hypotheses and/or accidental duplicate investigations.

Guideline 3 (Study protocol)

An epidemiological study is based on a detailed and binding study protocol, in which the study elements are defined in writing

The creation of a study protocol (study plan) before the beginning of a study is a fundamental methodological requirement for ensuring the quality of the study. The study protocol is a

compilation of the most important information necessary for the implementation, application, and evaluation of the study.

Guideline 4 (Quality Assurance)

In epidemiological studies, an accompanying quality assurance of all relevant instruments and procedures is to be guaranteed

An internal quality assurance is an indispensable element of every epidemiological study. This is to be assured by the description of its methods and the designation of the responsible people. The scope of the quality assurance based on its associated costs has to be related to the entire scope and costs of the study. The targets of the quality assurance are set by the chronological, organizational and technical rules of conduct that are described in the study protocol and operations manual.

Guideline 5 (Data management and documentation)

A detailed concept is to be developed in advance for the compilation and management of all data collected during the study, including the editing, plausibility verification, and coding of data, as well as the provision of data for transfer

Guideline 6 (Analysis)

The analysis of epidemiological studies should be carried out using adequate methods and without unreasonable delays. The data underlying the results are to be kept for a minimum of 10 years in a complete reproducible form.

The analysis of epidemiological studies should occur in agreement with the analysis plan in the study protocol quickly, validly as well as transparently and this should be completely reproducible to a third (uninvolved) party. The requirement that analyses be carried out quickly after the conduct of epidemiological studies arises, in general, from public interest in these

results. Investigations, for example of risks at work or in conjunction with environmental impacts often occur in the health care policy context as a result of requests by public authorities, ministries, etc. These clients have a right to the earliest possible completion of the most important analyses in order for them to comply with their mandate to effectively protect the health of the public.

Guideline 7 (Data protection)

In the planning and conduct of epidemiological studies, compliance with applicable data protection regulations is to be respected in order to protect the right to informational self-determination.

Guideline 8 (Contractual conditions/frameworks)

The conduct of an epidemiological study presumes certain defined legal and financial conditions. Therefore, legally binding agreements are to be sought between contractor (sponsor) and consignee (researcher), as well as between all partners of research collaborations.

Larger epidemiological studies are nowadays usually externally funded, at least to a substantial degree. Contractors are often institutions of research promotion, as well as clients in public and private realm. The charters of some research institutes provide conditions for the conduct of externally funded research. Also, many contractors have qualifications for and restrictions on the allocation of the research-contracts that are to be fulfilled.

Guideline 9 (Interpretation)

The interpretation of the results of an epidemiological study is the duty of the author(s) of the publication. The basis of every interpretation is a critical discussion of methods, data, and results of one's own research in the context of existing evidence. All publications should be subjected to an external review.

Guideline 10 (Communication and public health)

Epidemiological studies, which by nature concern the translation of results into real effects on health, should strive to adequately involve the affected population groups, and to report a qualified risk-communication to the interested public

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. These guidelines should serve to establish standards of quality for epidemiological research. They should help to eliminate scientific fraud, to ensure transparency in research, and to promote trusting collaborations among scientists. The guidelines, however, should not be as limiting or inflexible as to threaten the freedom of scientific research in Epidemiology. Rather, the guidelines should define the framework within which epidemiological research can be used to its fullest benefit, in all of its facets and relating to all of its areas of application.

Working with personal data

Data collection and recruitment of volunteers for research in many countries are subject to legal controls but many other areas of activities are not guided by legal principles. Working with personal information given by participants in research is a privilege that should be respected by making the best possible scientific use of the data and by making sure confidentiality and correctness of data are maintained.

Teaching good research behavior in schools

A study of members of the American occupational medical association found that ethical conflicts were perceived as relatively frequent occurrences in research practices. Most

respondents stated that in dealing with these ethical conflicts, they relied heavily on their education and training. This reliance raises the question of whether training in medical ethics can be relied on to sustain and improve ethical standards in the profession regardless of countervailing economic pressures (Brandt, 1989). To authors, there is a need to make a distinction between possible improved understanding of ethical issues because of ethics teaching, and its impact on actual ethical practice. Beyond teaching ethics, many American medical schools have instituted other mechanisms for inculcating ethical behavior in the doctor's they produce. For example, in one survey, 54.5 percent of medical schools had established humanistic criteria such as honesty and aiding others to be used in conjunction with academic criteria in the evaluation of their students (Miller et al, 1989)

Conclusion

Provided were the ten guidelines of the German Society for Research for conduct of Good Epidemiological Practices (GEP). The extensive application of the GEP in all areas of Epidemiology is encouraged by participating scientific societies. The GEP is today accepted by the great majority of the epidemiological researchers, the public, many private sponsors, as well as evaluators, peer reviewers, and editors of scientific journals. The application comprises all areas of descriptive and analytic Epidemiology and covers the whole spectrum of epidemiological topics. This wide application requires applying and adapting the general recommendations of the GEP to specific research questions, data bases and methodological contexts of the different specialties in Epidemiology.

Health surveys undoubtedly are important, but need to be conducted with utmost care and with the availability of sufficient resources. Unethical and deceitful research leads to incorrect

decisions that may also have a profound negative impact on people's health. Particular care should be taken to avoid publication of data that may lead to discrimination against vulnerable groups in society. Epidemiological research is needed in health care, disease prevention and health promotion. This research should be of good quality, done in a timely manner and should follow recognized ethical standards. Ultimately, ethical evaluations should take into consideration the risk of not doing as well as the risk of doing research.

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