From Theory to Practice in Environmental Epidemiology: Developing, Conducting and Disseminating Health Research

UNDP Azerbaijan

UNIVERSITY OF ALBERTA
EDMONTON, ALBERTA, CANADA

WORLD HEALTH ORGANIZATION
EUROPE

Colin L. Soskolne
Department of Public Health Sciences
School of Public Health
University of Alberta, Edmonton, Canada

James E. Andruchow and Francesca Racioppi
WHO European Centre for Environment and Health, Rome,
WHO Regional Office for Europe

with the support of

the United Nations Development Programme (UNDP), Azerbaijan

World Health Organization
Regional Office for Europe
Scherfigsvej 8, DK - 2100 Copenhagen Ø, Denmark
Tel.: +45 39 17 17 17. Fax: +45 39 17 18 18. E - mail: postmaster@euro.who.int
Web site: www.euro.who.int

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Colin L. Soskolne

Department of Public Health Sciences

School of Public Health

University of Alberta, Edmonton, Canada

James E. Andruchow and Francesca Racioppi

WHO European Centre for Environment and Health, Rome,

WHO Regional Office for Europe

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ABSTRACT

This Manual is one of the deliverables from an international collaborative research project undertaken in Sumgayit, Azerbaijan. It stems from an environmental epidemiology study, entitled "Cancer incidence and mortality in the industrial city of Sumgayit, Azerbaijan: A descriptive study". One of the major aims of the project was to strengthen local research capacity in Azerbaijan. This Manual is addressed primarily to novice researchers, health care professionals, and medical or graduate students interested in the conduct of epidemiological research, especially in data-poor regions of the world. It can be used as a complement to intermediate level courses in epidemiology and biostatistics. The Manual discusses the various steps necessary to successfully plan and conduct an epidemiological research study, to anticipate and address many issues that may arise during a research study, and to produce and publish research findings in the international literature. While fundamental concepts and research methods are first presented in a more theoretical manner, practical examples of implementing these methods also are provided in case study format, drawn from the research conducted for the Sumgayit Cancer Study. Despite the fact that the examples are derived from a single environmental epidemiology cancer study, the utility of this Manual extends to other specialized fields of epidemiological research. This Manual is intended for dissemination to several target audiences in regions of the world where health research capacity is being built, including universities and government departments, nongovernmental organizations and other research institutions.

Keywords
EPIDEMIOLOGIC RESEARCH DESIGN
EPIDEMIOLOGIC MEASUREMENTS
BIOMETRY
GUIDELINES
ENVIRONMENTAL MONITORING
NEOPLASMS – epidemiology

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Foreword

Environmental pollution poses a challenge to the social and economic development of the regions and communities it affects. These challenges are particularly prominent in countries already facing preexisting political and economic problems, and can present major obstacles toward improving quality of life for these populations.

By understanding the health effects consequent to pollution at the local level, we empower ourselves on a broader scale. Knowledge extracted from local experiences can be applied elsewhere to benefit the health and well-being of people globally. Documenting and assessing the links between human activities and their effects, both on the environment and on health and well-being, is important for identifying and prioritizing interventions. It is also important for increasing transparency to the public so that informed decisions can be made on economic and industrial development with respect to the health and socioeconomic well-being of affected communities.

Assessing risk from environmental pollution requires infrastructure with the capacity to evaluate and document toxic hazards and the effects that exposure to these hazards may have on health. This requires political commitment to strengthen the capacity of health systems for investigating environmental health issues. In addition, a sustained investment is needed for cultivating skills in new generations of experts, scientists and practitioners to understand these issues, identify potential problems, document their relevance, contribute to the process of risk identification and management, mobilize resources, and communicate effectively and transparently with policymakers and the general public.

This Manual provides the basis for building scientific capacity to address “environment and health” questions. It is the result of an extensive collaboration between the WHO and UNDP Azerbaijan, under the framework of the project "Environmental Rehabilitation of Sumgayit", a project designed to document and assess the severe and long-term environmental pollution in the Azerbaijan city of Sumgayit, as well as its human health effects. The project’s implementation was made possible through the commitment and collaboration of a number of partners, including the University of Alberta, Canada, the WHO Country Office, Azerbaijan, the Sumgayit Centre for Environmental Rehabilitation, and the Government of Azerbaijan, particularly the Ministry of Health, the Bureau of Information and Statistics, the National Oncological Centre, and the State Committee on Statistics.

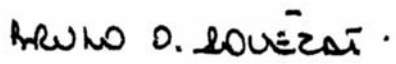
Not only has the project provided the foundation for conducting the first quantitative assessment of cancer risk in the city of Sumgayit secondary to environmental pollution, but it also has provided a unique opportunity for strengthening local capacity in environmental health. The latter was achieved by involving Azerbaijan experts and young scientists in the development and implementation of the project.

By generalizing this project experience to illustrate, step-by-step, the fundamentals of state-of-the-art research in environmental epidemiology, it is our hope that scientists and practitioners from Azerbaijan and neighbouring countries will find rich guidance in this Manual for their work and research, based on real-life conditions relevant to this part of the European Region. Moreover, we hope this Manual will find broader appeal, and that newcomers to the field of environment and health research from many parts of the world will find it useful.

Should this Manual succeed in its intent, then the lessons learned through the experience of the "Environmental Rehabilitation of Sumgayit" project will become a resource for the broader community of environmental health scientists and policy-makers, contributing to the stronger role of stewardship that health systems can play in better ensuring the prosperity of our communities.

Nedret Emiroglu, M.D.
Director a.i.
Division of Health Programmes
World Health Organization
Regional Office for Europe

Bruno Pouezat
Resident Representative
United Nations Development Programme
Baku, Azerbaijan



Preface

This Manual is an extension of an international collaborative research project undertaken in Sumgayit, Azerbaijan. It stems from an environmental epidemiology study, entitled "Cancer incidence and mortality in the industrial city of Sumgayit, Azerbaijan: A descriptive study," which henceforth will be referred to as the 'Sumgayit Cancer Study.' The project examined a suspected link between exposures resulting from industry in the city of Sumgayit, Azerbaijan, and perceived negative health effects among the residents of Sumgayit, studying selected cancers as the health outcomes of interest. The Sumgayit Cancer Study had multiple objectives, however, and apart from its scientific goals, one of the major aims of the project was to strengthen local research capacity in Azerbaijan.

Providing a framework for successfully conducting epidemiological research, this Manual is designed to guide novice researchers in the practical aspects of research, particularly in countries where advanced training and experience in epidemiology are not well-developed. This Manual does not attempt to provide the uninitiated reader with an exhaustive discussion of epidemiological theory and terminology; rather, it is structured for people already possessing a good understanding of fundamental epidemiological principles. Thus, its content is directed primarily towards novice researchers, health care professionals, and medical or graduate students interested in the conduct of, and perhaps pursuing a career in, epidemiological research. Pre-requisites to using this Manual include intermediate level courses in epidemiology and biostatistics; in fact, this Manual could be used as a complement to such courses.

In this Manual, the various steps necessary to successfully plan and conduct an epidemiological research study, and to produce and publish high-quality research findings in the internationally competitive literature are discussed. Its content is to be used as a guide for the novice researcher, to identify priorities in planning and conducting epidemiological research, and to anticipate and address many issues that may arise during a research study.

While fundamental concepts and research methods are first presented in a generalized manner, practical examples of implementing these methods also are provided in case study format, drawn from the research conducted for the Sumgayit Cancer Study. Despite the fact that the examples are derived from a single environmental epidemiology cancer study, the utility of this Manual extends to other specialized fields of epidemiological research. This Manual is intended for dissemination to several target audiences that could find its contents useful, including (Azeri) universities and government departments, NGOs, and also in any other regions of the world where health research capacity is being built.

An early draft of this Manual was previewed in a one-day workshop held in Baku, Azerbaijan on February 21, 2003 by a number of potential readers, including medical sciences students from Khazar University, and participants of joint UNDP-WHO training courses held in Baku in 2000. The feedback received there has been used to revise and improve both the content and presentation of this Manual.

Acknowledgements

At the time of the development of this Manual, Dr Roberto Bertollini was the Director of the Special Programme on Environment and Health of the World Health Organization (WHO) Regional Office for Europe. In 2007, he relocated to WHO headquarters. While at the Regional Office, he set the foundation for this WHO collaboration in Azerbaijan, and supported the implementation of this project. Without his long-term commitment and initiative in developing partnerships between WHO and the international agencies, such as the United Nations Development Programme (UNDP), already active in Azerbaijan, this project would not have been possible.

The authors acknowledge with gratitude all of the agencies that contributed to the conduct and success of the Sumgayit Cancer Study. We thank the WHO European Centre for Environment and Health (WHO-ECEH) for facilitating the development of the project, and the UNDP, Azerbaijan, for funding its conduct. We further thank the WHO-ECEH and the UNDP Azerbaijan Office for funding the production and publication of this Manual. We also greatly appreciate the support and cooperation of the following agencies: the WHO Azerbaijan Country Office, the Sumgayit Centre for Environmental Rehabilitation (SCER), and the Government of Azerbaijan, particularly the Ministry of Health (MOH), the Bureau of Information and Statistics (BIS), the National Oncological Centre (NOC), and the State Committee on Statistics (SCS).

The authors thank the participants of the workshop held in Baku, Azerbaijan, on February 21, 2003 where a preliminary draft of this Manual had been previewed. Their feedback was instrumental in developing the current content and format for this Manual, making a valuable contribution to this work. In particular, the contributions of Dr Fuad Mardanli and his students from Khazar University are gratefully acknowledged. We are also greatly indebted to the two external and independent reviewers, Dr Jouni Jaakkola and Dr Richard Clapp, who ensured both the scientific and practical rigour of this work. Particular thanks go to Mr Alessandro Borghi, WHO-ECEH, for reviewing and updating the web sites provided in the manual.

Finally, the excellence of the thesis upon which the case-study examples are based was ensured through the dedication of the Supervisory Committee, including Ambikaipakan Senthilselvan, Nicola Cherry and Heather Bryant.

Epidemiology is an applied science in which the distribution (i.e., the 'where' and 'when') and determinants (i.e., the 'why') of health-related conditions or events in specified populations are studied and then applied to the control of **health** problems. It aims, through space and time, to specify and clarify relationships between the state of human health and well-being and its underlying causes, with the goal of using that knowledge to promote, maintain, and improve human health. Like geology, meteorology, hydrology, astronomy, sociology, anthropology and many other scientific disciplines, epidemiology is largely an observational science. It relies heavily on the examination of existing patterns and events in the world, rather than on active experimentation, in order to propose and test hypotheses about **disease** causation and propagation in human populations. The use of "**natural experiments**" is fundamental to the conduct of epidemiological research because it often is unethical or logistically impossible for scientists to conduct such experiments themselves. Epidemiologists will study any intervention, intentional or not, that can be used to understand the cause of disease so as to prevent further disease and promote well-being in human populations.

While epidemiology began through the study of communicable diseases, such as cholera and tuberculosis, changing patterns of disease among humans have caused a shift in more recent times toward the study of chronic diseases, such as cancer and heart disease, and the influence of the environment on health. As such, new methods and study designs have been developed to aid in the study of chronic diseases and environmental determinants of health.

At its most basic level, epidemiology seeks to uncover associations between risk factors and human diseases, with a view to demonstrating a causal link between the two. **Risk factors** are those agents - physical, biological, chemical, environmental or social - known to increase the probability of disease in humans. However, because of the biological variability inherent in individuals, in individual susceptibility, and in **exposure**-disease interactions, not every exposure of an individual to a risk factor will necessarily result in disease in that person. Because of this, some degree of uncertainty and variability exists even among causal exposure-disease relationships. Epidemiology therefore uses statistics as an integral tool for evaluating the evidence for or against a particular exposure-disease relationship.

In many ways, epidemiology has become increasingly mathematical in nature, often depending on access to large administrative databases and government surveys, and using advanced statistical methods and computer software to examine disease relationships in ways never before possible. From basic qualitative studies of exposures and diseases have come complex quantitative mathematical models, incorporating sophisticated technologies such as Geographical Information Systems (GIS). While these tools present new research opportunities, they are not essential to the study of epidemiology. Many of epidemiology's contributions have come from the making of connections between exposure and disease through astute observation.

A great deal of meaningful epidemiological work can be conducted even today using many of the more traditional and less complex methods. Perhaps the renowned epidemiologist, Sir Richard Doll said it best "…epidemiology is the simplest and most direct way of studying disease in humans, and many major contributions have been made by studies that have demanded nothing more than an ability to count, to think logically, and to have an imaginative idea… [Though] epidemiological research is becoming more complex, the core of the subject remains essentially simple." *(Excerpted from Hennekens and Buring, 1987)*.

While epidemiological research has both scientific and academic implications, its greatest utility may lie in its social significance. Epidemiology is an important method of providing factual and evidence-based information on any number of health concerns, and can thereby be used to prioritize the allocation of limited societal resources. Thus, findings obtained through epidemiological research can and should be used to improve **public health**, either through the provision of information directly to the public, through the creation of intervention or assistance programmes, or through influencing government policy.

For more information on the terminology, principles, and concepts of epidemiological research, please refer to the "Key References" section at the end of this Manual.

While the careers of scientific researchers can be very fulfilling, with many benefits and rewards, they are not easy. Research is a competitive occupation, by virtue of accessing public funds to undertake research and in proposing novel research topics. It requires a great deal of knowledge, creativity, diligence, and initiative to propose new research and obtain funding, and to then successfully conduct and manage the many aspects of a study. Thus, to be successful, researchers should possess several important attributes and skills.

The first, and likely the most important, of all traits for researchers to possess must be that they are passionate about their work, passionate about their science, and passionate about serving the public interest over any other interest. Passion must be distinguished from zealousness, which can lead to poor and inappropriately conducted research. Passion results in caring about the work, and a sense of personal investment in it. The quality of research by such persons is likely to be much higher than those who do it for other reasons. Furthermore, because of the demands that a research career exerts, persons who are not passionate and committed to their work may become disinterested in, or negative toward their work when challenges arise. Those who are highly motivated, however, will look beyond the immediate obstacles and difficulties, and see the rewards that lie ahead through the contributions to society anticipated from the work. Persistence, diligence, and tenacity, in addition to passion, are of the utmost importance in conducting research, particularly during the (often unpaid) groundbreaking and developmental stages of a study. As with any scientific inquiry, a key attribute of the successful researcher is to be able to ask a question that addresses a particular problem.

Public health researchers should have a keen interest in promoting and advancing public health and the public good. The researcher must be able to see the broader relevance of his or her work, and the potential that it has to benefit hundreds, thousands, or even millions of people. Focus on the ultimate goal of improving the public health will help to overcome some of the difficulties that may be associated with the conduct of any research project. It is also important for researchers to understand the links between science and policy, and to use their research in a proactive manner to inform the public, and to directly or indirectly influence public policy.

Researchers must also have the ability to work well within a group or team setting. Because of the increasing complexity of research and the multidisciplinary approaches often being utilized today, large research teams are common, which require people with different motivations, ideas, and perspectives to work closely together and interactively.

It is thus of paramount importance that researchers (particularly leaders of research teams) possess good interpersonal skills and are able to manage potential conflicts that may arise between team members, and be able to keep the entire team motivated and focused through what can be long and trying periods of time. Managing egos can be a challenge for the best of team leaders. Good management skills and sensitivity to the needs of others are especially important for addressing differences in perspective resulting from cultural diversity that may arise in any research project involving persons of different ethnic origins.

Successful researchers will be thorough and patient, taking the time to become properly informed on a topic of study before attempting to conduct any research, and ensuring that ethical standards are maintained from the inception. During the conduct of the research, good researchers will also be very precise and meticulous in the collection and analysis of data, and thus prevent the entry of careless mistakes into the findings. There can be no substitute for diligence and attention to detail.

Researchers should be cautious, rational and honest about the interpretation of a study's findings, and should not attempt to stretch the conclusions reached beyond the limitations of the data and/or the study design or allow them to be misinterpreted. Good science and good ethics go hand in hand. Finally, good researchers will have the humility to accept that they may be wrong, that contrasting opinions to their own may be correct, and that the results of their work may be disproved over the course of time. These characteristics are of the utmost importance not only for science in general and for the researchers' field of study in particular to advance most expeditiously, but for the researchers to grow and develop to their full potential as reputable scientists.

This Manual is to be used as a complement to, and not a replacement for, more detailed theoretical texts on epidemiology and biostatistics. It is designed to provide a person already educated in basic epidemiological principles with a step-by-step guide to the practical considerations that must be taken when proposing, conducting, and disseminating new research. It will help to provide directions and channels to allow researchers to independently seek more detailed information on most of the common issues that will be encountered during the conduct of an epidemiological study. It is thus a "self-help" guide to epidemiological research. This Manual will ideally be used in conjunction with mentorship from teachers and more experienced researchers, so that the concepts and considerations described here can be explained more fully if needed. There can be no substitute for good mentorship.

Important steps in the planning and conduct of a study are presented throughout in a logical manner, in order to help the researcher to organize his or her thoughts throughout the various stages of a study. It must be stated that while the steps to planning and conducting a study in this Manual are presented in what is usually the most appropriate order of their completion, there may be considerable variation between studies. Thus, in some instances it may be preferable to undertake some steps concurrently, or in a slightly different order than presented here. Moreover, certain steps pertaining to specialized studies may have been omitted, while some of the general steps discussed here may not be pertinent to all studies.

While most concepts will be discussed in the text, some discussions will be supplemented by the use of diagrams, tables or figures. Concepts of fundamental importance to the successful conduct of epidemiological research will be emphasized in boxes such as this:

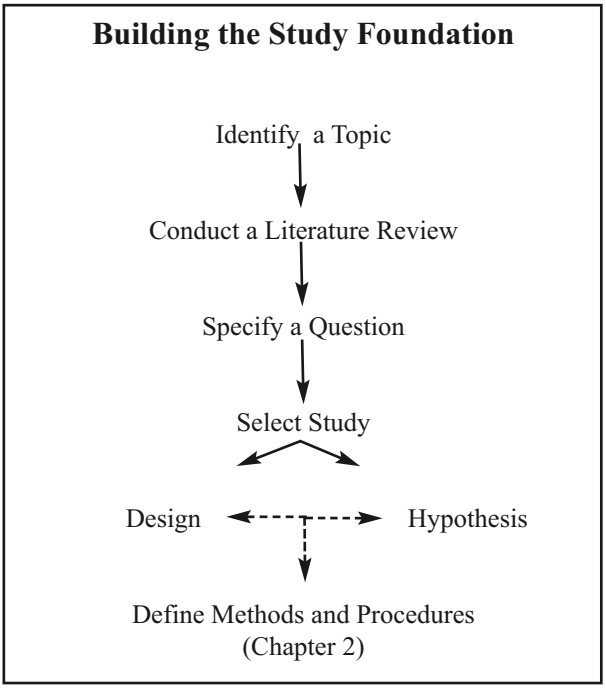
Key Concept:

Key terms presented throughout the Manual are presented in **bold text**, and are defined explicitly in the Glossary at the end of the book (all pages 206 et seq.).

This Manual cannot be expected to provide a novice researcher with all of the answers necessary to conduct a study alone, nor can reading it guarantee success. No textbook can be expected to address adequately the dynamic process of research, nor can any scientific study be assured a positive experience, simply because of the unpredictability of the future and unforeseen difficulties that may be encountered. In fact, studies rarely go perfectly according to plan, so it is often necessary to be flexible and to develop new solutions during the course of the research. Use common sense to judge what is best for your study, always in collaboration with your team and subject to ethics oversight. In research, as in life, one can look to resources such as this Manual for guidance, but one ultimately must find the real answers to his or her problems through logical thought and experience, intuition, help from others, and sometimes even trial-and-error. The authors of this Manual wish its readers and users success in all of their future endeavours, whatever they may be.

**Note: A great deal of internet content is presented in this Manual. Because the authors cannot guarantee the permanence of all internet websites or their URL's (web addresses), readers may experience occasional "broken links" when attempting to access the content presented in this Manual. Readers are reminded that although web addresses may change, the content may still be present on the internet under a new address. Therefore, readers finding broken links are advised to attempt an internet search for the desired material, as a secondary method of locating the online information.*

All links presented in this Manual were current as of November 7, 2007.



Part 1: Theory

The success of any epidemiological study is dependent on the development of a solid foundation for conceptualizing and, eventually, implementing the study. Because the planning stage requires attention to many details, it may appear intimidating to a novice researcher, but by breaking the process into its components and identifying the steps necessary for success, planning can be greatly simplified. The more solid the foundation through good planning, the more likely the project is to be successful.

1.1. Identifying a Research Topic

Before study planning can begin, one must first identify a research topic of interest. Community concern and personal commitment should be the most important factors dictating the choice of a research topic. Choosing a topic of personal interest can result in a very fulfilling experience for the researcher, and encourage future success and advancement in the field. Furthermore, the personal sense of satisfaction that can arise from being truly invested in a project can serve to improve greatly the quality of the final product.

Researchers will generally choose topics on which they already have a good deal of background knowledge, ensuring that they are well-prepared for a detailed examination of the problem and its associated issues, or simply because it is this knowledge that has

initially aroused their interest in further study of the area. If a new topic is chosen for investigation, researchers must take the extra time to become familiar with the topic, enabling them to be comfortable with key concepts and issues. Knowing what research has already been done on a particular topic can be invaluable for identifying what new or corroborative work may be useful. Researchers may wish to further develop their knowledge in a particular area by actively seeking formal education in the area of interest, contacting knowledgeable peers, or on an individual basis by obtaining textbooks and published articles on the topic. This step is important because interest alone is insufficient to fully appreciate the complexities and issues involved in planning a study in an unfamiliar area.

1.2. Conducting a Literature Review

Once a research topic has been identified, even researchers with experience on the topic should conduct a formal literature review to become familiar with the body of current and historical scientific literature already in existence. A **literature review** is a methodically conducted review of published academic reports in **peer-reviewed** journals. There are several methods by which this may be accomplished, though if internet access is available, the most efficient way may be to use one or several of the modern computerized databases cataloguing current research. Online databases such as Medline, PubMed, or the Cochrane Library can be very useful for quickly scanning the published literature and locating pertinent basic science and review articles (*For links to selected online databases see Toolkit №1*: *Useful Epidemiology and Public Health Websites and Online Resources*). Unfortunately, these searches are not all-inclusive, and may omit articles from new or lesser-known journals, or those written in languages other than English. Because access to most peer-reviewed journals requires the payment of what can be substantial subscription fees, access by researchers from developing countries with minimal financial resources can be problematic. To combat this problem, the World Health Organization (WHO) is now providing free internet access to many key public health and scientific journals. More information on this initiative is also available in Toolkit *№1*: *Useful Epidemiology and Public Health Websites and Online Resources.*

Another method that can be used independently (but, best in conjunction with the abovementioned database search) is to locate several papers addressing the topic of interest, and to closely examine the literature referenced within while reading them. The researcher can then manually select pertinent articles or books from the reference list at the end of the paper for further reading. By repeating this process of obtaining journal articles and researching the references within them, one can develop a good understanding of the current level of

knowledge within the field, as well as for the methods that have been used to examine the issues.

Communicating with researchers and agencies that have experience in studying the research topic of interest may also be a useful method for obtaining more information on a study topic, including unpublished or internally published results and subjective impressions (so-called "**grey literature**").

1.3. Specifying a Research Question

The next step in planning an epidemiological study must be the specification of a suitable research question. An appropriate research question should satisfy several criteria, including:

1) Being of some importance and relevance to the community
2) Having implications for improving or maintaining public health
3) Being scientifically important, relevant and original
4) Being sufficiently specific and practical to be answerable through available epidemiological methods and resources

1.3.1. Community Importance and Relevance

Epidemiological research should focus on questions that have some interest or relevance to the communities in which they are based. Research questions often arise as a direct means of examining topical issues, but lesser-known issues may be of equal importance to the health and well-being of the community. For example, a topical question might revolve around public concern of increased cancer risk following exposures from a particular polluting industry. Another could be the relationship between socioeconomic status and infant birth weight. Though the latter may not appear to be as newsworthy, both are relevant and important to the community. Issues of community importance may be identified through personal experience or through contact with stakeholders, including: health care professionals, policy makers, citizen groups, and in some cases, the media.

1.3.2. Public Health Implications

In keeping with the mission of epidemiology, epidemiological research should be conducted with the intent of maintaining or improving health in human populations. This

does not necessarily mean that the findings of a study must result in immediate human health benefits, but that, either directly or indirectly, the results of the research should contribute to understanding exposure-disease relationships and/or discovering methods of promoting human health. In fact, most epidemiological research is an attempt to address health concerns or to investigate health problems afflicting human populations, whether the causes of these problems are known or not. Epidemiologists need not focus only on potential risk factors, but may also choose to study **protective factors** (those exposures which promote or improve some aspect(s) of human health). Regardless of the topic of study, researchers should always bear in mind the goal of protecting and promoting public health.

1.3.3. Scientific Importance, Relevance, and Originality

The next criterion, that the research question has scientific importance, relevance, and originality may be the most important for producing findings that will be recognized as a useful contribution to the field. It is important to choose research questions that can contribute to scientific knowledge because success in a research career depends on the production of novel and meaningful research findings. Research questions with scientific merit are those that have not yet been conclusively answered by the body of scientific literature, have been proposed but not been addressed, or in some cases have not yet been posed.

A good scientific study will produce findings that will contribute new information to the body of scientific knowledge on certain topics. Proposed research should be sufficiently original as to provide the scientific community with new data, new interpretations of previously collected data, or novel methods to examine a particular issue. At any rate, the researcher should avoid unnecessary duplication of experiments or results, but should instead aim to advance knowledge within the field. While replication has its place for demonstrating causality, duplication of results already accepted as scientifically valid does not advance knowledge, and will most likely be seen by the academic community as an inefficient use of scarce resources. Studies duplicating results are unlikely to be funded or supported, and even if conducted, will do little to advance the reputation of the researcher or encourage future investment in research conducted by that individual by donor agencies.

1.3.4. Specificity and Practicality

A research question must be sufficiently specific and practical to be answered within the confines of a study having limited resources. Overly general research questions are unlikely to be answered in sufficient depth to advance knowledge in any useful way, or be able to be addressed at all because of logistical constraints.

Complex research initiatives that do not involve recognized and/or highly skilled individuals as part of the research team and which require large amounts of funding are unlikely to be supported, and thus would be unable to be conducted. Because of the competitive environment in which research funding is awarded, applications from experienced, senior researchers are most likely to be favoured. Novice researchers without extensive research credentials or only scarce resources must be particularly aware of the need to develop research questions that are answerable through the means available to them. Success for novice researchers thus entails identifying research topics that are attractive to, and likely to be funded by donor agencies, or those that can be funded through other personal or private means. Researchers must be prepared to justify how efficient use will be made of the funding that they are requesting for the study.

1.4. Formulating an Hypothesis and Selecting a Study Design

The formulation of a study hypothesis and selection of a study design are closely related concepts, and cannot be conducted entirely independently of one another. The type of hypothesis that can be tested varies considerably with study design, and conversely, the type of study being used depends on the hypothesis being tested. Serious consideration must be paid to each of these topics when planning a study. While a distinction can be made between hypotheses that conform to reductionist approaches compared to those that are more systemic in nature, it is beyond the scope of this Manual to adequately explicate these differences. For a fuller understanding of the significance of this point, the reader may refer to any one of the modern texts in epidemiology *(see Key References)*.

1.4.1. Formulating an Hypothesis

A careful and critical review of the literature (See Section 1.2) is needed to enable the researcher to formulate an hypothesis. A good research hypothesis will be specific and direct, and must be scientifically testable and refutable in accordance with the scientific method. A good epidemiological research hypothesis will identify five major points:

1) The study population(s)
2) The risk factor(s) being studied (exposures and confounders)
3) The health outcome(s) being studied
4) The time period(s) being studied
5) The relationship being studied

These components are required to make an hypothesis specific, direct, and testable. Ideally, a research hypothesis will be a one-sentence statement based on initial observations that has the potential to be tested by a scientific study. While hypotheses can take many forms, a simplified example of a null hypothesis, or an hypothesis of no effect, is presented below:

"At time T in population P, risk factor X is not related to health outcome Y."

In accordance with the scientific method, one cannot conclusively prove that a null hypothesis is true (e.g., that risk factor X is not causally-related to health outcome Y), but a study can serve to falsify the **null hypothesis** (by demonstrating that, under the conditions of the study, risk factor X and health outcome Y are related).

1.4.2. Selecting a Study Design

It is essential to choose a study design that is appropriate to the type of research question being asked, the study hypothesis, and to the available resources. While there are many different types of studies, most operate on a fundamental comparison: that of an exposed group to a **reference group** (also known as a "**control**" group), i.e., one group of people that possesses a characteristic with another that does not. Epidemiological studies can be classified by the way these comparisons are made into two broad groups:

1) descriptive and

2) analytic (Figure 1.1).

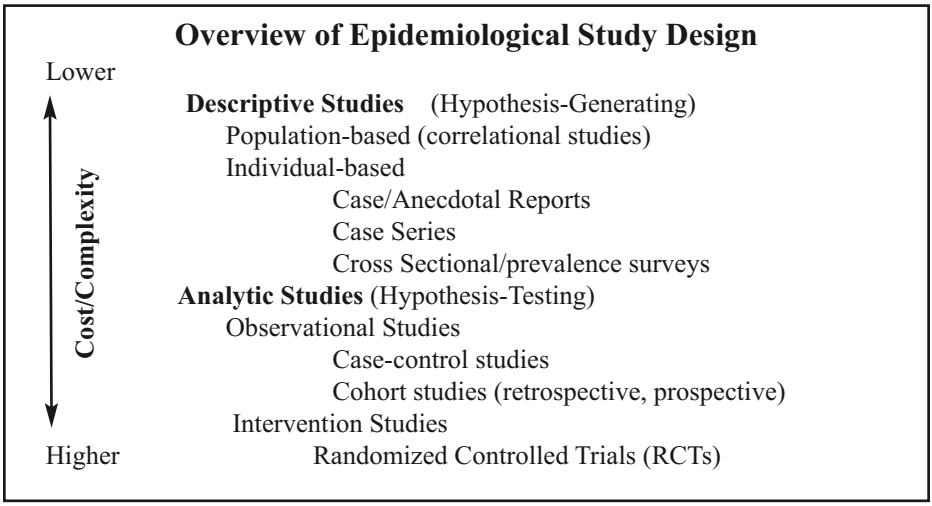


Figure 1.1. Overview of epidemiological study designs (adapted from Hennekens & Buring 1987).

Descriptive studies, as the name suggests, are concerned primarily with describing patterns in, or relationships between variables, often at the population level. They generally do not attempt to test hypotheses, but rather aid in **hypothesis generation**. While not offering the same level of scientific rigour as analytic studies, they are less complex and require a lower investment of time and money. For this reason, descriptive studies are ideal for exploratory research on new topics, and/or when funds and resources are limited. Some of the most common types of descriptive studies can be seen in Figure 1.1.

Analytic studies focus on **hypothesis testing**, usually to verify or disprove a suspected relationship between (a) certain risk factor(s) and disease(s). While comparisons of exposure and disease status in descriptive studies tend to be implicit, those in analytic studies are explicit. That is, analytic studies directly test associations between exposures and health-states, whereas descriptive studies attempt to illustrate these same relationships on a more qualitative level, by describing patterns in these variables relative to one another. Analytic studies consequently tend to require a greater amount of investment of both time and money by the researcher to successfully plan and conduct them.

In return for this greater investment, the researcher tends to generate results that are more quantitative and generalizable. Because of the extra time, money, and rigour involved in conducting analytic studies, they are best reserved for situations in which exploratory research has already been conducted, and the required logistical and financial resources are readily available. Some common types of analytic studies are shown in Figure 1.1.

The types of conclusions that can be drawn from a study will be dictated by the study design, and therefore great care must be exercised to ensure that conclusions drawn from a piece of research are appropriate to the design employed. Likewise, vice versa: if a certain question must be answered, then the study design appropriate to answering that specific question must be employed. In practice, however, the study design will be able to be implemented only if its individual requirements can be met, e.g., sample size: that adequate numbers of exposed and unexposed people are available to participate. Thus, practical considerations such as the calculation of the sample size necessary for the study are critical for determining whether the proposed design will be appropriate and feasible *(See Section 2.5. Sampling, Sample Size, and Power).*

For detailed information on the theoretical bases for, and instructions for the planning and conduct of these studies, please refer to the Key References section at the end of this text.

Part 2: Case Study Example

1.1. Identifying the Research Topic and Question

The city of Sumgayit was a major industrial production centre for the former Soviet Union, and had more than forty large factories producing a wide array of chemical and industrial products for about four decades. Unfortunately, there was poor regulation of environmental health, occupational health and safety standards, which resulted in high levels of chemical pollution in both the workplace and the environment. Consequently, serious public concern arose that the health of Sumgayit residents and workers was compromised by these exposures. These allegations were restricted to anecdotal reports, however, as there was no scientific evidence to support them.

The Sumgayit Cancer Study was conceived during the conduct of jointly-sponsored UNDP/WHO Introductory and Advanced Environmental Epidemiology training courses in Baku, Azerbaijan, during February and December of 2000, respectively. Two of the course instructors, Colin Soskolne and Francesca Racioppi, had the opportunity to visit the UNDP-funded Sumgayit Centre for Environmental Rehabilitation (SCER) during their stay in Azerbaijan. The SCER was created by the UNDP in order to address the serious environmental health issues raised by the concentration of industry in the city of Sumgayit, Azerbaijan.

While examining the pollution data collected by the SCER, Dr Soskolne and Ms Racioppi recognized the long-term environmental and occupational exposures plaguing Sumgayit. Furthermore, they were able to examine some cancer data for the city of Sumgayit, which appeared to show higher than expected rates of cancer. Given the potential link between high degrees of environmental and occupational pollution and increased cancer rates, as well as community concern about the issue, a study to quantify the cancer burden, if any, in the city of Sumgayit was proposed.

The Sumgayit Cancer Study was thus born largely as an attempt to address community concerns, and attempted to confirm or deny, based on available evidence, the perceived increased health risks resulting from past and present industrial activities in the city. Through so doing, the study was to provide an evidence-based assessment of current health issues in Sumgayit, and would be useful both to address public concerns and to provide factual information to policy-makers for use in prioritizing issues, allocating resources, and advancing public health.

Selected cancers were chosen as the health outcomes of study for several reasons. Following the dissolution of the Soviet Union in the early 1990s, the industrial productivity of Sumgayit decreased dramatically, and accordingly so did pollution levels. Thus, it was not practical to examine short-term effects of pollution, such as ambient air quality on respiratory effects. In contrast, the **latent period** of 10 years or more for most cancers suggested that cancer rates in the 1980s and 1990s would be useful for measuring the effects of exposures from Sumgayit industry during the late-1970s and 1980s, correspon-

ding to the highest levels of production from the factories, and thus, the highest expected exposure levels. Because many compounds present in Sumgayit industry have known causal associations with cancers and, given the alleged high levels of exposures for workers, it is likely the exposures experienced would have contributed to increased cancer rates. Finally, high-quality cancer data for Sumgayit and the rest of the country were believed to be readily available.

Thus, the general form of a research question was identified: "Does an increased cancer risk exist among the residents of the city of Sumgayit, Azerbaijan, as a result of past and present industrial activities?" This question was relevant to the community of Sumgayit, had implications for improving public health, was original in the sense that it was the first formal quantitative attempt to evaluate the cancer health effects of Sumgayit industry, and was sufficiently practical to be answered using available resources.

1.2. Conducting a Literature Review

Once the research topic and question were selected, a literature review was conducted using the MEDLINE online database *(See Toolkit №1: Useful Epidemiology and Public Health Websites and Online Resources*), supplemented with references taken from articles already collected, to gain familiarity with topics relevant to the proposed study. These included: environmental and occupational cancer, epidemiological (particularly cancer epidemiology) research already conducted in the former Soviet Union and Commonwealth of Independent States (CIS) , and primary studies exploring associations between chemicals present in Sumgayit industry and cancer. The exercise provided a great deal of information useful for conducting the Sumgayit study, including examples of study designs useful for answering the research question, potential issues that could be encountered while conducting cancer epidemiology research in the former Soviet Union, and evidence of strong associations between particular compounds present in Sumgayit industry and certain cancers.

1.3. Formulating an Hypothesis and Selecting a Study Design

1.3.1. Formulating an Hypothesis

Because the study was the first of its type in the region, its primary scientific goal was first to provide an appraisal of the cancer burden in Sumgayit and Azerbaijan (**risk assessment**), and second to provide some direction for future research or remediation efforts in the region (hypothesis-generation). However, the descriptive study design limited the types of hypotheses that could be tested to those testing statements at the population level, and excluded those testing direct causal relationships. On this basis, the study hypothesis was formulated as follows:

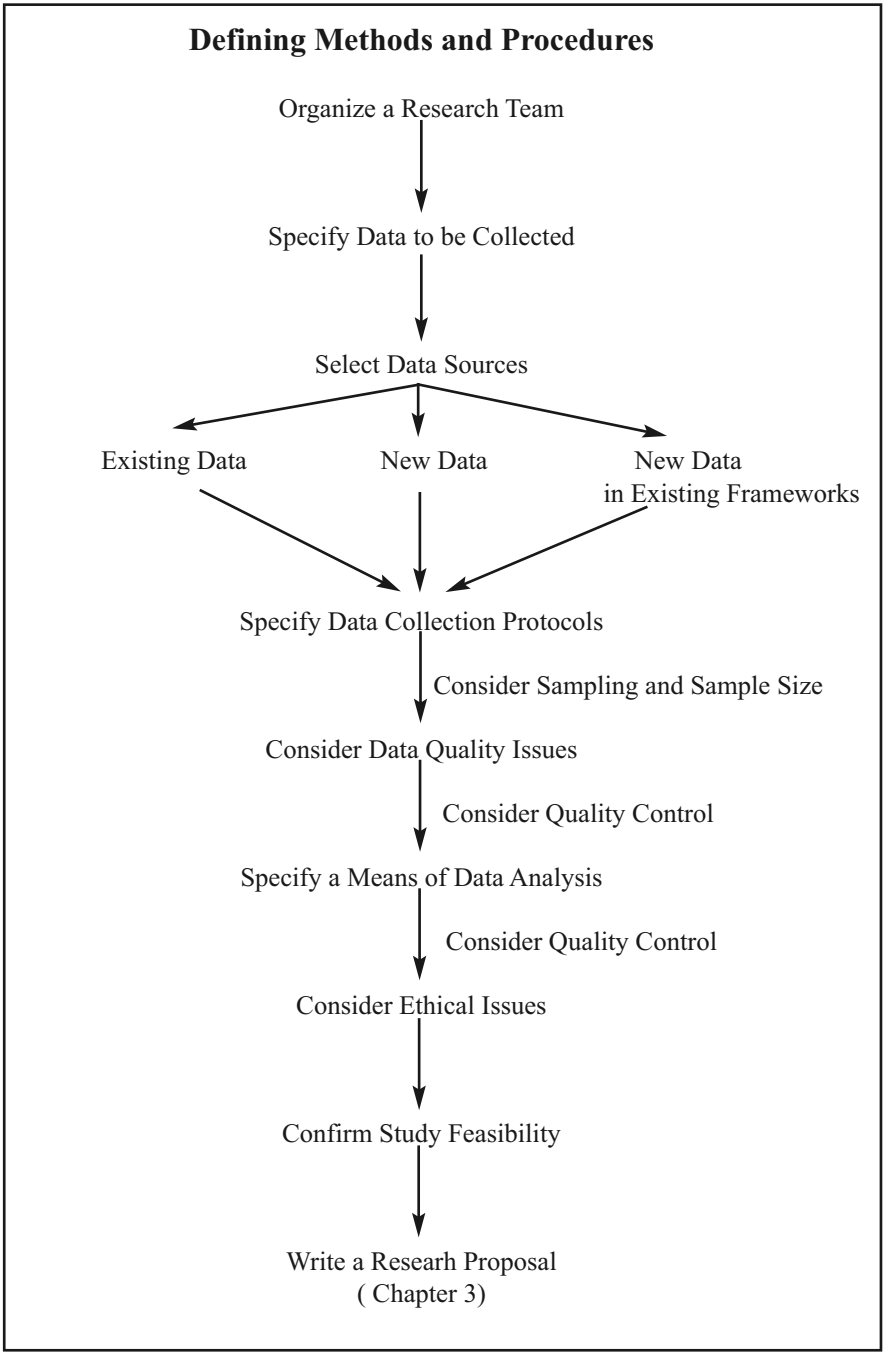
Cancer incidence and mortality rates in the city of Sumgayit over the period 1980-2000 do not differ from those of:

1) Other selected regions of Azerbaijan
2) Azerbaijan national data
3) Other Newly Independent States and the Russian Federation
4) Canada

1.3.2. Selecting a Study Design

Given that little epidemiological research and, in particular, cancer epidemiology had been conducted in Azerbaijan at the time of planning this study, a low-cost, exploratory study using a population-based descriptive study design appeared to be the best way of addressing the concerns of the residents of Sumgayit. The study question asking if cancer rates were indeed elevated in Sumgayit because of industrial exposures was easily addressed through a descriptive study comparing cancer rates in Sumgayit to other regions of the country that had different exposure levels. Because one of the goals of the project was the involvement of local researchers from Azerbaijan in an effort to strengthen local capacity, a descriptive study, being less complex than an analytical one, was seen as the preferable method of involving persons without extensive research training or experience. In addition, because descriptive studies can rely on summary data, which were believed to be readily available from the Ministry of Health (MOH) of Azerbaijan, the process of data collection was expected to be a straightforward and efficient process. Finally, given the limited resources available to conduct the study, the use of a cost-effective descriptive design had added appeal.

Both national and international populations were selected for use in comparisons, in order to provide credibility to the study's findings, and to maximize the interpretive insights that could be gained from them. Comparisons of populations within Azerbaijan were useful because they likely were similarly affected by social, political, and economic events during the study period, thus reducing any potentially confounding influences by these factors. Data quality was expected to be uniform across the country. Comparisons with international populations again were useful because individual nations were expected to experience different influences and to have different social, political and economic processes at work than in Azerbaijan. As such, if biases were present in national or regional data in Azerbaijan, the use of both internal and external populations for comparison was expected to increase the likelihood that these biases would be detected, and to reduce the likelihood of erroneous conclusions being reached from the various comparisons.


Defining Methods and Procedures
Organize a Research Team
Specify Data to be Collected
Select Data Sources
Existing Data
New Data
New Data
in Existing Frameworks
Specify Data Collection Protocols
Consider Sampling and Sample Size
Consider Data Quality Issues
Consider Quality Control
Specify a Means of Data Analysis
Consider Quality Control
Consider Ethical Issues
Confirm Study Feasibility
Write a Researh Proposal
(Chapter 3)

Part 1: Theory

For the purposes of preparing a formal research proposal, one must specifically identify the methods and procedures to be utilized for implementing the study design. Researchers must describe in detail such matters as the members of the research team, the type of data that will be necessary for the study, the sources from which these data will be obtained, the methods of obtaining the data, how quality control will be ensured at each stage of the study, and how the quality of the collected data will be assessed. These issues must be considered before creating the research proposal because they have major implications for the requirements, costs, logistics and, ultimately, the feasibility of the study.

2.1. Organizing a Research Team

One of the most important aspects of conducting a successful epidemiological study is to assemble a suitable research team to aid in the technical, logistical, and financial aspects of the study. A novice researcher would do well to incorporate some senior members with research experience and credentials to contribute not only in the conduct of the research, but also to aid in the scientific development of the study design and to strengthen funding proposals. Mentoring by experienced researchers should be sought on all matters in designing and conducting a study, if only through review and approval of proposed methods and procedures. Suitable members could include an epidemiologist with methodological experience in the area of study or a related field, a clinician with a thorough knowledge of the health outcome(s) being studied, and a biostatistician to aid in study design (particularly sample size, power, and the statistical analysis of data). It is important to have a diversity of experience on the research team in order to ensure that study issues can be addressed in a balanced, knowledgeable fashion. This is a key criterion by which funding agencies measure the strength of funding proposals. So, it is important not only for the eventual conduct of the study, but for the initial success of funding applications that a comprehensive research team is organized. Including junior members on the research team is beneficial also for building research capacity.

Novice researchers in countries without well-established training facilities and research infrastructures may wish to build partnerships with professionals in areas of the world where scientific, technical, and financial resources are more readily available. Such international collaboration can benefit local researchers by providing them with better ac-

cess to resources and modern scientific expertise, and more credibility for research proposals and funding applications. In turn, they can also benefit international researchers by allowing them access to new data and new research opportunities, and exposure to new health issues and approaches to solving them that would otherwise be unavailable. Contact with experienced researchers can be made through a number of international professional associations (*See Toolkit №2: Professional Organizations and International Opportunities for Environmental Epidemiologists*).

It may not always be possible, or in some cases even necessary, to assemble a formal research team, though the diversity of experience and opinions that the team can offer can be invaluable to develop the study, and in managing unforeseen problems. In general, public health problems are multidisciplinary in scope and are complex, and hence a team comprising all relevant disciplines is more likely to lead to successfully funded and conducted research. A team with defined roles makes it unlikely that conflicts among researchers will occur in the conduct of the study, that all expertise is utilized, and that all contributions are duly acknowledged and responsibilities assigned.

Professional guidelines that have been developed for the ethical conduct of epidemiological research encourage the inclusion of community members and other stakeholders as part of a "**steering committee**" to guide the research project. Steering committees link scientific members of the project with representatives from the community, academia, government, industry, and other relevant **stakeholders**. Establishing a steering committee can require a major investment of time and energy to create and maintain, but can have major benefits for researchers, and for the communities in which they work, particularly by focusing and directing strengths, concerns, abilities, and expertise so that they may be utilized most fully. For example, long-time community members may have knowledge of past practices or exposures in a community that could be invaluable to researchers for the design of a study or the interpretation of the study findings. Likewise, the concerns of the community can be communicated effectively to the researchers. These efforts help to ensure that research proceeds in an ethical fashion.

(The complete ethics guidelines for environmental epidemiologists are listed on the webpage of the International Society for Environmental Epidemiology (See Toolkit №2: Professional Organizations and International Opportunities for Environmental Epidemiologists.))

2.2. Specifying Data for Collection

The type of data required for a particular study differs greatly by the type of study design being used and the study hypothesis being tested. Thus, it is important to carefully consider these together when identifying what specific data are necessary for a particular study. Correctly specifying the data required for a study requires that the researcher addresses several key points of the study hypothesis:

1) The study population(s) (define attributes such as: geographical boundaries, age, gender, race, and/or employment)
2) The risk factor(s) being studied (exposures and control of confounders)
3) The health outcome(s) being studied (specifically, including internationally recognized coding, if applicable)
4) The time period(s) being studied

While the study hypothesis identifies, in general form, the information necessary for the conduct of the study, it is essential to clearly specify what data will actually be collected (e.g., numbers of new lung cancer cases or deaths in both sexes for the period 1990-2000, the presence or absence of upper respiratory tract infection in children aged 17 or younger in 2002, demographic distributions, and the like). This is important because the ability to successfully conduct a study and answer a research question depends on the collection of specific data. Thus, if the required data are not specified clearly, it becomes difficult or even impossible to assess study feasibility and/or to examine samples of the data prior to beginning the study.

The researcher must then specify into what **variables** these data will then be coded and recorded. The type of variables chosen will have implications for how data will be analyzed, results presented, and conclusions drawn, so it is important to consider this issue early in the planning of a study. Variables can be classified into two major types.
Categorical variables are those that can assume values belonging only to a limited number of individual categories, with no intermediates or gradients between them. Categorical variables can be further classified into two groups: **dichotomous (binary**) and **polytomous.**

Dichotomous variables are those that can classify data in only two different categories (e.g., presence/absence, yes/no), while polytomous variables can classify data into several different categories (e.g., age groups: 0-4, 5-9, 10-14, …, 75+).

Continuous variables are those that can assume any particular value (usually within a specified range) and are not restricted to certain categories; thus, the level of detail of the data recorded relies on the precision of the measuring instrument (or process). Examples of continuous variables include height, weight, and the concentration of particulate pollution in ambient air.

2.2.1. Confounding and Bias

No discussion on the planning of data collection for a study can be considered complete without including the topics of confounding and bias. Both represent serious threats to the validity of results generated from any study, unless specific steps are taken to address and assess them. A good knowledge of the exposures and diseases being studied, in combination with a thoughtful and meticulous experimental design and data collection procedures, however, can essentially eliminate these problems.

Confounding arises when an apparent association between a risk factor (E - exposure) and a health outcome (D - disease) being studied is the result of a third variable that is not of direct interest to the study (F – confounding factor) (Figure 2.1). By definition, confounders must be risk factors for the disease being studied, and must be associated with the particular risk factor(s) being studied. A classic example of confounding that has been identified is the apparent relationship between alcohol consumption and lung cancer. Data collected have shown that higher levels of alcohol consumption are correlated with higher risk for lung cancer, implying a (causal) relationship between the two. Further research has shown, however, that this is not the case. A more detailed examination of the situation revealed that increased levels of alcohol consumption are correlated with higher levels of cigarette smoking, one of the strongest risk factors for lung cancer. In fact, cigarette smoking is responsible for the increased lung cancer risk. The relationship between alcohol consumption and lung cancer appears to exist only because of the confounding influence of cigarette smoking.

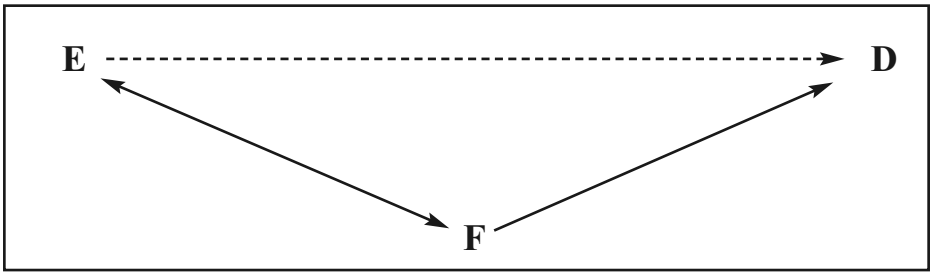


Figure 2.1. Confounding. Variable F is a risk factor for disease (D), and associated with exposure (E). Thus, exposure (E) and disease (D) appear to be associated because of their mutual relationship to F. F is a confounding variable. (Adapted from Hennekens & Buring 1987).

Variables representing intermediate steps in the causal pathway between exposure and disease cannot be confounders (Figure 2.2). A good example illustrating this is the relationship between (low) calcium consumption, osteoporosis, and hip fracture. Both calcium consumption and osteoporosis are risk factors for hip fracture, and are indeed associated with each other (low calcium consumption is causally-related to an increased risk of osteoporosis). Although it would appear at first glance that osteoporosis could confound the relationship between calcium consumption and hip fracture, this is not possible, because osteoporosis represents an intermediate step in the causal pathway. Because low calcium consumption acts only through osteoporosis to increase risk of hip fracture, osteoporosis cannot independently link low calcium consumption with hip fracture, and cannot confound the relationship.

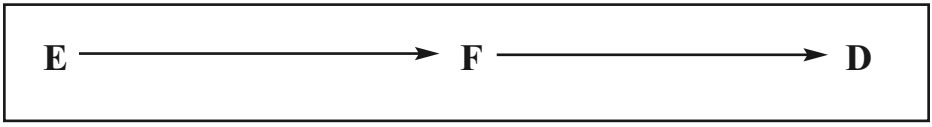


Figure 2.2. No confounding. Variable F is an intermediate step in the causal pathway between exposure (E) and disease (D). F therefore cannot be a confounder. (Adapted from Hennekens & Buring 1987).

By understanding the concept of confounding, and possessing a thorough knowledge of the exposure(s) and disease(s) being studied, researchers can generate a list of potential confounders before the study begins. By measuring the distribution of potentially confounding variables in the same manner that study variables are measured, the presence

of confounding can be identified during data analysis, and with appropriate statistical methods, it can be controlled. If confounders are not measured, it then becomes impossible to control for them during data analysis, and confidence can be lost in a study's findings. Potential confounders can be selected from risk factors other than the primary exposure(s) being studied; for example, lifestyle parameters such as diet, smoking, and alcohol consumption.

KEY CONCEPT: MEASURE POTENTIAL CONFOUNDERS

Confounders that are not measured cannot be controlled for during data analysis, and confidence can be lost in the study's findings.

Biases also pose serious threats to the validity of findings produced by a study. Biases are systematic errors introduced into the data, usually during data collection, which compromise data quality, and can severely damage or entirely invalidate a study's findings. They are classified into several major categories, including: **selection bias**, **observer bias** (**e.g., interviewer, misclassification, recall**), but may include other possibilities, such as errors introduced during data entry. The presence of biases in the data can usually be avoided by strict adherence to rigorous data collection methods and data entry procedures, which include adequate worker training and quality control procedures.

For more detailed discussions of confounding and bias, please refer to the Key References.

2.3. Selecting Data Sources

One of the major challenges researchers face when conducting studies is identifying and deciding from what source(s) they will obtain their data. There are three major ways in which data can be obtained for a study, from:

1) pre-existing sources,
2) active collection of new data, or
3) use of existing information systems as a framework for new data collection.

Each of these methods has advantages and disadvantages that must be discussed.

2.3.1. Pre-Existing Sources

Pre-existing data offer benefits to the researcher primarily in terms of financial and logistical considerations. Pre-existing data tend to be easily collected, as the process often may only require approvals from the appropriate source agency, the payment of access or administrative fees, and in some cases a need to recode the data into a suitable format for the research project. Researchers are saved significant expenditures of funds and energy required to plan and conduct the collection and recording of new data. Recent health and exposure data are available in electronic format from many administrative agencies or disease registries around the world, though in some regions, or for older, archived data, they may be available in only hardcopy form. In these situations, a further process of data abstraction and input to electronic form is required, though this method is still far more cost-effective than collecting data de novo.

Unfortunately, there are a number of problems associated with the use of pre-existing data for research. These data are often collected for purposes other than research; consequently, the data may not conform to the ideal needs of the study. Variables may be recorded in a manner inappropriate to the needs of the research, such as being coded into categories that are not conducive to data analysis, being recorded in insufficient detail, or omitting key points of interest for the researcher. Furthermore, it is often impossible to examine the methods by which the data were collected or recorded, and thus data quality cannot be assessed conclusively.

Depending on the study design, its particular requirements, and the methods of data-collection, recording, and storage by the source agency, pre-collected data may range from being ideal to being completely useless for the purposes of the study. It is therefore imperative that researchers secure assurances from the source agency regarding exactly what data they will receive, the time frame for their receipt, and also a reasonable assessment of their quality should be conducted prior to beginning the study. Ideally, the researcher will obtain a sample of the data and evaluate their suitability for the specified research. Failing to do so could result in the collection of useless data, unnecessary delays, wasted funds, or the outright failure of the study.

2.3.2. Collection of New Data

Collecting new data is the preferred method of obtaining data for a scientific study when resources are available because of the direct control the researcher can exert over what data are collected. The major advantage of collecting new data is that the data collection and recording procedures can be specifically tailored to answering the research question. This means that the method of data collection, the actual data collected, and the coding and recording of the data can all be designed in ways that facilitate the inquiry and study goals, and ensure that any potential concerns or issues regarding the data can be easily investigated. Well-planned collection of data means that their quality can be immediately verified, and they can be analyzed quickly and efficiently.

The drawbacks associated with collecting new data revolve primarily around the cost, time, and effort required to collect them. Obtaining adequate sample sizes for statistical analyses often means that the researcher must hire and train assistants to collect data, whether that means poring over individual case histories, or interviewing persons from the study population, or depending on mailed self-administered questionnaires. Depending on the needs of the study and the type of data that are being collected, the process of data collection can range from being a simple, short-term procedure to being so lengthy, complex, and expensive that it may not even be possible, given available resources. Practical, legal or ethical considerations may also inhibit the collection of new data.

For instance, people may no longer be alive to participate, in which case researchers may need to depend on historical records or surrogates such as next-of-kin. The law may not permit access to data of a criminal nature on adolescents. Ethical analysis may reveal that to obtain new data could cause more harm than good to the study population.

2.3.3. Collection of New Data in Existing Frameworks

Collecting new data within the framework of an existing information system is a hybrid approach that blends aspects of each of the previous two methods. This approach offers advantages including reduced costs associated with using pre-collected data, while retaining high data quality, characteristic of collecting new data.

This is typically accomplished by collecting data in parallel with the existing information flows, while ensuring that the principles and procedures necessary for collecting high quality, detailed and relevant data are followed. Thus, the need to develop new sampling frames and information flows is avoided, and costs associated with such endeavours are reduced. This method also offers the possibility of evaluating the efficacy of the current methods of data collection for research purposes, permitting the development of recommendations for the improvement and strengthening of the existing system to better serve research needs. It has recently been successfully used in the Russian Federation (Jaakkola et al. 2000).

This method may be applicable in only those situations where existing data collection frameworks are of suitable quality and type, and where appropriate permissions to access the existing frameworks are available.

2.4. Specifying Data Collection Protocols

Once the researcher has identified the specific data required, the source(s) from which they will be obtained, and the owners of the data (Table 2.1), further specifications must be made as to how those data will actually be collected. The protocols for collecting data for any single study are immediately constrained by the study design, hypothesis, and the data required. There remain numerous ways by which the necessary data can be collected, each with their own advantages and disadvantages.

Table 2.1. Specification of data required, sources, and owners.

Data Type	Specific Data Required	Source(s)	Owner(s)
Exposure	?	?	?
Confounding	?	?	?
Outcome	?	?	?
Population	?	?	?

The specification of data collection methods must include whether the data will be collected in a **retrospective** or **prospective** fashion, and by what method they will be ob-

tained (e.g., from interviews, medical records, or administrative databases). It is thus extremely important to clearly specify exactly how the data for any particular study will be collected, and to ensure that these methods are feasible. To do so, the researcher must identify the source of the data, the methods (and instruments, if applicable) to be used, specify the units and variables into which the data will be recorded, and confirm that both the necessary permissions and logistical considerations can be achieved.

An occupational case-control study examining respiratory health in relation to employment in a wood processing plant, for example, must collect both exposure and outcome data at an individual level, though there are several ways this can be accomplished. A novice researcher might feel that it is adequate to state in a research proposal that exposure data will be collected by inserting stationary sampling devices at specified locations in the workplace, which will take periodic measurements during the employee's workday. In fact, this description is entirely vague and does not allow an assessment of the scientific quality of the methods, the feasibility of collecting the data, or the usefulness of the collected data.

Data collection specifications must be very detailed and precise in order to be assessed meaningfully. For the above example, the researcher could state that exposure data will be collected prospectively, by actively sampling air quality in the workplace. From this statement, further specifications of what and how the exposure data will be collected must be made, including, but not restricted to, such factors as identifying what air quality parameters will be examined (e.g., particulate matter, organic solvents, specific compounds), in what units measurements will be made, the frequency with which measurements are to be taken, the period during which measurements will be made, and how individual worker exposures relative to these measurements will be calculated. In contrast, the researchers may wish to use personal sampling devices that are attached to the clothing of the workers, simplifying the calculation of individual exposure levels, but the types of exposures measured as well as the frequency and duration of measurements still must be defined.

Health outcome data collected must also be clearly defined. For the current example in which respiratory health is the general outcome, the researcher must define which individual parameters are to be measured as indicators of respiratory health. Respiratory health can be assessed through spirometric tests measuring lung function, such as Forced Expiratory Volume in One Second (FEV1), Forced Vital Capacity (FVC), Peak Expira-

tory Flow Rate (PEFR), or Forced Expiratory Flow (FEF). Physical examinations, which may include a chest x-ray, could also be a useful method for assessing gross respiratory pathology. Data could be collected directly from study participants through questionnaires asking for a personal assessment of their own respiratory health status, in terms of signs, symptoms, and/or performance parameters. Other parameters to be evaluated might be airway resistance, or structural changes of the airway under moderate exercise. The list can go on and on. The point is that there are many ways to collect data for a single study. Thus, it is necessary to define explicitly and in detail what data will be collected, and to then evaluate the feasibility of doing so before a study begins.

Data collection protocols must further specify who will collect the data and what training they will require, as well as the specific way in which they will actually record the data they collect (e.g., directly to computer; first on paper forms, then entered to computer; and so on). Identifying suitable and diligent persons for conducting data collection, adequately training them, and informing them of the goals of the study and the importance of their roles in it, also in relation to maintaining the confidentiality of the data, are fundamental to the collection of meaningful data.

2.4.1. Interview Data

While interviews are only one of many methods used to collect data in epidemiological studies, they represent a special case because of the frequency with, and diversity of study types in which they are used. These data are commonly collected for almost all types of epidemiological studies, including cross-sectional surveys, case-control studies, and cohort studies. Furthermore, because of the variety of problems that are associated with the careless collection of interview data, special discussion is warranted.

Interview data are collected during direct and interactive contact with participants, often in person or on the telephone, and generally consist of study personnel (i.e., interviewers) asking participants a set of predetermined questions, usually based on a questionnaire. Interviews offer many advantages that are appealing for scientific data collection: individual-level data can be obtained quickly and efficiently with relatively low expenditure of financial and logistical resources, the interviewer can be sure of who is answering the questions, and the interviewer can "**probe**" for full answers, when they are not initially provided. With well-trained and attentive interviewers and the use of simple and direct questions, the data collected from interviews can be of very high quality.

Unfortunately, adequate preparatory time is often not taken to ensure that interviewers are sufficiently trained and that the questions being asked are appropriate for the collection of quality data. **Interviewer bias** commonly occurs when the interviewers do not adhere to the standards and protocols for asking the questions and recording responses, and they err in a systematic fashion. Some common examples of problems introduced by interviewers include varying the wording of questions asked among participants, leading or biasing participants (consciously or unconsciously) to obtain a particular answer, and/or misunderstanding or incorrectly recording the responses of participants. The systematic errors that can be introduced to a data set can have major and detrimental effects for data quality, and may invalidate study findings altogether. Many of these concerns are addressed more fully elsewhere (*See Key References*).

Selecting attentive and diligent persons for the interviewing positions, and then providing them with sufficient training and practice to properly develop and hone their interviewing skills is important for significantly reducing or eliminating interviewer bias. Researchers must take the time to inform interviewers about the inclusion/exclusion criteria for the study, what each of the questions on the questionnaire means, and the types of responses that must be elicited (e.g., yes/no, numerical, open-ended, and the like). Training sessions, in which experienced interviewers role-play as either interviewer or participant (i.e., interviewee) are invaluable to provide the interviewers-in-training with the range of scenarios and responses likely to occur in an actual interview, and appropriate methods for dealing with them. Trainers can provide immediate feedback to interviewers during this time as to their effectiveness. Following the role-playing sessions, the researchers can examine the data recorded by each interviewer, and can use the exercise both to further comment on each interviewer's performance, as well as to improve the questionnaire.

There are basic rules that interviewers should follow. Interviewers must be trained to ask only the question they are given, and if the participant interviewed does not understand or does not hear initially, only to repeat the question verbatim, rather than to explain it in his or her own words. Interviewers are to be sure that the person fully understands the question before they accept an answer, and may be trained to ask the participant what his or her interpretation of the question is, if he or she has any doubts. If participants appear unable to answer a question, the interviewers may be allowed to read from only an approved set of "probing" statements, if available, to help the person.

The work of interviewers can be made much easier, and the quality of data collected can be improved greatly by an adequately tested and refined questionnaire. Questionnaires should be pre-tested before they are actually used to collect study data, in order to verify that participants (and interviewers) interpret the questions correctly, that appropriate responses are being generated, and that the data are being recorded correctly. While it may be convenient to conduct pre-testing of questionnaires on colleagues or friends, such volunteers must not represent the exclusive testing population. It is best to pre-test the questionnaire on persons from the actual study population, as their understanding of questions and their provided responses may vary considerably from those of friends or colleagues of the researcher, particularly if educational, language, and/or cultural barriers are involved.

Questionnaires should use numerical or categorical "select the best answer" responses, rather than open-ended "fill in the blank" responses whenever possible. Continuous variables should be recorded in a numerical fashion in which the units of measurement are clearly specified to avoid confusion (e.g., weight in kilograms, height in centimetres). Numerical or categorical responses restrict the responses and improve participants' understanding of questions, are easier to code, and produce less variation in the type and quality of responses.

Researchers should be aware that there are pre-tested and validated questionnaires and data collection procedures available for examining specific issues. They not only offer the researcher the advantages of being ready-made, easily accessible, and methodologically "trustworthy," but they facilitate the pooling of data from individual studies into larger datasets. Thus, "multi-centre" studies can often be consolidated, producing more detailed and robust conclusions than any individual study.

2.5. Sampling, Sample Size, and Power

Sampling is a technique used by researchers in virtually every scientific discipline, including epidemiology, allowing them to collect data that would otherwise be extremely difficult, or impossible to obtain. Because human populations are large, and resources available for conducting studies are limited, it is not usually possible to collect data from every person in a population (i.e., a census). Therefore, researchers select a **sample** of the population for study, and from the results obtained for that subset, generalize the findings to the whole population.

Sampling can be expected to yield useful results, however, only if the sample obtained from the population is a **representative sample**. A representative sample is one that approximates, within its smaller numerical size, the distribution of variables and characteristics in the entire population. Because researchers cannot possibly be aware of all population parameters at any one time, attempts to manually select a representative sample from a population are doomed to failure. The best way of obtaining a representative sample is through a random sampling technique, in which individuals are selected from the larger population in such a way that each individual has an equal probability of being included in the sample. A **random sample**, thus, is most likely to include, within its smaller size, the best estimate of the variability and patterns in the whole population. There are a number of tools useful for devising random sampling methods, including statistical software, computerized random number generators, and even the random number charts located in most statistical textbooks.

Once the researcher understands the basic principles behind sampling, he or she must then decide how large a sample should be collected. Collecting samples of the appropriate size is important because of the influence sample size exerts on obtaining statistically significant findings, which are crucial to the success of a research project. As a rule, larger sample sizes will provide higher levels of statistical significance (i.e., greater certainty in the conclusions drawn); however, increasing sample size requires greater investments of time and money by the researcher to collect and process the larger amount of data. If a larger sample than is needed is obtained, this represents a waste of resources. In the interests of efficiency, researchers can calculate the sample sizes required for the particular levels of statistical significance and statistical power that are to be sought.

Sample size calculations use mathematical formulae to determine the number of study participants needed to achieve a desired level of significance in statistical analyses. In other words, they provide a proactive approach to ensuring that **statistical significance** can be achieved in the results. Sample size calculations vary by the type of data collected, and the type of statistical tests to be performed. Many are mathematically simple and take only a matter of minutes to calculate. Most biostatistical textbooks present a number of sample size calculation formulae that are useful for several different circumstances, and several computer software programmes are also available to do sample size calculations.

KEY CONCEPT: CALCULATE SAMPLE SIZE

Because inadequate sample size can reduce the ability of a study to identify a real difference when it exists, it is imperative that sample size calculations are made prior to data collection to ensure adequate statistical power.

One of the most disappointing and frustrating things that can happen to a researcher is to find interesting or surprising trends in the data during analysis that would be highly publishable and noteworthy, except for the fact that they do not achieve statistical significance because of an inadequate sample size. While in some cases it may be possible to collect more data and increase the sample size to a sufficient level, in many instances it may be extremely difficult, costly, or simply impossible to collect data after a "window of opportunity" has passed. In such cases, researchers may never know whether their findings were statistically significant, and their only means of re-examining the issue may be to repeat the entire study. Because of the relative ease with which sample size can be calculated, and the potential costs of not doing so, it is of the utmost importance that researchers calculate the necessary sample sizes before conducting the study.

While attaining statistical significance is a desirable goal, noteworthy results should be publishable even if they do not reach an arbitrary level of statistical significance. Even results with marginal statistical significance can be important for advancing knowledge, particularly if they are consistent with other studies, are well supported by corroborative evidence, and are biologically plausible.

Power measures the ability of a study to detect a difference in a measured parameter, assuming that a difference does indeed exist. Unlike sample size calculations, power is used to predict what level of statistical difference a study can detect based on study design, sample size, and **magnitude of effect**. Thus, while sample size calculations are completed to aid in the design of a study, power calculations are done primarily to determine the usefulness of a study that has already been designed. Statistical software programs are available to aid in the calculation of power.

2.6. Considering Data Quality

All scientific studies operate on one common currency – data. Whether they are epidemiological, clinical or basic science in nature, the success and utility of a study and its findings rests heavily on the quality of the data on which it is based. Thus, the collection of quality data is essential to any research project. What is **data quality**, however? It is defined by two principles: completeness and validity.

Data **completeness** relates both to numerators and denominators. Numerators are concerned with the proportion of events (e.g., cases or deaths) from the total number of events actually occurring in a study population that the data collection process is able to secure. Denominators are concerned with the accurate enumeration of the study population. They refer to the total number of individuals being studied, from which the numerator events could have emerged.

If the collected data account for only a small proportion of the actual total (whether discussing numerator or denominator data), resulting in low completeness, then the quality of the data suffers because they are unlikely to reflect the actual condition of the population. Data completeness can be influenced by a number of factors, including the diligence of data reporting and recording, and the mechanisms of data collection. Issues of data completeness are particularly important to studies based on the calculation of rates and those comparing rates between different regions. If data from different regions have varying levels of completeness, comparisons made based on the data likely will be biased, and may result in erroneous conclusions.

Data **validity** describes the 'truthfulness' of the data: that is, the extent to which the recorded data correctly reflect the actual state of a variable in the population. A number of factors can influence data validity, including diagnostic accuracy and misdiagnoses, the effectiveness and accuracy of measurement equipment, data collection and recording errors, the possibilities of data censorship or fabrication, and data completeness. It is of paramount importance to secure valid data for a study, because invalid data cannot be expected to generate useful findings.

KEY CONCEPT: Only Valid Data Can be Used for Epidemiological Research

The quality of data used in most epidemiological studies is imperfect. However, even data suffering from a lack of completeness can generate useful study results if they are valid. Invalid data cannot be expected to generate useful findings.

While both data completeness and data validity are important aspects of data quality, in situations where one must be sacrificed, a lack of data completeness is likely to be less problematic. While incomplete data may allow the researcher to develop at least a partial answer to the study question, invalid data cannot be expected to generate useful conclusions and are wasteful of study resources.

2.6.1. Quality Control

Quality control is undoubtedly one of the most important aspects of data collection because it acts to ensure data quality. Because data quality is integral to the production of meaningful study findings, and great lengths are often gone to in securing access to data from high-quality sources, it is important to ensure that the quality of the data is maintained through the processes of collection, entry, and analysis. Even if high quality data are made accessible to the researcher, careless data entry, inappropriate analyses, and/or other introduced errors can result in degradation in the quality of the study findings.

These problems can be largely reduced, or eliminated altogether, by adherence to several protocols. Adequate training in the tasks required for data collection (e.g., conducting interviews, retrieving data, and data entry) is invaluable to the collection of high quality data. Furthermore, ensuring that technicians understand the broader significance of the study and the reasons why they are completing their assigned tasks is likely to make them more interested in their work and/or more attentive to potential problems with the data. Strict supervision and random checks of the work of technicians or co-workers can ensure that instructions have been understood and that the desired data are being

recorded in an appropriate manner. Helpful to understanding issues of data quality is the maintenance of a **log book** in which the project staff record any deviances from the specified protocol of the study. This is maintained on a moment-by-moment basis in that entries are made each time a deviation (actual or perceived) in protocol arises. Thus, if questions arise regarding data quality or the procedures that were used in a study, they can be referenced quickly.

Accuracy of data entry should be confirmed, either by duplicate-entry, through the use computer software, or by inspection. The best method of confirming the accuracy of data entry may be through duplicate-entry, whereby two different people input the same raw data into separate files (based on the same template), completely independently of one another. When both are complete, the two data files can then be compared for consistency, and any inconsistencies between the two can be investigated and corrected immediately. Because it is highly improbable that the same random data entry error would occur in the same place in two different data files, most random data entry errors are likely to be caught. Computer software can also be useful for finding abnormalities and errors in the data, such as by screening the dataset according to some preset parameters, or by using mathematical formulas to cross-reference data amongst related variables. Examples of the types of random errors detected might include identifying a person recorded as 444 years old in a study of middle-aged men, or noticing a 23-year old person who has smoked for 45 years. Manually inspecting data (preferably those entered by another person) may be helpful to an extent, but is likely to catch only obvious errors.

KEY CONCEPT: Quality Control Must Encompass All Aspects of Research

Quality control should be restricted not only to data collection and data entry, but also should encompass all aspects of the research, including data analysis, generation of results, and presentation of findings.

2.7. Considering Data Analysis

Data analysis refers to the methods and procedures used to produce results, such as summaries, measures of risk, or descriptions of patterns or trends, from the **raw data** collected for a study. This is an important process to understand, primarily because of its complexity and potential to compromise study findings if done erroneously.

2.7.1. The Role of Statistics

The role of statistics in any epidemiological study is to evaluate the effect of chance on the study results that have been obtained. Because of the variability inherent in exposure-disease relationships, not every exposure to a risk factor by an individual will result in that individual acquiring the disease. In contrast, spurious associations can result between risk factors and diseases that are not related to one another, simply because of chance. Statistical analysis allows the researcher to draw conclusions about the presence or absence of associations between a risk factor and disease, with a certain degree of probability.

While the types of epidemiological study designs have changed little since their inception aside from methodological refinements, statistical analyses of study data have grown immensely, particularly with the advent of computers and affordable statistical analysis software. Perhaps the most pronounced change has been the accessibility of powerful statistical software to anyone willing to purchase it. Though this has the benefit of allowing conscientious and knowledgeable researchers to conduct their data analyses quickly and independently without needing to employ a statistician or data analysis agency, used carelessly, the results can be very damaging. Commercially available statistical software can have the unfortunate effect of allowing persons without adequate understanding of the principles or assumptions of the statistical methods being used to conduct analyses that are not appropriate given the data collected or the study design. They may therefore produce results that appear rigorous on first appearance, but are in actuality erroneous. Because such practices are not always easily recognizable, results from such analyses are particularly dangerous because they may be unknowingly accepted as legitimate.

For these reasons, it is necessary that researchers understand both the assumptions of the statistical tests and the purposes for which the tests were designed. It is strongly recommended that researchers attend formal education in both basic and advanced statistics

prior to beginning a research project, and certainly prior to conducting any analyses. In regions of the world where training in the use of advanced statistics is not available, researchers should at the very least study the fundamental concepts of statistical analysis and acquaint themselves with the assumptions, data requirements, and purposes of any statistical methods or tests they consider using. A good guideline for conducting data analysis is that if one does not fully understand the assumptions and data requirements of a particular method of data analysis, one should not use it. In cases where personal statistical knowledge is lacking, researchers are encouraged to seek assistance from statisticians or epidemiologists experienced in their area of study, many of whom can be identified and contacted at the international level through professional organizations (*See Toolkit №2: Professional Organizations and International Opportunities for Environmental Epidemiologists*).

Statistical analyses vary in complexity from simple mathematical formulas that can be solved easily by hand, to large multivariate models that require high-powered computers with specialized software to be calculated. A detailed discussion of statistical methods is beyond the scope of this Manual. However, readers are referred to a specialized statistics text for more information on this topic, such as Epidemiologic Methods by Kleinbaum, Kupper & Morgenstern (*See Key References*).

2.7.2. Specifying a Means of Data Analysis

Once the type of data that will be collected has been identified, researchers should propose, at least in general terms, how that dataset will be analyzed. Before deciding on a method of data analysis, researchers must be sure that they understand the assumptions and the principles on which the proposed statistical tests are based. The selection of an appropriate method of data analysis is essential not only to provide the most detailed and robust results from a study, but also to generate results that are valid. The careless or uninformed selection of a means of data analysis can be detrimental to a study. Thus, the selection of data analysis methods should always occur in collaboration with, or with the approval of one experienced in the use of biostatistics, and preferably a specialized biostatistician.

When the method of analysis has been chosen, the researcher might even decide to prepare a mock set of the data he or she expects to collect, and run a preliminary analysis on those data to test if the statistical methods and the type of data being collected will be suitable.

2.8. Considering Ethical Issues

Increasing awareness of human rights and privacy issues has brought the topic of research **ethics** to the forefront of epidemiology in recent years. Investigators must ensure that the research they conduct does not violate the rights and freedoms of the study **participants** (often referred to as study **subjects**). At many of the larger, modern academic institutions, formal research ethics boards have been established to ensure that ethical standards are maintained in all research conducted there.

At smaller institutions, or in regions of the world where the field of research ethics is developing, there may be no formal committee to critique and approve research proposals. It therefore becomes the responsibility of the researcher to ensure that the rights of participants are respected, and that no unnecessary procedures are conducted or data collected that could in any way harm them. Such issues include respect for confidentiality, privacy, voluntary participation, and the right to withdraw from the study at any time. Full and adequate disclosure of all procedures involved and data collected in a study must be made so that **informed consent** is obtained before persons are included as participants in a study.

For a discussion of this topic in greater detail, the reader is referred to Soskolne and Light 1996, International Guidelines for Ethical Review of Epidemiological Studies (Geneva: CIOMS/WHO 1991) and International Ethical Guidelines for Biomedical Research Involving Human Subjects (Geneva: CIOMS/WHO 1993) (See Key References). International guidelines for the ethical conduct of research are also available on the website of the International Society for Environmental Epidemiology (See Toolkit №2: Professional Organizations and International Opportunities for Environmental Epidemiologists).

2.9. Confirming Data Quality, Availability and Study Feasibility

Once the study design and means of data analysis have been decided upon, researchers must confirm that all required data are indeed available. This requires a clear statement of the types of data needed, the specific data sources, and timelines for access to/provision of the data. While this point may appear to be trivial, one cannot assume that the

necessary data will be available without direct confirmation from the source. This is particularly important for studies relying on pre-collected data, because while initial impressions or reports from the source agency may suggest the data are available, subsequent detailed examinations of the data may find records to be lacking, seriously deficient, or missing altogether. Furthermore, if the source cannot provide the needed data in a timely fashion, the entire study can be jeopardized. It is thus good practice to prepare a "back-up" data collection plan; that is, a secondary possible source of data should the primary source fail. While it is to be hoped that data from the primary source will indeed be available, should they not be, accessing the secondary data source could make a study already in progress "salvageable" and ensure that resources are not wasted.

The difficulty in collecting, and quality of, data required for a study can be examined by collecting small amounts of the proposed data source using the methods specified in the study design. Researchers may also wish to analyze the data collected with the proposed statistical methods to assess their suitability for the study. This pre-testing of data collection and analysis methods can provide valuable information about their effectiveness, and be used to refine and further develop logistical procedures prior to actual study conduct. If time and resources are available, researchers may wish to go a step further and conduct a pilot study.

A pilot study is a small-scale version of the study planned to be used for an investigation. Pilot studies are useful for testing the effectiveness of proposed study methods and data collection procedures, often with minimal cost and effort. Because pilot studies collect real data in real study situations, they can be used to test and improve study questionnaires, train interviewers and assistants, and evaluate data analysis procedures. While pilot studies are helpful in "fine-tuning" research methods, their greatest advantage may be in determining whether or not a study is feasible at all. Unexpected complications or logistical difficulties may become apparent during the conduct of the pilot study that could inform the researcher that the project is not feasible or that certain aspects need to be redesigned. Thus, wasted time and effort on a full-scale study could be avoided. For these reasons, the conduct of a pilot study is recommended whenever possible because of the invaluable information it can provide the researcher about study feasibility.

Part 2: Case Study Example

2.1. Organizing a Research Team

To aid in the scientific development of the cancer study, experts from a number of different fields were asked to participate as members of the research team. Azeri partners included a number of agencies and individuals, such as junior epidemiologists, two local experts from the Public Health Team of the Sumgayit Centre for Environmental Rehabilitation, statisticians and support staff from the MOH Bureau of Information and Statistics (BIS), staff of the National Oncological Centre (NOC), and statisticians and interviewers from the State Committee on Statistics (SCS). In addition, major facilitation roles were played by the United Nations Development Programme (UNDP), the WHO Country Office, and the Ministry of Health.

International members included a technical officer with the WHO European Centre for Environment and Health (WHO-ECEH), Rome, Italy; an epidemiologist from the University of Alberta, Edmonton, Canada, with prior experience in both cancer epidemiology and research ethics; and, a graduate student in an epidemiology Masters program also at the University of Alberta. To complete the research team, several other members were asked to participate, including a biostatistician at the University of Alberta, an occupational epidemiologist at the University of Alberta, and an epidemiologist with substantial cancer registry experience with the Alberta Cancer Board, Calgary, Canada.

2.2. Specifying Data for Collection

To test the study hypothesis, the following data were required:

1) Demographic data for each of the selected study populations (Sumgayit, Ganja, Lenkoran-Astara, and Azerbaijan as a whole) on an annual basis, and stratified by sex and 5-year age groups (necessary for the calculation of age-specific rates and/or age-standardized rates) for the period 1980-2000

2) Numbers of incident cancer cases and new cancer deaths on an annual basis (also stratified into sex and 5-year age groups) for each of the following cancer sites for the period 1980-2000:

a. All cancers combined (ICD-9: 140-208)
b. Larynx (ICD-9: 161)
c. Trachea, bronchus, and lung (ICD-9: 162)

d. Urinary bladder (ICD-9: 188)
e. Female breast (ICD-9: 174)

3) **Prevalence** data on potential confounding variables (e.g., smoking, alcohol consumption, diet, family history of cancer)

4) Summary cancer incidence and mortality rates for the countries of Armenia, Georgia, the Russian Federation, and Canada for the above-mentioned cancer sites

Quantitative assessments of exposures in each of the study regions were not calculated for the purposes of the study; instead, only summary data describing the scale of production and types of compounds present in Sumgayit industry were to be collected. Study populations thus were selected in large part because of the known qualitative differences in exposure levels amongst them.

Study and Comparison Populations

The study population selected was the city of Sumgayit. This population was chosen because it could be easily defined, exposure and outcome data were available from the SCER and the MOH respectively. A large proportion of the Sumgayit population was believed to have had significant hazardous exposures from Sumgayit industry, either through direct contact with pollution sources during employment in the factories, from ambient pollution in the city, or from contaminated clothing or other articles taken into the home from the workplace, and thus could be considered an "exposed group." Because the selected study design was descriptive and population-based, the identification of several comparison populations was necessary to provide a basis on which data from Sumgayit could be contrasted.

The primary contrast of the study was that of cancer rates in Sumgayit to the Azerbaijan national data. National data were expected to be the most stable over time because of the large population from which they were based, thereby minimizing the effects of **stochastic** variation on cancer rates. Furthermore, any regional variations in data collection or quality would be averaged in the national dataset, reducing the likelihood of serious biases adversely affecting the comparison of the data with Sumgayit.

Three regions of Azerbaijan were also selected for the comparison of cancer incidence and mortality rates with Sumgayit. Study regions were selected by three primary criteria:

1) assured access by the MOH to high quality demographic and cancer incidence and mortality data,

2) sufficient population size to ensure stable cancer rates appropriate for statistical analysis, and

3) qualitatively different levels of exposure to occupational and environmental pollutants.

The populations were selected to be as similar as possible to the Sumgayit population, except for the risk factors being studied (the risk factors of interest were the known long-term occupational and environmental exposures resulting from industry). In contrast to Sumgayit, the populations of Ganja and Lenkoran-Astara did not suffer from similar chemical exposures from industry, thus representing useful choices for comparison populations. Brief overviews of each region are provided in tabular format (Table 2.2).

Table 2.2. Overview of comparison populations within the nation of Azerbaijan.

Characteristic	Azerbaijan	Sumgayit	Ganja	Lenkoran -Astara
Population (2000)	8,048,600	286,000	300,700	277,800
Main Employer(s)	Agriculture, Petroleum	Chemical industry	Metallurgy/ manufacturing	Agriculture
Expected Industrial Pollutant Exposures	Average	High	Above Average	Below Average

Figure 2.3, Map of Azerbaijan denoting study regions.
Map depicting the location of Azerbaijan in Asia and the study regions within the country. (Reprinted with permission: Central Asia, Map No. 3763 Rev. 4 October 1998. *http://www.un.org/Depts/Cartographic/english/htmain.htm* of the United Nations Cartographic Section).

NOTE: The designations employed and the presentation of this material do not imply expressions of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitations of its frontiers or boundaries.

Ganja is the second largest city in Azerbaijan (population ~300,000), and is located in the west of the country, near the border with Armenia (Figure 2.3). Ganja was chosen as a comparison city because of its similar population size, demography and general characteristics to Sumgayit, also being an industrial city. As such, the high degree of similarity between Sumgayit and Ganja was expected to better control confounding related to population-level variations in lifestyle characteristics.

A potential weakness that was identified in using Ganja as a comparison city was that its population could not be considered "truly unexposed," owing to the industrial nature of the city. As such, there was the risk that using Ganja as a reference in comparisons with

Sumgayit would have produced diluted **measures of effect**, e.g., rate ratios nearer to unity. Still, Ganja presented an interesting comparison because although its population was subjected to occupational and environmental exposures, the exposures were different from those experienced by the residents of Sumgayit. Unlike Sumgayit, production in Ganja focused primarily on manufacturing and metallurgy, rather than on chemical production. Because cancers at specific anatomical sites are generally related to specific exposures, site-by-site comparisons of cancer rates minimized any dilution of effects that may not have been noticed had all cancers been compared as a group among regions.

Lenkoran and Astara are regions located in the extreme southeast of the country (Figure 2.3). Being primarily agricultural districts, the probability that residents were exposed to industrial pollutants in Lenkoran and Astara was much lower, and consequently they were chosen as unexposed populations. Owing to their small sizes, data were pooled from the regions of Lenkoran and Astara. By so doing, a population similar in size to Sumgayit and Ganja was created, better facilitating comparisons across the regions through the generation of more stable cancer rates.

Owing to the predominantly agricultural occupations of residents in the Lenkoran and Astara regions, more profound differences in confounding lifestyle factors were expected than amongst the large industrial centres. For this reason, it was acknowledged that comparisons between Lenkoran-Astara and the other regions were to be interpreted cautiously.

Although the capital city, Baku, appeared to be an obvious choice as a comparison city, with its large population, close geographic proximity to Sumgayit, and relative lack of heavy industry, several methodological problems were identified that prevented its inclusion in the study. One of the most serious concerns was that accurate population data were not available for this city. Although official data possessed by the Azeri Government estimated Baku's population at approximately 1.7 million persons, the actual number of persons living in the city was suspected to be much higher (nearer the 2.5-3.0 million mark), an opinion expressed by the MOH. This was believed to be the result of the inaccurate enumeration of residents during the census period, and influxes of refugees and internally displaced persons following the armed conflict with Armenia.

Another problem was that large numbers of Baku residents were employees in Sumgayit industry at the time of the study or in the past and, despite residing in the capital, commuted daily to Sumgayit to spend their workday. During this time, they would have also experienced many of the same occupational exposures as Sumgayit residents. Thus, including Baku as a comparison city would have created a contaminated "unexposed" group, resulting in diluted measures of effect.

Georgia and Armenia were selected as comparison populations because of their population sizes (which are sufficiently large for cancer rates to be relatively stable), geographic proximity to Azerbaijan, and historical similarities in political and health care systems. The Russian Federation also shares many of these similarities, but differs somewhat in its economic and political situation following the break-up of the Soviet Union. It was suspected that the Russian Federation was better able to cope with the break-up of the former USSR because much of the economic and political infrastructure necessary for independent function was already present from the Soviet period. For this reason, it was believed to be useful for examining temporal variations in health services and health data quality that may have resulted in the smaller republics following the dissolution of the USSR. Selected comparisons were also made with Canadian data. Because of the differences in health care and cancer registry systems, and the independence of Canada from all processes associated with the break-up of the USSR, Canadian data were expected to provide an important contrast to each of the selected former Soviet republics.

Risk Factors: Exposures

Detailed exposure data were not selected for collection in this study because there were known qualitative differences in exposure levels between the study populations. As discussed above, Sumgayit was a major industrial centre, and both anecdotal and scientific reports detailed extreme levels of occupational and environmental pollution resulting from the concentration of heavy industry in the city. Underscoring this point was the designation of Sumgayit as an "ecological disaster area" by the Azerbaijan Government as a result of the pollution experienced. Finally, because many highly toxic and/or carcinogenic agents were present in Sumgayit industry, and safety equipment and protocols in the industrial facilities were lacking, exposures experienced by residents (and particularly by factory workers) were potentially very high.

In contrast, the residents of the comparison regions were not believed to have been exposed to the high levels of chemical pollution that citizens of Sumgayit were. As mentioned previously, exposures in Ganja were believed to be substantially lower, and different in kind from those in Sumgayit, as industry there was primarily metallurgical and manufacturing in nature, rather than chemical. Exposures in Lenkoran-Astara were expected to be the lowest of all study regions, owing primarily to the agrarian lifestyles of the residents and lack of industrial facilities. At the population level, each of the nations of Azerbaijan, Armenia, Georgia, the Russian Federation, and Canada were expected to have experienced low levels of exposure relative to Sumgayit.

Outcomes: Cancer Sites of Interest

Because the term "cancer' is actually a very broad descriptor, describing a large number of diseases with very different causes, frequencies of occurrence, and pathology, it was necessary to select only indicator cancer sites for study. Cancers were primarily selected according to two criteria: **aetiology**, and frequency of occurrence. Cancer sites were first selected by their association (or lack of association) with exposure to chemicals and other agents produced in Sumgayit. Second, in order to provide rates stable enough for meaningful statistical analysis, the selected cancers had to be sufficiently common for stable rates to exist in the relatively small (~300,000 person) populations being studied.

Laryngeal (**ICD-9**: 161), trachea, bronchus and lung (ICD-9: 162), and urinary bladder (ICD-9: 188) cancers, as well as all cancers combined (ICD-9: 140-208), were selected for study because they occur with sufficient frequency to generate stable rates for analysis, while being related to environmental and occupational exposures. In contrast, female breast cancer (ICD-9: 174) was selected as a control to evaluate cancer reporting across regions, because it is not strongly associated with environmental exposures. Since the occurrence of breast cancer was not expected to vary as greatly in response to chemical exposures as the other selected cancers, breast cancer rates were expected to be relatively similar among study regions if cancer reporting among the regions was uniform. If major differences in breast cancer burden were seen between regions, and these differences were not explainable by variations in lifestyle, one could have suspected that differential cancer reporting between regions was a potential reason for the differences. Childhood neurological cancers and leukemia (ICD-9: 191,192, 204-208) were also selected as indicators of environmental exposure.

2.3. Data Sources

The Sumgayit Cancer Study was exploratory in nature, designed to provide an overview of cancer burden in the city of Sumgayit while making efficient use of limited resources. Thus, pre-collected data seemed most appropriate. The MOH assured access to high-quality cancer incidence and mortality summary data in 5-year age groups for each of the selected Azeri study populations over the study period, 1980-2000.

The absence of pre-collected data estimating the prevalence of potentially confounding lifestyle factors in each of the regions required collection of new data through interview-based administration of a lifestyle questionnaire.

2.4. Specifying Data Collection Protocols

Regional-level summary cancer data were selected for collection from the archives of the MOH in Baku. Hardcopy summary cancer reports submitted to the MOH from cancer dispensaries in each region were to be used to obtain the required cancer incidence and mortality data. All required data were to be abstracted from hardcopy records and input directly into electronic format.

A special protocol for collecting information on potentially confounding factors was required owing to the fact that no pre-collected data were available. Several potentially confounding lifestyle factors were identified for the purposes of the study, including: tobacco smoking, alcohol consumption, diet, and family history of cancer. Prevalence data for these factors were to be collected either by incorporating a questionnaire (*See Toolkit №8: Sample Research Proposal*) into the "Quarterly Questionnaire on Incomes and Expenditures of Households" administered by the SCS, or by using market research survey techniques (personal interviews by standardized administration of questionnaires) of random persons encountered in the streets or by random visits to homes in the selected regions of Sumgayit, Ganja, and Lenkoran-Astara. This approach was to be used only if the National Household Quarterly Survey sampling frame could not be made available. Approximately 350 people (a number determined by sample size calculations) were to be selected to provide answers to the questions in each population being compared (i.e., Sumgayit, Ganja, and Lenkoran-Astara).

Study protocols dictated that persons were only to be allowed to participate in interviews if they were adults between 18 and 80 years of age and had resided in the study region for at least 18 years. Persons not meeting these criteria were to be excluded. Consent for conducting interviews was to be obtained by trained Azeri interviewers approaching potential participants in the local market places. An information letter was read to each potential participant prior to the interview, and offered to all participants following the completion of in the interview (*See Toolkit №7: Information Letter*). Because the survey was designed with a low-intensity approach in which interviews were conducted in the market places, Azeri interviewers were to be instructed and trained to appreciate the need for a polite introduction and to engage people only if they were willing. A record of the number of refusals was to be kept. No signed informed consent was to be included; instead, participation was conditional on **tacit consent**.

2.5. Sampling, Sample Size, and Power

Because new exposure data were not being collected, and pre-collected summary cancer data were already available from the MOH Archives, there was no need to develop a specific sampling strategy for these data.

In contrast, the collection of data regarding potentially confounding lifestyle factors through an interview required the specification of a sampling strategy and the calculation of sample size. It was decided that a lifestyle survey would be conducted in each of the three regional study populations of Azerbaijan (Sumgayit, Ganja, or Lenkoran-Astara). Smoking was considered the most important potential confounding variable. Sample size (n) for the lifestyle survey was determined using the formula below, because proportion (**prevalence**) data were to be measured for smoking, the most important variable of interest.

$$n = \frac{Z^2_{\alpha(2)} pq}{\delta^2}$$

where Z is the 2-tailed normal deviate (in this case, 1.96)
p and q are the expected sampling proportions
and δ is the desired sampling error (for this study, 0.05)

Smoking prevalence in Azerbaijan was estimated to be 30% (p = 0.30, q = 0.70). A sample size of 323 was adequate to estimate a smoking prevalence of 30% with ±5% error. Thus, sample sizes of 350 for lifestyle survey were specified for collection in each of the regions. Three-hundred fifty was chosen as a sample size to ensure that even if data from some individuals were not suitable for use, the desired sample size of 323 was still likely to be attained.

2.6. Considering Data Quality

The MOH assured researchers involved with the Sumgayit Cancer Study that all required cancer and demographic data were available, and of high quality, although it was unable to provide samples of the data prior to the initiation of the study.

2.7. Specifying a Means of Data Analysis

In order to facilitate easy interpretation of results as well as efficiency in conducting the data analysis proportion of the study, several basic epidemiological methods were chosen for the analysis of the data. Cancer incidence and mortality were to be analyzed through **age-specific rates, age-standardized rates, standardized incidence ratios (SIRs)**, and **proportional incidence ratios** and **proportional mortality ratios (PIRs and PMRs**). These methods were selected primarily because of their ability to effectively analyze potential differences in cancer rate data, while being easily calculated and interpreted, which was important given the involvement of persons in the study without advanced training in epidemiology or statistics.

2.8. Considering Ethical Issues

Because this was a population-based study relying largely on pre-collected summary data, the scope of ethical issues necessary to consider was rather limited. Primary concerns revolved around the confidential and appropriate use of the data collected, though because the data were not linked to individuals, issues of respecting personal privacy were not encountered. Ownership of all data collected remained with the Azerbaijan Ministry of Health.

Individual-level data were collected for the Lifestyle Survey in order to evaluate the prevalence of potentially confounding lifestyle factors in each of the populations; thus, a more detailed consideration of ethical issues was required. Care was taken to ensure that only data necessary for the survey were to be collected, and that access to the data would be granted to partners only for the purposes of the study. Tacit consent was to be obtained prior to the conduct of interviews, and refusals to participate were to be respected. Training procedures for interviewers were outlined, ensuring their adherence to ethical and scientific protocols and respect for the rights of participants and potential participants.

2.9. Confirming Data Quality, Availability, and Study Feasibility

Access to all necessary cancer data required for the purposes of the study, as well as its quality being suitable for research were explicitly assured by the Azerbaijan MOH. Necessary funding to conduct the study was assured through an inter-agency agreement between UNDP and WHO.

Part 1: Theory

In this Manual, the term "**research proposal**" refers to a complete, formatted, professional document that describes not only the study methods and procedures, but includes additional detail in terms of study background, literature review, study requirements/deliverables, and researcher credentials. The primary purpose of preparing a research proposal is to describe the planned research to a person or agency that is not directly involved in it. It is essential to prepare a research proposal in order to guide the conduct of a planned study, and so that the proposed research can be peer-evaluated by others, particularly by agencies granting authorizations, funding, or ethical approvals.

3.1. Sources of Research Funding

What may often be one of the most difficult steps in conducting a study for a novice researcher, particularly those in nations without well-developed research infrastructures, is securing sufficient amounts of research funding. Because of the expenses involved in the conduct of research, ranging from employment of assistants for data collection and analysis, fees associated with obtaining pre-collected data, and logistical requirements, independent researchers must almost always seek funding from external sources. Research funding in most Western nations originates from specifically allocated governmental sources, specialized endowments, or research foundations. This research funding is usually allocated only for researchers based within the funding nation, though exceptions do exist.

Many non-governmental organizations (NGOs) also provide funding for health research. NGOs may be the best source of funding for researchers in countries without well-developed research infrastructures, as internal governmental funding is generally lacking. Because individual NGOs have differing agendas, the researcher should direct applications for funding to those NGOs whose mandates and areas of interest most closely match the focus of their own research in order to have the best likelihood of obtaining funds. Because pools of money in both governmental and non-governmental organiza-

tions are usually dedicated to certain areas of research, applications describing research outside the mandate of the funding agency to which they are submitted are unlikely to be successful. *(Please see Toolkit №3: Funding Agencies for a list of funding agencies and their mandates).*

3.2. Preparing a Research Proposal for Submission

Once the key components of the study design have been identified, and the methods of addressing them established, the next step must be the preparation of a research proposal. Research proposals serve the purpose of describing the study in a professional manner to outside agencies or persons unfamiliar with the study. These agencies may need to understand the study in order to approve the study methods, ensure ethical standards are met, and/or award research funding. It is thus essential that a high quality research proposal document be prepared. A high quality proposal is one that describes, in a clear and concise manner, the rationale for, and methods being used to conduct a study, justification for the procedures involved, acknowledgement of ethical considerations and documentation of all budgeted expenses, if applying for funding.

Research proposals can be prepared in a number of ways, and often the individual agencies to which they are being submitted will have their own application forms and specific formats. Researchers must be aware of these standards, and conform to them if specified. This is not always the case, however, and because research proposals must address a number of topics, including those that may be unfamiliar to new researchers, an example of a commonly accepted format is presented in *Toolkit №6: Research Proposal / Funding Application Templat*e. This general format (usually limiting the description of the intended research to about 10-20 pages of 12 point font with 1.5 line spacing, not including appendices) is perhaps best designed for a scientific approval of a study proposal, but can be used for other purposes. While the exact content of the proposal will vary depending on the purpose for which it will be used, the general template presented in this Manual can provide a useful framework for developing a proposal for submission to a funding agency or research ethics committee.

3.2.1. Applying for Research Funding

An award of research funding usually occurs through an application and competition process, in which researchers submit their research proposals in the manner specified by the funding agency and, based on the submitted application package, a committee or review panel judges the merits of the proposed research. Applications more likely to be successful are those that possess a detailed and coherent description of the study design, those including a good balance of expertise and experience in the research team, and those that attempt to answer relevant questions or address issues of particular concern within a justified budget.

While the decision to award funding is beyond the control of the researcher personally, he or she can maximize the chances of success by submitting a robust and meticulously prepared application package with clearly stated objectives, procedures, and deliverables. Because funding agencies seek to ensure efficient and appropriate use of any money they award, applications with detailed and transparent budgets that make efficient use of requested funds are likely to be favoured. Furthermore, studies that promise concrete deliverables, whether in the form of publishable findings, measurable outcomes, or summary reports are more supportable.

Unfortunately, the assessment of research proposals submitted for funding often disadvantages researchers from non-English speaking nations. Because many applications for funding at the international level must be completed in English, persons who do not speak English as a first language may have difficulty completing an application to the level of detail and grammatical correctness as native English speakers.

Consequently, these applications may not effectively convey their messages to the selection committee, or may appear to be less carefully prepared and edited than those of native English speakers. For this reason, it is strongly recommended that native speakers of the language of submission are included on the research team, or at the very least that someone fluent in the language of submission proofread the application package.

While matters of scholarly excellence in the preparation of a research proposal have been addressed, it also is important to recognize that other mechanisms can be set in motion to influence the decision to provide support for new or on-going research activities. These influences include public concern, direct lobbying of decision-makers, and media engagement. Furthermore, corporate, community, labour, or other interest groups can sway government priorities, and thereby can directly or indirectly encourage or discourage particular research agendas.

These mechanisms, however, are not consistent with the notion of scientific objectivity and rigour, but do occur in practice. For these reasons, membership in professional associations can provide support to individual researchers in coping with what may be, is perceived to be, impropriety. Sometimes, serving in an advocacy capacity jointly with stakeholders can help to ensure that the public interest is served above all other interests in addressing matters of public health concern.

3.2.2. Obtaining Ethics Approval

If a research ethics board exists either at the institution of study or employment, or at a regional or national level, researchers will have to prepare an ethics proposal to be approved by the board. While an application designed for approval by an ethics committee will be similar to that of a generalized research proposal, greater focus must be placed on the interactions of the study with its participants, data sources, and collected data *(See Toolkit №7: Ethics Review Template)*. The researcher must document all data collected, any potentially invasive or harmful procedures that may be carried out, where data will be stored and secured to protect people's privacy, how the data will used, and who will have access to the archived data and study results.

All procedures must be justified, and the researcher must demonstrate to the reviewers that the participants are not being placed at undue risk or harmed. It must be demonstrated in the proposal that all necessary and available means are being taken by the researchers to protect the rights, freedoms, and well-being of all participants in the study.

Part 2: Case Study Example

3.1. Sources of Research Funding

Funding for the study and for the researchers involved was supplied by several different sources. The Sumgayit Cancer Study was initiated in the framework of the UNDP project "Environmental Rehabilitation of Sumgayit," the Public Health Component of which was conducted by the WHO, and consequently it was known from the planning stages of the research that limited funding would be made available for the study through an inter-agency agreement between the UNDP and the WHO. Thus, unlike most independently-proposed research, the study proposal did not have to be entered into a competition for research funding; however, the design of the study was constrained by the limited amount of funding available. While these funding issues restricted the study to a more basic and affordable descriptive design, the descriptive study chosen was appropriate to the situation in Azerbaijan and goals of the project. Being the first study of its type, it was seen as desirable to use resources as sparingly as possible. Furthermore, a simple, descriptive design was seen as preferable for involving researchers without extensive research experience. The UNDP-WHO funds paid for the travel expenses of Dr Soskolne and Ms Racioppi to Azerbaijan, salaries to local professionals directly involved in the study (Mr Emin Makhmudov, Dr Anar Asadov), data access retrieval fees, and all logistical aspects of the research.

Limited funding was obtained from other sources identified independently by James Andruchow. The travel of Mr Andruchow to Azerbaijan was funded through his independent application for and award of the "Edmonton Consular Corps Consular Ball Scholarship." The scholarship was designed to fund the travel of students of the University of Alberta in Canada to facilitate their ability to conduct research abroad. Funds to support Mr Andruchow during his two years of graduate studies at the University of Alberta were provided primarily by a Natural Sciences and Engineering Research Council (NSERC) post-graduate scholarship. This scholarship was also independently applied for and won by Mr Andruchow in advance of this study. The remainder of his funding was supplied through a Programme of Research in Environmental Etiology of Cancer (PREECAN) Training Award, an award designed to facilitate the study of the environmental causation of cancer by Canadian researchers.

3.2. Preparation of Research Proposal for Submission

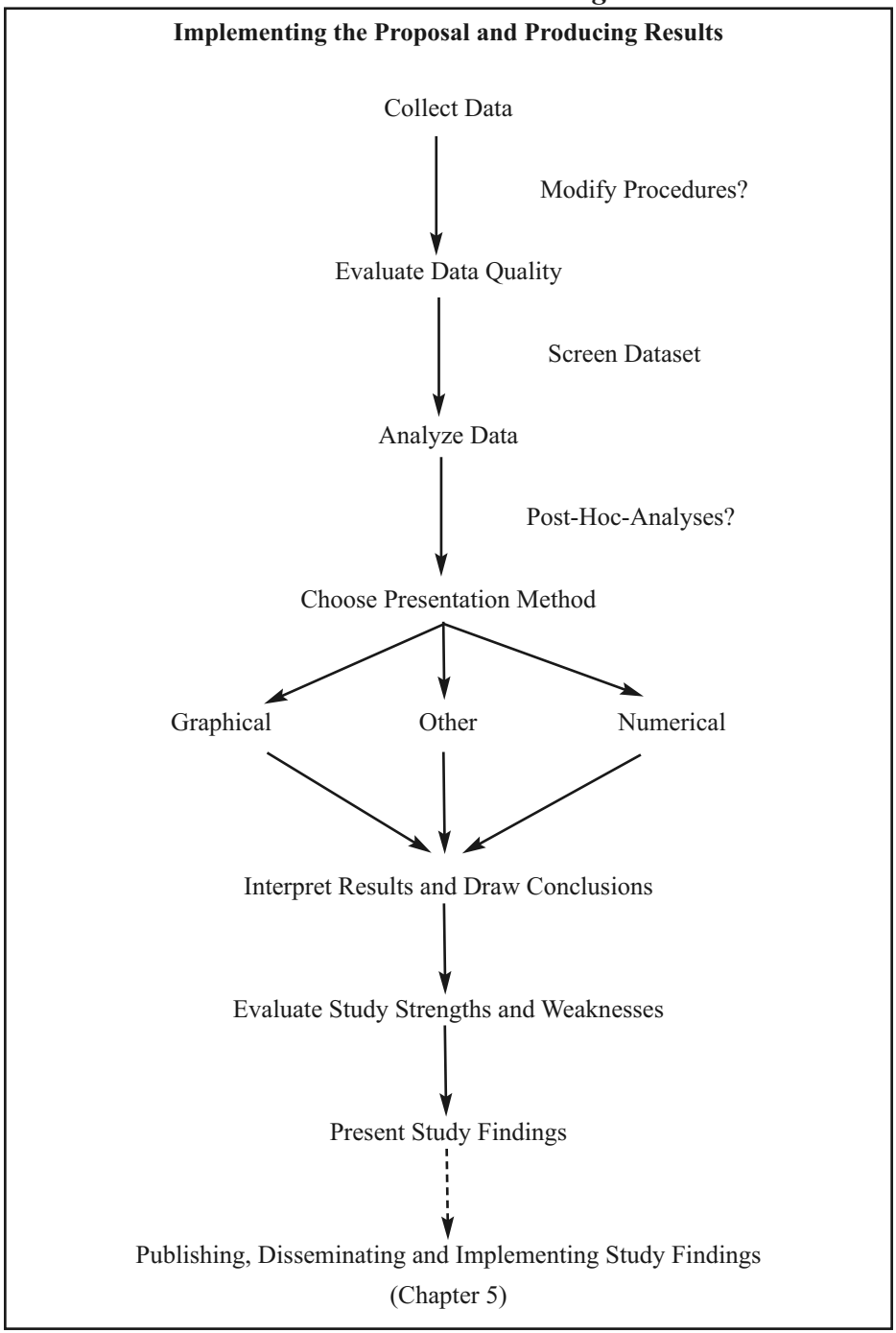
A research proposal describing the study was prepared, primarily for the purposes of describing the research to all of the partners, to formalize the statement of methods for, and to guide the conduct of the study *(See Toolkit №8: Sample Research Proposal)*.

3.2.1. Applying for Research Funding

While the PREECAN scholarship listed above was not used to fund the research directly, it required the completion of a detailed application similar to that required for most research funding proposals *(See Toolkit №6: Research Proposal / Funding Application Template)*. The PREECAN scholarship was applied for in the specific context of the Sumgayit Cancer Study, and was a collaborative effort between Canadian members of the research team. It is therefore considered a successful application for research funding for the Sumgayit Cancer Study.

3.2.2. Applying for Ethics Approval

An application for ethics approval was made according to the requirements of the University of Alberta Health Research Ethics Board (HREB) in Edmonton, Canada. For a sample research ethics application, please see *Toolkit №7*: Ethics Review Template. Both the questionnaire used for the lifestyle survey, and the entire study proposal were submitted for ethical review to the HREB. Ethics approval for all data collection (including administration of two lifestyle surveys in Azerbaijan) and analytical procedures was obtained from the HREB in May 2001.


Implementing the Proposal and Producing Results
Collect Data
Modify Procedures?
Evaluate Data Quality
Screen Dataset
Analyze Data
Post-Hoc-Analyses?
Choose Presentation Method
Graphical
Other
Numerical
Interpret Results and Draw Conclusions
Evaluate Study Strengths and Weaknesses
Present Study Findings
Publishing, Disseminating and Implementing Study Findings
(Chapter 5)

Part 1: Theory

In most studies, unexpected circumstances or discoveries encountered during study conduct result in deviations from the study protocol, which may be alarming to a novice researcher. These deviations do not necessarily represent threats to study quality; in fact, the changes may improve study rigour. It is thus important for researchers to remain flexible in the face of changing circumstances, resources, and expectations while still keeping study objectives and scientific excellence as the top priorities.

4.1. Data Collection

Data collection should follow the research proposal as closely as possible in most cases. It is important to do so because the data collection protocols outlined in the research proposal should have been carefully selected and reviewed by several experts before being approved and, as such, meet scientific and ethical standards, as well as being appropriate to the goals of the study. Unilaterally changing these protocols during study conduct without adequate thought about the potential repercussions can have disastrous consequences.

Circumstances may arise or issues become apparent during the conduct of the study that can make the original study proposal either unsuitable, or even entirely inappropriate. If issues arise that suggest that the original protocols may not be optimal for the study, and suitable alternatives are available, the researcher is encouraged to consider modifying the proposal. This should be done only after consulting with other team members, and ensuring that the changes do not compromise scientific or ethical considerations, where a significant enough change arises, formal approval of both the funding agency and the ethics review committee may be required. The possibility exists that some issues may not be able to be addressed by simply altering the study proposal, and may result in the halting of the research, and potentially the failure of the study. If adequate planning and investigative work were done examining study feasibility during the preparation of the study proposal, it is highly improbable that such circumstances would occur.

4.2. Evaluating Data Quality

The quality of data to be used for a study should be assessed thoroughly prior to their analysis or use in generating results. Because data quality has such profound implications for the type and validity of findings generated from the study, it is important that the researcher develops a good understanding of their quality as early as possible during the conduct of the study, in order to appreciate their strengths and weaknesses. The evaluation of data quality does not have to be withheld until all data are collected, nor does it have to be restricted to the completed dataset itself. Evaluation of data quality can begin even at the data collection stage, including such steps as assessing the data collection protocols, adherence to defined procedures, accuracy and precision of instruments, diligence and attentiveness of workers, and cooperation of data sources. Because these factors can influence the quality of study data, but may not be apparent from an examination of the dataset alone, it is important to consider them from the onset of study conduct and data collection.

4.3. Data Analysis

Data analysis and the production of results are fundamental components of any research study. The choices of the correct measures of effect and types of statistical analysis are imperative to the production of valid, objective and meaningful study findings. Though it is in the best interests of the study for the researcher to choose, or at the very least, anticipate what types of statistical analysis the study will use even prior to the collection of data, unforeseen issues may result in changes to the type or quality of data collected, or new methods of statistical analysis may present themselves even late in the study. For these reasons, the researcher should remain ready to adapt as needed to changing challenges or opportunities that the data may present.

4.3.1. Proposing Data Analyses

As previously mentioned, data quality should be assessed in a general fashion prior to conducting any analyses.

Many statistical tests and procedures are based on detailed assumptions about the type and characteristics of the collected data, requiring the researchers to conduct more detailed investigations into data quality. The detail of investigations required can differ greatly by the type of data analysis method being used and its individual assumptions. The researcher must then fully understand the assumptions of the particular tests being used, as well as the means of testing them. For example, an assumption that must be satisfied for a number of common statistical procedures using continuous data is that the data conform to a normal distribution.

During data analyses, the researcher must ensure that appropriate procedures are followed, and that he or she understands each of the steps involved. Computer-based data analysis software has both advantages and disadvantages in this regard. While some programs can be very "user-friendly" and allow the researcher to easily conduct powerful analyses with little effort, others can have complex user-interfaces and poorly designed (or even flawed) analytical methods. It is thus highly recommended that persons conducting data analysis seek assistance if they are not very familiar and comfortable with the software being used. In contrast, some studies may only require the use of basic statistics that can be calculated manually. Regardless of the method being used, a good understanding of the procedures involved and attention to quality control should always be primary components.

As with the conduct of data collection, data analysis should follow the procedures outlined in the research proposal, and should be altered only with justification and with the approval of the entire research team.

4.3.2. Post-Hoc Analyses

Post-hoc analyses refer to data analyses proposed and conducted on the basis of results already obtained from the initially completed analyses. The results of analyses may point researchers in a certain direction, or make them aware of a new aspect of the data that can be explored, through new or modified data analysis techniques.

Post-hoc analyses can increase the robustness of results obtained from a study, and can be used to comment on issues not even considered in the initial study proposal. The limitation of these analyses, however, is that they can be biased, because these analyses are influenced by the researcher's observation and/or interpretation of the data and the patterns in it. Because no a priori hypothesis is necessarily involved, a researcher may detect a potential pattern in the results, statistically verify its presence, and then develop an hypothesis to favour its explanation. Thus, while the relationship that the researcher observes in the data may simply be the result of coincidental correlation, he or she may erroneously conclude that it is a real phenomenon. While the results of post-hoc analyses may indeed be correct, the scientific method does not favour such an approach because of the potential for this type of logical fallacy. The results of post-hoc analyses, therefore, should always be identified as such, and interpreted with this caveat in mind.

4.4. Presenting Results of Analyses

The most common result presented following analysis of epidemiological data is a **point estimate**. Point estimates represent the single best approximation of a particular parameter of interest, based on study results. In epidemiological studies, point estimates commonly refer to measures of effect (such as odds ratios, relative risks, or rate ratios) or to the prevalence of certain parameters (including risk factors such as smoking, or of disease). While point estimates are useful for providing the reader a quantitative approximation of a certain parameter, because they are generated from samples, a certain degree of variability is always associated with them. Statistical tests, and their resultant **p-values**, assess the likelihood that the observed point estimate has occurred owing to chance alone, but do little to convey to the reader the amount of uncertainty associated with the accuracy of the point estimate; **confidence interval**s, in contrast, are useful for precisely this purpose. It is recommended that confidence intervals be included in addition to tests of significance whenever presenting epidemiological results.

Results of analyses can be presented in a number of different ways, ranging from textual descriptions to tables, figures, or pictures. Text has the advantage of presenting detailed information, while being able to discuss simultaneously its significance, strengths, and weaknesses. The major disadvantage of text is that it may be a difficult or laborious process for the reader to assimilate and understand, particularly if a great deal of information is presented. In such situations, tables and figures can be very useful for presenting results. Tables allow large amounts of data to be presented in an efficient and organized manner, providing the reader access to precise quantitative data, which can be useful for examining results in detail. Tables are commonly used to present results in situations where the display of precise numerical estimates is desirable, where large amounts of data must be presented, and/or where the goal is to present results so that the reader can make basic comparisons amongst them. It may be difficult, however, for a reader to recognize and appreciate patterns or trends in the data from large tables, or to absorb effectively information from them. Despite being a relatively simple tool, tables are quite versatile, and can be useful in a wide variety of situations.

Figures further simplify the presentation of results by condensing them into a more qualitatively presented visual form, often into a graph or other visual presentation method. Because figures often present data only in a summarized form, without explicitly identifying individual data points, some information may be lost in the construction of figures. Their usefulness, therefore, relies primarily on their ability to efficiently convey qualitative trends or patterns to the reader. Figures are not restricted to the presentation of data or results, but can be useful for presenting concepts, relationships among different variables or events, and/or steps in a process. Examples of these types of figures include concept-maps, organization charts, **Gant charts**, and flow charts.

For examples of various methods of data presentation, including textual discussion, tables, and figures, the reader is referred to the thesis: Cancer incidence and mortality in the industrial city of Sumgayit, Azerbaijan: A descriptive study (See Key References).

4.5. Interpreting Results and Drawing Conclusions

The interpretation of study results and drawing of conclusions requires not only scientific skill, but the use of common sense to create meaningful and credible study findings. Researchers must interpret their results with the overall picture of the study in mind, including the study design, hypothesis, and the data used, as well as issues encountered during study conduct. Strengths and weaknesses of the data, and the methods used to analyze them must also be taken into account when interpreting findings. Researchers must be aware of the limitations of their research, and take care not to draw conclusions beyond the capabilities of the study.

When interpreting study findings, researchers must, of course, use statistical results if available, but the conclusions of any study should not be based on statistical analyses alone. Careless use of statistics, and p-values in particular, to draw conclusions has been criticized in the scientific literature for its potential to produce misleading or erroneous findings. Focusing solely on the numerical results of statistical analyses can cause the researcher to lose sight of larger patterns in the study, and the overall context of the research.

For example, researchers have been known to declare an association or a conclusive result simply on the basis of a marginal p-value statistic. One must remember that the boundaries set for the rejection or acceptance of statistical results are arbitrary, and thus do not correspond to conclusive "yes/no" answers in reality. P-values are simply expressions of probability, the likelihood that an event will occur, and thus p-values marginally above or below a set threshold (e.g., $p=0.05$) are not strong evidence for or against a study hypothesis. In situations such as these, the overall qualitative patterns or trends in the data are likely to be more valuable than the statistical analyses themselves. These statements do not apply to p-values only, but, in general, to all aspects of interpreting study results.

The correct interpretation of study results requires the informed and expert opinion of those involved in the study (and perhaps others), and a discussion of the results in the context of the entire study, and other research. This approach should be used for all interpretations of statistical results, especially for those analyses with marginal results, but even for those presenting strong quantitative evidence.

4.6. Evaluating Study Strengths and Weaknesses

Researchers must be objective and honest about the quality of the study design, conduct, and results produced. It is often difficult for a researcher to admit weaknesses in study quality or the strengths of its findings following what can be a major personal and professional investment. It is of the utmost importance that researchers discuss the strengths and weaknesses of their study, both for the benefit of themselves and of the scientific community. By openly discussing them, both the researchers and their peers can learn from the study, and use that knowledge to improve future research. Peers may even contact the researcher with suggestions of how to improve, or new interpretations of, the results of the study, which could result in major benefits for the researcher. Attempts to conceal weaknesses or exaggerate strengths of a study are likely to be discovered by others, and can result in damage to the integrity of the researcher in the scientific community, and potentially his or her career. Similarly, misinterpreting or misrepresenting the results of a study to the affected population can damage the researcher's reputation in the community and jeopardize future collaborations, not to mention the harm to public health.

4.7. Presenting Study Findings

The presentation of a study's findings is somewhat different from the presentation of results of analyses. The presentation of study results occurs immediately after data analysis and is conducted primarily to more clearly convey their information to the researcher, so that he or she can interpret them and use them to draw conclusions. In contrast, for the purposes of this Manual, the term "study findings" refers to the combination of the results, their interpretation by researchers, and the conclusions drawn from them. Study findings are communicated to persons outside the immediate research team, and thus must be presented with some background to allow those people without prior knowledge of the study to appreciate and comment on them. Soliciting feedback from peers external to the project is a desirable step for ensuring excellence.

The method in which study findings should be presented depends on the study type, the target audience, and the reason for which the results are being presented. Considerations should include the level of scientific vs. lay content, whether the presentation is designed to create a general impression of the study or convey specific results, and the level of detail to be presented (i.e., precision vs. visual impression). These are but a few of the considerations that can be taken into account, because the types of issues to be considered in presenting study findings will depend largely on the means of dissemination chosen, which is discussed in detail in *Chapter 5: Publishing, Disseminating and Implementing Study Findings.*

Part 2: Case Study Example

4.1. Data Collection

Data collection for the Sumgayit Cancer Study began in May 2001, and was conducted primarily by Mr Andruchow, Mr Makhmudov, and Dr Asadov and made possible through the offices of Dr Akhundov of the MOH. The first priority was identified as the collection of all necessary cancer incidence and mortality data for the selected study regions. Cancer data spanning the regions and years requested in the study proposal were not available in their entirety directly from the MOH archives. Thus, a secondary approach to collecting the necessary data was required. Attempts to collect missing data were made by contacting local oncological dispensaries in each of the study regions. This approach was partially successful, filling some of the gaps in the data; however, not all missing data could be obtained. Further, it introduced a concern about data quality, because in some instances where data were available from both the MOH archives and the local oncological dispensaries, discrepancies were noted. Where discrepancies existed, the data from the local dispenser were taken as correct, because they were the original source of the data, and thus believed less likely to contain errors.

All available incidence and mortality data for the following cancer sites were collected for both sexes for the period 1980-2000: cancer of the larynx (ICD-9: 161), cancer of the trachea, bronchus, and lung (ICD-9: 162), cancer of the urinary bladder (ICD-9: 188), and all cancer sites combined (ICD-9: 140-208). Data were also collected on female breast cancer (ICD-9: 174). It was noted unexpectedly that breast cancer mortality was recorded in a combined category (ICD-9: 174, 175), where male breast cancer (ICD-9: 175) and female breast cancer (ICD-9: 174) mortality were lumped together.

Data collected included both the number of incident cancer cases, and the number of cancer deaths per year for each of the selected cancer sites in each of the study regions. Wherever available, these data were collected by sex and 5-year age groups. In the instances where age and sex-specific data were not available, crude numbers were recorded. All data were abstracted from hardcopy forms into Microsoft® Excel electronic worksheets.

Attempts were also made to collect data for childhood cancers from the MOH archives, though these data were generally of poor quality and/or unavailable. Consequently, a further effort to collect childhood cancer data was made by visiting the Children's Oncological Centre in Baku. Hardcopy individual case histories spanning the period 1980-2000 were reviewed and all childhood leukemias (ICD-9: 204-208) or neurological cancers (ICD-9: 191, 192) were recorded. For each case, cancer site, age at diagnosis and/or death, name, and rayon of residence were documented.

Population data for each of the study regions were provided in electronic form by the SCS. Demographic data were supplied by sex and 5-year age groups for each year over the period 1980-2000. Population sizes were necessary to provide denominators for rate calculations. Crude cancer incidence and standardized mortality rates for several of the cancer sites being studied were obtained for the selected international populations of interest from the WHO's European Health for All Database *(WHO HFA Website – See Key References).*

4.1.1. Interview Data Collection

Two separate interview-based surveys were conducted, one in Sumgayit by students of a local medical university, and another in each of the study regions in Azerbaijan (Sumgayit, Ganja, and Lenkoran-Astara) conducted by the SCS.

Student-Administered Survey

In order to validate the results of a larger survey of potentially confounding lifestyle factors which was to be later administered by the SCS, and to pre-test the questionnaire on which the SCS-survey would be based, a survey of similar size (294 persons) *(see Section 2.5: Sampling, Sample Size, and Power)* was conducted in selected districts of Sumgayit. A group of fifteen student volunteers from Khazar University, a post-secondary medical institution located in Baku, administered the anonymous questionnaires as a practical extension of their course work. The students travelled as a group by bus to each of the districts, at which point they separated to conduct interviews individually.

Travelling as a group had several advantages, offering improved supervision of students and quality control, better security, and easier logistics. Although using such a large number of interviewers increased the risk of introducing inconsistencies into data collection, given the logistics, time restrictions, and financial constraints of the study, it was not feasible to conduct the pre-test of the survey any other way.

Efforts were made to minimize any potential problems arising from the large number of interviewers. Unfortunately, owing to limited time and resources, only a short training session was provided to the students in preparation for the interviews. Prior to administering questionnaires, students were allowed to familiarize themselves with the questionnaire and instructed on standardized methods of conducting anonymous interviews, in an effort to improve the quality and consistency of data collection. The training session gave students an opportunity to discuss and practice how to administer the questionnaire, how to select only eligible persons, and to respect the rights of individuals who refused participation.

A randomized sampling method was used to ensure that a representative sample of adults would be generated. Students were instructed to select every 5th person on the street and/or every 10th apartment for a potential interview. Interviewers were instructed to appreciate the need for a polite introduction and to engage people only if they were willing to participate. Issues concerning the interviews and the suitability of questions used in the questionnaire during the conduct of the student-administered survey were noted and used to improve the questionnaire prior to its administration by the SCS.

State Committee on Statistics (SCS)-Administered Questionnaire

The SCS was recommended by the MOH as the agency best able to efficiently conduct the lifestyle survey in each of the study regions. The MOH provided assurances that the SCS interviewers were well-trained professionals who already had considerable experience at such tasks. Randomly selected households had already been identified in each of the study regions for the SCS annually-conducted "Income and Expenditures Questionnaire," so that the administration of the lifestyle questionnaire could be done concurrently, making its conduct much more affordable. Three-hundred-fifty people were interviewed in each of the study regions:

1) Sumgayit,
2) Ganja, and
3) Lenkoran-Astara.

The questionnaires were administered in either Russian or Azeri, according to the preference of the participants.

4.2. Evaluating Data Quality

Quality of cancer data is also determined by completeness and validity. Cancer data completeness is concerned with obtaining all events originating in a catchment area, and properly recording them, as well as accurately enumerating the size of the population from which the events are derived. This also includes reporting cases that seek treatment outside the catchment area, ensuring that no individuals are missed, and that those individuals with multiple tumours are not registered multiple times.

Cancer data validity focuses on whether or not the recorded data are correct, such as whether or not cancer diagnoses were confirmed microscopically, or if data were checked following entry and coding. While the large proportion of missing data and lack of age-specific data collected for the period 1980-2000 and reports of the methods of diagnoses, data reporting, and the lack of a registry system were suggestive of poor cancer data quality in Azerbaijan, the Sumgayit Cancer Study was not able to quantitatively evaluate either the overall completeness or validity of cancer data collected in the country. Doing so correctly would have required the construction of a modern cancer registry in Azerbaijan, a resource-intensive venture that would take years to accomplish.

Analyses of data quality on a macroscopic level demonstrated that cancer incidence and mortality data varied considerably in terms of both detail and availability over time and across regions. The type of cancer incidence data collected by the MOH Archives changed over the period 1980-2000. Only crude cancer incidence data were recorded during the period 1980-1988, while during 1989-1990, cancer incidence rates were also categorized by sex. Starting in 1991, national summary cancer incidence reports included both sex and 5-year age categories (e.g., 0-4, 5-9, 10-14…), although this level of detail was not included in regional summaries until 1992. For all years beyond 1992, age and sex-specific cancer incidence reports were collected for all regions. In contrast, only crude cancer mortality data were collected over the entire study period 1980-2000 in all regions. Significant amounts of data were missing for individual years and regions throughout the study period, for both cancer incidence and mortality.

4.3. Data Analyses

The analysis of cancer data for the Sumgayit Cancer Study was complicated by the temporal and regional variations in data quality and availability. Therefore, several different methods were used to analyze cancer incidence and mortality data for each of the cancer sites, in order to provide the most robust study results, given the available data. Both crude and age-standardized cancer incidence rates were plotted to aid qualitative analyses of regional differences. In addition, the statistically robust multivariate Poisson regression analysis was utilized to analyze subsets of the data. Brief descriptions of each of the data analysis methods used in the Sumgayit Cancer Study are presented below.

4.3.1. Proposed Analyses

The age and sex-specific cancer incidence data required for more detailed analyses, such as the Standardized Incidence Ratio (SIR) analysis, were available for all study regions only for the period 1995-2000. As such, less statistically rigorous quantitative methods were utilized to provide more complete overview of the cancer experience in Azerbaijan. Proportional Incidence Ratios (PIRs) and Proportional Mortality Ratios (PMR) were able to be conducted on the available crude incidence and mortality data for the entire study period (1980-2000) because they do not rely on age- or sex-specific data.

Incidence and Mortality Rates

Numbers of new cancer cases and cancer deaths were used to calculate cancer incidence and mortality rates, respectively, per 100,000 population in each study region. As previously mentioned, cancer and demographic data collected separately from the Lenkoran and Astara regions were pooled in order to create a larger single population with more stable cancer rates. Crude incidence and mortality data were pooled annually for all years spanning 1980-2000 where data were available. Because age- and sex-specific data were missing for certain years for each of the regions, only age- and sex-specific data for the years 1995-2000 could be pooled.

Incidence and mortality rates were calculated as a first step in the data analysis. Where data were available, age and sex-specific rates were calculated in addition to the crude rates. Rates for each year were calculated by dividing the number of incident cases (or deaths) in each age-sex group for each year and region by the population size corresponding to that demographic. The result of this calculation was then multiplied by 100,000 to provide a rate per 100,000 population (see below).

Incidence per 100,000 Population/year = $\frac{\text{Number of new cancer cases}}{\text{Population at risk x 1 year}}$ x 100,000 persons

Mortality per 100,000 Population/year = $\frac{\text{Number of cancer deaths}}{\text{Population at risk x 1 year}}$ x 100,000 persons

For example, the crude incidence in males for all cancers combined for the year 1995 was calculated by dividing the total number of new cancer cases in all age groups (3,238) by the size of the population of males at risk (3,778,650), and then multiplied by 100,000 to produce a final result of 85.69 cases per 100,000 population per year (See Table 4.1).

Table 4.1. Calculation of age-specific incidence rates for all cancers combined (ICD-9: 140-208), for males in Azerbaijan in the year 1995.

Age	Number of New Cases	Population at Risk	Incidence per 100,000
0-4	12	422600	2.84
5-9	15	450000	3.33
10-14	14	408600	3.43
15-19	8	349600	2.29
20-24	33	339500	9.72
25-29	59	329400	17.91
30-34	80	328400	24.36
35-39	114	284050	40.13
40-44	182	226450	80.37
45-49	227	119750	189.56
50-54	310	98550	314.56
55-59	471	146050	322.49
60-64	561	118650	472.82
65-69	564	84250	669.44
70-74	374	35200	1062.50
75+	214	37600	569.15
All ages (crude rate)	3238	3778650	85.69

Rate Standardization

Rate standardization is a technique that allows incidence or mortality rates to be compared among different populations while controlling for differences in the age and sex structures of the populations. Rate standardization is accomplished by multiplying age and sex-specific outcome rates by the age distribution of an external reference population. The sum of the stratum-specific products is then divided by the total population size of the reference population.

$$\text{Age-adjusted rate} = \frac{\Sigma\,[\text{Age-specific rates}_{\text{(study population)}}\ \mathbf{X}\ \text{Age distribution}_{\text{(reference population)}}]}{\text{Total size of the reference population}}$$

An example of the age-standardization of the incidence of all cancers combined (ICD-9: 140-208) for males in Azerbaijan for the year 1991 using the world standard population is shown below (Table 4.2). Age- and sex-specific cancer rates for males in Azerbaijan were first calculated, as discussed in the section above entitled *Incidence and Mortality Rates*. For each 5-year age-group, these rates were then multiplied by the population sizes of the world standard population. The products of these calculations were then summed and divided by the total size of the world standard population to produce the age-adjusted incidence rate.

Table 4.2. Age-standardization procedure example for Azerbaijan males, incidence of all cancers combined (ICD-9:140-208), 1995.

Age in years	World standard population	Cancer incidence per 100,000 in Azerbaijan	Expected number of incident cases in world standard population
0-4	12000	2.84	0.34
5-9	10000	3.33	0.33
10-14	9000	3.43	0.31
15-19	9000	2.29	0.21
20-24	8000	9.72	0.78
25-29	8000	17.91	1.43
30-34	6000	24.36	1.46
35-39	6000	40.13	2.41
40-44	6000	80.37	4.82
45-49	6000	189.56	11.37
50-54	5000	314.56	15.73
55-59	4000	322.49	12.90
60-64	4000	472.82	18.91
65-69	3000	669.44	20.08
70-74	2000	1062.50	21.25
75+	2000	569.15	11.38
Total	100000		123.72

Thus, the age-adjusted incidence rate (per 100,000 persons) for all cancers combined is 123.72 for Azeri males in 1995, which is considerably different from the crude rate of 85.69.

Rates calculated from the Azerbaijan data were standardized both against the world standard population and the 1991 Azerbaijan national population.

Proportional Mortality Ratios (PMRs)

The Proportional Mortality Ratio (PMR) is a means of estimating the burden of a disease in an exposed population by comparing the proportions of disease from selected causes to those in a reference population. This measure was particularly useful for the Sumgayit Cancer Study because age- and sex-specific data were unavailable for a number of years, and because PMRs do not require that the population structure be known, were able to be calculated for the entire study period (1980-2000). The PMRs compared the proportion of incident cases or deaths from each cancer in the Sumgayit (exposed) population to the corresponding proportion in the national population (unexposed) population. By so doing, relative excesses or deficits of mortality for certain cancers were examined in the Sumgayit population. Because PMRs deal only with proportions, which are not necessarily dependent on age or sex distributions of the population from which they were taken, potential confounding owing to temporal or regional differences in age and sex distributions of the populations being compared was controlled.

A PMR > 1 means that the outcome of interest occurs proportionately more in the exposed than the reference population, and implies that the exposed population is at greater risk for that outcome. PMR results must be interpreted cautiously because variations in the frequencies of other diseases can have major effects on the proportionate mortality caused by the specified disease(s) of interest, which may lead to erroneous conclusions. It is therefore imperative to have a good understanding of the population at risk, and to carefully examine cause-specific mortality rates before drawing conclusions from PMR analyses. The analogue to a PMR that uses incidence, rather than mortality data, is known as a Proportional Incidence Ratio (PIR), and is calculated and interpreted similarly.

$$\text{PMR} = \frac{\text{proportion of deaths from specified cause (exposed population)}}{\text{proportion of deaths from specified cause (reference population)}}$$

Given that only crude cancer incidence and mortality data were available for much of the study period, the use of PIRs and PMRs was particularly helpful for examining the cancer experience between regions. PIR and PMR analyses allowed the calculation of a single summary statistic for each cancer site including all data from the years 1980-2000, providing a semi-quantitative measure of differences in cancer burden between regions for the entire study period.

An example of the calculation of PIRs for the Sumgayit study is provided below (Table 4.3). In each region, the numbers of incident cases for each of the selected cancers were first obtained for each of the selected cancer sites over the study period (1980-2000), and then summed to produce the total "all cancers combined" category. The proportion of the total cancer incidence that each cancer site contributed was then calculated by dividing the number of incident cases at each of the cancer sites (e.g., larynx) by the total number of incident cases recorded for all cancers combined. When the proportions of total incidence were calculated for each of the cancer sites and each of the study regions, those for the study region (Sumgayit) were divided by those of the reference population (Azerbaijan) on a stratum-specific basis (for each cancer site) to produce a PIR.

Table 4.3. Sample calculation of PIRs for cancer incidence in Sumgayit (relative to Azerbaijan national data) for the period 1980-2000.

Cancer Site	Incident Cases (1980-2000)		Proportion of Total Incidence		PIR
	Azerbaijan	Sumgayit	Azerbaijan	Sumgayit	
Larynx	4420	150	0.033	0.025	0.77
Trachea, bronchus, & lung	15987	740	0.119	0.125	1.05
Urinary bladder	3605	211	0.027	0.036	1.33
Female breast	13872	571	0.103	0.097	0.94
Others	96582	4236	0.718	0.717	1.00
All cancers combined	134466	5908	1.000	1.000	-

Standardized Incidence Ratio (SIR) Analysis

The Standardized Incidence Ratio (SIR) provides a population summary statistic. An SIR is a ratio of actual to expected incident cases for a particular population. The number of expected cases for a study area is calculated by multiplying the age-specific cancer rates from a reference population by the demographic distribution of residents in the study area. For the Sumgayit Cancer Study, the Sumgayit region was used as the study population, while the entire nation of Azerbaijan was used as the reference population. The total number of observed cases was then divided by the sum of age-specific expected values to produce a ratio for each pairwise comparison. The SIR was used to determine if excesses or deficits for any health outcome (e.g., lung cancer incidence) existed between any of the study and reference groups.

$$SIR = \frac{\text{observed deaths (O)}}{\text{expected deaths (E)}} \quad (\text{x } 100\%)$$

An SIR > 1 indicated that the particular cancer occurred at a greater rate in the Sumgayit population than the national population, and implied that the population of Sumgayit was at greater risk for that outcome in that period. The results of the SIR analysis could be used to provide suggestive evidence that the health status of the Sumgayit population had been adversely affected (by industrial exposures). SIR analyses were restricted to data from 1995-2000, because age- and sex-specific data prior to that time were missing for certain regions and years.

A sample SIR calculation is presented below (Table 4.4). Age-specific incidence rates for the reference population (Azerbaijan) were first calculated, then multiplied by the age-distribution of the study population (Sumgayit) on a stratum-specific basis to produce the number of expected cases in the Sumgayit population. The stratum-specific numbers of expected and observed cases were then summed to produce totals, and the total number of observed cases was divided by the total number of expected cases, the result of which was multiplied by 100% to produce the SIR summary statistic.

Table 4.4. Sample SIR calculation for males in the city of Sumgayit relative to Azerbaijan for the incidence of all cancers combined, 1995.

Age in years	Cancer incidence per 100,000 in Azerbaijan	Population Distribution of Sumgayit	Expected number of incident cases in Sumgayit	Observed number of cases in Sumgayit
0-4	2.84	15178	0.43	0
5-9	3.33	16162	0.54	0
10-14	3.43	14675	0.50	0
15-19	2.29	12556	0.29	0
20-24	9.72	12193	1.19	2
25-29	17.91	11830	2.12	3
30-34	24.36	11794	2.87	1
35-39	40.13	10202	4.09	0
40-44	80.37	8133	6.54	12
45-49	189.56	4301	8.15	3
50-54	314.56	3539	11.13	16
55-59	322.49	5245	16.92	16
60-64	472.82	4261	20.15	26
65-69	669.44	3026	20.26	33
70-74	1062.50	1264	13.43	23
75+	569.15	1350	7.68	13
Total			116.29	148

SIR = (148/116.29) x 100% = 127%

4.3.2. Additional Analyses

Owing to the problems noted with data quality and completeness, the analyses initially suggested in the study proposal were not sufficient to fully explore the collected data. As such, two additional analyses were proposed to better explore the data: 1) Mortality:Incidence Ratios (MIRs), and 2) Poisson Regression Analysis. These cannot be considered post-hoc tests, however, even though they were proposed after the conduct of the originally suggested data-analyses because they were only methods of exploring data quality, and re-examining the same study hypothesis, respectively.

Mortality:Incidence Ratios (MIRs)

One technique, among several, used to gain some sense of data quality, was to take the ratio of mortality (number of deaths) to incident cases for each of several cancer sites being considered in the study. Because not all cancer cases die, one expects that the number of new cases should always exceed cancer deaths in any one year, and that the

ratio between the two should be proportional to the known survival for each particular site, if incidence and mortality were being reported accurately. For example, cancers with poor survival, such as lung cancer, were expected to have an MIR closer to 1 than cancers with better survival, such as testicular cancer, or in the Sumgayit Cancer Study, breast cancer. If one were to find the MIR to exceed unity, this could signify a problem with the quality of the data. MIRs were calculated using crude incidence and mortality count data for all years from 1980-2000 for which data were available.

$$\text{MIR} = \frac{\text{\# deaths over a specified length of time}}{\text{\# incident cases over the same period of time}}$$

A sample MIR calculation is provided in Table 4.5 below. MIRs are calculated by first taking the sum dividing the total number of deaths (mortality) by the total number of new cases (incidence) for a specified period of time. MIRs are calculated annually, as well as for the entire study period 1980-2000.

Table 4.5. Sample calculation of MIRs for Azerbaijan, all cancers combined, annually and for the entire period 1980-2000.

Year	Mortality	Incidence	MIR
1980	4568	5918	0.77
1981	4626	5927	0.78
1982	4615	6181	0.75
1983	4590	6150	0.75
1984	4829	6226	0.78
1985	4716	6470	0.73
1986	4824	7765	0.62
1987	5049	8277	0.61
1988	4661	8433	0.55
1989	6336	8479	0.75
1990	4403	8886	0.50
1991	4436	7537	0.59
1992	4447	6485	0.69
1993	3696	5179	0.71
1994	3456	5279	0.65
1995	3556	6223	0.57
1996	3666	5498	0.67
1997	3542	5253	0.67
1998	3855	4838	0.80
1999	3861	4658	0.83
2000	3869	4804	0.81
Total	91601	134466	0.68

Sample Calculation of MIR for the period 1980-2000:
MIR = 91601/134466 = 0.68

Poisson Regression Analysis

One of the most rigorous approaches to comparing disease rates between populations is the multivariate Poisson regression analysis. Poisson regression analysis is a technique used to model dependent variables describing count (discrete) data. The model relies on the assumption that the dependent variable (Y) has a Poisson distribution. An example of a Poisson probability distribution with parameter μ is described below:

$$pr(Y; \mu) = \frac{\mu^{Y} e^{-\mu}}{Y!}, \quad Y = 0, 1, 2, \ldots, \infty$$

The output of a Poisson regression analysis is a rate ratio (or, risk ratio, relative risk (RR)). Simply put, a rate ratio describes the risk of acquiring a disease in one population relative to the risk in another. Rate ratios can be expressed in the form:

$$RR = \frac{\lambda_{ij} \text{ (exposed group)}}{\lambda_{ij} \text{ (reference group)}}$$ where λ is the true (population) risk in the $(i, j)^{th}$ group

An example of an equation describing risk for a population as the result of several variables is as follows:

$$\ln[\lambda] = \alpha + \beta_1 X\neg_1 + \beta_2 X_2 + \ldots + \beta_n X_n$$

where α represents the intercept
β represents a regression coefficient
X represents a design variable

From this foundation, one can develop an equation predicting the count (number) of incident cases or deaths (Y) in a given population, given the risk of disease in the population (λ), and population size (l):

$$\ln[Y] = \ln[l] + \ln[\lambda] + \text{Error}$$

This method can be used to develop equations predicting rate ratios between several independent populations, while controlling for confounding variables, and taking into account potential pairwise and higher-order interactions between variables. Although the output of the Poisson regression is somewhat similar to SIR analysis in that it yields as a result a ratio between populations, Poisson analysis is more rigorous because it can adjust for variables simultaneously other than age and sex. In the Sumgayit Cancer

Study, the Poisson regression analysis was used primarily to test the association between region and cancer incidence or mortality rates, rather than for rigorous model building. Variables entered into the Poisson model for the Sumgayit cancer study to explain patterns in cancer incidence and mortality rates included region, year, age, and sex, as well as interactions between age-sex and area-year. A generic form of the Poisson model used for the Sumgayit study is as follows:

$$\lambda = \alpha + \beta_1 \text{Area} + \beta_2 \text{Year} + \beta_3 \text{Sex} + \beta_4 \text{Age} + \beta_5 \text{Age*Sex} + \beta_6 \text{Area*Year}$$

For more information on the Poisson Regression method, please refer to Breslow & Day 1987 listed in the Key References section.

Interview Data Analysis

All data collected in either of the student- or SCS-administered surveys were first screened for completeness and errors. Because the inclusion criteria were not always followed perfectly by interviewers in either survey, individuals not meeting the pre-determined inclusion criteria were excluded prior to analysis. This was accomplished by using a computer program to sort the data so data exceeding the ranges specified for the study could be excluded (e.g., persons less than 18 years old). Data were also cross-referenced between related variables, such as number of years smoked, age started smoking, and current age. Erroneous cells were corrected if errors were obvious, or otherwise excluded from further analyses. Descriptive statistics were obtained for all continuous data using SPSS 10.0©. For binomial population parameters, 95% confidence intervals were generated using the formulae below (Breslow & Day 1987):

$p = r / N \quad q = 1 - p$
$\text{S.E.}(p) = (pq / N)^{1/2}$
$95\%\ \text{CI} = p \pm 1.96 * \text{S.E.}(p)$

Regional differences in potentially confounding lifestyle factors were then examined by comparing 95% confidence intervals for all parameters.

4.3.3. Post-Hoc Analyses
No post-hoc analyses were conducted in the Sumgayit Cancer Study
(See Section 4.3.2. Additional Analyses).

4.4. Presenting Results of Analyses

A number of different methods were used to present the results of cancer data analyses, ranging from simple tables and graphs of crude cancer rates, to results of complex analyses such as the Poisson regression. Brief descriptions of some of these methods of presentation are listed below.

All cancer rates calculated were presented in tabular form to facilitate the visualization of possible patterns in the data, and to categorize and communicate all of cancer data collected for the study as easily and efficiently as possible. Examples of such tables are presented below (Table 4.6, Table 4.7).

Table 4.6. Number of cancer cases and crude cancer incidence rates per 100,000 population of all cancers combined (ICD-9: 140-208) for selected regions of Azerbaijan, males and females (1980-1988).

Site	Year	Azerbaijan		Sumgayit		Ganja		Lenkoran-Astara		Lenkoran		Astara	
		N	CR	N	CR	CR	N	N	CR	N	CR	N	CR
All Sites	1980	5918	94.7	212	97.5	-	-	-	-	-	-	-	-
ICD-9:	1981	5927	93.3	227	100.8	100.2	250	171	80.2	134	89.3	37	58.6
140-208	1982	6181	95.8	248	107.3	109.5	277	168	77.2	142	92.8	26	40.3
	1983	6150	93.8	236	100.0	89.5	229	-	-	121	77.3	-	-
	1984	6226	93.5	231	95.5	-	-	-	-	-	-	-	-
	1985	6470	95.8	224	91.0	109.1	289	-	-	-	-	-	-
	1986	7765	113.2	242	95.4	105.8	285	-	-	128	78.1	-	-
	1987	8277	118.7	286	111.1	106.8	293	-	-	118	71.3	-	-
	1988	8433	119.4	287	113.0	94.5	265	-	-	-	-	-	-

*Note: N= Number of new cases; CR = Crude incidence rate. Hyphens (-) represent missing data.

Table 4.7. Annual cancer incidence per 100,000 population by sex and age group, all cancer sites combined (ICD-9: 140-208), Azerbaijan

Year	Cases	0-	5-	10-	15-	20-	25-	30-	35-	40-	45-	50-	55-	60-	65-	70-	75+	CR	ASR (AZE)	ASR (W)
Males																				
1989	4834	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	139.0	-	-
1990	4698	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	134.1	-	-
1991	4173	4.0	7.6	7.6	8.7	18.2	27.9	43.3	71.6	119.2	323.3	295.1	495.4	687.4	1165.4	1418.8	641.4	117.5	133.0	178.1
1992	3415	1.8	6.3	6.7	11.8	16.3	12.8	33.3	58.0	97.9	235.8	263.1	445.4	583.3	732.3	945.6	552.4	94.6	104.9	136.6
1993	2825	1.3	2.3	2.6	2.7	10.8	17.6	26.8	50.6	76.2	204.3	260.6	297.0	415.3	698.1	879.7	361.8	76.9	83.8	111.9
1994	2898	1.2	5.2	3.5	4.1	9.3	13.6	27.8	37.7	86.9	219.9	313.7	301.3	420.7	524.1	912.4	413.7	77.7	84.9	112.3
1995	3238	2.8	3.3	3.4	2.3	9.7	17.9	24.4	40.1	80.4	189.6	314.6	322.5	472.8	669.4	1062.5	569.1	85.7	93.8	123.7
1996	2931	2.9	3.3	4.3	6.4	10.1	14.3	16.1	26.9	39.8	122.7	255.6	277.7	487.5	673.5	958.8	577.1	76.6	84.1	110.2
1997	2741	1.3	3.3	4.5	5.5	5.4	8.8	14.9	35.5	55.3	117.3	305.4	266.9	429.7	571.3	861.8	375.8	70.9	77.0	100.9
1998	2447	3.6	2.8	3.6	4.3	8.7	12.8	15.0	35.2	42.0	113.2	222.1	279.3	365.3	519.7	571.1	371.5	63.0	67.5	86.8
1999	2343	1.4	4.9	4.1	9.0	5.7	9.1	14.4	29.1	41.2	98.1	210.9	367.7	333.3	415.4	508.2	406.9	60.1	66.5	83.3
2000	2373	2.4	3.7	6.3	6.4	7.9	8.9	16.2	28.5	49.2	103.7	163.0	317.5	329.1	379.3	619.0	411.1	60.3	63.6	81.0
Females																				
1989	4151	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	113.9	-	-
1990	4636	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	126.2	-	-
1991	3581	2.6	4.3	5.7	4.6	10.2	17.7	39.1	80.2	163.1	381.2	319.0	401.8	431.3	500.6	410.0	147.6	96.3	90.6	119.2
1992	3070	1.7	6.4	5.9	4.3	7.2	18.1	47.0	79.0	139.0	222.6	219.2	290.3	312.5	368.4	486.1	303.1	81.4	74.6	94.9
1993	2403	1.2	1.9	2.7	2.7	13.8	17.0	20.2	42.9	82.1	147.5	191.5	218.1	309.1	384.0	385.9	141.5	62.9	56.9	73.6
1994	2381	1.7	3.6	1.8	6.0	6.5	12.3	23.0	55.7	96.3	188.1	203.6	231.2	245.2	333.5	297.3	109.3	61.6	55.5	71.9
1995	2985	2.3	2.8	1.8	3.5	10.1	10.6	33.8	57.2	99.8	225.8	321.3	246.0	304.9	372.5	471.3	197.3	76.4	69.7	90.3
1996	2567	2.4	3.7	2.5	3.2	10.1	10.8	20.5	34.3	64.4	141.2	246.0	216.2	331.4	412.4	419.4	136.6	65.2	58.8	76.2
1997	2512	3.0	4.2	3.7	3.1	5.2	12.7	24.0	40.1	72.9	167.6	275.0	183.5	315.5	327.8	352.8	141.5	63.2	57.9	74.5
1998	2391	2.5	2.5	2.8	2.2	5.9	11.7	21.1	34.7	66.9	117.5	225.1	229.4	287.4	358.6	339.2	149.4	59.3	54.5	69.3
1999	2315	2.5	3.4	5.6	6.0	4.4	7.3	19.0	37.2	74.5	127.3	222.6	251.3	229.6	308.4	336.1	136.1	56.7	52.8	67.2
2000	2431	1.7	5.6	5.3	2.0	1.5	8.9	22.4	40.9	73.9	133.5	198.0	231.5	203.3	313.8	352.8	253.3	59.1	52.9	67.3

*Note: Hyphens (-) represent missing data, CR refers to crude rates, ASR (AZE) refers to rates age-standardized to the 1991 Azeri Population, ASR (W) refers to rates age-standardized to the world standard population.

Cancer incidence rates were smoothed for data presentation purposes by taking three-year moving averages (MAs) of the rates to decrease the effects of stochastic variation. The MA is accomplished by taking the mean of cancer rates over successive 3-year periods. For example, using this method, the cancer rates for each of the years 1980, 1981, and 1982 were averaged to produce a single data point (1980-82). Similarly, the next data point would be calculated by taking the mean of cancer rates from 1981, 1982, and 1983; the third data point by the mean of 1982, 1983, and 1984; and so on. Examples of graphs comparing regional data in terms of both crude cancer incidence and three-year MAs of the crude rates are presented below (Figure 4.1, Figure 4.2).

Note: In the thesis, the MAs were erroneously referred to as Time Weighted Averages (TWAs).

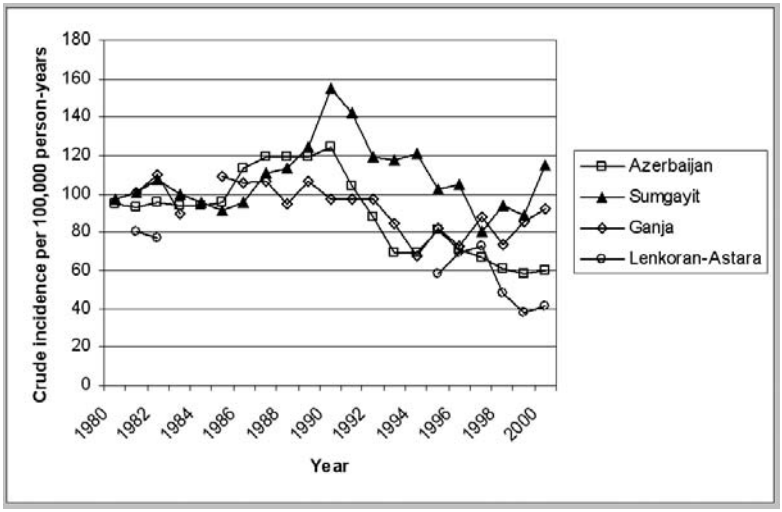


Figure 4.1. Annual crude cancer incidence for selected regions of Azerbaijan, males and females, all cancer sites combined (ICD-9: 140-208).

Though having the positive effect of reducing stochastic variability and facilitating the visualization of temporal trends and regional patterns, this method also had some drawbacks. One such problem is decreasing the total number of data points from the available data, and in the instances where data for certain years were missing and three successive years could not be obtained, the number of data points decreased dramatically. It must also be noted that because a mean of the data from three years was taken, data points in the presented figures do not represent actual cancer rates, only summary statistics, and in calculating these averages, potentially important individual data points could have been omitted.

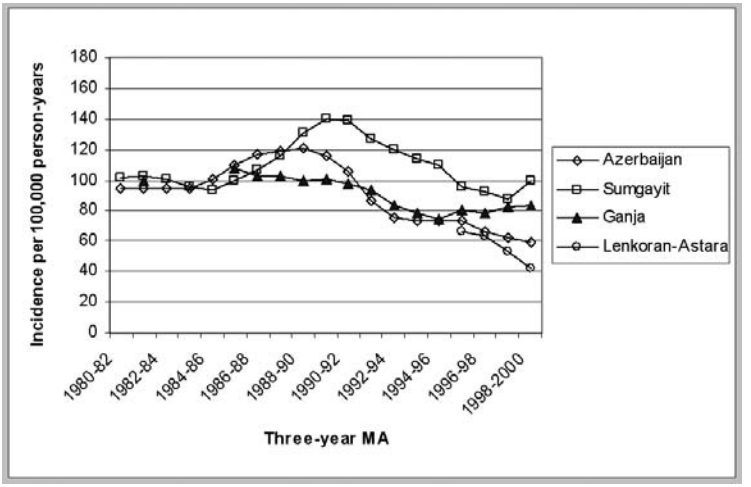


Figure 4.2. Three-year moving averages (MAs) of crude cancer incidence for selected regions of Azerbaijan, males and females, all cancer sites combined (ICD-9: 140-208).

Results from the Poisson regression analyses of cancer incidence and mortality data were presented in tabular form, which included both point estimates in the form of Rate Ratios (RRs) and 95% confidence intervals for them. See Table 4.8 for an example of the presentation of univariate Poisson regression results.

Table 4.8. Descriptive results of univariate Poisson regression analyses for incidence of all cancer sites combined (ICD-9: 140-208).

Model	Rate Ratio (RR)		
	Estimate	95% CI	
		Lower	Upper
Area			
Other regions	*1.00*	-	-
Sumgayit	1.51	1.43	1.58
Ganja	1.27	1.20	1.34
Lenkoran-Astara	0.84	0.79	0.90
Year			
1995	*1.00*	-	-
1996	0.87	0.84	0.91
1997	0.83	0.80	0.86
1998	0.76	0.73	0.78
1999	0.72	0.69	0.75
2000	0.74	0.71	0.77
Sex			
Female	*1.00*	-	-
Male	1.10	1.07	1.12
Age Group			
0-14	0.32	0.29	0.35
15-34	*1.00*	-	-
35-54	8.22	7.81	8.65
55+	32.21	30.68	33.82

4.5 Interpreting Results and Drawing Conclusions

The results of the Sumgayit Cancer Study had to be interpreted cautiously because of the issues of data quality that were identified during its conduct. These data quality issues required that several different approaches to data analysis be used in order to provide the most robust results from the available study data. Each data analysis method produced slightly different results, and thus, no single summary result was able to be reported for the study. All of the data analysis methods used, however, produced results that were qualitatively similar, despite minor quantitative differences.

Almost all analyses suggested that Sumgayit did indeed have significantly higher cancer incidence and mortality rates than the comparison populations for the following cancer sites (larynx, lung, bladder, & all cancers combined), although Ganja had the highest rates for breast cancer. While the quantitative estimates of the increased cancer burden in Sumgayit differed among the various cancer sites, the qualitative patterns were basically the same. The largest elevations in cancer rates, in order of decreasing magnitude of effect, were bladder cancer, lung cancer, and all cancers combined, as would be expected if cancer rates were influenced by Sumgayit industry, given the strong associations of these cancers with chemical and industrial exposures. In contrast, the smallest observed increase in cancer burden in Sumgayit occurred for breast cancer, which shows only weak associations with industrial exposures. These results thus supported the perceived association between industrial exposures and increased cancer burden in Sumgayit.

Examinations of possible regional variations in data quality and potentially confounding lifestyle factors did not provide any substantive evidence that either of these variables could be responsible for the observed patterns. Although the Sumgayit Cancer Study was not able to precisely quantify the increase in cancer risk resulting from exposures originating from Sumgayit industry, the study was able to conclude that cancer burden in the city of Sumgayit indeed was elevated.

The Sumgayit Cancer Study provided factual and quantitative evidence on a number of other issues, including international comparisons of cancer rates, temporal changes in data quality and cancer rates, and the prevalence of potentially confounding lifestyle factors. Owing to limitations of space, they are not presented here, but they can be viewed in the thesis entitled: "Cancer incidence and mortality in the industrial city of Sumgayit: A descriptive study," also available online *(See Key References)*.

4.6. Evaluating Study Strengths and Weaknesses

Any epidemiological study has strengths and limitations that can influence the type and usefulness of the results obtained from it. These characteristics were documented for the Sumgayit Cancer Study in an effort to better understand the particular utility of the study.

Strengths

The greatest strength of the Sumgayit Cancer Study was its utility in examining the feasibility of, and issues associated with conducting cancer epidemiology research in Azerbaijan. Through the study, numerous issues were identified as being problematic to research, including data availability, accessibility, and data quality. Only in recent years, 1991 and beyond, were age- and sex-specific data collected at the regional level in Azerbaijan. Prior to this time, only crude data are summarized in the MOH Archives, making rigorous analyses of pre-existing summary cancer data impossible (prior to 1991). Access to pre-existing data proved problematic, in that hardcopy records were, in many cases, unable to be secured from either the Ministry of Health, or from the local oncological dispensaries. Furthermore, the quality of the data in the Sumgayit Cancer Study was found to be problematic from both the reporting and the recording perspectives. Similar problems to these have been found in Soviet cancer data by other researchers (e.g., incompleteness of data, problems with information flow from the local to the regional, and to the national levels, and the poor quality control of health data) (Rahu 1992, Jaakkola et al. 2000).

While the findings generated from the study were imperfect, and not as precise as originally expected owing to limitations of data quality, they do represent a major step in the assessment of health effects associated with Sumgayit industry, and will be very useful to future researchers attempting further research in the country. Thus, another strength of the Sumgayit Cancer Study was that it represents the first quantitative assessment of cancer risk resulting from long-term environmental and occupational pollution in the city of Sumgayit, and the country.

The study has also demonstrated that international partnerships can be successfully formed in order to complete health research in Azerbaijan. Buy-in from a large number of national and international agencies was secured, and numerous agencies have worked collaboratively to facilitate the progress of this work. Ensuring a sense of co-ownership of the study and a full appreciation of its broader significance and value for the development of epidemiological research and evidence-based policy making in the country were identified as important challenges. These issues were identified as being relevant to investigators developing new collaborative research projects in the region.

Limitations

The most prominent limitation of the study was its inability to allow precise conclusions to be drawn about cancer risk in Sumgayit, owing to, in large part, issues of data quality and availability. Although evidence suggested cancer risk was elevated in Sumgayit, there were a number of issues identified which could have affected the accuracy of the findings; thus, the results of the study must be interpreted cautiously. Despite its shortcomings, however, the Sumgayit Cancer Study provided the first quantitative assessment of the cancer burden in Sumgayit and, as such, represented the best available knowledge on cancer burden in Sumgayit at that time.

4.7. Presenting Study Findings

While all study findings are presented in the 252-page Masters thesis (*See Key References*), two summaries were prepared in order to convey the key study findings to lay audiences. The first was a two-page lay report designed to identify only the most important aspects of the study (*See Toolkit №10: Sample Report*), while a twenty-page executive summary was also prepared for individuals or agencies desiring a presentation with greater depth. Both summaries presented study findings through a combination of text, tables, and figures.

Chapter 5: Publishing, Disseminating and Implementing Study Findings

Part 1: Theory

The publication and dissemination of findings represent the culmination of the work done for a particular study. By so doing, the findings of the study are made available to a broader audience, to inform them of the work and to provide them an opportunity to review and critique it. Not only does the publication of results impart the knowledge gained by the study to others, it also acts to advance the career and reputation of the researcher. High quality work should be recognized as such, and garner credit for the author(s), while work with a lesser degree of refinement or with obvious shortcomings may reflect poorly on the author(s), if accepted for publication at all. Nonetheless, it is the duty of all researchers to publish the methods and findings of their successfully completed work in order that they are subjected to broader peer review, and so that the community can benefit from the investment made in the research. Benefits can arise directly from the knowledge gained from the research, and also indirectly by increasing awareness in the scientific community and the public. Awareness can serve, in turn, to attract funds to the study area for new research, or government attention to modify or develop policies to address concerns uncovered through the research.

5.1. Disseminating Study Findings

There are several media commonly used to disseminate study findings, each with its own advantages and disadvantages. The means of disseminating findings are not mutually exclusive, and more than one method is often used for a single study. Brief discussions follow of several common means of dissemination, listed below:

1) Conference/Symposium Presentations
2) Peer-reviewed journals
3) Mass media
4) Public Forums
5) Other individual means

5.1.1. Conference/Symposium Presentations

The presentation of study findings at scientific conferences or symposia is a useful method of sharing results, particularly very new or interim results, with the scientific community. While publication of results in peer-reviewed journals tends to be the best way of disseminating completed research findings, presentation of results at conferences or other academic meetings also has advantages. Because conferences are often designed to focus on the presentation of topics falling under only one of several themes, they tend to attract researchers with specialized interests. By presenting results at a conference focused on the researcher's topic of study, he or she is likely to reach many of the key figures in the field with a single presentation.

Presentations also have the advantage of including an interactive component, whether the formal question-answer session immediately following the talk, or the informal discussions that often occur between researchers during the course of the conference. Through such contact with other professionals, a researcher can make contacts in his or her field, develop professional relationships that may result in future collaboration, and receive immediate feedback on the findings of his or her study. One disadvantage of presenting results at conferences is that scheduling issues may result in members of the target audience missing the presentation. On the other hand, persons who would not have otherwise learned about the work may be given the opportunity to do so. Above all, presentations at conferences can serve the advantage of presenting work at a stage just prior to final preparation for publication. The feedback that one receives at such conferences then can be included to make the paper for submission to a journal all the more complete.

5.1.2. Peer-Reviewed Journals

Peer-reviewed journals are the most common and desirable medium of publication for researchers. As their name implies, peer-reviewed journals are just that, journals that publish articles that have undergone scientific scrutiny by a group of peers in order to validate their methodological quality and interpretation of results. If shortcomings are detected by the journal editors, the author will be required to make the suggested changes in order for the article to be accepted for publication. Because of this quality control in the publication process, articles published in peer-reviewed journals tend to be of a higher calibre than those published elsewhere. Publication of a study in a peer-reviewed journal thus adds a sense of credibility to the work completed. Furthermore, because the primary (if not nearly exclusive) method by which other academics communicate findings is

through peer-reviewed journals, and because the published article is then retained in a permanent record, publication of an article in a peer-reviewed journal is likely to result in the largest academic audience being reached.

5.1.3. Mass Media Releases

The term mass media refers primarily to the common forms in which information is relayed to the public (i.e., television, radio, newspapers, internet sources). Presentation of study findings through the mass media may be a tempting way of achieving dissemination of results to the public; however, mass media should be used only if appropriate caution is exercised. Researchers must bear in mind that journalists tend not to be experts in the researcher's field of study, so there is usually no meaningful critique of study quality or the validity of the findings prior to publication. For this reason, it is recommended that study findings are first accepted by a peer-reviewed journal to ensure quality control before they are released to the media. Release of study findings to the media prior to adequate peer-review may result in a loss of credibility for the researcher within the academic community. Copyright requirements must also be observed to ensure that a media release does not conflict with copyright timing by the journal that has accepted the paper for publication, and because the time to publication can be several months, patience and discretion are needed before involving the media.

Because the mass media communicates primarily with the public (a lay audience), care must be taken to ensure that the correct conclusions are relayed to them. With the goal of stimulating audience interest, and presenting stories in a short and concise manner, journalists may misinterpret or misrepresent the findings of research. Presentation of results through the mass media also runs the risk of sensationalism, a situation in which results are exaggerated or misrepresented to give them greater public appeal. Researchers must take the time to explain the broader significance of the study in lay terms to the media agency prior to publication, and should preferably submit a document with a clear description of their findings which is unlikely to be misinterpreted, along with any interviews or short statements to the mass-media in order to ensure that the media convey the appropriate messages to the public. Researchers must remember that while mass media are useful for alerting the public to particular issues of concern, they are often ineffective at communicating all but the most basic of study findings.

5.1.4. Public Forums

Public forums, also known as "town hall meetings" are appropriate for presenting results when there is a great deal of public interest or investment in study findings. Though the findings of a particular study may represent a major contribution to the scientific world, a great deal of academic research has little immediate relevance to the public in general. Most scientific findings must first be discussed in the light of other research before a generalized statement can be put forward by the academic community to influence public decision-making or government policy. Exceptions may include the findings of a study designed to examine a particular issue of public concern, studies that produce conclusive results with immediate implications for maintaining or improving public health, or, in extreme cases, findings that will be used to create public support for a policy change.

Similar to the release of research findings to the mass media, researchers must be sure to communicate their results to the public effectively in lay terms in order to avoid any misunderstandings about the study findings. The inclusion of a lay summary report of one to two pages in length can be helpful for the understanding and retention of study findings by the audience. One major advantage of a public forum presentation of results is that members of the audience can ask questions, and the researcher can take the necessary time to explain study findings fully so that the audience does indeed receive the correct message. One disadvantage of public forum presentations is that audience size is often limited by the logistical constraints of organizing such large meetings and limited public attendance.

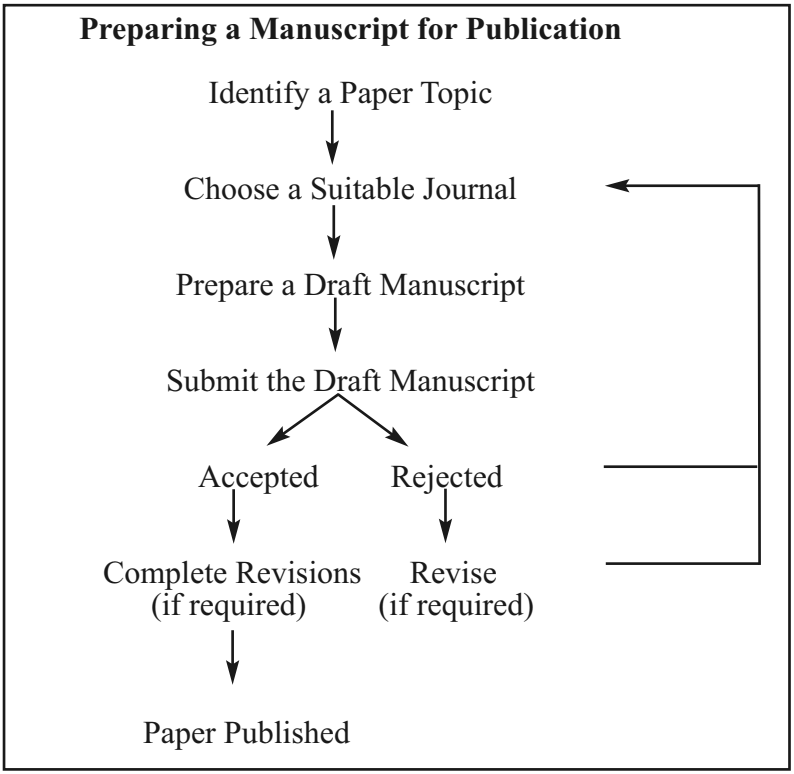
5.1.5. Other Individual Means

Researchers may also choose to make their important study findings available on a limited basis directly through personal means. Some common methods of doing this are by placing study findings and documents on personal webpages in electronic format, by making reprints of published articles or study summaries available, or by conducting speaking engagements. The effectiveness and usefulness of each of these methods varies according to the goals of the researcher. Providing results or publications on a personal webpage allows for wide access to the researcher's results on a global scale with little cost or effort, but does little to reach out to individuals or agencies. Making reprints available on request allows the researcher to provide information to interested individuals

on a limited basis with moderate effort. Conducting personal speaking engagements requires a large investment of time and money (for preparation and travel), but has the advantage of allowing the researcher to speak directly to a target audience and discuss with them the value of his or her study findings, which may be very useful for goals such as influencing policy or obtaining research funding.

5.2. Preparing a Manuscript for Publication

If a researcher has conducted a study in a rigorous manner, and attention has been paid to ensure that study methods are sound, and that the conclusions drawn from study results are both meaningful and valid, he or she should attempt to publish the work for broader readership and scrutiny in the scientific literature. There are a number of steps that should be undertaken in order to facilitate the process of preparing a manuscript for acceptance by a peer-reviewed journal.



5.2.1. Identifying a Paper Topic

From most epidemiological studies that were designed with the principles outlined in this Manual, a paper should be written outlining the methods and results of the study. One must bear in mind that even if the results were negative (i.e., revealed no association between study variables), this does not preclude them from being worthy of publication. On the contrary, results demonstrating no association between certain variables can be equally important as those demonstrating strong relationships. Some studies may have sufficient content and depth in the study findings to warrant writing more than one paper based on them, provided that the topics are sufficiently independent and developed to warrant individual publication. The topic and title of the paper(s) to be published should be agreed upon in advance by all potential co-authors (i.e., people who have contributed to the intellectual and practical aspects of the project).

5.2.2. Choosing a Suitable Journal

Once the topic of a manuscript has been decided upon, the next step is to choose the most appropriate journal to which it should be submitted. It is necessary to select the journal to which the manuscript will be submitted before writing it, because most journals have their own individual requirements and formatting directions for submitted manuscripts. By obtaining these directions prior to actually writing the manuscript, a great deal of time and energy can be saved by avoiding unnecessary reformatting. In addition, the focus of the journal can be borne in mind through the writing stage, thereby ensuring maximal relevance to its readership. For cases in which multiple papers are to be published from a single study, the researcher may wish to publish the papers as a series in a single journal so that they can complement and expand upon each other, even though the individual papers may differ in focus. This is largely a matter of preference, however, and depends on the extent to which the manuscripts differ and the goals of the researcher in terms of publication. Selection of the best journal is generally determined by three main factors: the journal's research focus, target audience, and reputation.

The first factor in choosing a journal to which to submit a manuscript should be the research focus of the journal. In order to maximize the chances of the manuscript being accepted for publication, the researcher should choose the journal whose interest most closely matches the area of his or her research. For example, a person conducting an international cancer epidemiology study may choose from journals with foci in any of the following topics: international health, cancer research, or epidemiology in general.

The next factor in choosing a journal should be the target audience of the journal. While the study design and type of results obtained might favour one type of journal, a journal that publishes slightly different research may be more appropriate to the researcher's needs because of different patterns of readership. To continue with the international cancer epidemiology example, a researcher primarily interested in pursuing a career in international health, though not necessarily cancer research, may choose to publish the results in an international health journal rather than a cancer or general epidemiology journal. The international health journal is more likely to be read by other international health researchers, while the cancer journal may be oriented slightly more towards clinicians studying cancer risk factors and treatments, while the general epidemiology journal might have a greater focus on epidemiological methods in general, and be read by a less specialized audience.

Another factor to be considered in choosing a journal for publication is the reputation of the journal. Journals vary greatly in terms of the quality of research and the importance and relevance of the study findings that they publish. Older, established journals such as "Science," "Nature," or the "American Journal of Epidemiology" are prestigious and have large readerships, but receive many manuscript submissions and thus have to be highly selective in the research that they will publish. In contrast, newer or regional epidemiological journals are more likely to accept research for publication, but may include research of slightly lower quality, and have lower readership than well-known journals. It is in the researcher's best interests to identify the level of quality that his or her research possesses, and to choose the highest quality journal likely to accept the work.

Publication of study findings in a reputable and recognized journal adds credibility to the work done by a researcher, and increases the size of the audience to which the results will be presented, thus most effectively advancing both the researcher's study findings and career. It is important to be realistic in the choice of a journal, particularly for a novice researcher, because submitting a manuscript to a journal that demands higher quality methods or more relevant study findings than what the study can provide will result in rejection of the paper by the journal, and wasted time and energy for the researcher.

Please see Toolkit №11: Prominent Peer-Reviewed Journals for a list of prominent epidemiological and public health journals and their primary areas of interest.

5.2.3. Preparing a Draft Manuscript

Once the journal has been decided upon, the researcher should then obtain all formatting and submission instructions from the journal itself, so that he or she can format the manuscript accordingly, and avoid last minute formatting changes. These instructions can often be obtained online from the journal website, from the journal editors or persons on a review committee, and often from within published volumes of the journal itself.

While the individual formatting requirements and submission instructions are likely to differ slightly for each journal, preparation of a draft manuscript for most scientific disciplines tends to follow a similar format. Manuscripts usually first present the title, author(s) and author contact information, followed by a brief (less than 250 words) structured abstract summarizing the background, objectives, methods, results and conclusions of the study. Next, authors present an introduction and a brief review of pertinent literature, in order to provide the context in which the research was based.

A methods section usually follows the introduction, in which the researcher details the study design (including ethics approval), study population, risk factors and outcomes of interest, means of collecting data, and sample size determination. The results section is presented next, in which the qualitative and quantitative measures of the study are presented, often with the aid of figures or tables. The discussion section then attempts to link all of the preceding sections by considering the study results in light of the methods used to generate them, and the overall context of the study.

Wrapping up the body of the text, the major messages of the study are presented in a conclusions section. Acknowledgements usually follow, in which the researcher identifies the funding sources of the research, and provides any special thanks as appropriate. Concluding the manuscript is a reference list of all literature cited in the paper.

(Please see Toolkit №12: Template for a Draft Manuscript for a generalized draft manuscript template).

5.2.4. Submitting the Draft Manuscript

Prior to submitting the manuscript for publication, the author should closely proofread the document personally, and forward it to all members of the research team for their input and approval. When all suggestions have been addressed, and all co-authors are positive that the manuscript is of sufficient quality, and that all formatting conforms to the requirements of the journal, the lead author should then submit the manuscript to the journal's editor-in-chief for review. Some journals accept manuscripts electronically, while others require hard copy, together with an electronic version; preferred methods of submission should be ascertained and followed.

There are several possibilities for response by the peer-review committee of any journal following their review of a submitted manuscript:

1) they may decline to publish the manuscript,
2) they may accept the manuscript with the proviso that certain revisions are made, or
3) they may accept the manuscript for publication as is.

If the manuscript is rejected, the author can choose another journal, reformat it as per the requirements of the new journal (paying attention to the reasons for rejection by the first journal), and submit it there. If the editorial committee requires revisions to the manuscript prior to publication, the author should complete them as soon as possible provided that the selected changes do not conflict with the author's findings or intended message, and then return the revised manuscript to the journal editor-in-chief. If the author feels that the recommended revisions compromise the integrity or theme of the paper, he or she should bring the matter up with the journal editor-in-chief. If no compromise can be reached, the author may wish to submit the manuscript to another journal.

When the manuscript is accepted, the researchers' work on the study has come to fruition, and they can look forward to seeing the recognition deserved for their hard work through the impact that the work has on future research and on public policy.

5.3. Implementing Study Findings

Because it is the fundamental goal of epidemiology not only to study disease in human populations, but to use the knowledge gained to prevent disease, epidemiologists should concern themselves not only with the dissemination of their research findings, but also with the implementation of those results to effect beneficial change for human populations. One of the best ways in which epidemiological research can effect such change is by informing public health policy. Policy, however, is influenced by many competing interests, of which only one is science. Thus, in order for research findings to successfully influence policy, epidemiologists must understand how policy is influenced, and be able to use effective methods for accomplishing this.

Some researchers believe that scientific evidence and knowledge should be referred directly to policy makers, allowing policy to be directly influenced. Because scientific interests compete with others in influencing policy making, it is unlikely that such a "top-down" approach alone will result in policy changes. Thus, researchers often use "bottom-up" approaches, utilizing dissemination methods such as the media, to influence public opinion, and place pressure on government. Scientists may take more active approaches toward influencing public opinion and government policy, such as advocacy or lobbying through public health interest groups. These actions may in some instances come into conflict with the positions or interests of their sponsors or employers, which could result in ethical conflicts. Scientists must therefore clearly define and acknowledge their roles and obligations when acting in such capacities.

Caution must be taken when there is evidence of hazardous exposures to which a community is being exposed. In some circumstances, people with vested interests in maintaining the status quo may pressure researchers to pursue further scientific proof of causation, in order to delay public health action. The role of public health is to protect the public health interest above any other interest and, consequently, when there is evidence of hazardous exposure, demands for further research can serve to jeopardize people's health by delaying action to address the issues. Because research can never provide definitive answers, there will always remain some degree of uncertainty about any purported exposure-disease association. Thus, pressures that require waiting for more science must be carefully weighed against the risks to health that continue while the science advances.

What can add greater credibility and strength to the opinions and recommendations of scientists in policy circles are partnerships in which several interests come together for a common goal. These partnerships are greatly facilitated through the construction of steering committees including community members of an affected community at the onset of any piece of research.

Implementing the findings of rigorous scientific study into meaningful change for human populations is not expected to be a quick or easy task for researchers. However, through recognition of the processes involved, building of partnerships among stakeholders, and a long-term commitment to both quality and ethical principles, real and beneficial impacts can be made.

Part 2: Case Study Example

The findings of the Sumgayit Cancer Study were shared with two primary audiences: 1) the international community, and 2) stakeholders (the people of Azerbaijan, and the residents of Sumgayit, in particular). Because of the different needs and perspectives of the two groups, particular methods were tailored to reach each of them. A number of different media were used to disseminate the key findings of the study, including distribution of the completed thesis, manuscript submission to a peer-reviewed journal, and a public forum.

5.1. Disseminating Findings

5.1.1. To Local Stakeholders

Several key methods have been identified for sharing research findings with stakeholders in Azerbaijan, including data custodians, policy makers, researchers and the public. Copies of the Masters thesis based on the Sumgayit Cancer Study have been provided to key policy makers in Azerbaijan, including the MOH-BIS and the MOH-NOC. Copies also were provided to other partners in Azerbaijan, including the WHO-LO, the UNDP Country Office, and to the SCER.

The meetings were attended by local partners, government representatives, researchers, and non-governmental agencies, and thus reached a diverse audience. The thesis is available in Adobe Acrobat .pdf format on the personal website of Dr Colin Soskolne for general accessibility.
(*Note: This is a large document, ~20MB, and may take some time to download). http://www.ualberta.ca/~soskolne/Thesis-FINAL-UofA-Lodged-Jan6-2003.pdf

It is also available on the WHO European Centre for Environment and Health website

http://www.euro.who.int/ecehrome
(http://www.euro.who.int/healthimpact/MainActs/20020730_1)

Key international members of the research team, including James Andruchow, Colin Soskolne and Francesca Racioppi, returned to Azerbaijan for two presentations of study results, one at the UNDP Azerbaijan Country Office in Baku, and another at the Sumgayit Centre for Environmental Rehabilitation in the city of Sumgayit, where questions and concerns were addressed. A lay summary of the study and its findings was offered to all people attending the meeting, and arrangements were made to make more available to those who were not able to attend. The culmination of dissemination to the public occurred with a press release being provided to local media.

5.1.2. To the International Community
Several presentations describing the Sumgayit Cancer Study have already been made to the international scholarly community, including an oral presentation of the study design at the 2001 International Society for Environmental Epidemiology (ISEE) Conference in Garmisch-Partenkirchen, Germany, and a poster presentation of preliminary study findings at the ISEE 2002 conference in Vancouver, Canada. In conjunction with the presentations made at the ISEE conferences, abstracts for each of the presentations were published in the peer-reviewed journal, "Epidemiology."

Bound copies of the Masters thesis produced from the study were presented to the WHO European Centre for Environment and Health, the UNDP, and the Canadian Society for International Health. As mentioned above, the thesis is available in electronic format on the personal website of Dr Colin Soskolne.

5.2. Preparing a Manuscript for Publication

Two manuscripts based on the Sumgayit Cancer Study have been prepared for submission to peer-reviewed journals. They have both been published, but only after some considerable effort in responding to the critiques of anonymous peer reviewers and after some considerable effort to find a journal willing to publish this material. The final product is one that the research team and sponsors can be duly proud. The full citation for each of the two published papers follows:

> Andruchow JE, Soskolne CL, Racioppi F, Senthilselvan A, Makhmudov E and Asadov A. Cancer incidence and mortality in the industrial region of Sumgayit, Azerbaijan. International Journal of Occupational and Environmental Health (IJOEH) 2006;12(3):234-241.

> Andruchow JE, Soskolne CL, Racioppi F and Bertollini R. Capacity building for epidemiological research in the Newly Independent State of Azerbaijan. Annals of Epidemiology. March 2005, Vol 15(3):228-231. (PMID# 15723769)

The process of manuscript preparation and submission is described below.

5.2.1. Identifying a Paper Topic

The Sumgayit Cancer Study was a large, international collaborative project and addressed several important areas of public health: environmental cancer, data quality, and capacity building. Thus, it was decided that three manuscripts would be submitted for publication in order to address fully each of these important dimensions. As with most research studies, a manuscript was prepared describing the scientific aspects of the study, including design, methods, results, and conclusions. A second manuscript was deemed necessary to address the serious data quality issues that were identified during the course of the research, which have implications for the accurate generation of health statistics in the country. Finally, a third manuscript was required to address the capacity-building component of the project, including assessments of the goals, methods used, and results.

5.2.2. Choosing a Suitable Journal

While the paper topics identified could have been submitted to any number of journals with a focus on epidemiology, environmental epidemiology, international health, or cancer research, it was decided that the primary focus of the papers, and their unifying theme was that of conducting epidemiological research internationally. Because of its strong focus on international health research (epidemiology in particular) and reputation as a high-quality and widely-read publication, the International Journal of Epidemiology was selected as the journal to which each of the manuscripts would initially be submitted. However, this Journal was not amenable to publishing our research. Other Journals were approached (including the American Journal of Epidemiology, Epidemiology, and the European Journal of Public Health), also without success. Ultimately, the Annals of Epidemiology became interested in publishing the one paper on "capacity building", and the International Journal of Occupational and Environmental Health became interested in publishing the major "methods and results" paper (citations are provided above).

5.2.3. Preparing a Draft Manuscript

Following the identification of the International Journal of Epidemiology as the publication to which the manuscripts would initially be submitted, formatting directions for the manuscript to be submitted were obtained. This was accomplished by visiting the website of the journal's publisher (http://ije.oupjournals.org/), and accessing the "Instructions To Authors" link. Preparation of the manuscript in conformity with these instructions is essential.

5.2.4. Submitting the Manuscript

Following the completion of each manuscript, ensuring the full participation of all co-authors and the clearance needed by partner agencies, the papers are submitted. Even if submission results in rejection, the rejection often is accompanied by some level of critique, which can be helpful in revising the manuscript, either for resubmission (if invited to do so), or for submission to another appropriate journal.

Toolkit №1: Useful Epidemiology and Public Health Websites and Online Resources

Understanding and Keeping Informed about Epidemiology

- Supercourse: Epidemiology, The Environment, & Global Health:

This course is designed to provide an overview of epidemiology and the Internet for medical and health-related students around the world. Supercourse is not a substitute for the existing educational model, but a teaching-support system. It provides high quality lectures to the teachers of students in medical, dental, nursing schools, and those in public health. These are passionate lectures by experts in the field, and can be used directly by teachers and students.

  - Main Website: http://pcwww.liv.ac.uk/supercourse/
  - Mirror Listing: http://pcwww.liv.ac.uk/supercourse/mirror/index.htm
  - Russian Overview: http://pcwww.liv.ac.uk/supercourse/assist/Russian/index.htm

- "Epidemiology for the Uninitiated": http://www.bmj.com/epidem/epid.html
  - Sponsored by the British Medical Journal (BMJ)

- The Epidemiology Monitor: http://www.epimonitor.net
  - The Epidemiology Monitor, published ten times each year, is the only newsletter covering the field of epidemiology. It is written by epidemiologists for epidemiologists, and contains information not available elsewhere, articles that are quick and easy to read, and uses an attractive, inviting-to-read design and format in print version.

    Regular features include:
    - News articles - the latest updates on breaking news in epidemiology
    - Book reviews - expert evaluations on the newest books by fellow epidemiologists
    - Job bank - the most comprehensive free listing of jobs available anywhere
    - Career marketplace - dozens of detailed job advertisements from employers of all kinds
    - On the light side - something to smile about in each issue
    - Resources - leads to free or inexpensive materials epidemiologists can use
    - Notes on people - news about colleagues in the field
    - EpiNetwork international - news from epidemiologists at work around the world
    - Epiware - the latest on software developments of interest to epidemiologists
    - Calendar - the most complete list of events taking place in the epidemiology community
    - EpiOnline - internet developments and resources of interest to epidemiologists

Relevant Public Health Organizations

World Health Organization (WHO) Online Resources:

- WHO International: http://www.who.int/
  - Gives access to the WHO library and to documents related to all the main programs and activities of WHO

- WHO Regional Office for Europe: http://www.who.dk/
  - Provides information on WHO programs and activities carried out at the regional level

- WHO European Centre for Environment and Health (ECEH), Rome Division

  http://www.euro.who.int/ecehrome
  - From here, one can obtain information on what WHO-ECEH is doing, and have access to many on-line documents, including the food safety newsletter

- International Agency for Research on Cancer (IARC): http://www.iarc.fr/
  - This WHO agency coordinates and conducts research on the causes of human cancer, the mechanisms of carcinogenesis, and develops scientific strategies for cancer control
  - Access the IARC Monographs on the Evaluation of Carcinogenic risk to Humans and to the classifications of the evaluated agents, mixtures and exposures: http://monographs.iarc.fr/

- International Programme on Chemical Safety: http://www.who.int/pcs/index.htm
  - IPCS is a joint programme of three co-operating organizations, International Labour Organization (ILO), United Nations Environmental Programme (UNEP) and WHO, implementing activities related to chemical safety. From this site, it is possible to access:
    - INTOX Project: a global endeavour promoting poison control and chemical safety and international co-operation in this field: http://www.intox.org/
    - International Chemical Safety Cards (available also in Russian): http://www.cdc.gov/niosh/ipcs/icstart.html

Other United Nations Online Resources:

- United Nations Development Programme (UNDP): www.undp.org
  - The development agency of the United Nations. See Toolkit *№3*: Funding Agencies for more information.

- United Nations Environment Programme (UNEP): www.unep.org
  - UNEP strives to provide leadership and encourage partnership in caring for the environment by inspiring, informing, and enabling nations and peoples to improve their quality of life without compromising that of future generations.

- United Nations Fund for International Partnerships (UNFIP): http://www.un.org/unfip/
  - Serves as the interface between the United Nations Foundation (UNF) and the United Nations, and promotes new United Nations partnerships and alliances with a variety of sources, including companies and foundations, as well as bilateral and multilateral donors.

Other Agencies:

- The Centers for Diseases Control and Prevention (CDC): http://www.cdc.gov/
  - The CDC (Atlanta, Georgia) is an agency of the USA Department of Health and Human Services. Useful pages include:
    - Agency for Toxic Substances and Disease Registry (ATSDR): http://www.atsdr.cdc.gov/
    - The homepage of the EPI-INFO software, which can be downloaded for free, including its tutorial:
    - http://www.cdc.gov/epiinfo/
    - The CDC site for environmental health matters: http://www.cdc.gov/node.do?id=0900f3ec8000e044&print=on
- Occupational Safety and Health Administration: http://www.osha.org/
  - Provides information on occupational health-related matters, standards and regulations

- US Environmental Protection Agency: http://www.epa.gov/
  - Provides information on environmental issues, standards, regulations, databases

- A few of the most prestigious academic institutions for public health and environmental epidemiology are:
  - Johns Hopkins School of Hygiene and Public Health: http://www.jhsph.edu/dept/EHS/
  - The London School of Hygiene and Tropical Medicine: http://www.lshtm.ac.uk/
  - The Harvard School of Public Health: http://www.hsph.harvard.edu/
  - The University of North Carolina at Chapel Hill http://www.unc.edu/

Online Databases and Literature Sources

*The descriptions below have been extracted from the websites of each of the following online databases.

Health InterNetwork (HIN):
http://www.healthinternetwork.net/
The Health InterNetwork was created to bridge the "digital divide" in health, ensuring that relevant information - and the technologies to deliver it - are widely available and effectively used by health personnel: professionals, researchers and scientists, and policy makers. Launched by the Secretary General of the United Nations in September 2000 and led by the WHO, the Health InterNetwork has brought together public and private partners under the principle of ensuring equitable access to health information. The core elements of the project are content, Internet connectivity and capacity building.

Health InterNetwork Access to Research Initiative (HINARI):
As the first phase of making vital health content available, the Health InterNetwork provides a vast library of the latest and best information on public health: more than 2,000 scientific publications, one of the world's largest collections of biomedical literature.

This collection is available through the efforts of WHO together with the 6 biggest biomedical publishers: Blackwell, Elsevier Science, the Harcourt Worldwide STM Group, Wolters Kluwer International Health & Science, Springer Verlag and John Wiley. It has been described by WHO Director-General Dr Gro Harlem Brundtland as "perhaps the biggest step ever taken towards reducing the health information gap between rich and poor countries."

Public institutions in two groups of countries can sign up for the Health InterNetwork Access to Research Initiative. The country lists are based on GNP per capita (World Bank figures, 1998). Institutions in countries with GNP per capita below $1000 are eligible for free access to the literature. Institutions in countries with GNP per capita between $1000-$3000 are eligible for access at reduced prices.

Within these countries HINARI will benefit bona fide academic, research and government institutions. Eligible institutions whose staff and students may have access to the journals are: schools of medicine, nursing, public health and pharmacy; universities; health and medical research institutes; government offices working in the health sector, and medical libraries. Participating institutions need computers connected to the Internet with a high-speed (56k baud rate or higher) link.

Joining the initiative is possible through the use of an online registration form. Only one registration is required per institution. An agreement will be sent to all institutions which register, which requires a signature for terms of use, and instructions for getting started. If your institution is not eligible for access to journals through HINARI, you may be eligible through another initiative. See the HIN website for more details.

The Cochrane Library:
http://www.update-software.com/clibng/cliblogon.htm
The Cochrane Library consists of a regularly updated collection of evidence-based medicine databases, including The Cochrane Database of Systematic Reviews - evidence based systematic reviews prepared by the Cochrane Collaboration which provide high quality information to people providing and receiving care and those responsible for research, teaching, funding and administration at all levels.

Healthy People 2010 & Environmental Health
http://www.phf.org/EH/index.htm
This site is part of a national, public-private effort to provide easy access to information useful in the development of environmental health objectives and for other environmental health planning projects. It focuses on the six major topic areas within the Healthy People 2010 Environmental Health Focus Area: Outdoor Air Quality, Water Quality, Toxics and Wastes, Healthy Homes and Healthy Communities, Infrastructure and Surveillance, and Global Environmental Health.

ISI Web of Knowledge:
http://isi4.isiknowledge.com/
Introduced in May 2001, the ISI Web of KnowledgeSM is a powerful Web-based platform providing coverage of the highest quality content while maintaining and improving the access and links between users of scholarly information and additional repositories of relevant research. This single, sophisticated platform extends and deepens the research coverage available through one resource by integrating journal, patent, proceedings, and life science literature with Web resources and other scholarly content.

MEDLINE (available through PubMed):
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi
MEDLINE is the National Library of Medicine's (NLM) premier bibliographic database covering the fields of medicine, nursing, dentistry, veterinary medicine, the health care system, and the preclinical sciences. MEDLINE contains bibliographic citations and author abstracts from more than 4,600 biomedical journals published in the United States and 70 other countries. The file contains over 11 million citations dating back to the mid-1960's. Coverage is worldwide, but most records are from English-language sources or have English abstracts. Citations prior to the mid-1960s can be found in NLM's OLDMEDLINE database.

NLM Gateway:
http://gateway.nlm.nih.gov/gw/Cmd
The NLM Gateway is a Web-based system that lets users search simultaneously in multiple retrieval systems at the U.S. National Library of Medicine (NLM). It allows users of NLM services to initiate searches from one Web interface, providing "one-stop search-

ing" for many of NLM's information resources or databases. One target audience for the Gateway is the Internet user who is new to NLM's online resources and does not know what information is available there or how best to search for it. This audience may include physicians and other health care providers, researchers, librarians, students, and increasingly, patients, their families, and the public. Other users may find the Gateway useful for an overall search of NLM's information resources. Some searchers may locate what they need immediately, while others will utilize the Gateway as an adjunct tool to other NLM search services such as PubMed® and MEDLINEplus®.

OLDMEDLINE (available through NLM Gateway):
http://gateway.nlm.nih.gov/gw/Cmd
OLDMEDLINE contains citations to articles from international biomedical journals covering the fields of medicine, preclinical sciences and allied health sciences during the period 1957 through 1965. Search OLDMEDLINE via the NLM Gateway.

PubMed:
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi
PubMed provides access to bibliographic information which includes MEDLINE as well as:

- The out-of-scope citations (e.g., articles on plate tectonics or astrophysics) from certain MEDLINE journals, primarily general science and chemistry journals, for which the life sciences articles are indexed for MEDLINE.
- Citations that precede the date that a journal was selected for MEDLINE indexing.
- Some additional life science journals that submit full text to PubMedCentral and receive a qualitative review by NLM.

WHO Health for All Database (WHO-HFA):
http://data.euro.who.int/hfadb/

- From this site you can download for free the WHO Health for All statistics database, which provides time series statistics on key health indicators, at a national, sub-regional and regional basis.

Toolkit №2: Professional Organizations and International Opportunities for Environmental Epidemiologists

Professional Organizations

(Note: A selection, likely incomplete)

European Public Health Association (EUPHA):

www.eupha.org

The European Public Health Association, or EUPHA in short, is an umbrella organization for public health associations in Europe. EUPHA was founded in 1992. EUPHA is an international, multidisciplinary, scientific organization, bringing together around 9000 public health experts for professional exchange and collaboration throughout Europe. We encourage a multidisciplinary approach to public health.

Objectives/aims:

- To promote and strengthen public health research and practice in Europe
- To improve communication between policymakers, researchers and practitioners
- To provide a platform for the exchange of information, experience and research
- To encourage and promote effective European joint research and other activities

in the field of public health research and health services research in Europe

EUPHA publishes a scientific journal four times a year entitled European Journal of Public Health (EJPH). The EJPH does not only publish refereed original articles, but also provides a forum for discussion and debate of current international public health issues with a focus on the European region. EUPHA convenes a scientific conference every year, bringing together public health experts throughout Europe and beyond. The conferences offer a platform for the exchange of information and an opportunity for international research groups to meet and present their work.

EUPHA encourages the creation of sections for specific public health themes, which are international and open to all regular EUPHA members. The goal is to bring together researchers and public health professionals working in the same field for the exchange of information and the setting up of joint policies, reports and research.

Current sections:

- Health promotion
- Food and nutrition
- Epidemiology
- Social security and health
- Youth
- Public health practice and policy
- Health services research

To contact EUPHA:

Drieharingstraat 6, Postbox 1568
3500 BN Utrecht
The Netherlands
Telephone : +31302729709
Fax : +31302729729
Email : d.zeegers@nivel.nl

International Association for Impact Assessment (IAIA):
www.iaia.org
IAIA is the International Association for Impact Assessment, organized in 1980 to bring together researchers, practitioners, and users of various types of impact assessment from all parts of the world. IAIA involves people from many disciplines and professions. Its members include corporate planners and managers, public interest advocates, government planners and administrators, private consultants and policy analysts, university and college teachers and their students.

One of the unique features of IAIA is the mix of professions represented, which provides outstanding opportunities for interchange: to advance the state of the art and science of impact assessment in applications ranging from local to global to develop international and local capability to anticipate, plan and manage the consequences of development to enhance the quality of life for all.

IAIA members now number more than 2,500 and represent more than 100 countries. Organizations are active in Brazil, Cameroon, Central and Eastern Europe, Japan, New Zealand, Nigeria, Ontario, Quebec, Senegal, South Africa, and the United States. International conferences are held annually. Regional conferences are organized to make information exchange and networking opportunities available to those who might not be able to attend the international conferences, as well as to focus attention to specific issues. Training programs are held regularly in conjunction with IAIA international conferences. These range from one day to one week in duration and deal with a variety of impact assessment issues.

IAIA's quarterly journal, Impact Assessment and Project Appraisal (IAPA), contains a variety of peer-reviewed research articles, professional practice ideas, and book reviews of recently published titles. IAPA provides a one-source link to the latest ideas in the wide-ranging field of impact assessment.

IAIA has entered into strategic partnerships with a number of national and international organizations. Among these are The Netherlands Association for Environmental Professionals (VVM), the World Bank, various United Nations organizations, the Canadian International Development Agency (CIDA), the U.S. Council on Environmental Quality (CEQ), and the Canadian Environmental Assessment Agency (CEAA). These partnerships have been mutually beneficial, enabling the IAIA to accomplish jointly a number of projects that the organization likely would not have been able to undertake alone.

IAIA activities seek to (1) develop approaches and practices for comprehensive and integrated impact assessment, (2) improve assessment procedures and methods for practical application, (3) promote training of impact assessment and public understanding of the field, (4) provide professional quality assurance by peer review and other means, and (5) share information networks, timely publications, and professional meetings.

For information about membership or answers to questions about IAIA, contact the International Headquarters, info@iaia.org.

International Headquarters
1330 23rd Street South, Suite C
Fargo, ND 58103 USA
Phone: 1-701-297-7908
Fax: 1-701-297-7917

International Clinical Epidemiology Network (INCLEN):
www.inclen.org
INCLEN comprises health specialists concerned with the availability, effectiveness and efficiency of health care in their home countries. Created in 1980 as a project of The Rockefeller Foundation, INCLEN has been an independent non-profit organization since 1988. For 21 years INCLEN has helped clinicians and other scientists obtain the knowledge and tools to improve the health of people in the developing world. Through carefully designed training and other support, INCLEN helps them critically to assess the factors that determine the most effective prevention and treatment strategies.

Today our membership includes 64 medical institutions in 26 countries throughout the world. The multi-disciplinary faculty includes clinical epidemiologists, health social scientists, biostatisticians, and clinical economists, each of whom believes that fighting disease in an age of limited financial resources depends on integrating the principles of clinical epidemiology into his or her practice.

INCLEN provides a forum for researchers to discuss critical health issues through educational programs, global meetings, and an international communications network. It supports young researchers and provides network members opportunities to participate in collaborative clinical studies. As a partnership of clinicians and health scientists who are trained to use and produce the best possible evidence in their medical decision making, INCLEN can have a profound impact on health care practices globally.

INCLEN, Inc. Office
1420 Walnut St., Suite 411
Philadelphia, PA 19102-4003, U. S. A.
inclen@inclen.org
Phone: 1-215-222-7700
Fax: 1-215-222-7741

International Society of Exposure Analysis (ISEA):
www.iseaweb.org
The International Society of Exposure Analysis (ISEA) was established in 1989 to foster and advance the science of exposure analysis related to environmental contaminants, both for human populations and ecosystems. The membership promotes communication among all disciplines involved in exposure analysis, recommends exposure analysis approaches to address substantive or methodological concerns, and works to strengthen the impact of exposure assessment on environmental policy.

Any individual with a professional interest in exposure analysis is invited to join. The Society seeks broad participation from various disciplines such as: exposure assessment, chemistry, biochemistry, risk assessment, biostatistics, physiology, toxicology, epidemiology, ecology, environmental engineering, and others. You may join by submitting an application and the annual membership fee to the Treasurer of the Society. Students and international professionals with an interest in exposure assessment are especially encouraged to join.

Upon joining, the ISEA, members are entitled to the following benefits: a one-year subscription to the Journal of Exposure Analysis and Environmental Epidemiology (6 issues); Increased opportunities for scientific exchange, through the ISEA's website and at the annual Scientific Conference and General Meeting; The quarterly ISEA newsletter; Voting privileges in election of officers/councillors.

Application forms can be downloaded from the ISEA website. They can then be printed, completed, and mailed to the following address.

International Society of Exposure Analysis
c/o JSI Research and Training Institute
44 Farnsworth Street
Boston, MA 02210-1211 USA
Phone: 617-482-9485 Fax: 617-482-0617

Copies of the application form from can be requested from carol_rougvie@jsi.com of JSI, Secretariat of ISEA. Please include a fax number to have the application form faxed to you.

International Society for Environmental Epidemiology (ISEE):
http://www.iseepi.org
The International Society for Environmental Epidemiology (ISEE) provides a forum for the discussion of problems unique to the study of health and the environment. With membership open to environmental epidemiologists and other scientists worldwide, ISEE provides a variety of forums for discussions, critical reviews, collaborations and education on issues of environmental exposures and their human health effects. These include annual meetings, newsletters, workshops and liaisons with academic, governmental, inter-governmental, non-profit and business institutions.

Topics addressed by ISEE members include environmental exposures (e.g. air pollution, hazardous waste, metals, pesticides, radiation), health effects (e.g. cancer, cardiovascular disease, neurological effects, reproductive effects), methodology (e.g. biomarkers, ecologic investigations, experimental design, exposure/dose assessment, meta-analysis, risk assessment, statistics), environment-gene interactions, and ethics and law.

To foster the study of health and the environment, ISEE encourages and supports the following:

- Epidemiological studies on the health effects of environmental exposures
- Communication among epidemiologists, toxicologists, exposure analysts, and other environmental scientists and moral philosophers worldwide
- Innovative approaches to substantive or methodological problems and applications of environmental epidemiology
- The use of environmental epidemiology to inform public policy
- Involvement of scientists from developing countries in ISEE activities, reduced dues for members from developing countries and establishment of regional ISEE chapters throughout the developing world (e.g., Central and Eastern Europe, Latin America and the Caribbean, and for the Eastern Mediterranean)

ISEE Secretariat, JSI Research & Training Institute
44 Farnsworth Street, Boston, Massachusetts, USA.
Contact: Carol Rougvie:
Telephone: +1-617-482-9485
Fax: +1-617-482-0617
Email: iseepi@jsi.com

A regional chapter for the Caucasus region had been established in Azerbaijan, providing an excellent opportunity for researchers in this region to have contact with a well-established and knowledgeable group of peers. For more information about this initiative, please contact:

Dr Samaya Ismayilova
6, Mushfig st., ap 4, Zeynalabdin set.
Sumgayit, 373263 Azerbaijan
Phone: 99 450 321 5676
Email: ismayilovasy@hotmail.com

Associazione Italiana di Epidemiologia (Italian Epidemiological Association):
http://www.epidemiologia.it/
One of the more active and pioneering epidemiological associations in the world.

For more information, please contact:

c/o CPO - Piemonte
Via San Francesco da Paola, 31 - 10123 TORINO
011-6333860 (dir)
011-6333863 (segr)
011-6333861 (fax)
segreteria.aie@cpo.it

International Opportunities for Study and Development
Erasmus Summer Programme:
www.erasmussummerprogramme.nl
To improve epidemiological expertise in all countries of Europe, and particularly those in Eastern Europe, the Netherlands Institute for Health Sciences (NIHES) offers limited fellowships to young, talented and motivated clinicians, epidemiologists and public health professionals to participate in the Erasmus Summer Programme.

The Erasmus Summer Programme comprises modules on biostatistics, clinical research, public health, genetics and epidemiology taught by leading international experts. The first week provides introductory courses, the second week is devoted to methodology courses and the third week offers advanced courses. It is possible to mix and match courses from different disciplines in order to design your own individual programme. Courses are held in the Erasmus MC, Rotterdam, the Netherlands. More information can be found on the website: http://www.nihes.nl.

United States Agency for International Development (USAID):
http://www.usaid.gov/
Human capacity development is a fundamental building block of any stable society. Education and training are required to enable full participation in community, national and global development. A nation's ability to contribute to the world economy, as well as to manage its own, is directly related to the development of its human resources.

The Center for Human Capacity Development is responsible for implementing the Agency's goal of "Building Human Capacity Through Education and Training". The Center provides field support, technical leadership and research to help nations and field missions improve education and training and to help develop stable, democratic countries with thriving market economies and healthy, well educated families.

The Center for Human Capacity Development has Strategic Objectives in the areas of:

- Basic Education
- Higher Education, Partnerships and Skills for Employment
- Telecommunications
- Training

For more information on these programs, see:
http://www.usaid.gov/our_work/education_and_universities/
USAID provides economic and humanitarian assistance around the world. It does this by administering the official United States Government bilateral assistance program. Each USAID-funded activity must meet a specific USAID strategic objective. This web site, and the individual USAID office in the country where it provides assistance, can provide you with more details about USAID programs. In some instances, specific USAID activities may include some training in order to achieve a specific goal or objective. This may or may not be the case in your home country. However, please note: USAID does not provide scholarships directly to individuals.

The following is a list of Internet resources regarding financial assistance or scholarships for international students, provided courtesy of USAID. Please see the respective websites for more information.

U.S. State Department, Bureau of Educational and Cultural Affairs (ECA):
http://exchanges.state.gov/education/
The Bureau of Educational and Cultural Affairs (ECA) fosters mutual understanding between the United States and other countries through international educational and training programs. The bureau does so by promoting personal, professional, and institutional ties between private citizens and organizations in the United States and abroad, as well as by presenting U.S. history, society, art and culture in all of its diversity to overseas audiences.

U.S. State Department, Bureau of Educational and Cultural Affairs
U.S. Department of State SA-44
301 4th Street, SW, Room 246
Washington, DC 20547
Telephone: 202-205-0525
Fax: 202-260-7985

The Association of International Educators (NAFSA):
http://www.nafsa.org/
NAFSA: Association of International Educators promotes the exchange of students and scholars to and from the United States. The Association sets and upholds standards of good practice and provides professional education and training that strengthen institutional programs and services related to international educational exchange. Additionally, they house publications on U.S. institutions of higher education and other sources that offer financial aid and possible sponsorships.

NAFSA: Association of International Educators
1307 New York Avenue, N.W., Eighth Floor
Washington, D.C. 20005-4701 USA
Telephone: 202-737-3699
Fax: 202-737-3657
inbox@nafsa.org

The National Science Foundation (NSF):
http://www.nsf.gov/home/int/
The National Science Foundation is an independent U.S. government agency responsible for promoting science and engineering through programs that invest over $3.3 billion per year in almost 20,000 research and education projects in science and engineering. Research and education in science and engineering benefit immensely from international cooperation. NSF enables and encourages U.S. scientists, engineers, and their institutions to avail themselves of opportunities to enhance their research and education programs through international cooperation. NSF also provides opportunities for future generations of U.S. scientists and engineers to gain the experience and outlook they will need to function productively in an international research and education environment. International Dimensions of NSF Research and Education, which documents highlights of accomplishments from NSF international activities, is now available.

The NSF supports international research and education through a variety of programs that include:

- Fellowships
- Travel grants
- Summer Institutes
- Workshops
- Research and education projects
- Antarctic projects

National Science Foundation
4201 Wilson Blvd.
Arlington, VA 22230 USA
Telephone: (703) 306-1234
http://www.nsf.gov

Interagency Working Group on U.S. Government-Sponsored International Exchanges & Training (IAWG):
http://www.iawg.gov
The purpose of the IAWG is to recommend measures for improving the coordination, efficiency, and effectiveness of United States Government-sponsored international exchanges and training.

Specifically, the IAWG is tasked to:

- establish a clearinghouse to improve data collection and analysis of international exchanges and training;
- promote greater understanding of and cooperation on common issues and challenges faced in conducting international exchanges and training programs;
- identify administrative and programmatic duplication and overlap of activities by the various United States Government agencies involved in government-sponsored international exchanges and training programs;
- develop a coordinated strategy for all government-sponsored international exchanges and training programs;
- develop recommendations on performance measures for all United States Government-sponsored international exchanges and training programs;
- develop strategies for expanding public and private partnerships in, and leveraging private sector support for, United States Government-sponsored international exchanges and training activities.

Interagency Working Group on U.S. Government-Sponsored
International Exchanges and Training
301 4th Street, SW, Room 320
Washington, DC 20547
Telephone: 202-260-5124
Fax: 202-260-5122
Email: IAWGMail@pd.state.gov

The World Bank/Joint Japan Graduate Scholarship Program (WBGSP):
www.worldbank.org
In l987, the World Bank, with funding from the Japanese Government established the World Bank Graduate Scholarship Program (WBGSP) for graduate studies in subjects related to economic development. This program awards scholarships to individuals from World Bank member countries to undertake graduate studies at universities renowned for their development research and teaching.

More information is available at http://www.worldbank.org/wbi/scholarships/

The World Bank Joint Japan/World Bank Graduate Scholarship Program
1818 H Street, NW - MSN J4-402
Washington, DC 20433 USA
Telephone.: 202-473-6849:
Fax: 202-522-4036
Email: jjwbgsp@worldbank.org

National Security Education Program (NSEP),
Academy for Educational Development:
www.aed.org
Every year, AED administers a range of programs that expand the horizons of their participants through support of education and intercultural exchange. It administers:

- professional exchange programs for visitors from around the world;
- fellowships for U.S. graduate students to study the languages and cultures of countries not typically studied;
- fellowships for minority students pursuing careers in public service; and
- fellowships to develop leadership capacity in NGOs.

More information is available at
http://www.aed.org/Education/
AED Headquarters
1825 Connecticut Ave., NW
Washington, D.C. 20009-5721
Tel. 202-884-8000
Fax 202-884-8400
admindc@aed.org

(Note: A selection, likely incomplete)

Bill & Melinda Gates Foundation:
www.gatesfoundation.org
The Bill & Melinda Gates Foundation is dedicated to improving people's lives by sharing advances in health and learning with the global community. The foundation was created in January of 2000, through the merger of the Gates Learning Foundation, which focused on expanding access to technology through public libraries, and the William H. Gates Foundation, which focused on improving global health. Led by Bill Gates' father, William H. Gates, Sr., and Patty Stonesifer, the Seattle-based foundation has an endowment of approximately $24 billion.

Of particular relevance to readers of this textbook is the Global Health Program, which directs its resources to:

- Promote research and development of health technologies that will accelerate prevention, elimination or eradication of diseases, as well as increase their affordability in low-resource settings
- Support programs that demonstrate effectiveness and feasibility of wide scale implementation of innovative health interventions, allowing other organizations and governments to confidently invest in similar models
- Encourage sustainable access by developing countries to existing and future health technologies interventions through catalytic financing mechanisms
- Increase visibility of effective public health approaches and strengthen support for public health leadership in developing countries

The Global Health Program provides funding in three major priority areas: 1) Infectious Diseases; 2) HIV/AIDS and Tuberculosis; and 3) Reproductive and Child Health. Organizations working within these priority areas may submit a Letter of Inquiry. Please note that the foundation does not accept unsolicited proposals. Initiatives selected for funding will be those which, to the greatest extent possible:

- Address important disease burdens in the poorest countries;
- Offer an opportunity to achieve leverage, catalyzing a larger response or mobilizing new resources to improve health;

- Form creative partnerships or coalitions to achieve project objectives;
- Have global relevance or provide results which transcend any country or regional focus;
- Result in measurable benefits to impoverished groups;
- Focus on interventions with high potential cost-effectiveness; and,
- Ensure broad dissemination and utilization of results and lessons learned.

Current priorities do not include the following:

- Construction or procurement of equipment for health facilities or research laboratories;
- Endowments or core funding to support institutions;
- Support for recurrent costs of personnel or health service delivery;
- Interventions that will provide substantial or earlier health benefits for industrialized countries; and
- Support for ongoing programs.

Letters of inquiry may be submitted electronically (info@gatesfoundation.org) or by mail (Grants Inquiry Coordinator, P.O. Box 23350, Seattle, WA 98102 USA).

Canadian International Development Agency (CIDA):
www.acdi-cida.gc.ca
CIDA supports sustainable development activities in order to reduce poverty and to contribute to a more secure, equitable and prosperous world. Development is a complex, long-term process that involves all of the world's people, governments and organizations at all levels. Working with partners in the private and public sectors in Canada and in developing countries, and with international organizations and agencies, CIDA supports foreign aid projects in more than 100 of the poorest countries of the world. The objective is to work with developing countries and countries in transition to develop the tools to eventually meet their own needs.

CIDA has Program Branches for each of the following areas:
http://www.acdi-cida.gc.ca/cidaweb/acdicida.nsf/En/JUD-112911223-LTK

- Africa and the Middle East
- La Francophonie
- Americas
- Asia
- Canadian Partnership
- Central and Eastern Europe
- Multilateral

Canadian International Development Agency
200 Promenade du Portage
Hull, Quebec
K1A 0G4
Tel: 1-819-997-5006
Fax: 1-819-953-6088
E-mail: info@acdi-cida.gc.ca

Country Analytic Work (CAW):
http://www.countryanalyticwork.net
The CAW website has been developed to facilitate coordination and cooperation among countries and donors with goals toward improving development impact and cost-effectiveness for both capacity building and knowledge sharing. Country analytic work encompasses the analysis and advice necessary to strengthen policy dialogue, develop and implement country strategies, and carry out sound lending operations. Through an active exchange of information, all partners stay up to date on development challenges and successes in a particular country or region with the benefit of common thematic activities and diverse opinions.

The CAW website provides:

- a Document Library with access to project documents from partner agencies;
- Contact Points for the agency people with whom to communicate;
- Main Product Toolkits for the main diagnostic products;
- Procedures for conducting analytic work; and
- Examples of Best Practices; plus more to explore.

The partners who maintain the CAW website are committed to expanding inter-agency cooperation on country analytic work in various areas. CAW believes that its active participation in this knowledge sharing exercise will improve its capacity to serve client's needs for technical assistance and policy reform as well as provide the general public with insight as to how it performs its work. For more information on CAW's Partner Agencies, please visit the "Partners" page on the website.

An extensive list of contacts is available on the website.

Danish International Developmental Assistance (DANIDA):
www.ngo.dk
Danish International Developmental Assistance (DANIDA) is the part of the Danish Ministry of Foreign Affairs which administrates the Danish development aid.
Compared to its size, Denmark is one of the biggest donors of development aid in the world. The developmental aid amounts to more than 1% of the Gross National Product (GNP). The aid for the year 2000 equivalents 12 billion Danish crowns (1.5 billion US dollars). The money is not only used on developmental projects, but also on emergency aid, information activities in Denmark, and cultural co-operation and exchange etc. A large part of the aid is managed by the Danish non-governmental organizations (NGOs).

On the website, you can find information in English about the Danish organizations that work in and with third world countries. On the website you can find the large and the small, the known and the unknown, the national and the non-governmental organizations. The website is a catalogue of Danish organizations, initiatives, and research centres from Danish Red Cross, and DANIDA, to the Danish Centre for Human Rights and Bicycles For Senegal. Ngo.dk is produced by u-land.dk. U-land.dk is open to all Danish organizations that want to make active use of the projects that the association develops. The organizations that you can find in ngo.dk's database are responsible for updating the information, which can be accessed on http://www.u-land.dk

For questions or criticism please contact:
Helle Jardenna Lyhne, helle@u-land.dk
Borgergade 14, 1
DK1300 Copenhagen K, Denmark
Phone: (+45) 77 31 01 22
E-mail: u-land@u-land.dk

Department for International Development (DFID):
http://www.dfid.gov.uk/
DFID can provide assistance in response to natural and technological disasters anywhere outside the UK. Other humanitarian assistance including the response to complex political emergencies is limited to developing countries and the countries in transition of Central and Eastern Europe and Central Asia.

DFID's emergency funds are available for:

- Rapid onset disaster relief (definition at Annex D)
- Gradual onset disaster response
- Complex political emergencies, technological, or natural disasters
- Natural and technological disaster preparedness, prevention and mitigation
- Post disaster repair and rehabilitation
- Conflict preparedness, prevention and reduction, and mitigation
- Policy and institutional development, including monitoring and evaluation, training and research in all the above areas
- Geographical range

Registered charities, and other established bodies (such as academic institutions and companies) in UK, rest of Europe, and elsewhere are eligible to receive DFID emergency aid funds. Also eligible are inter-governmental bodies and agencies of the United Nations and Red Cross/Red Crescent systems.

Correspondence to the Secretary of State and Parliamentary Under-Secretary of State, and to DFID senior management, should be sent to:

DFID, 1 Palace Street, London SW1E 5HE, United Kingdom
Telephone: 44 (0) 20 7023 0000 (Switchboard)
Fax: 44 (0) 20 7023 0019
Email: enquiry@dfid.gov.uk

Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ):
www.gtz.de
The Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ) GmbH is a government-owned corporation for international cooperation with worldwide operations. GTZ's aim is to positively shape the political, economic, ecological and social development in our partner countries, thereby improving people's living conditions and prospects. Through the services it provides, GTZ supports complex development and reform processes and contributes to global sustainable development.

The GTZ was founded in 1975 as a corporation under private law. The German Federal Ministry for Economic Cooperation and Development (BMZ) is its main financing organization. GTZ also undertakes commissions for other government departments, for governments of other countries, for international clients such as the European Commission, the United Nations or the World Bank, as well as for private-sector corporations. The GTZ operates on a public-benefit basis. Any surpluses are exclusively rechanelled into its own development-cooperation projects.

The organization has more than 10,000 employees in around 130 countries of Africa, Asia, Latin America, in the Eastern European countries in transition and the New Independent States. Around 8,500 are locally-contracted nationals ("national personnel"). The GTZ maintains its own field offices in 63 countries. Some 1,000 people are employed at Head Office in Eschborn near Frankfurt am Main.

To contact Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ) GmbH:
Mail: l Dag-Hammarskjöld-Weg 1-5 l 65760 Eschborn
Telephone: 49/(0)6196/79-0 l Fax: 49/(0)6196/79-1115

Or fill out the online contact form at:
http://www.gtz.de/en/kontakt/684.htm

European Bank for Reconstruction and Development (EBRD):
http://www.ebrd.org/
The European Bank for Reconstruction and Development was established in 1991 when communism was crumbling in Central and Eastern Europe and ex-soviet countries needed support to nurture a new private sector in a democratic environment. Today the EBRD uses the tools of investment to help build market economies and democracies in 27 countries from central Europe to central Asia.

The EBRD is the largest single investor in the region and mobilises significant foreign direct investment beyond its own financing. It is owned by 60 countries and two inter-governmental institutions. But despite its public sector shareholders, it invests mainly in private enterprises, usually together with commercial partners.

It provides project financing for banks, industries and businesses, both new ventures and investments in existing companies. It also works with publicly owned companies, to support privatisation, restructuring state-owned firms and improvement of municipal services. The Bank uses its close relationship with governments in the region to promote policies that will bolster the business environment. The mandate of the EBRD stipulates that it must only work in countries that are committed to democratic principles. Respect for the environment is part of the strong corporate governance attached to all EBRD investments.

Every EBRD investment must

- Help move a country closer to a full market economy: the transition impact
- Take risk that supports private investors and does not crowd them out
- Apply sound banking principles

Through its investments, the EBRD promotes

- Structural and sectoral reforms
- Competition, privatisation and entrepreneurship
- Stronger financial institutions and legal systems
- Infrastructure development needed to support the private sector
- Adoption of strong corporate governance, including environmental sensitivity

Functioning as a catalyst of change, the EBRD

- Promotes co-financing and foreign direct investment
- Mobilises domestic capital
- Provides technical assistance

Contact Information:

EBRD Headquarters
One Exchange Square
London EC2A 2JN, United Kingdom
Switchboard Telephone: +44 20 7338 6000
Central Fax: +44 20 7338 6100
Telex: 8812161 EBRD L G
SWIFT: EBRDGB2L

General enquiries about the Bank:
Tel: +44 20 7338 6372
Fax: +44 20 7338 6690
Email: generalenquiries@ebrd.com

European Community (EC):
http://europa.eu.int/
The EC has a number of programmes and activities designed to facilitate development, including:

- Europe Aid: http://europa.eu.int/comm/europeaid/projects/
  - Contained here is a list of projects and programmes of Europe Aid, sorted by countries, geographic regions, and themes.
  - For more information on Europe Aid, please see the following FAQ (frequently asked questions) webpage: http://europa.eu.int/comm/europeaid/general/faq_en.htm
  - An example of one such programme for Eastern Europe is the Tacis Programme
- Tacis Programme: http://europa.eu.int/comm/europeaid/projects/tacis/index_en.htm
  - The EU's relations with the countries of Eastern Europe and Central Asia (EECA) were underpinned in 1991 through a programme of technical assistance called Tacis. The Programme supports the process of transition to market economies and democratic societies in the EECA countries, and in the first eight years of its operating, committed a total of Euro 4,226 million of funding to projects.

Until the end of 2006, its focus was on key areas of activity in the region, namely:

- Support for institutional, legal and administrative reform.
- Support for the private sector and assistance for economic development.
- Support for addressing the social consequences of transition.
- Development of infrastructure networks.
- Nuclear safety.
- Promotion of environmental protection and management of natural resources.
- Development of the rural economy.

The programme is multi-faceted and over time a number of special sub programmes have been developed. At any given time there are hundreds of on-going projects across all sectors, countries and regions, some examples of which are available as case studies. The countries covered by the European Union's co-operation programmes in Eastern Europe and Central Asia are: Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Mongolia, Russian Federation, Turkmenistan, Tajikistan, Ukraine and Uzbekistan.

General information on the European Commission is available as follows:
Telephone: 00 800 678 91011
E-mail: mail@europe-direct.cec.eu.int

An extensive list of contacts for each of EC's associated agencies can also be found on the website.

The Hewlett-Packard Corporation (HP):

www.hp.com

The Hewlett-Packard Corporation provides funding for a number of philanthropic objectives in different regions of the world. One of these development regions is Europe, Middle East, and Africa (EMEA). The goal of the EMEA Program is to help fulfil Hewlett-Packard's citizenship objectives through a sustained, conscientious program of corporate giving that addresses long-term societal needs while earning goodwill and respect for the company.

Some of the objectives include:

- to improve the quality of education with emphasis on the science, engineering fields;
- to accelerate the process of innovation in teaching curricula, and helping with scientific and technical discovery in the public domain;
- to support initiatives addressing societal needs (disadvantaged minorities, handicapped people).

These objectives are achieved through the following means:

- grant programs
  - o preference is given to equipment grants which have a clear philanthropic intent within the program goals described above.
  - o grantees must be non-profit or educational institutions, request from individuals are not considered
- digital community Centres and digital villages
  - o they are created on an on-going basis to help underserved communities in Europe, Middle-East and Africa to access education through information technologies.

Contact information and grant applications for non-profit institutions or organizations in the regions of Europe, Middle East, and Africa are available on the HP website: http://government.hp.com/grants.asp?agencyid=136

For more information, email HP at philanthropy_ed@hp.com.

International Development Research Centre (IDRC), Canada:
http://www.idrc.ca/

The International Development Research Centre (IDRC) is a public corporation created in 1970 to help developing countries find long-term solutions to the social, economic, and environmental problems they face. IDRC's mandate is to initiate, encourage, support, and conduct research into the problems of the developing regions of the world and into the means for applying and adapting scientific, technical, and other knowledge to the economic and social advancement of those regions.

IDRC's objectives:

- to assist scientists in developing countries to identify sustainable long-term, practical solutions to pressing development problems.
- to mobilize and strengthen the research capacity of developing countries, particularly capacity for policies and technologies that promote healthier and more prosperous societies, food security, biodiversity, and access to information.
- to develop links among developing-country researchers, and provide them access to the results of research around the globe, in particular through developing and strengthening the electronic networking capacity of institutions in developing countries that receive IDRC funding.
- to ensure that the products from the activities it supports are used by communities in the developing world, and that existing research capacity is used effectively to solve development problems.

To achieve these objectives, IDRC funds the work of scientists working in universities, private enterprise, government, and nonprofit organizations in developing countries and provides some support to regional research networks and institutions in the Third World. This support is designed to build a corps of researchers in each country and to help develop the networks of people and institutions that can undertake effective research and use the results of research to effect change.

For more information, please contact info@idrc.ca

The Rockefeller Foundation:
www.rockfound.org
The Rockefeller Foundation is a knowledge-based global foundation with a commitment to enrich and sustain the lives and livelihoods of poor and excluded people throughout the world. In order to maximize its resources and leverage the Foundation's strengths, grant-making is organized around four thematic lines of work:

- Creativity & Culture
- Food Security
- Health Equity
- Working Communities
- A cross-theme of Global Inclusion supports, promotes, and supplements the work of the above themes.

The Foundation makes grants according to four program themes and one cross-theme, which are areas of grant-making. Each theme and cross-theme has a program strategy. The grants are organized in these categories: by themes, cross-theme, Regional Programs and Special Programs (which includes Global Philanthropy, Next Generation Leadership, Population and the Cairo Agenda, Communication for Social Change and Other Grants).

The Foundation is a proactive grant-maker-that is, the staff seek out opportunities that will advance the Foundation's long-term goals rather than reacting to unsolicited proposals. Foundation staff receive more than 12,000 unsolicited proposals each year, more than 75 percent of which cannot be considered because their purposes fall outside the Foundation's program guidelines.

The Foundation strongly discourages unsolicited grant proposals. The Rockefeller Foundation does not use an application form or standard format for proposals. Organizations seeking funding should carefully review the Foundation's grant-making guidelines included in this publication or visit the Foundation's Web site at www.rockfound.org to determine if their project conforms to the Foundation's strategic interests. Only then should organizations send a short letter of inquiry addressed to the director of the subject area of interest.

Inquiries can also be sent electronically to the e-mail addresses listed for each of its working themes. Letters of inquiry should briefly describe the purpose of the project for which funds are being requested; the issues the proposed project will address; information about the organization; estimated budget and period for which funds are being requested; and qualification of key personnel involved in the project. Please do not send attachments.

Letters of inquiry will be considered as they are received throughout the year. Inquiries take from six to eight weeks for review. Organizations submitting inquiries that are of interest to the Foundation may be asked to submit a proposal. It is important to note that, as a matter of policy, the Foundation does not give or lend money for personal aid to individuals or, except in rare cases, provide general institutional support, fund endowments, or contribute to building and operating funds.

Rockefeller Foundation,
420 Fifth Avenue, New York, N.Y. 10018.
Fax: (212) 852-8441
Email: csc@rockfound.org,

Soros (Soros Foundations Network):
www.soros.org
The Soros Foundations Network includes Soros Foundations that operate in individual countries or regions; the Open Society Institute (OSI) and its offices; OSI initiatives supporting the work of the Soros foundations; and U.S. Programs, which are initiatives that operate in the United States only. Its foundations and initiatives operate in more than 50 countries in Central and Eastern Europe, the former Soviet Union, Africa, Asia, and the Americas. Its annual reports include in-depth information about the entire organization.

The goal of the Soros foundations network throughout the world is to transform closed societies into open ones and to protect and expand the values of existing open societies. The concept of open society is, at its most fundamental level, based on the recognition that people act on imperfect knowledge and that no one is in possession of the ultimate truth. In practice, an open society is characterized by the rule of law; respect for human rights, minorities, and minority opinions; democratically elected governments; a market economy in which business and government are separate; and a thriving civil society.

In pursuit of the Soros foundation network's mission, OSI and the foundations established and supported by George Soros seek to strengthen open society principles and practices against authoritarian regimes and the negative consequences of globalization. The Soros network supports efforts in civil society, education, media, public health, and human and women's rights, as well as social, legal, and economic reform.

During most of the 1990s, the Soros Foundations network developed in the former Soviet empire, helping countries in transition from authoritarian rule build open, democratic societies. Over the past several years, it has expanded its geographical horizons to other parts of the world. Together with partners that share its principles and goals, the network is laying the foundation for a truly global alliance for open society.

More information on applying for Soros funding can be obtained on the Soros webpage under the "Grants" link. Here, persons can generate grant inquiries at a country-specific level, view lists of previously awarded grants, and obtain applications for a select number of Soros programs.

Contact information for individual programs and regions of the world are available on the Soros website: http://www.soros.org/minidir/index.html#National%20Foundations. For more general information on Soros, persons can contact the Office of Communications at the Open Society Institute in New York by telephone at 212-548-0668 or visit the website www.soros.org.

United Nations Development Programme (UNDP):
www.undp.org
UNDP is the United Nations' global development network, advocating for change and connecting countries to knowledge, experience and resources to help people build a better life. UNDP is on the ground in 166 countries, working with them on their own solutions to global and national development challenges. As they develop local capacity, they draw on the people of UNDP and UNDP's wide range of partners. World leaders have pledged to achieve the Millennium Development Goals, including the overarching goal of cutting poverty in half by 2015. UNDP's network links and coordinates global and national efforts to reach these Goals. UNDP's focus is helping countries build and share solutions to the challenges of:

- Democratic Governance
- Poverty Reduction
- Crisis Prevention and Recovery
- Energy and Environment
- Information and Communications Technology
- HIV/AIDS

UNDP helps developing countries attract and use aid effectively. In all UNDP activities, the organization promotes the protection of human rights and the empowerment of women. More general information about the UNDP can be found on the Frequently Asked Questions (FAQ) section of the website: http://www.undp.org/faq

Contact information for the UNDP:
One United Nations Plaza
New York, NY 10017, USA
Tel: (212) 906-5558
Fax: (212) 906-5364

UNDP has its headquarters in New York City, but cooperates with governments and peoples largely in developing countries throughout the world. It works through its offices in more than 130 countries. For country-specific information on the worldwide work of the UNDP, or for contact information, please visit the UNDP Country Office Websites at: http://www.undp.org/countries/

United Nations Fund for International Partnerships (UNFIP):
http://www.un.org/unfip/flash/index.html
The mission of UNFIP comprises two mutually reinforcing tasks:

- To serve as the interface between the United Nations Foundation (UNF) and the United Nations system by:
  - Supporting the development of high-impact programmes and projects from United Nations organizations
  - Encouraging innovative partnerships between the United Nations and civil society.

- To promote new United Nations partnerships and alliances with a variety of sources, including companies and foundations, as well as bilateral and multilateral donors, in furtherance of the Millennium Development Goals. Working with the Office of the Secretary-General and the Deputy Secretary-General, UNFIP facilitates partnerships with the private sector by:
  - Providing one-stop shopping for partnership opportunities with the United Nations family
  - Facilitating access to the United Nations system, including by providing advice on United Nations processes, best practices and lessons learned.

UNF and UNFIP support projects to better achieve the Millennium Development Goals in four priority areas: children's health, population and women, environment, and peace security and human rights.

- The Children's Health Programme supports the United Nations' approach to enhance global public health systems through preventive interventions. Its areas of concentration are the eradication of polio and other infectious diseases; the prevention of tobacco use; and the reduction of child mortality by strengthening health systems and community initiatives, micronutrient interventions, and through the prevention of mother-to-child transmission of HIV/AIDS and the reduction of measles mortality.
- The Population and Women Programme supports United Nations efforts to improve the quality of sexual and reproductive health. Programme activities also focus

on encouraging significant social and economic progress for adolescent girls and women, increasing their educational and employment opportunities as well as improving the quality and availability of reproductive and sexual health care.

- The Environment Programme fosters renewable energy and energy efficiency projects to combat climate change in developing nations and supports long-term initiatives to protect the world's biodiversity.
- The Peace, Security and Human Rights Programme promotes integrated structural approaches to conflict prevention while also strengthening the United Nations' central position in the cause of human rights.

Project proposals are submitted to the UNFIP Advisory Board, chaired by the United Nations Deputy Secretary-General. The Advisory Board's recommendations are submitted to the UNF Board of Directors for consideration. The UNF Board makes final decisions regarding project approval and funding amounts. As of December 2001, UNF/UNFIP have programmed over $420 million for a total of 223 projects distributed in 124 countries. These projects are implemented by more than 30 United Nations entities.

UNFIP accepts proposals from the United Nations' system only. However, in line with the Secretary-General's approach to engage all the actors, UNFIP and UNF are strongly interested in involving civil society, including the private sector and encourage them to contact appropriate United Nations agencies, funds and programmes to enter into partnership. The UNFIP Advisory Board and the UNF Board of Directors meet twice each year, to consider proposals for funding in specific thematic areas. A proposal would need to be received by UNFIP at least two months prior to the board meetings. Programme development schedules are issued in January and July with specific indications of the thematic focus and deadlines to facilitate timely project development and submission.

Please see the website for more information.

United States Agency for International Development (USAID):
http://www.usaid.gov/
The United States has a long history of extending a helping hand to those people overseas struggling to make a better life, recover from a disaster or striving to live in a free and democratic country. U.S. foreign assistance has always had the twofold purpose of fur-

thering America's foreign policy interests in expanding democracy and free markets while improving the lives of the citizens of the developing world. Spending less than one-half of 1 percent of the federal budget, USAID works around the world to achieve these goals.

USAID is an independent federal government agency that receives overall foreign policy guidance from the Secretary of State. The agency works to support long-term and equitable economic growth and advancing U.S. foreign policy objectives by supporting:

- economic growth, agricultural and trade;
- global health; and,
- democracy, conflict prevention and humanitarian assistance.

It provides assistance in four regions of the world:

- Sub-Saharan Africa
- Asia and the Near East
- Latin America and the Caribbean
- Europe and Eurasia

With headquarters in Washington, D.C., USAID's strength is its field offices around the world. USAID works in close partnership with private voluntary organizations, indigenous organizations, universities, American businesses, international agencies, other governments, and other U.S. government agencies. USAID has working relationships with more than 3,500 American companies and over 300 U.S.-based private voluntary organizations.

For more information, visit the USAID FAQ:
http://www.usaid.gov/faqs.html
Or use the online contact form: http://www.usaid.gov/public_inquiries.html

U.S. Agency for International Development Information Centre
Ronald Reagan Building
Washington, D.C. 20523-1000
Telephone: 202-712-4810
Fax: 202-216-3524

For information about scholarships or internships, please read this information first.
http://www.usaid.gov/careers/studentprograms.html

World Bank:
www.worldbank.org
The World Bank is one of the world's largest sources of development assistance. Its primary focus is on helping the poorest people and the poorest countries. The World Bank website provides an overview of how the Bank uses its financial resources, its highly trained staff, and its extensive knowledge base to help developing countries onto paths of stable, sustainable, and equitable growth. In 2002 the World Bank provided $19.5 billion to developing countries and worked in more than 100 developing economies, bringing finance and/or technical expertise toward helping them reduce poverty.

The World Bank works to bridge economic divides among nations and turn rich country resources into poor country growth. One of the world's largest sources of development assistance, the World Bank provides financing that supports efforts of developing country governments to build schools and health Centres, provide water and electricity, fight disease, and protect the environment.

The World Bank is not a bank, but rather a specialized agency. The World Bank is not a "bank" in the common sense. It is one of the United Nations' specialized agencies, and is made up of 184 member countries. These countries are jointly responsible for how the institution is financed and how its money is spent. The "World Bank" is the name that has come to be used for the International Bank for Reconstruction and Development (IBRD) and the International Development Association (IDA), a trust fund managed by the IBRD to provide grants and interest-free credits to the world's poorest countries. Together these organizations provide low-interest loans, interest-free credit, and grants to developing countries.

Headquarters - General Inquiries
The World Bank
1818 H Street, N.W.
Washington, DC 20433 U.S.A.
Telephone: (202) 473-1000
Fax: (202) 477-6391
Electronic messages can be sent to the World Bank through the
"Feedback" service, at the following web address:
http://lnweb18.worldbank.org/institutional/EFeedBk.nsf/MainTopic

(Note: A selection, likely incomplete)

British Overseas NGOs for Development (BOND):
http://www.bond.org.uk/index.html
BOND is the United Kingdom's broadest network of voluntary organizations working in international development (often called non-governmental organizations, or NGOs). BOND was founded in June 1993, on the initiative of 61 NGOs, and now has over 270 members. It is officially recognised by the UK government's Department for International Development (DFID).

BOND aims to improve the UK's contribution to international development by promoting the exchange of experience, ideas and information amongst BOND members between networks of NGOs in the UK and internationally with the UK government between BOND members and other UK bodies with an interest in international development. To support this work, BOND manages training, advocacy and information services.

The website also contains a number of useful links to other NGOs and development organizations: http://www.bond.org.uk/eu/weblinks.html

To contact BOND:
Regent's Wharf, 8 All Saint's Street
London N1 9RL
Tel: 020 7837 8344
Fax: 020 7837 4220
For all general enquiries: bond@bond.org.uk
For information about BOND publications: information@bond.org.uk
For training and event enquiries: lgoulei@bond.org.uk

David Suzuki Foundation (DSF):
www.davidsuzuki.org
The David Suzuki Foundation works through science and education to protect the balance of nature and our quality of life, now and for future generations. These goals are worked toward through three major methods:

- Research

DSF seeks out and commissions the best, most up-to-date research to help reveal ways we can live in balance with nature.

- Application

DSF supports the implementation of ecologically sustainable models - from local projects, such as habitat restoration, to international initiatives, such as better frameworks for economic decisions.

- Education

DSF works to ensure the solutions developed through research and application to reach the widest possible audience, and help mobilize broadly supported change.

David Suzuki Foundation:
Suite 219, 2211 West 4th Avenue
Vancouver, BC V6K 4S2 Canada
Phone: (604) 732-4228,
Fax: (604) 732-0752
E-mail: solutions@davidsuzuki.org

European Consumer Safety Association (ECOSA):

www.ecosa.org

ECOSA was established in 1985 as a non-profit organization to promote consumer safety. The founding members were senior representatives of governmental and non-governmental organizations with expertise in the field of product safety and the promotion of home and leisure safety. At present, the Association consists of 60 members, representing governmental departments (including consumer protection agencies), medical and research institutes, trade and business representatives, and consumer organizations.

ECOSA's mission is to provide a forum to discuss and analyse consumer safety matters among a diverse group of interested parties at national and international levels, both governmental and non-governmental. The Association promotes an exchange of knowledge and experience among experts and institutes, with the goal of improving home, leisure, and product safety. ECOSA stimulates and promotes scientific research and educational programs and advises national authorities and (inter)national interest groups on activities related to product safety within the field of home and leisure accident prevention. (Drugs, foodstuffs and motor vehicles are dealt with by other agencies).

ECOSA's principle aim is to put consumer safety policy on the primary agenda of national and European authorities, whereby national action programmes for consumer safety are implemented in each European country. The ultimate objective of these programmes is to reduce the number of injuries and deaths due to home and leisure accidents by 25% in the first two decades of the 21st century.

See the ECOSA website for more information.

European Forum on International Cooperation (EUFORIC):
http://www.euforic.org/
Europe's Forum on International Cooperation - Euforic - is the focal point on the Internet and beyond for communities involved in Europe's international cooperation. More and more organizations use Euforic as the platform for debating topical issues and highlighting their latest information. It is a powerful answer to the need for more transparency on Europe's international cooperation, as Euforic improves the access to scattered information on the Internet, and brings people together.

Euforic focuses on European development cooperation policies and related issues. The website contains a wealth of information of various kinds and in different languages. The main audiences are experts and students in development issues from all over the world. Several thousands of documents are presented in full text. Other types of information - such as a calendar of activities, directories, country specific information and discussions - complete the broad spectrum of Euforic's content.

Electronic conferencing is becoming increasingly important today. As a multi-actor forum, Euforic is the ideal place for discussions to take place, thus facilitating dialogue between the various actors in Europe's international cooperation. Euforic stimulates further coordination of Europe's policy on international cooperation, and supports the involvement of the actors in the South.

Euforic is an independent non-profit Cooperative owned by the members who influence its development and orientation. Membership is open to any organization that is committed to sharing information, and has shown itself to be contributing to the aims of international cooperation. Current members include leading research organizations, NGOs, advisory groups, governmental agencies and NGO networks. The variety and standing of the organizations involved ensures that Euforic offers visitors quality information on the key debates in the sector and guarantees the strength of the basic concept of Euforic. A great deal of information is available on the Euforic website, including an extensive listing of (primarily European) NGOs.

To contact Euforic:
Post: Wycker Grachtstraat 38, 6221 CX Maastricht, The Netherlands
Telephone: +31 43 3285 180
Fax: +31 43 3285 185
E-mail: info@euforic.org

Friends of the Earth (FOEI):
http://www.foei.org
Friends of the Earth International is a federation of autonomous environmental organizations from all over the world. FOEI members, in 68 countries, campaign on the most urgent environmental and social issues at present, while simultaneously catalyzing a shift toward sustainable societies.

Friends of the Earth International Secretariat
PO Box 19199, 1000 GD Amsterdam, The Netherlands
Telephone: 31 20 622 1369
Fax: 31 20 639 2181

European Public Health Association (EUPHA):
www.eupha.org
See Toolkit №2: Professional Organizations and International Opportunities for Environmental Epidemiologists for more information.

Greenpeace:
www.greenpeace.org
Greenpeace is a non-profit organization, with a presence in 40 countries across Europe, the Americas, Asia and the Pacific. To maintain its independence, Greenpeace does not accept donations from governments or corporations but relies on contributions from individual supporters and foundation grants. As a global organization, Greenpeace focuses on the most crucial worldwide threats to our planet's biodiversity and environment.

Greenpeace organises public campaigns for:

- The protection of oceans and ancient forests.
- The phase out of fossil fuels and the promotion of renewable energy to stop climate change.
- The elimination of toxic chemicals .
- The prevention of genetically modified organisms being released into nature.
- An end to the nuclear threat and nuclear contamination.
- Safe and sustainable trade.

Greenpeace is committed to the principles of non-violence, political independence and internationalism. In exposing threats to the environment and in working to find solutions, Greenpeace has no permanent allies or enemies. It exists to expose environmental criminals, and to challenge government and corporations when they fail to live up to their mandate to safeguard the environment and the future.

Greenpeace International
Keizersgracht 176
1016 DW Amsterdam, The Netherlands
Telephone: +31 20 523 62 22
Fax: +31 20 523 62 00
Email: supporter.services@ams.greenpeace.org

International Research and Information Network on Children's Health, Environment, and Safety (INCHES):
www.inchesnetwork.org
INCHES is a global network of people and organizations interested in promoting the protection of children from environmental and safety hazards. INCHES represents many interests and will speak from the experience and expertise of members of the network, of science and of the best practices in policies and programmes. Promoting children's health requires protecting them from harmful environmental exposures. These exposures include: harmful physical, chemical and biological microorganisms and pollutants in water, air, soil and food.

INCHES will disseminate information and initiate research on the relationship between environmental factors and child health. Solid facts and good examples will be made easily available on the Internet as the network develops. Parents, researchers and scientists, children's organizations, children themselves are all potential partners with a stake in INCHES.

Children are more susceptible to environmental hazards than previously thought. Children are in a dynamic state of growth, as many vital systems such as the nervous, immune, and respiratory systems are not fully developed at birth. Because children are still developing, exposure to environmental hazards may result in disruption of their normal development and may cause damage.

Peter van den Hazel, M.D., M.P.H.
Dutch Association of Environmental Medicine
President ISDE
P.O.Box 163
6950 AD Dieren
The Netherlands
tel. +31 26 3773915
fax +31 26 3773847
E-mail: P.J.van.den.Hazel@inter.NL.net

International Society of Doctors for the Environment (ISDE):
www.isde.org
ISDE is an environmental NGO of medical doctors. It is an independent, non-governmental non-profit organization. It was created on 25 November 1990 and has now national and regional member organizations in over 35 countries. Physicians from these countries are invited to join their national organizations; physicians from other countries are invited to join as direct members. The Executive Office of ISDE is located in Switzerland. ISDE also has a scientific office, which coordinates research, information and training activities.

Doctors for the Environment includes family doctors, researchers, clinicians, as well as specialists of all branches who are only too aware of the ecological problems impinging on our health and safety and who strive to promote healthier lifestyles. ISDE members are professionals, who in the face of growing pollution and environmental decay, are concerned about the rise in incidence of pathological conditions related to environmental degradation, and are resolved to offer to our patients not only an answer in terms of medical care, but to also advocate, initiate and promote effective preventative actions. This goal is the foundation of ISDE, and since its inception many doctors have joined.

The main purpose of ISDE is to help defend our environment both locally and globally to prevent numerous illnesses, ensure the necessary conditions for health, and improve the quality of life. In order to safeguard the health of this generation and of future ones, care for the environment is essential.

ISDE was established as a tool for educating and updating physicians and the general public, and stimulating awareness and initiatives by public and private bodies, in particular governmental agencies. The Association intends to reach out to all, as fellow citizens of the world.

International Society of Doctors for the Environment (ISDE)
Rue de la Muse, 9
CH-1205 Geneva
Switzerland
Phone: +41-21-802-6553
Fax: +41-21-802-6554
E-mail: info@isde.org

Médecins Sans Frontières (MSF):
www.msf.org
Médecins Sans Frontières (MSF), also known in English as "Doctors without Borders," is an international humanitarian aid organization that provides emergency medical assistance to populations in danger in more than 80 countries. In countries where health structures are insufficient or even non-existent, MSF collaborates with authorities such as the Ministry of Health to provide assistance. MSF works in rehabilitation of hospitals and dispensaries, vaccination programmes and water and sanitation projects. MSF also works in remote health care centres, slum areas and provides training of local personnel. All this is done with the objective of rebuilding health structures to acceptable levels.

MSF is a private international organization. Most of its members are doctors and health workers, but many other support professions contribute to MSF's smooth functioning. All of them agree to honour the following principles:

- Médecins Sans Frontières offers assistance to populations in distress, to victims of natural or man-made disasters and to victims of armed conflict, without discrimination and irrespective of race, religion, creed or political affiliation.
- Médecins Sans Frontières observes neutrality and impartiality in the name of universal medical ethics and the right to humanitarian assistance and demands full and unhindered freedom in the exercise of its functions.
- Médecins Sans Frontières' volunteers undertake to respect their professional code of ethics and to maintain complete independence from all political, economic and religious powers.
- As volunteers, members are aware of the risks and dangers of the mission they undertake, and have no right to compensation for themselves or their beneficiaries other than that which Médecins Sans Frontières is able to afford them.

MSF International Office
Rue de la Tourelle,
39, Brussels, Belgium
Phone: +32-2-280-1881
Fax: +32-2-280-0173

Pollution Probe:

www.pollutionprobe.org

Pollution Probe is a Canadian environmental organization that:

- Defines environmental problems through research
- Promotes understanding through education
- Presses for practical solutions through advocacy

Pollution Probe is dedicated to achieving positive and tangible environmental change, and has four major programmes and several special programme areas.

Major Programme Areas include:

- Air: Pollution Probe's air programme promotes tougher controls on urban smog, reduced acid gas emissions, improved public transit, and cleaner vehicles and fuels.
- Water: Pollution Probe is re-building its water programme, following on the extensive work done on the Great Lakes in North America. The initial phase of the water programme has focused on ensuring clean, safe drinking water in the Canadian province of Ontario. It is now developing concepts, tools and partnerships to promote a new approach to water management, focusing on creating a water ethic that is global in outlook.
- Energy: In its early days, Pollution Probe successfully promoted energy conservation as an alternative to unlimited expansion of energy generation capacity. Today, this work continues, notably in the Canadian province of Ontario's Energy Board hearings, where it consistently promotes the '3 Es' of responsible energy use: Energy efficiency, Energy from renewables, and Emission reductions from generating plants.
- Indoor Environments: Pollution Probe's environmental health programme is the first initiative by a Canadian environmental organization to link the quality of the indoor environment to human health, climate change, water quality and smog.

Non-Smokers' Rights Association(NSRA):
http://www.nsra-adnf.ca
The Non-Smokers' Rights Association is a non-profit health organization that has been at the forefront of tobacco-control efforts in Canada and around the world for the past quarter-century. The NSRA was founded in Toronto in 1974 by Rosalee Berlin, a registered nurse whose allergies made her particularly sensitive to second-hand smoke. It began as a small volunteer group dedicated to achieving clean air for non-smokers.

Professional, dynamic advocacy based on solid research and critical thinking have been the hallmark of the NSRA since its inception. Thanks to ongoing efforts in coalition-building with national, provincial and local health and community groups, the association has helped bring about a sea change in Canadian attitudes towards the tobacco industry and its deadly products.

World Resources Institute (WRI):
www.wri.org
World Resources Institute is an environmental research and policy organization that creates solutions to protect the planet and improve people's lives. WRI's work is concentrated on achieving progress toward four key goals:

- Protect Earth's living systems
- Increase access to environmental information
- Create sustainable enterprise and opportunity
- Reverse global warming

WRI is an independent, non-partisan organization that works closely with governments, the private sector, and civil society groups in more than100 countries around the world. Its strength is the ability to catalyze permanent change through partnerships that implement innovative, incentive-based solutions founded upon hard, objective data. WRI believes that harnessing the power of markets will ensure real, not cosmetic, change. WRI demands measurable results from its work; ideas must lead to action.

World Resources Institute
10 G Street, NE (Suite 800)
Washington, DC 20002 USA
Phone: 1+202/729-7600; Fax: 1+202/729-7610
Email: front@wri.org

Worldwatch Institute:

http://www.worldwatch.org/

Founded by Lester Brown in 1974, the Worldwatch Institute offers a unique blend of interdisciplinary research, global focus, and accessible writing that has made it a leading source of information on the interactions among key environmental, social, and economic trends. Its work revolves around the transition to an environmentally sustainable and socially just society-and how to achieve it.

Worldwatch Institute
1776 Massachusetts Ave., N.W.
Washington, D.C. 20036-1904, USA
Phone: (202) 452-1999
Fax: (202) 296-7365
worldwatch@worldwatch.org

World Wide Fund for Nature/ World Wildlife Fund (WWF):

http://www.wwf.org/

A large international organization dedicated to the preservation of endangered species and habitats. WWF has many regional and national offices internationally. For more information, please see the website.

Free Software

(Note: A selection, likely incomplete)

Epi Info:

http://www.cdc.gov/epiinfo/

Epi Info is a freely available software package designed specifically for use in the collection and analysis of data from epidemiological data. With Epi Info 2002 and a personal computer, epidemiologists and other public health and medical professionals can rapidly develop a questionnaire or form, customize the data entry process, and enter and analyze data. Epidemiologic statistics, tables, graphs, and maps are produced with simple commands such as READ, FREQ, LIST, TABLES, GRAPH, and MAP. Epi Map 2002 displays geographic maps with data from Epi Info 2002.

Translations of Epi Info 6 are available in at least 15 languages, for many regions of the world. The Russian translations of Epi Info 6 and Epi Map 6 can be downloaded for free at the following locations:

Epi Info: ftp://ftp.cdc.gov/pub/Software/epiinfo_dos/RUSSIAN
Epi Map: ftp://ftp.cdc.gov/pub/Software/epimap_dos/RUSSIAN

Advantages: Designed specifically for epidemiological research, available at no cost and in several languages
Disadvantages: Limited range of analyses available

Commercially Available Software

(Note: A selection, likely incomplete. Inclusion in this category does not imply endorsement of any particular product.)

Microsoft Excel:

http://www.microsoft.com/office/excel

Included as part of the Microsoft Office package, Excel is a useful program for data entry, data management, and basic data analyses. Very user-friendly and widely available, it can be a helpful tool for collecting, screening, and describing data.

Advantages: Easy to use, widely available, available in several languages
Disadvantages: Cost, limited range of analyses available

SAS/STAT:

http://www.sas.com/products/stat/index.html

Modern and sophisticated, SAS/STAT software provides extensive statistical capabilities with tools for both specialized and general analytical needs. Ready-to-use procedures handle a wide range of statistical analyses, including analysis of variance, regression, categorical data analysis, multivariate analysis, survival analysis, psychometric analysis, cluster analysis, and nonparametric analysis.

Advantages: Highly powerful, very modern
Disadvantages: Cost, difficult learning curve

SPSS:

http://www.spss.com/spssbi/spss/

SPSS is a modular, tightly integrated, full-featured product line for the analytical process - planning, data collection, data access and management, analysis, reporting and deployment. Using SPSS with a combination of add-on modules and stand-alone software that work with the base product enhances SPSS' capabilities. The graphical user interface (GUI) makes it easy to use — yet it gives you modern data management, statistics and reporting methods useful to accomplish most analyses. SPSS is available in English, Japanese, French, German, Italian, Spanish, Chinese, Polish, Korean and Russian. Contact a local office to find out version information and more (www.spss.com/worldwide/).

Advantages: Powerful, modern, relatively easy to use,
many languages supported
Disadvantages: Cost

Toolkit №6: Research Proposal / Funding Application Template

NOTE: *Funding agencies usually have their own preferred templates for the submission of funding proposals. Applicants are strongly advised to inquire about the existence of such documents before preparing their applications*

Title/Research Question:

Should incorporate: study design, population, place, exposures/outcomes of interest, and time period.

Author Name(s)
Author Contact Information
Author Affiliation(s)

Abstract/Summary: A synopsis of the study or research to be conducted, in lay terms (about 250 words maximum, double spaced, and on a separate page)
Rationale/Background: Why is the question being asked? In what context does the study take place?
Objectives: What are the goals of the study? What are the deliverables?
Hypothesis (H0): What is the (null) hypothesis of the study? What is being tested?
Literature Review: Researcher should demonstrate a good grasp of current knowledge in the published literature to date, and identify key issues, authors and progress on the topic. (length may vary by topic, but typically will be in the range of 2-4 pages).
Methods: Researcher should describe, in a clear and concise fashion:

- Study Design
  - Sample size
  - Power
- Measurement Issues
  - Confounding
  - Reliability
  - Validity
  - Control of potential biases
  - Quality assurance
- Statistical Methods
  - Point estimates
  - Statistical tests
  - Modelling
  - Predictive models

Feasibility: Researcher should demonstrate that the conduct of the study will be possible

- Assessment of logistical issues/potential difficulties
- Consideration of financing
- Pilot study results

Interpretation: Recognize both strengths and weaknesses/limitations of the study
Ethical Issues: Considerations for the protection of human rights and personal privacy
Dissemination: Plan for subjecting methods and results

- To peer review:
  - Conferences
  - Journal publication
- To the public:
  - Town hall meetings
  - Media
  - Lay reports

Stakeholder engagement plan (Optional): Establishing a steering committee with stakeholders to ensure the relevance of the work to & contact of researchers with the community
Time Lines: Projected dates or lengths of times for each stage of the project (e.g., Gant chart)
Budget and Budget Justification: Detailed description of projected expenses and rationale for costs
Archival Plan: Strategy for recording and preserving all collected data, log books and coding manuals
Literature Cited: List of all references present in the proposal
Appendices: May include, but are not restricted to:

- Draft Informed Consent Document
- Draft Questionnaire(s)
- Draft Coding Manual(s)
- Letter(s) of Support
- Research Team Curriculum Vitae's (CVs) / biographical-sketches

Note:

1. Justify and defend all approaches that you are proposing to take that are intended to address the research question.
2. If you do not agree with any reviewer's criticism from the agency to which it has been submitted, then please simply better-defend your position.

The document should be presented in a professional format: it should have a title page containing full author and contact information and affiliation(s), the abstract/summary should appear on its own page, etc. In addition, all line spacing should be at least 1.5, and the font size should be 12 point, with at least 1 inch (2.54 cm) margins all round.

(Note: Example only)

HEALTH RESEARCH ETHICS BOARD*
REQUEST FOR ETHICS REVIEW FORM

SECTION A: GENERAL INFORMATION

A1. Project Title
Title of Project:

A2. Applicant Information			
Name:			
Title:			
Department:			
Mailing Address:			
City & Province:	Postal Code:	Phone:	Fax:
E-mail Address:			
Signature:			Date:

A3. Co-Applicant Information			
Name:			
Title:			
Department:			
Mailing Address:			
City & Province:	Postal Code:	Phone:	Fax:
E-mail Address:			
Signature:			Date:

A4. Authorizing Signature	
Indication of Department Support for the Implementation of the Project.	
Name of Dept. Chair, Assoc. Dean of Research, or Supervisor:	
Title:	
Signature:	Date:

* *University of Alberta, Edmonton, Canada*

A5. Co-Investigators / Thesis Committee		
Is this project for a graduate thesis? ( ) Yes ( ) No *If yes, please provide the names, departments, and phone numbers of your thesis committee.*		
Name:	*Department/Program:*	*Phone:*

A6. Expedited Review	
*If the study procedures are **LIMITED** to any of the following, please check (√):*	
	Analysis of blood, urine, or any other biological specimen already collected.
	Examination of patient, medical, or institutional records. Modification of a previously approved protocol (specify title and approval date):
	Secondary analysis of data.
	Use of biological specimens normally discarded.

A7. Type of Investigation			
Which one of the following best describes the type of investigation proposed? Check (√) more than one if appropriate.			
	Clinical Trial		Multi-centre Trial
	Drug Study		Pilot Study
	Epidemiological Study First Application in Humans		Qualitative Study Technology Assessment / Development
	Sequel to Previously Approved Project (specify title and approval date):		
	Other (specify):		

A8. Site of Research

Where will the research be conducted? Specify the area/department/program.

Letters of Support:

( ) Pending ( ) Attached ( ) Not Applicable

A9. Funding / Budget

How is the project funded? Please check (√) the appropriate box.

Funding approved; specify source(s):

Funding pending; specify source(s):

No external funding required.

Budget

Please check here (√) that you have attached a budget summary. The summary must include details of investigator payments and recruitment incentives (if present). Please attach the budget as an appendix to the form.

A10. Remuneration

Are any of the investigators involved receiving any directs personal remuneration or other personal or family financial benefits (either direct or indirect) for taking part in this investigation?

Yes. If so, append a letter detailing these activities. Please attach this letter to your budget summary.

No.

A11. Safety Approvals

Please check (√) whether or not this study requires any of the following safety approvals. If a safety approval is needed, please indicate whether the approval documentation is pending or attached as an appendix to this form.

Biohazardous Materials:		
Not Applicable	Pending	Attached
Electromechanical:		
Not Applicable	Pending	Attached
Health Protection Branch or Other Canadian Federal Agency:		
Not Applicable	Pending	Attached
Radiation:		
Not Applicable	Pending	Attached

SECTION B: DETAILS OF PROJECT

Description of the Project

B1. Provide a clear statement of the purpose and objectives of the project.

B2. State the hypotheses and/or research questions.

B3. Briefly summarize past human and/or animal research that has lead to this project.

Description of Sample/Population

B4. Describe the numbers and type(s) of subjects to be included. If appropriate, specify the number of subjects in each study group. Provide a rationale for the sample size and include sample size calculations where appropriate.

B5. List any subject inclusion/exclusion criteria.

B6. Please check (√) if any of the subjects who will be recruited fall into one or more of the following categories:

	Under 18 years of age
	Cognitively Impaired Residing in institutions (e.g. prison, extended care facility)
	Students Employees of researchers' organization
	Have language barriers (e.g. illiterate, not English-speaking, dysphasic) In another country

Description of Research Procedures

B7. Provide a summary of the design and procedures of the research. Provide details on the methods of data collection and data analysis, time commitment for the subjects etc. Please note that any and all study measures need to be appended to the copies of the research / grant proposal (e.g. questionnaire, interview guides, rating scales etc.).

B8. Which treatments or procedures are additional to those required for standard patient care?

B9. If the procedures include a blind, under what conditions will the code be broken and what provisions have been made for this? Who will have the code?

Obtaining Consent
B10. Clearly detail who will be recruiting subjects and obtaining consent, and the procedures for doing this. If appropriate specify whether subjects will be randomly assigned to groups before or after consent has been attained. B11. Specify methods for dealing with groups identified in #B6. If the subjects are not able/competent to give fully informed consent, who will consent on their behalf? B12. If the subjects will be offered compensation for participating in the research, provide details. Specify the amount, what the compensation is for, and how payment will be determined for subjects who do not complete the study.
B13. Do any of the procedures include the use of deception or partial disclosure of information to subjects? If yes, provide rationale for the deception or partial disclosure. Describe the procedures for (a) debriefing the subjects and (b) giving them a second opportunity to consent to participate after debriefing.

Recruitment Aids/Information Letters/Consent Forms			
B14. Are you planning to use any recruitment aids such as posters, newspaper advertisements, radio announcements, or letters of invitation? If so, please indicate the reading level of each aid and check (√) if it has been attached to the form as an appendix.			
Recruitment Aid #1 – Specify (e.g. poster, letter etc.):			
Not Applicable		Reading Level	Attached
Recruitment Aid #2 – Specify:			
Not Applicable		Reading Level	Attached
Information Letter #1 – Specify (e.g. Letter for interviews, focus groups etc.):			
Not Applicable		Reading Level	Attached
Information Letter #2 – Specify:			
Not Applicable		Reading Level	Attached
Consent Form #1 – Specify (e.g. Consent for interview, focus group etc.):			
Not Applicable		Reading Level	Attached
Consent Form #2 – Specify:			
Not Applicable		Reading Level	Attached
B15. What steps have been taken to make the recruitment aids, information letters, and consent forms comprehensible to the person(s) giving consent?			

Risks and Benefits
B16. What are the benefits of the proposed research for the subject and/or for scientific knowledge in general?
B17. What adverse effects may result from the research? How will adverse effects be dealt with? Please note that adverse effects are not limited to physical risks, but include psychological, emotional, and spiritual risks as well.

Privacy and Confidentiality
B18. What steps will be taken to respect the privacy of the subjects and protect confidential data? B19. Identify any agencies or individuals who will have access to confidential data now or in the future. B20. Do you anticipate any secondary analysis of the data? Please note that any secondary analysis requires further research ethics approval.

Please note: In 2008, the University of Alberta introduced an on-line process for submitting to ethics review. The link to this is:

https://www.ualberta.ca/~ais/PublicResCert/HERO_DEMO.htm

Cancer incidence and mortality in the industrial city of Sumgayit, Azerbaijan: A descriptive study

James E. Andruchow and Colin L. Soskolne - University of Alberta, Edmonton, Canada

Francesca Racioppi –WHO European Centre for Environment and Health, Rome, WHO Regional Office for Europe

Oktay Akhundov – Azerbaijan Ministry of Health (MOH), Bureau of Information and Statistics, Baku, Azerbaijan

Emin Makhumdov and Anar Asadov – Sumgayit Centre for Environmental Rehabilitation, Sumgayit, Azerbaijan

Hiroko Takasawa – UNDP Country Office, United Nations Development Programme, Baku, Azerbaijan

Supervisory Committee (as per University of Alberta Faculty of Graduate Studies & Research requirements):

Colin L. Soskolne (Supervisory Committee Chair)
Ambikaipakan Senthilselvan (Committee Member)
Nicola Cherry (Committee Member)
Heather Bryant (Committee Member)

Abstract

Serious concerns exist that the health of residents of the city of Sumgayit, Azerbaijan, has been negatively impacted by long-term exposures from industry. To provide an evidence-based assessment of these concerns, the proposed study will use population-level annual summary cancer data and vital statistics over the period 1980-2000, supplemented with lifestyle survey data, to make comparisons of cancer rates in Sumgayit with selected other populations, both within Azerbaijan and internationally. Cancer has been selected as the health outcome of study because of its known associations with industrial exposures, and because of assured access by Azerbaijan MOH to annual summary cancer reports. The proposed study is an international collaborative effort involving both Azeri and international agencies and expertise. An important objective of the study will be the strengthening of local research capacity by direct involvement and training of local experts in the conduct of the research.

This research proposal has been initiated within the framework of the UNDP project "Environmental Rehabilitation of Sumgayit," for which Azerbaijan State Committee on Ecology and Nature Utilization Control is the local counterpart. This study belongs to the activities carried out by the Public Health component of the project, implemented by the World Health Organization in collaboration with Azerbaijan Ministry of Health (Bureau of Information and Statistics, National Oncological Centre), the University of Alberta (Canada), and the Sumgayit Centre for Environmental Rehabilitation. This study has been developed to address concerns regarding the consequences of environmental and occupational exposures to industrial pollutants experienced in Sumgayit since 1949. Numerous partners are working collaboratively in this study, and its conduct will test local research capacity. Successful completion of the study is expected to strengthen research capacity in the region, through the identification of relevant research directions, training of local professionals, and by improving the credibility of new funding applications.

Background and Rationale

Founded in 1949, the city of Sumgayit, Azerbaijan was a showcase of large-scale production for the former Soviet Union. More than 40 factories were active in the production of chemicals and industrial products (including petrochemicals, chlorine, and aluminium) for four decades, providing high levels of employment for residents. In the quest for maximum output and cheap production, development in Sumgayit was pursued without adequate consideration of environmental and occupational health consequences.1 Economic gain thus came at the cost of severe workplace and environmental pollution. While the dissolution of the Soviet Union in 1991 resulted in economic disaster for Sumgayit because of the loss of export markets for its products, it had the positive side-effect of dramatically reducing pollutant output.

The greatest victims of the ensuing "Sumgayit Crisis" have been the approximately 300,000 inhabitants of Sumgayit, forced to live in the economic and ecological ruins of the former industrial giant.2 With newly gained freedoms and a reviving economy, many of Sumgayit's citizens have begun voicing concerns regarding the occupational and environmental practices of the former Soviet regime. Although Sumgayit's industrial facilities have been operating at 10-15% of their capacity since the early 1990s, fears persist that the health of Sumgayit's residents has been compromised through historical and ongoing occupational and environmental exposures.

The proposed study will provide the basis for assessing health concerns, by evaluating whether an excess of cancer exists in Sumgayit because of long-term exposures. Furthermore, attempts will be made to identify specific cancer sites of concern. By demonstrating the ability to successfully conduct research through this first such study, future proposals for research in the country will be more credible, and therefore more likely to

secure donor funding. This exercise serves as a practical extension of two WHO-UNDP funded training courses in Environmental Epidemiology held in Baku during February and December of 2000 and aims to strengthen research capacity in Azerbaijan.

Relevance for Public Health

Evidence is needed to support government and policy makers to set priorities for allocating resources and for designing public health intervention programmes. Determining whether or not Sumgayit has carried an additional cancer burden as a result of past and present industrial activities would provide an evidence-based assessment to support or dismiss the perception that industrial pollution negatively impacted the health of the people of Sumgayit.

All cancer data collected during this study will be computerized and provided to the MOH to aid construction of health information systems, including a national cancer registry database, and expansion of the Mednet website. Improvement of the Azerbaijan's health information system will be of vital importance to future health research and policy making, enabling the delivery of the best possible health care to its citizens.

Objectives

- To estimate whether exposure of the resident population of Sumgayit to emissions and pollutants from industrial activities has contributed to a higher level of cancer compared to selected populations in Azerbaijan and other Caucasus countries, while controlling for possible confounding factors (including tobacco smoking, alcohol, diet, and family history of cancer)
- To quantify rates of selected cancers in Sumgayit and selected other regions of Azerbaijan
- To provide the MOH, the Sumgayit government and the local community with factual information on cancer in relation to industrial activities
- To provide the basis for recommending public health interventions and/or further studies (e.g., secondary and tertiary prevention programmes or possible case-control studies. Recommendations regarding these potential interventions and/or research studies could be developed in the form of proposals to be submitted for funding by interested donors (e.g., international co-operation agencies, research institutions)

Hypothesis

Cancer incidence and mortality rates in the city of Sumgayit over the period 1980-2000 do not differ from those of:

1) *Other selected regions of Azerbaijan*
2) *Azerbaijan national data*
3) *Other Newly Independent States*
4) *Canada*

Literature Review

Increased cancer incidence and mortality has long been associated with occupational exposure to industrial chemicals and processes. In fact, epidemiological research has estimated that up to 10% of all cancers may be attributable to occupational exposures.[3] Studying cancer as a health outcome may be particularly appropriate for the Sumgayit situation given that many forms of cancer have long latency periods, often up to 20 years.[4] Therefore, current cancer rates should be sensitive for measuring the effects of occupational and environmental exposures over the past decades, when the industrial facilities were operating at full capacity. Because the population of Sumgayit has been growing in a stable manner over the past 50 years and population size data are available, calculation of disease rates will be achievable and should accurately gauge the effects of carcinogenic exposures experienced by residents. Certain cancer sites have been selected according to both their frequency and etiology. Lung, laryngeal, urinary bladder, and all neoplastic conditions are selected because they occur in adequate numbers to generate stable rates for analysis, while being related to environmental and occupational exposures.[5,6,7,8] In contrast, female breast cancer has been selected because of its weak association with industrial exposures, and will thus be useful for examining possible differences in cancer reporting across regions. Childhood leukaemia (males and females) has also been selected as an indicator of environmental exposure.[9]

Several facts support the perception that the residents of Sumgayit may be at increased risk of developing cancer. A number of IARC-classified[10]Group 1 definitive human carcinogenic agents have been identified in the various production facilities of Sumgayit, including: benzene, ethylene oxide, occupational exposure to strong inorganic acid mists, isopropyl alcohol production and rubber manufacturing.[11] A large number of agents present in Sumgayit have been associated with increased risk of cancer at various sites. Increased risk of lung cancer has been associated with exposure to inorganic arsenic, sulphur dioxide, isopropyl alcohol manufacture, and industrial air pollution.[12,13] Epidemiological studies have linked occupational exposure to sulphuric acid mists with laryngeal cancer.[14] Occupational exposures during chemical manufacture, aluminium production, and the rubber industry have been linked to increased risk of urinary bladder cancer.[15,16,17] Direct exposures of children to chemicals and parental occupational exposures have shown associations with a number of cancers in children.[9] Thus, given the long-term potential exposures of parents (and likely their children) to a variety of chemicals, increased rates of childhood leukaemia may be expected.

Adding to health concerns is an extensive list of probable and possible human carcinogens present in Sumgayit industry (Appendix not included). Exposure to other agents may be equally hazardous because although many of these compounds may be classified as definitive carcinogens in the future, they are not so at this point only because research is lacking. Although not addressed directly in this study, if and to what extent workers were exposed to specific carcinogens should be a focal point of future research.

Given that such occupational exposures are largely avoidable with appropriate safety equipment and protocols, much of the cancer burden attributed to such sources can be effectively prevented. Unfortunately, such preventative measures have only been adopted to any significant extent in the industrialized nations. In contrast, developing economies such as Azerbaijan historically suffer from a number of characteristics that increase the vulnerability of their populations to occupational carcinogenesis. Seven such conditions have been identified:[18] 1) a paucity of quality worker health legislation; 2) absence of exposure thresholds to toxic substances; 3) insufficient investment in occupational health workers; 4) poor reporting of occupational diseases; 5) lack of epidemiological understanding of occupational exposure and health relationships 6) low level engineering guidelines; and 7) inadequate occupational health training in agencies monitoring workplace health conditions. To this list might be added: a lack of occupational safety training, poor worker awareness of hazards, and absent or ineffective personal protective equipment. For these reasons, we may suspect a priori that Sumgayit residents suffer from an excess cancer burden.

Methods

The proposed research consists of a population-based study, utilizing annual summary cancer data collected at the district (rayon level). Age and sex-specific cancer incidence and mortality rates will be compared between the city of Sumgayit and several reference groups: 1) Baku, the capital city of Azerbaijan, 2) a reference city (i.e., one similar demographically to Sumgayit, but without industrial exposures likely to result in the above-selected cancers) 3) the whole of Azerbaijan, and 4) the neighbouring countries of Armenia and Georgia. The cancer experience for both sexes at several cancer sites (lung larynx, urinary bladder, and all cancers combined, and childhood leukemia) and for female breast cancer, will be assessed in Sumgayit and the selected comparison populations. Cancer burdens across regions will be examined using age and sex-specific comparisons, PMRs (Proportional Mortality Ratios) and SIRs or SMRs (Standardized Incidence Ratios or Standardized Mortality Ratios).

Data on potentially confounding lifestyle factors (e.g. tobacco smoking, alcohol consumption, diet, and family cancer history) will be collected. This will be accomplished either by incorporating the questionnaire into the "Quarterly Questionnaire on Incomes and Expenditures of Households" administered by the State Committee on Statistics (SCS), or by using market research survey techniques (personal interviews by standardized administration of questionnaires) of people shopping in bazaars in selected regions of Sumgayit, Baku, and the reference city (See attached Lifestyle Questionnaire). Based on sample size calculations, approximately 350 people will be sought to participate in the survey in each centre being compared (i.e., Sumgayit, Baku and one comparison city). For the lifestyle survey, people will be asked to participate only if they are adults between 18 and 80 years of age and have resided in the study city for 18 years or more. People who do not meet these criteria will be excluded.

Consent for conducting interviews will be obtained by trained Azeri interviewers approaching potential participants in the local market places. Because it will be a low intensity survey conducted in the market places, Azeri interviewers will be instructed to appreciate the need for a polite introduction and to engage people only if they are willing. A record will be kept, however, of the number of refusals. No signed informed consent will be included; instead, participation will be conditional on tacit consent. An information letter will be offered to each participant after the interview (See Information Letter). This approach may not be used if the National Household Quarterly Survey sampling frame of the SCS can be made available.

A basic approach to comparing cancer risks among populations is the use of age-sex specific rates. Using this approach, cancer incidence and mortality rates are stratified into age and sex-specific strata, facilitating comparisons between populations on a stratum-by-stratum basis. For each of the cancer sites chosen, incidence and mortality rates will be compared across each stratum of the populations in order to visualize relative excesses or deficits for individual cancer sites in the city of Sumgayit. Some advantages of this method of comparing population data are that differences in rates particular to certain demographics are easily visualized, demographic trends in cancer rates will be observable, and that the procedures involved are not overly complex.

PMRs are a semi-quantitative method of comparing the causes of death between groups, used mainly for hypothesis generation regarding potential exposure-disease relationships. The PMR is obtained simply by calculating for each population the proportion of deaths that have occurred from specific causes. By comparing the proportions of mortality

from certain diseases between populations, relative mortality excesses or deficits for particular causes of death can be visualized. Care must be exercised, however, as PMRs have the potential to provide deceiving results about exposure-disease associations. PMRs may be most useful for directing future research on certain cancers.

An SMR provides a population summary statistic. It is a ratio of actual to expected incidence or mortality rates for a study population. Expected rates in Sumgayit will be calculated by multiplying age-specific cancer rates from the reference (comparison) populations by the demographic distribution of residents in the city of Sumgayit. The total number of observed cases is then divided by the sum of age-specific expected values to produce a ratio. The SMR can be used to determine if excesses or deficits for any health outcome (e.g., cancer) occur between the comparison and reference groups. An SMR > 1 means that the health outcome occurs at a greater rate among the study population than the reference population, and suggests that the study population is at greater risk for that outcome. The statistical significance of the SMR can be tested using a **c**-score statistic based on the Poisson distribution.[19] The results of the SMR analysis will provide insight into whether the health status of the Sumgayit population has been adversely affected by industrial exposures.

Results

Analyses are to be completed with the participation of all partners at the appropriate stages of the project (See Toolkit *№9*: Planning Tools and Timelines).

Conclusions

This study will provide a quantitative evaluation of the perceived increased cancer burden in Sumgayit resulting from long-term occupational and environmental exposures. The availability and accessibility of health data suitable for epidemiological research will be constructively evaluated, with the goals of facilitating research and contributing to the improvement of health information systems in the country.

Results will build a better understanding of possible associations between exposures and selected cancers, and will provide evidence-based support for allocating resources for current remediation efforts and future research in the area. In so doing, this project will build new partnerships between the MOH (Bureau of Information and Statistics (BIS), National Oncological Centre (NOC)), Azerbaijan State Committee on Ecology and Nature Utilization Control (SCE), the Sumgayit Centre for Environmental Rehabilitation

(SCER), the WHO (European Centre for Environment & Health, Rome (WHO-ECEH); WHO Country Office, Baku (WHO-LO)), the United Nations Development Programme (UNDP), Azerbaijan State Committee on Statistics, the Canadian Society for International Health (CSIH), among others, hopefully encouraging further collaborations.

Feasibility

At present, a number of international organizations are involved in the economic and ecological rehabilitation of Sumgayit, including the WHO, and the United Nations Development Programme (UNDP), responsible for establishing the Environmental Rehabilitation of Sumgayit project. The Azerbaijan MOH and SCE are supportive of such collaborative efforts and encourage continued international cooperation. In addition, the CSIH has activities currently underway in Azerbaijan and ultimately desires to integrate this proposed project into the overall health activities in the country. As such, both the partnerships and infrastructure are in place to maximize the success of future health research in Azerbaijan.

This population-based study will rely heavily on population-level, annual summaries of demographic and cancer data provided by the Azerbaijan MOH (National Oncological Centre, and Bureau of Information and Statistics). Cancer data for both Armenia and Georgia will be obtained through the Caucasus Health Net[20] and/or WHO Health for All21 databases. Necessary data for Azerbaijan will include age and sex-specific cancer incidence and mortality rates annually over the period 1980-2000, such that standardized measures may be calculated. To achieve this, the corresponding population demographic data will be needed. Data specific to the cities of Baku, Sumgayit, and the reference city will be obtained through examination of reports possessed by the MOH.

National data from 1997 to the present are currently available on the Mednet website.[22] As the website is still under construction, several inconsistencies/omissions have been noted (Appendix not included). One of the goals of this study will be to expand and improve the website by providing a constructive critique of all cancer data currently presented on the website, and to provide all cancer data collected in the course of this study in electronic form to the MOH. This will allow the activation of a number of undeveloped links to district-level, and national data on the Mednet website. Furthermore, all data collected relating to Sumgayit may be incorporated in the Geographic Information System (GIS) developed by the SCER.

Following arrival in Azerbaijan and familiarization with persons and facilities, priority has been placed on obtaining the population-level demographic and annual summary cancer incidence/mortality data for selected cancer sites from the Azerbaijan MOH (BIS, NOC). The ability to obtain such data, particularly those specific to Sumgayit, Baku, and the reference city, is crucial to the population-based descriptive study. The agencies in Azerbaijan possessing the health data have emphasized their willingness and ability to supply the necessary data (Appendix not included). Because it appears that high-quality data will be obtained in good time for the descriptive study, the case-control approach initially discussed as an alternative will not be required.

Data will be collected through an approximately one-month visit to Azerbaijan by the researchers, with the help of partners at the SCER, and support from other relevant agencies of the MOH (Appendix not included).

Logistics

The project will be accomplished through an international collaborative effort, involving local partners and researchers from abroad. Local partners directly involved in the research include professionals whom participated in the UNDP-WHO funded Introductory and Advanced Environmental Epidemiology classes (Mr Emin Makhmudov, Dr Anar Asadov), Dr Oktay Akhundov from the MOH-BIS, and Dr Fuad Mardanli of the MOH-NOC. International partners include Dr Colin Soskolne, his Master of Science student, Mr James Andruchow, and Ms Francesca Racioppi, together with Mr Andruchow's Supervisory Committee. A draft research proposal was developed by early March 2001 for consideration by all potential partners. This document is the product of feedback received on that draft by the other partners. James Andruchow and Professor Soskolne will arrive in Azerbaijan in late April 2001 to conduct the needed research. Professor Soskolne (who visited Azerbaijan and most of the key players twice in 2000) will spend about a week and a half in Sumgayit with Mr Andruchow, ensuring that the work is set in motion. Prior to departure, however, buy-in will be secured with assurances of and access to data. Professor Soskolne then will leave Mr Andruchow in Sumgayit for a further approximately three weeks to complete all of the data collection needed while in Azerbaijan, in close collaboration with all partners. During that 3-week period, Mr Andruchow will be in e-mail contact with Professor Soskolne. James Andruchow has a basic understanding of the Ukrainian language and Cyrillic alphabet that will make his reading of documents and tabular data possible.

The data analysis will be completed in Edmonton, and a thesis will be produced (property of the University of Alberta) with a final report and paper(s) for publication following. All partners will have the opportunity to ensure that the thesis, report and paper for publication are each consistent with their knowledge of the situation in Azerbaijan; scientific concerns will provide the basis for all feedback. In accordance with University of Alberta regulations, all students must have a Supervisory Committee to ensure the scholarly excellence of the student's thesis project.

Ethics Approval

Following agreement in principle to the proposal by all partners, ethics clearance has been obtained at the University of Alberta.

Partnerships

All partners in the conduct of the research are identified in the appended Agreement of Understanding (See attached Agreement of Understanding). Partners are expected to contribute with data and expertise needed for the successful conduct of this research.

The University of Alberta (Canada) will remain involved through the duration of the research. Similarly, WHO-ECEH (Rome), the MOH, the UNDP, and the WHO-LO in Azerbaijan will continue to ensure quality control and cooperation among partners until completion.

Team of Investigators

The following are expected to have contributed to the intellectual development of both the thesis and scientific paper(s) for publication:

Colin L. Soskolne
James Andruchow
Francesca Racioppi
Nicola Cherry
Heather Bryant
Oktay Akhundov
Anar Asadov
Emin Makhmudov
Fuad Mardanli

Data Management and Ownership

Data will be made accessible and managed by the team of investigators. The ownership of the original data remains with the relevant agencies of the MOH. The ownership of the data sets as extracted, treated, analysed and used for the purpose of this study will be shared among the relevant agencies of the MOH and the SCER. For any thesis resulting from this study the University of Alberta will retain copyright with the student who produced it.

A complete archive of all data sets used for this investigation will be kept both in Alberta and in Azerbaijan, including at the MOH, SCER, and other involved agencies, as appropriate. The team of investigators will retain the right of further accessing, analysing and using for scientific work the data collected for the purpose of this research. Any copyright data, analyses, or software will remain with the legal owner/licensee.

Any publication resulting from this study will be co-authored by those members of the team contributing to its preparation. In compliance with the normal practice of scientific publications in peer reviewed journals, the copyrights on papers arising from the research, will be assigned by the co-authors to the Journal(s) in which the work is finally published.

Co-authorship and Acknowledgements

Those members of the team who contribute to the intellectual development of the study, the execution of the work and who can defend the scientific presentation of the findings will be eligible for co-authorship. Others and appropriate agencies will be acknowledged in the dissemination of the results of the study. Any publication will indicate that funds to carry out the research were provided by the UNDP project Environmental Rehabilitation of Sumgayit, through an Inter Agency Agreement (IAA AZE/97/010) between UNOPS and WHO.

Francesca Racioppi set the foundations for this research, linking all partners, and continued contributions to the development of the proposal. The Azerbaijan MOH has offered to provide the assistants access to the necessary cancer and demographic data, facilities for data extraction, and staff to assist in the project.

In particular, we acknowledge the efforts of Dr Akhundov in facilitating this work, through assuring access to computers and the necessary data. Finally, the contributions of all partners to making this work possible is acknowledged, in particular, the UNDP, the SCER, the WHO Country Office, and numerous people in Azerbaijan for agreeing to participate in the study.

References:

[1] UNDP (United Nations Development Programme).
Azerbaijan Human Development Report 1999, Baku: UNDP: 1999: 36-39.

[2] Imanov D. Sumgayit: Birth, Blossoming, Decadence and Renaissance of a City.
Baku: Alyans Press, 1997: 4.

[3] Pastorino U, Berrino F, Gervasio A, Pesenti V, Riboli E, Crosignani P.
Proportion of lung cancers due to occupational exposure. Int J Cancer 1984; 33:231-237.

[4] Roe FJC. Occupational cancer: where now and where next?
Scand J Work Environ Health 1985; 11:181-187.

[5] Pastorino U, Berrino F, Gervasio A, Pesenti V, Riboli E, Crosignani P.
Proportion of lung cancers due to occupational exposure. Int J Cancer 1984; 33:231-237.

[6] Flanders WD, Cann CL, Rothman KJ, Fried MP.
Work-related risk factors for laryngeal cancer. Am J Epidemiol 1984; 119(1):23-32.

[7] Flanders WD, Rothman KJ. Occupational risk for laryngeal cancer.
Am J Public Health 1982; 72:369-372.

[8] Anton-Culver H, Lee-Feldstein A, Taylor TH. Occupation and bladder cancer risk.
Am J Epidemiol 1992; 136(1):89-94.

[9] Greenberg RS, Shuster JL Jr. Epidemiology of cancer in children.
Epidemiol Reviews 1985; 7:22-48.

[10] International Agency for Research on Cancer (IARC):
Monographs Programme on the Evaluation of Carcinogenic Risks to Humans – Website:
http://www.iarc.fr/

[11] Makhmudov E, Asadov A (personal communication)

[12] Ives JC, Buffler PA, Greenberg SD. Environmental associations and histopathologic patterns of carcinoma of the lung: the challenge and dilemma in epidemiologic studies.
Am Rev Respir Dis 1983; 128: 195-209.

[13] Fraumeni JF. Respiratory carcinogenesis: an epidemiologic appraisal.
J Nat Cancer Inst 1975; 55(5): 1039-1046.

[14] Soskolne CL, Zeighami EA, Hanis NM, Kupper LL, Herrmann N, Amsel J, Mausner JS & Stellman JM. Laryngeal cancer and occupational exposure to sulfuric acid. Am J Epidemiol 1984; 120(3): 358-369.

[15] Ronneberg A, and Langmark F. Epidemiologic evidence of cancer in aluminium reduction plant workers. Am J Ind Med 1992; 22: 573-590.

[16] Wynder EL, Goldsmith R. The epidemiology of bladder cancer. Cancer 1977; 40: 1246-1248.

[17] Ross RK, Jones PA, Yu MC. Bladder cancer epidemiology and pathogenesis. Seminars in Oncology 1996; 23(5):536-545.

[18] Taba, A-H. Problems of occupational carcinogenesis in developing countries. Cancer Detect Prev 1981; 4:25-30.

[19] Rothman KJ, Greenland S. Modern Epidemiology. 2nd ed. Philadelphia: Lippincott Williams & Wilkins, 1998: 234-239.

[20] Caucasus Health Website - http://www.caucasushealth.net/

[21] WHO Health For All Website - http://www.who.dk/country/country.htm

[22] Azerbaijan Ministry of Health Website - http://www.mednet.az/

Inormation Letter

Dear Participant,

We are conducting a study on the health effects of long-term pollution in Sumgayit, in conjunction with the United Nations Development Programme's Environmental Rehabilitation of Sumgayit Project. We would like to ask you a few questions about your day-to-day life that will be helpful in allowing us to understand more about the residents of this city. Your name will not be collected; all information will be kept confidential, and only used as part of the above research. There are no risks associated with your participation in this research. Are you willing to answer a few questions that will take no more than about 3-4 minutes of your time?

If you have any further questions or concerns about your participation in the study, please feel free to contact us at the

Sumgayit Centre for Environmental Rehabilitation.
16 Nizami Street, Sumgayit
Azerbaijan

Telephone: (994164) 22612
Email: sum@sec.sumqait.az

Thank you for your time.

Ministry of Health and State Committee of Statistics of the Azerbaijan Republic,
UNDP center for Environment Rehabilitation in Sumgait city,
University of Alberta (Canada)

LIFESTYLE QUESTIONNAIRE
(To be filled by people in the age range from 18 and over)

A. Polling area:

City
Address: _____
District, town, village

Street and number _____ № apartment ☐

B. Personal information: 1. Sex; M. - 1 F. - 2 ☐ 2. Age ☐ Years

3. Duration of residing in given city ☐ Years

a) In case of change of residence, indicate last two area, and also terms of residence in area

Address	Number of years

4. Profession In case of change of profession indicate previous two and occupation time record each of them

Profession	Seniority (year)

V. The tobacco consumption:

5. Do you smoke? Yes - 1 No - 2 ☐
If "Yes" Specify,:
a) For how many years do you smoke? ☐ Years
б) How many cigarettes per day? ☐ Pieces

If "No", Specify;
6. Whether you smoked earlier? Yes - 1 No - 2 ☐
a) If "Yes", Specify
6.1 At what age have you started to smoke? ☐ Year
6.2. How many cigarettes per day? ☐ Pieces
6.3. How many years you smoke? ☐ Years
6.4. When did you quit smoking? ☐ Year

Q. The alcohol consumption:

7. Quantity of alcohol consumption within a week

	Gram	At what age have you started to use alcohol? (Age)
7.1. Beer		
7.2. Vine		
7.3. Brandy		
7-4. Vodka		
7.5. Other (Specify)		

Ministry of Health and State Committee of Statistics of the Azerbaijan Republic,
UNDP center for Environment Rehabilitation in Sumgait city,
University of Alberta (Canada)

D. Nutrition:

8. Sources of drinking water

Indicate concrete sources and duration of consumable water from each.

	From (year)	Till (Year)
8.1. Urban water line		
8.2. Blow well		
8.3. Well in a court yard		
8.4. Pushdown water in plastic bottles		
8.5. Other (Specify)		

9. Food ration

	How many times per week
9.1 Mutton	
9.2. Beef	
9.3. Fish	
9.4. Chicken	
9.5. Pork	
9.6. Potherbs and vegetables	
9-7. Fresh fruit	

E. Oncology anamnesis of family:

10- whether someone in your family suffered from oncology diseases?

Yes - 1, No - 2 , to be unaware - 3

10.1. Father		10,4, Sister	
10.2-Mother		10.5. Son, daughter	
10.3- Brother		10.6. Other relatives	

THANK FOR COLLABORATION

The examination is carried out in the season from July 23 till July 27, 2001 by specially trained recorders in cities Ganja, Sumgait, Lenkoran and Astara by polling of the population, with scope, approximately, 900-950 persons.
The questionnaire of examination is filled by an adult member in the age of 18 years and over of the household involved in sampling.
Item the indications for filling the questionnaire:

1 question - Either figure "1" or "2" is chosen depending on the sex of the person fillings questionnaire;

2 question - One indicates the exact number of years of the person fillings questionnaire;

3 question - The number of years of residence in the given city is indicated/ in case of change of place of residence within the city last two addresses are indicated along with the dates of residence;

4 and 5 questions - Figures corresponding to questions listed on the left are indicated

6 question - The exact quantity of indicated alcohol drinks as used per week by the respondent is described along with the number of years

7 question - A respondent indicates both the year from which and up to which the described source of drinking water was used

8 question - The approximate number of times per week that the products mentioned appear in the respondent's ration is indicated (for the first half of the year 2001)

9 question - The code for one of the given hints is listed: yes –1; No –2;
For question's 6, 7 and 8 one can use several hint versions.

Agreement of Understanding

Research Project

Cancer morbidity and mortality in the industrial city of Sumgayit, Azerbaijan: A descriptive approach

High quality epidemiological research results from successful collaboration among partners which, in turn, depends on trust and due diligence among them. All partners are equally essential links to the ultimate success of the research; the project will be only as good as its weakest link.

The primary purpose of this Agreement is to ensure that the objectives of the research proposal are met. An equally important objective is to extend the learning experience afforded through the two courses on Environmental Epidemiology through 2000 and held in Baku. This will be achieved by involving, all interested and willing partners in all aspects of the execution of the research, as a practical extension of the two courses. This document defines the roles and responsibilities of each concerned agency with regard to each activity to ensure mutual understanding.

The partners for this project comprise the respective agencies responsible for maintaining and providing relevant data and/or for designing and conducting the research. All noted partners will be invited and expected to participate by suggesting analytical approaches, and in interpreting the research findings as soon as final reports are drafted for comment. Their responsibility is to respond with constructive critique and input in a timely fashion, usually within two weeks. For this project, the partner agencies are:

- Ministry of Health (MOH), Azerbaijan
  - Bureau of Information and Statistics (BIS)
  - National Oncological Centre (NOC)
- State Committee on Statistics of Azerbaijan (SCS)
- Sumgayit Centre for Environmental Rehabilitation (SCER)

- State Committee on Ecology and Nature Utilization Control (SCE)
- World Health Organization (WHO)
  - European Centre for Environment & Health (ECEH), Rome
  - WHO Country Office (WHO-LO), Baku
- University of Alberta, Edmonton, Canada (UofA)
- United Nations Development Program (UNDP) Country Office in Azerbaijan
- United Nations Office for Project Services (UNOPS)
- Canadian Society for International Health (CSIH)

Ministry of Health (MOH), Azerbaijan
Will coordinate activities utilizing a national approach to facilitate the study of the impact of the environment on human health. Will facilitate access to the various data sources thereby strengthening the national health information system. (Main contact: Oktay Akhundov).

Bureau of Information and Statistics (BIS), MOH Archives
Will provide access to all needed cancer data (lung, larynx, breast, urinary bladder, childhood leukemia, and all cancers combined), by year from 1980 through 2000, together with appropriate denominator data in 5-year age intervals, by sex and districts, for all of Azerbaijan. Also, will provide expertise in interpreting changes in coding over the period. Will support the translation of the lifestyle questionnaires on potential confounder information that will be secured either through collaboration of the SCS or through Market Research surveys in selected cities/regions. Will make space and computers available for the abstraction of all needed data. Will provide the needed denominator data by age and sex, in 5-year age groups annually from 1980. (Main contact: Natalia Tselikovskaya).

State Committee on Statistics (SCS)
Will support, at a nominal cost, the inclusion of specified lifestyle questions in its Quarterly Household Income and Expenditure Survey. If agreement is reached, they will conduct this work and share the results within three months. (Main contact: Agadadash Mamedov).

National Oncological Centre (NOC)
Will provide access to all needed cancer data as above where confirmation or audit is required and to assist James Andruchow in the abstraction of cancer data (Main contact: Fuad Mardanli).

Sumgayit Centre for Environmental Rehabilitation (SCER)
Will provide assistance (Emin Makhmudov and Anar Asadov) to James Andruchow and will work cooperatively in the abstraction of cancer data. Will secure any needed cancer data as above where confirmation or audit is required.

Will support the translation of the lifestyle questionnaires on potential confounder information (if needed by virtue of the SCS being unable to accommodate this request) only for a Market Research survey in Sumgayit and other selected cities. (Main contacts: Arif Islamzadeh, Anar Asadov, Emin Makhmudov).

State Committee on Ecology and Nature Utilization Control (SCE)
As the Government counterpart for the Environmental Rehabilitation of Sumgayit Project, will provide general/overall support in the implementation of the activity, as necessary, as with other activities of the project. (Main contact: Fuad Akhundzadeh)

WHO Country Office (WHO-LO), Baku
Will facilitate communications among the respective partners. Will ensure, with the European Centre for Environment & Health (WHO), international standards and information on recent events related to the conduct of the research. (Main contact: Kamran Garakhanov).

WHO European Centre for Environment & Health (WHO-ECEH), Rome
As the implementing agency for the Public Health component of the Environmental Rehabilitation of Sumgayit Project governed by Inter-Agency Agreement with UNOPS, will provide overall supervision of the project, facilitate communications and aid in coordination of the activities, ensuring both process efficiencies and product excellence. (Main contact: Francesca Racioppi).

University of Alberta (UofA)
Will assume responsibility for leading the scientific component of the research, including the extraction, compilation, analysis and documentation of all data. This includes linking population data to health outcomes, taking into account the potential affects of confounders during interpretation of the data. Data will be copied for future use by any of the respective partners, on their written request.

All such activities will require the invitation to participate by all other partners. The cancer data used in this project will be computerized and will be provided to the Azerbaijan MOH for its web site/data base and cancer registry developments, and to the Sumgayit Centre. (Main contacts: Colin Soskolne and James Andruchow).

United Nations Development Program (UNDP) Country Office in Azerbaijan
As the sole funding body, will monitor and evaluate the implementation of the activity against the agreed-upon Work Plan and provide necessary local logistics support. (Main contact: Jamila Ibrahimova).

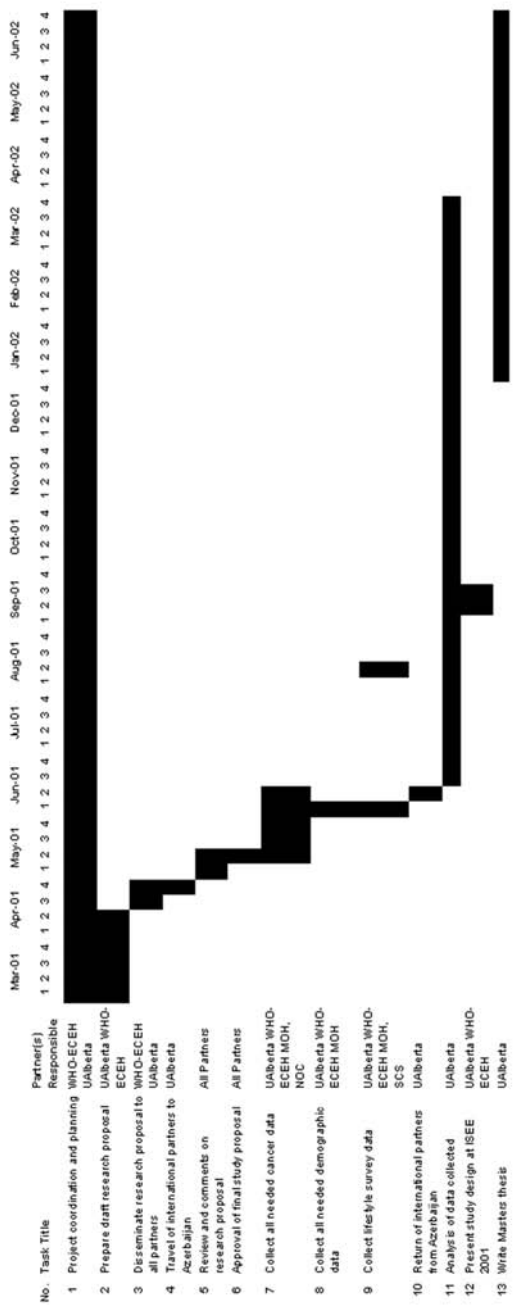
United Nations Office for Project Services (UNOPS)
As the executing agency of the Environmental Rehabilitation of Sumgayit Project, will ensure implementation of the activity by provision of oversight and facilitation as necessary. (Main contacts: Andrew Menz, Ulrike Meissner, Jill Nicholls).

Canadian Society for International Health (CSIH)
Will involve the University of Alberta, Sumgayit Centre for Environmental Rehabilitation, and Azerbaijan MOH in its 4-day Workshop in Ganja City from May 28, 2001. The intent is, in principle, to fold an environmental health research component into its existing main function of building health information systems in the Caucasus countries. (Main contacts: Chris Rosene and Valerie Douglas).

Budget Example

Sumgayit Cancer Study Itemized Budget Considerations	
Project Phase	**Item**
Data Collection, Analysis, and Preparation of Findings	Travel of Canadian researchers to Azerbaijan for study setup and data collection
	Azerbaijan MOH data access, travel, and professional fees
	Azerbaijan NOC data access, travel, and professional fees
	Conduct of lifestyle survey in Azerbaijan by SCS
	Fellowship for local experts during data collection
	Support for Canadian student during 2-year period of project
	Communication and reporting costs
	Professional fee for Canadian researchers in Azerbaijan
	Subtotal
Dissemination of Findings and Conclusion of Research	Travel of Canadian researchers to Azerbaijan to present results and conduct training session
	Travel of WHO officer from Italy to Azerbaijan to present results and conduct training session
	Workshop on manual/training event costs
	Professional fee for Canadian researchers during result presentation and workshop
	Communication and reporting costs
	Publication and printing costs
	Subtotal
Development of Manual	Translation of Manual
	Printing of Manual
	Fellowship for local experts during result presentation, and translation and dissemination of Manual
	Subtotal
	TOTAL

Toolkit №9: Planning Tools and Timelines: Sample Gant Chart



Jul-02 Aug-02 Sep-02 Oct-02 Nov-02 Dec-02 Jan-03 Feb-03 Mar-03 Apr-03 May-03 Jun-03 Jul-03 Aug-03 Sep-03
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No. Task Title Partner(s) Responsible
1 Project coordination and planning WHO-ECEH UAlberta
13 Write Masters thesis UAlberta
14 Poster presentation at ISEE 2002 UAlberta WHO-ECEH
15 Collect feedback from supervisory committee UAlberta
16 Write draft manual based on experiences UAlberta WHO-ECEH
17 Incorporate feedback on thesis UAlberta
18 Collect feedback from all partners All Partners
19 Defend Masters thesis UAlberta
20 Prepare executive summary, lay report UAlberta WHO-ECEH
21 Prepare draft manuscripts for publication UAlberta WHO-ECEH
22 Prepare travel to Azerbaijan, meetings All Partners
23 Present results in Azerbaijan All Partners
24 Receive input on manual All Partners
25 Incorporate feedback on, and complete manual UAlberta WHO-ECEH
26 Submit manual for peer-review UAlberta WHO-ECEH
27 Collect feedback on manuscripts All Partners
28 Submit manuscripts UAlberta WHO-ECEH
29 Incorporate feedback on manual UAlberta WHO-ECEH
30 Publish manual WHO-ECEH UAlberta UNDP
31 Translate manual WHO-ECEH UNDP
32 Disseminate manual WHO-ECEH UNDP

UNIVERSITY OF ALBERTA

Azerbaijan Republic Ministry of Health

Cancer Incidence and Mortality in the Industrial City of Sumgayit, Azerbaijan: A Descriptive Study

JE Andruchow, CL Soskolne, F Racioppi, A Senthilselvan, NM Cherry, HE Bryant, E Makhmudov, A Asadov, H Takasawa, O Akhundov, F Mardanli & A Islamzadeh

This study was conducted as a cooperative effort between the University of Alberta (UofA), Edmonton, the World Health Organization European Centre for Environment and Health (WHO-ECEH), Rome, the United Nations Development Programme (UNDP), the Sumgayit Centre for Environmental Rehabilitation and the Azerbaijan Republic Ministry of Health (MoH). The study is part of the implementation of the Public Health component of the UNDP project "Environmental Rehabilitation of Sumgayit.

Objective

The main goal of this project was to address public concerns that the health of Sumgayit residents has been negatively affected by long-term environmental and workplace pollution from industrial exposures.

The Study

Cancer rates[1] were compared between Sumgayit and selected comparison populations, both within and outside of Azerbaijan, over the period 1980-2000. Both the number of new cancer cases (incidence) and the number of cancer deaths (mortality) per year were studied, for several different cancers:

1) All cancers combined
2) Laryngeal
3) Lung
4) Urinary bladder
5) Female breast

A survey was also conducted to ensure that lifestyle factors, such as smoking, diet and alcohol consumption were not responsible for any of the observed differences in cancer rates.

Results

The available data suggest that, starting from about 1990, cancer rates in Sumgayit are higher than in the rest of the country. During the 1980s, no single region has noticeably higher or lower rates of cancer (Figure 1). Recorded cancer rates in all regions decreased substantially in the early 1990s, and tended to stabilize in the late 1990s. It should be noted that data were missing for a number of regions and years undermining the potential reliability of comparisons among cancer rates.

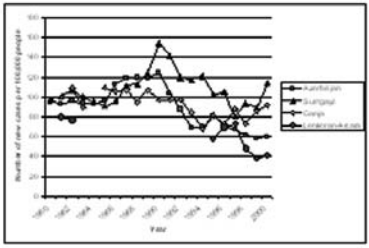

Figure 1. Cancer incidence in selected regions of Azerbaijan for all cancers combined, 1980-2000.

Estimates of cancer risk vary with the period of time being studied, as is evident in Table 1. Recorded cancer rates in Sumgayit and Azerbaijan are similar to those in Armenia and Georgia, but considerably lower than those in the Russian Federation (Figure 2). Azeri cancer rates are only one-third to one-half of those in Canada.

Results of the lifestyle survey suggest that smoking, diet, and drinking habits are similar among the study regions of Azerbaijan, and are not likely to be responsible for the observed differences in cancer rates.

[1] Cancer Rates are defined as the number of new cases of cancer (incidence) or the number of deaths (mortality) in a population divided by that population's size in a specified period of time (one year)

Table 1. Percentage differences in risk of developing cancer in selected regions of Azerbaijan in comparison to the rest of the country (1980-2000 & 1995-2000).

Region	% Difference in Risk of Getting Cancer	
	1980-2000	1995-2000
All cancers combined		
Sumgayit	22% more	51% more
Ganja	4% more	27% more
Lenkoran-Astara	33% less	16% less
Laryngeal cancer		
Sumgayit	7% less	39% more
Ganja	2% less	12% more
Lenkoran-Astara	44% less	33% less
Lung cancer		
Sumgayit	30% more	67% more
Ganja	16% more	49% more
Lenkoran-Astara	50% less	25% less
Urinary bladder cancer		
Sumgayit	64% more	149% more
Ganja	13% less	36% more
Lenkoran-Astara	51% less	28% less
Female breast cancer		
Sumgayit	16% more	21% more
Ganja	35% more	44% more
Lenkoran-Astara	45% less	41% less

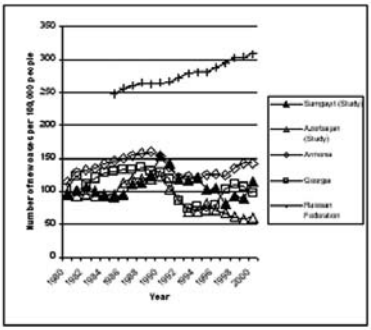

Figure 1. International comparisons of the incidence of all cancers combined per year, 1980-2000.

Discussion

Study results demonstrate that cancer rates are indeed higher in Sumgayit than in the rest of the country. However, the extent of the difference is difficult to estimate because of inadequacies with the data. The cancers that are most elevated in Sumgayit are urinary bladder cancer, lung cancer, and all cancers combined. The documented presence and use in the Sumgayit factories of a number of chemicals known or suspected to be able to cause cancer in humans lends plausibility to the study findings.

The decrease in cancer rates observed during the early 1990s in the city of Sumgayit, as well as Azerbaijan, Armenia, and Georgia suggests that the decrease was related to the social, economic and administrative changes that followed the end of the USSR. Owing to the difficulties the republics faced on independence, cancer diagnosis and cancer reporting likely dropped, even though the Actual number of cancers may not have changed. Cancer under-reporting is also likely to explain the lower than expected differences in cancer rates in Azerbaijan relative to Canada.

Conclusion

Cancer rates are higher in Sumgayit than the rest of Azerbaijan, most likely because of exposures from industry. However, because of missing information, it is difficult to be more precise on how much higher the cancer rates are in Sumgayit.

Recommendations

- Encourage local health researchers to conduct future studies specifically on urinary bladder or lung cancers.
- Build a cancer registry to accurately record new cancer cases and deaths.
- Seek international funding to aid in future research and infrastructure building.

For more information, please contact:

World Health Organization Regional Office for Europe
European Centre for Environment and Health (ECEH)
Via Francesco Crispi 10, 00187 Rome, Italy
Tel: +39 06 487 7550
Fax: +39 06 487 7599
Email: frr@who.it
Website: http://www.euro.who.int/healthimpact

***Note:** A selection, likely incomplete.*

****Note:** Many useful and prominent scientific journals are able to accessed with no charge by institutions in developing nations through a United Nations-WHO initiative. See Toolkit№1: Useful Epidemiology and Public Health Websites and Online Resources for more information.*

The list of journals that follows is not meant to be all-inclusive, nor does it suggest that journals not included in this list are of lesser quality. Instead, this listing is designed to provide readers who have limited experience with the international public health literature a foundation of reputable, high-quality journals they may consider for obtaining relevant information on the topics of public health and/or epidemiology or as potential destinations for publication of their own research. There are many other useful and high quality journals and publications for epidemiological and public health research which are not listed here.

American Journal of Epidemiology (AJE):
http://aje.oupjournals.org/
The American Journal of Epidemiology is a premier epidemiological journal devoted to the publication of empirical research findings, methodological developments in the field of epidemiological research and opinion pieces. It is aimed at both fellow epidemiologists and those who use epidemiological data, including public health workers and clinicians. Twenty-four issues are published annually.

American Journal of Industrial Medicine (AM J IND MED):
http://www.interscience.wiley.com/jpages/0271-3586/
The American Journal of Industrial Medicine considers for publication reports of original research, review articles, instructive case reports, and analyses of policy in the fields of occupational and environmental health and safety. The Journal also accepts commentaries, book reviews and letters of comment and criticism. The goals of the journal are to advance and disseminate knowledge, promote research and foster the prevention of disease and injury. Specific topics of interest include: occupational disease; environmental disease; pesticides; cancer; occupational epidemiology; environmental epidemiology; disease surveillance systems; ergonomics; dust diseases; lead poisoning; neurotoxicology; endocrine disruptors. Published six times annually.

American Journal of Preventive Medicine (AM J PREV MED):
http://www.ajpm-online.net/
The American Journal of Preventive Medicine is the official journal of the American College of Preventive Medicine and the Association of Teachers of Preventive Medicine, and publishes articles in the areas of prevention research, teaching, practice and policy. Original research is published on interventions aimed at the prevention of chronic and acute disease and the promotion of individual and community health. Of particular emphasis are papers that address the primary and secondary prevention of important clinical, behavioural and public health issues such as injury and violence, infectious disease, women's health, smoking, sedentary behaviours and physical activity, nutrition, diabetes, obesity, and alcohol and drug abuse.

Papers also address educational initiatives aimed at improving the ability of health professionals to provide effective clinical prevention and public health services. Papers on health services research pertinent to prevention and public health are also published. The journal also publishes official policy statements from the two co-sponsoring organizations, review articles, media reviews, and editorials. Finally, the journal periodically publishes supplements and special theme issues devoted to areas of current interest to the prevention community.

American Journal of Public Health (AJPH):
http://www.ajph.org/
The American Journal of Public Health (AJPH) is a high-quality publication dedicated to original work in research, research methods, and program evaluation in the field of public health. This prestigious journal also regularly publishes authoritative editorials and commentaries and serves as a forum for the analysis of health policy. All published papers have undergone rigorous peer review (only one out of five submitted papers is accepted for publication).

American Journal of Tropical Medicine and Hygiene (AM J TROP MED HYG):
http://www.ajtmh.org/
The American Society of Tropical Medicine and Hygiene (ASTMH) is the principal organization in the United States representing scientists, clinicians and others with interests in the prevention and control of tropical diseases through research and education. The interests of the Society lie in tropical medicine, including the varied parasitic and viral diseases of the tropics, as well as other infectious diseases, such

as enteric and mycobacterial infections. The Society publishes the monthly American Journal of Tropical Medicine and Hygiene, one of the most widely distributed journals of its type in the world. Its wide geographic distribution, broad technical coverage and prompt publication policy make it a favoured medium for communicating new findings in the area of tropical medicine.

Annals of Epidemiology (ANN EPIDEMIOL):
http://www.elsevier.com/locate/issn/10472797
Annals of Epidemiology is a peer reviewed, international journal devoted to epidemiologic research and methodological development. The journal emphasizes the application of epidemiologic methods to issues that affect the distribution and determinants of human illness in diverse contexts. Its primary focus is on chronic and acute conditions of diverse aetiologies and of major importance to clinical medicine, public health, and health care delivery. Annals encourages the use of epidemiology in a multidisciplinary approach to understanding disease aetiology. Review articles, reports from U.S. Federal and International sources, Editorials, Commentaries, Brief Communications, Letters to the Editor, Book Reviews, and selected papers from major symposia are also published.

Annual Reviews of Public Health (ANNU REV PUB HEALTH):
http://publhealth.annualreviews.org/
Because Annual Review chapters examine entire subfields in depth, they are written by experienced researchers upon invitation from one of our Editorial Committees. Annual Reviews Committees nevertheless welcome suggestions from its readers. Questions or comments about editorial content or policies should be directed to the appropriate production editor for the Annual Review series.

Archives of Environmental Health (ARCH ENVIRON HEALTH):
http://www.heldref.org/aeh.php
Archives of Environmental Health consolidates the latest research, both nationally and internationally, from such varying fields as epidemiology, toxicology, biostatistics, and biochemistry. Publishing only new research based on the most rigorous methods, Archives addresses such topics of current concern as health significance of toxic waste, new energy technology, industrial processes and the environmental causation of neurobiological dysfunction, birth defects, cancer, and chronic degenerative diseases. For more than 50 years, this noted journal has provided objective documentation of the effects of environmental agents on human, and, in some cases, animal populations.

British Medical Journal (BMJ):

www.bmj.com

The BMJ aims to publish rigorous, accessible and entertaining material that will help doctors and medical students in their daily practice, lifelong learning and career development. In addition, it seeks to be at the forefront of the international debate on health. To achieve these aims it publishes original scientific studies, review and educational articles, and papers commenting on the clinical, scientific, social, political, and economic factors affecting health. The BMJ is delighted to receive articles for publication in all of these categories - from doctors and others. The journal can publish only about 9% of more than 6000 articles that it receives each year, but the editors aim to give quick decisions to potential authors.

The BMJ is published weekly and has a circulation of about 108,500, of which 13,500 copies are distributed outside Britain. In addition, local editions reach another 173,000 readers. Material published in the weekly journal may be reproduced in these editions, in the student BMJ, and on the BMJ web site.

Bulletin of the World Health Organization (B WORLD HEALTH ORGAN):

http://www.who.int/bulletin/

The Bulletin's mission is "to publish and disseminate scientifically rigorous public health information of international significance that enables policy-makers, researchers and practitioners to be more effective; it aims to improve health, particularly among disadvantaged populations". The Bulletin welcomes unsolicited manuscripts, which are initially screened in-house for originality, relevance to an international public health audience, and scientific rigour. Twelve issues are published annually.

Cancer Causes & Control (CANCER CAUSE CONTROL):

http://www.kluweronline.com/issn/0957-5243/contents

Cancer Causes & Control is an international refereed journal that both reports and stimulates new avenues of investigation into the causes, control, and subsequent prevention of cancer. By drawing together related information published currently in a diverse range of biological and medical journals, it has a multidisciplinary and multinational approach. The scope of the journal includes: variation in cancer distribution within and between populations; factors associated with cancer risk; preventive and therapeutic interventions on a population scale; economic, demographic, and health-policy implications of cancer; and related methodological issues.

The emphasis is on speed of publication. The journal will normally publish within 30 to 60 days of acceptance of manuscripts. Cancer Causes & Control publishes original and review articles, hypotheses, comments, opinions, and letters to the Editor which will have direct relevance to researchers and practitioners working in epidemiology, medical statistics, cancer biology, health education, medical economics and related fields. The journal also contains significant information for government agencies concerned with cancer research, control and policy.

Environmental Health: A Global Access Science Source:
http://www.ehjournal.net/
This open access, online journal publishes papers on all aspects of environmental and occupational medicine and related studies in toxicology and epidemiology.

Environmental Health: A Global Access Science Source is published by BioMed Central, an independent publishing house committed to providing immediate free access to peer-reviewed biomedical research.

Environmental Health Perspectives (EHP):
http://ehp.niehs.nih.gov/
Environmental Health Perspectives is a peer-reviewed journal dedicated to the discussion of the effect of the environment on human health. EHP comprises 17 issues annually with monthly sections devoted to children's health and environmental medicine, a toxicogenomics research section published with toxicogenomics news in separate quarterly issues, and an annual review issue. EHP also publishes a quarterly Chinese-Language Edition and occasional special issues. In addition, publications of the National Toxicology Program including the Report on Carcinogens are available here.

Epidemiology (EPIDEMIOLOGY):
http://www.epidem.com/
Epidemiology is a peer-reviewed scientific journal that publishes original research on the full spectrum of epidemiologic topics. Journal content ranges from cancer, heart disease and other chronic illnesses to reproductive, environmental, psychosocial, infectious-disease and genetic epidemiology. The journal places special emphasis on theory and methodology, and welcomes commentaries that explore fundamental assumptions or offer provocative dissent.

Epidemiologic Reviews (EPIDEM REV):

http://epirev.oupjournals.org/

Epidemiologic Reviews is a leading review journal in public health. Published once a year, issues collect review articles on a particular subject. Recent issues have focused on prostate cancer, cohort studies, vaccines, and genetic epidemiology. The 2003 issue will focus on injury prevention.

European Journal of Public Health (EUR J PUBLIC HEALTH):

http://www3.oup.co.uk/eurpub/

The European Journal of Public Health is a multidisciplinary journal aimed at attracting contributions from epidemiology, health services research, management, ethics and law, health economics, social sciences and environmental health. The journal provides a forum for discussion and debate of current international public health issues with a focus on the European region. The journal is published four times annually, and contains refereed, original scientific articles; policy articles; reviews on major themes; editorials; commentaries; book reviews; news and letters; and announcements of forthcoming events.

International Archives of Occupational and Environmental Health

(INT ARCH OCCUP ENVIRON HEALTH):

http://link.springer.de/link/service/journals/00420/

All papers should be based on present-day standards and relate to occupational or ambient environmental problems, especially on one of the following topics:

- Clinical and epidemiological studies on morbidity and mortality
- Clinical and epidemiological studies on parameters relevant to the estimation of health risks
- Human experimental studies on environmental health effects (Animal experiments, only if relevant to pathogenetic aspects)
- Methods for studying topics mentioned above

The journal publishes the following types of articles:

- Concepts in occupational and environmental health
- Editorials

- Review articles
- Original articles
- Short communications
- Documents of international meetings and activities
- Reports on national health regulations

International Journal of Epidemiology (IJE):

http://ije.oupjournals.org/

The International Journal of Epidemiology is recommended to anyone who needs to keep up to date with epidemiological advances and new developments throughout the world. It encourages communication among those engaged in the research, teaching, and application of epidemiology of both communicable and non-communicable disease, including research into health services and medical care. Also covered are new methods, epidemiological and statistical, for the analysis of data used by those who practise social and preventive medicine. The International Journal of Epidemiology is published six times yearly.

International Journal of Occupational and Environmental Health (IJOEH):

http://www.ijoeh.com/

IJOEH will consider the publication of any original manuscript that deals with the broad field of occupational and environmental health.

Journal of Clinical Epidemiology (J CLIN EPIDEMIOL):

http://www.elsevier.com/locate/issn/08954356

Published monthly, the Journal of Clinical Epidemiology provides timely, authoritative studies developed from the interplay of clinical medicine, epidemiology, biostatistics and pharmacoepidemiology. Articles are oriented toward methodology, clinical research or both. A special section, Pharmacoepidemiology Reports, is dedicated to the rapid publication of articles on the clinical epidemiologic investigation of pharmaceutical agents.

Journal of Epidemiology and Community Health
(J EPIDEMIOL COMMUN HEALTH):

http://jech.bmjjournals.com/

The Journal of Epidemiology and Community Health is a truly international journal which encompasses all the aspects of epidemiology and public health. It publishes original papers, leading articles, reviews and short papers concerned with the study and improvement of communities worldwide. Published monthly, the journal is fully refereed and indexed in ISI Current Contents and MedLine/Index Medicus. The main sections of the journal are:

- Research reports
- Theory and methods
- Public Health policy and practice

Reduced subscription rates are available for all members of major epidemiology and public health societies.

Journal of Exposure Analysis and Environmental Epidemiology (JEAEE):

http://www.nature.com/jea/

The Journal of Exposure Analysis and Environmental Epidemiology, a peer-reviewed publication, is published six times a year. The journal publishes research important to exposure assessment, environmental epidemiology, and related disciplines. It also publishes manuscripts dealing with measurements, modelling, instrumentation, and questionnaires; studies on chemical, biological, and physical principles required to analyze human exposure from single and multiple media and routes; and epidemiological investigations. It is the official publication of the International Society of Exposure Analysis. Types of work considered include articles that describe original research results; reviews on subjects of importance to exposure assessment and epidemiology; preliminary communications; viewpoints; reports or proceedings of conferences; and brief announcements of scientific meetings or courses of study.

Journal of Occupational and Environmental Medicine
(J OCCUP ENVIRON MED):

http://www.acoem.org/journal/general.asp

The Journal of Occupational & Environmental Medicine is a leading scientific, peer-reviewed monthly publication in the specialty of occupational and environmental medicine. It serves as an indispensable source to in-depth, clinically oriented research articles and technical reports that keep readers up-to-date on cutting-edge medical developments in the field.

Lancet (LANCET):

www.thelancet.com

The Lancet is a high-profile international general medical journal that will consider any original contribution that advances or illuminates medical science or practice, or that educates or entertains the journal's readers.

Management of Environmental Quality
(formerly: Environmental Management and Health Journal):

http://www.emeraldinsight.com/info/journals/meq/meq.jsp

As the industrialized world advances in power, the increasing emphasis on technology, chemicals and intensive farming practices have created massive prosperity. But the price we pay for our wealth, in deteriorating health and disabling killer diseases, is regarded as too high. How do we tame the monster we have created? Management of Environmental Quality: An International Journal has become a highly respected international forum for the serious debate of environmental issues and their effect on human health.

New England Journal of Medicine (NEJM):

http://content.nejm.org/

Each week, the New England Journal of Medicine presents major, previously unpublished research results, clinical findings, updates, and opinions. Over 240,000 physicians, students, managers, and other medical professionals in more than 120 countries subscribe to the New England Journal of Medicine.

Scandinavian Journal of Work, Environment, and Health (SCAND J WORK ENVIRON HEALTH):

http://www.sjweh.fi/

The aim of the Scandinavian Journal of Work, Environment & Health is to promote research in the fields of occupational health and safety and the work environment and to increase knowledge through the publication of original and review articles. The journal also publishes short communications, case reports, commentaries, discussion papers, clinical questions, consensus reports, meeting reports, other reports, book reviews, a noted elsewhere section, news, and announcements. The journal deals with topics concerning the interactions between work and health in such fields as occupational medicine, toxicology, epidemiology, hygiene, physiology, psychology, ergonomics, and sociology. In addition, health topics related to work/home and work/outdoor environment interfaces are included, as well as studies of the effects of preventive measures and interventions in the work, home or outdoor environment. The journal is open to all authors without regard to nationality.

Statistics in Medicine (STAT MED):

http://www.interscience.wiley.com/jpages/0277-6715/

Statistics in Medicine will publish papers on practical applications of statistics and other quantitative methods to medicine and its applied sciences. It will embrace all aspects of the collection, analysis, presentation and interpretation of medical data. Specific areas will include clinical trials, diagnostic studies, quality control, laboratory experiments, epidemiology, and health care research. The journal will emphasize the relevance of numerical techniques and will aim to communicate statistical and quantitative ideas in a medical context. Examples of applications of statistics to specific projects, articles explaining new statistical methods and reviews of general topics will be published; papers containing extensive mathematical theory will be excluded. The main criteria for publication will be appropriateness of the statistical method to the particular medical problem and clarity of exposition. The ultimate goal of Statistics in Medicine is to enhance communication between statisticians, clinicians and medical researchers with the common purpose of advancing knowledge and understanding of quantitative aspects of medicine. It is intended that both the readers and authors of the Journal include statisticians, clinicians, epidemiologists, health researchers, mathematicians and computer scientists interested in medicine.

Toolkit №12: Template for a Draft Manuscript

Title: A concise, yet descriptive title appropriate to the study should be provided.

Names of Author(s): Provide the names of all persons who made a substantial intellectual contribution to the work.

Author Contact Information: List the institution of employment/affiliation, and means of contact (mailing address, email address, telephone number)

Abstract: A summary of the background, study design, methods, results, and conclusions of the study in 250 words or less.

Introduction: Provide the reader a brief background as to in what context the study was conducted. Briefly review the pertinent literature. Why was the study being conducted? What was being studied?

Methods: The author should list where, how, and when the study was conducted. Describe the study design, means of data collection and sample size, as well as the methods of data analysis.

Results: Detail the major qualitative and quantitative findings of the study. Provide the results of statistical tests if available. Graphics, figures, and/or tables may be helpful.

Discussion: What is the meaning and broader significance of the study results? What aspects of the study were seen as being strengths? What were the weaknesses? How could the study have been improved? Can future research be suggested?

Conclusions: What were the major findings of the study? What are the take-home messages for the reader?

Acknowledgements: List funding source(s). Provide special thanks as appropriate.

Key References

Andruchow, JE. Cancer incidence and mortality in the industrial city of Sumgayit, Azerbaijan: A descriptive study.
Available online at:
http://www.ualberta.ca/~soskolne/Thesis-FINAL-UofA-Lodged-Jan6-2003.pdf

Andruchow JE, Soskolne CL, Racioppi F, Senthilselvan A, Makhmudov E and Asadov A. Cancer incidence and mortality in the industrial region of Sumgayit, Azerbaijan. International Journal of Occupational and Environmental Health (IJOEH) 2006;12(3):234-241.

Andruchow JE, Soskolne CL, Racioppi F and Bertollini R. Capacity building for epidemiological research in the Newly Independent State of Azerbaijan. (Available on-line since October 22, 2004). Annals of Epidemiology. March 2005, Vol 15(3):228-231. (PMID# 15723769)

Baker D, Kjellstrom T, Calderon R, Pastides H (eds). Environmental Epidemiology: A Textbook on Study Methods and Public Health Applications.
World Health Organization: 1999.

Beaglehole R, Bonita R, Kjellstrom T. Basic Epidemiology. Geneva:
World Health Organization, 1993.

Breslow NE, Day NE. Statistical Methods in Cancer Research: Volume II – The design and analysis of cohort studies. Lyon: IARC Scientific Publications No. 82, 1987.

Environmental Epidemiology: Study Methods and Application. Editors: Dean Baker and Mark J. Nieuwenhuijsen. Oxford University Press, New York 2008.

Hennekens CH, Buring JE. Mayrent SL (ed). Epidemiology in Medicine.
Boston: Little Brown, 1987.

International Ethical Guidelines for Biomedical Research Involving Human Subjects (Geneva: CIOMS/WHO 1993)

International Guidelines for Ethical Review of Epidemiological Studies
(Geneva: CIOMS/WHO 1991)

Jaakkola JJK, Cherniack M, Spengler JD, Ozkaynak H, Wojtyniak B, Egorov A, Rakitin P, Katsnelson B, Kuzmin S, Privalova P, Lebedeva NV. Use of health information systems in the Russian Federation in the assessment of environmental health effects. Environmental Health Perspectives 2000; 108(7): 589-594.

Kleinbaum DG, Kupper LL, Morgenstern H. Epidemiologic Research: Principles and Quantitative Methods. Publ. Lifetime Learning Publications, Van Nostrand Reinhold Company, New York, 1982.

Last JM. A Dictionary of Epidemiology (Fourth Edition). New York: Oxford University Press, 2001.

Merletti F, Soskolne CL, and P Vineis. Epidemiological Method Applied to Occupational Health and Safety. In: International Labour Organization Encyclopaedia of Occupational Health and Safety (Ed. J.M. Stellman) (1998), pp. 28.2-28.6.

Merletti F, Soskolne CL, and P Vineis (eds). Epidemiology and Statistics - Chapter 28. In: International Labour Organization Encyclopaedia of Occupational Health and Safety (Ed., J.M. Stellman) (1998), pp. 28.1-28.39.

Rahu M. Cancer epidemiology in the Former Soviet Union. Epidemiology 1992; 3(5): 464-470.

Soskolne CL. Linkages between epidemiology and health policy. In: Challenges to Epidemiology in Changing Europe: Proceedings of the Conference. [Ed: W. Jedrychowski, J. Vena, U. Maugeri] July 2-3, 1999, Krakow, Poland: p. 173-184.

Soskolne CL, Light A. Towards ethics guidelines for environmental epidemiologists. The Science of the Total Environment, 184(1,2) May 17, 1996:137-147.

Stellman S and Soskolne CL. Questionnaires in Epidemiological Research. In: International Labour Organization Encyclopaedia of Occupational Health and Safety (Ed. J.M. Stellman) (1998), pp. 28.30-28.35.

Tulchinsky, TH. The new public health: An introduction for the 21st Century. San Diego, California : Academic Press (2000). 882 p.

World Health Organization Health For All Online (WHO-HFA) Database. http://www.who.dk/hfadb

Glossary

**Where available, definitions have been obtained from Last 2001, with permission of Oxford University Press.*

AETIOLOGY

Literally, the science of causes, causality; in common usage, cause.

AGE-SPECIFIC RATE

A rate for a specified age group. The numerator and denominator refer to the same age group. Example:

$$\text{Age-specific death rate (ages 25-34)} = \frac{\text{Number of deaths among residents age 25-34 in an area in a year}}{\text{Average (for midyear) population age 25-34 in that year}} \times 100{,}000$$

AGE-STANDARDIZATION

A procedure for adjusting rates, e.g., death rates, designed to minimize the effects of differences in age composition when comparing rates for different populations.

ANALYTIC STUDY

A study designed to examine associations, commonly putative or hypothesized causal disease relationships. An analytic study is usually concerned with identifying or measuring the effects of risk factors or is concerned with the health effects of specific exposure(s). Contrast with DESCRIPTIVE STUDY, which does not test hypotheses. The common types of analytic study are cross-sectional, cohort, and case-control. In an analytic study, individuals in the study population may be classified according to absence or presence (or future development) of specific disease and according to "attributes" that may influence disease occurrence. Attributes may include age, race, sex, other disease(s), genetic, biochemical, and physiological characteristics, economic status, occupation, residence, and various aspects of the environment or personal behaviour.

BIAS

Deviation of results or inferences from the truth, or processes leading to such deviation. Any trend in the collection, analysis, interpretation, publication, or review of data that can lead to conclusions that are systematically different from the truth. Among the ways in which deviation from the truth can occur, are the following:

1) Systematic (one-sided) variation of measurements from the true values (synonym: systematic error).

2) Variation of statistical summary measures (means, rates, measures of association, etc.) from their true values as a result of systematic variation of measurements, other flaws in data collection, or flaws in study design or analysis.

3) Deviation of inferences from the truth as a result of flaws in study design, data collection, or the analysis or interpretation of results.

4) A tendency of procedures (in study design, data collection, analysis, interpretation, review, or publication) to yield results or conclusions that depart from the truth.

5) Prejudice leading to the conscious or unconscious selection of study procedures that depart from the truth in a particular direction, or to one-sidedness in the interpretation of results.

The term "bias" does not necessarily carry an imputation of prejudice or other subjective factor, such as the experimenter's desire for a particular outcome. This differs from conventional usage in which bias refers to a partisan point of view. Many varieties of bias have been described.

BIAS, INTERVIEWER

Systematic error due to interviewer's subconscious or even conscious gathering of selective data.

BIAS, MEASUREMENT

Systematic error arising from inaccurate measurement (or classification) of subjects on the study variables.

BIAS, OBSERVER

Systematic difference between a true value and that actually observed due to observer variation. Observer variation may be due to differences among observers (interobserver variation) or to variation in readings by the same observer on separate occasions (intraobserver variation).

BIAS, RECALL

Systematic error due to differences in accuracy or completeness of recall to memory of prior events or experiences. Example: Mothers whose children have had or have died of leukemia are more likely than mothers of healthy living children to remember details of diagnostic x-ray examinations to which these children were exposed in utero.

BIAS, SELECTION

Error due to systematic differences in characteristics between those who are selected for study and those who are not. Examples include hospital cases or cases under a physician's care, excluding those who die before admission to hospital because the course of their disease is so acute, those not sick enough to require hospital care, or those excluded by distance, cost, or other factors. Selection bias also invalidates generalizable conclusions from surveys that would include only volunteers from a healthy population.

CONFIDENCE INTERVAL (CI)

The computed interval with a given probability, e.g., 95%, that the true value of a variable such as a mean, proportion, or rate is contained within the interval.

CONFOUNDING

1. A situation in which the effects of two processes are not separated. The distortion of the apparent effect of an exposure on risk brought about by the association with other factors that can influence the outcome.
2. A relationship between the effects of two or more causal factors as observed in a set of data such that it is not logically possible to separate the contribution that any single causal factor has made to an effect.
3. A situation in which the measure of the effect of an exposure on risk is distorted because of the association of exposure with other factor(s) that influence the outcome of study.

CONTROL GROUP
See REFERENCE GROUP.

DATA DREDGING
A jargon term, meaning analyses done on a post-hoc basis without benefit of pre-stated hypotheses, as a means of identifying noteworthy differences. Such analyses are sometimes done when data have been collected on a large number of variables and hypotheses are suggested by the data; the scientific validity of data dredging is at best dubious, usually unacceptable.

DATA QUALITY
Data quality is a term that refers to the usefulness of scientific data to generate precise, accurate, and meaningful study findings. High quality data allows for more robust conclusions to be drawn, and is much more useful to the researcher. Low quality data may generate less robust conclusions, or may not generate meaningful results at all. Data quality is commonly discussed in terms of completeness and validity:

COMPLETENESS
Completeness is concerned with the proportion of events (e.g., cases or deaths) from the total number of events actually occurring in a study population that the data collection process is able to secure. If the data account for only a small proportion, i.e., low completeness, then the quality of the data suffers because they are unlikely to approximate the actual conditions in the population. Data completeness can be influenced by a number of factors, including the diligence of data reporting and recording, and the mechanisms of data collection.

VALIDITY
Validity describes the 'truthfulness' of the data: that is, the extent to which the recorded data correctly reflect the actual state of a variable in the population. A number of factors can influence data validity, including diagnostic accuracy and misdiagnoses, the effectiveness and accuracy of measurement equipment, data collection and recording errors, and even the possibilities of data censorship or fabrication.

DESCRIPTIVE STUDY

A study concerned with and designed only to describe the existing distribution of variables, without regard to causal or other hypotheses. Contrast with ANALYTIC STUDY. An example is a community health survey, used to determine the health status of the people in a community. Descriptive studies, e.g., analyses of cancer registry data, can be used to measure risks, generate hypotheses, etc.

DISEASE

Literally, dis-ease, the opposite of ease, when something is wrong with a bodily function. The words, "disease," "illness," and "sickness" are loosely interchangeable, but are better regarded as not wholly synonymous. M.W. Susser has suggested that they be used as follows:

Disease is a physiological/psychological dysfunction.
Illness is a subjective state of the person who feels aware of not being well;
Sickness is a state of social dysfunction, i.e., a role that the individual assumes when ill.

EPIDEMIOLOGY

The study of the distribution and determinants of health-related states or events in specified populations, and the application of this study to the control of health problems. "Study" includes surveillance, observation, hypothesis testing, analytic research, and experiments. "Distribution" refers to analysis by time, place and classes of persons affected. "Determinants" are all the physical, biological, social, cultural, and behavioural factors that influence health. "Health-related states and events" include diseases, causes of death, behaviours such as the use of tobacco, reactions to preventive regimens, and provision and use of health services. "Specified populations" are those with identifiable characteristics such as precisely defined numbers. "Application to control…" makes explicit the aim of epidemiology – to promote, protect, and restore health.

EPIDEMIOLOGY, ENVIRONMENTAL

The study of the distribution of health-related states or events in specified populations in relation to determinants/hazards in the living environment of these populations, and the application of this study to the control of such hazards.

ETHICS

The branch of philosophy that deals with the distinctions between right and wrong – with the moral consequences of human actions. Ethical principles govern the conduct of epidemiology, as they do all human activities. The ethical issues that arise in epidemiological practice and research include informed consent, confidentiality, respect for human rights, and scientific integrity. Epidemiologists and others have developed guidelines for the ethical conduct of epidemiological studies.

EXPOSURE

1. Proximity and/or contact with a source of a disease agent in such a manner that effective transmission of the agent or harmful effects of the agent may occur.
2. The amount of a factor to which a group or individual was exposed; sometimes contrasted with dose, the amount that enters or interacts with the organism.
3. Exposures may of course be beneficial rather than harmful, e.g., exposure to immunizing agents.
4. The process by which an agent comes into contact with a person or animal in such a way that the person or animal may develop the relevant outcome, such as a disease.

GANT CHART

A graphical way of indicating those tasks that will be completed over specific time periods.

GREY LITERATURE

That store of knowledge that was not subjected to peer review with a view to publication in the accessible scientific literature.

HEALTH

The World Health Organization (WHO) described health in the preamble to its constitution as, "A state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity." The WHO description of health has been criticized because of the difficult of defining and measuring "complete" well-being.

There are several other definitions, including the following:

1. A state of dynamic balance in which an individual's or group's capacity to cope with all the circumstances of living is at an optimum level.
2. A state characterized by anatomical, physiological and psychological integrity, ability to perform valued family, work and community roles; ability to deal with physical, biological, psychological and social stress; a feeling of well-being; and freedom from the risk of disease and untimely death.
3. Rene Dubos offered the following definition: "A modus vivendi enabling imperfect men to achieve a rewarding and not too painful existence while they cope with an imperfect world."
4. The word "health" is derived from the Old English Hal, meaning hale, whole, sound in wind and limb.

HYPOTHESIS

1. A supposition, arrived at from observation or reflection, that leads to refutable predictions.
2. Any conjecture cast in a form that will allow it to be tested and refuted.

HYPOTHESIS-GENERATION

The process of creating an hypothesis based on observation and interpretation of available information.

HYPOTHESIS-TESTING

The process of scientifically assessing whether or not a particular hypothesis is in agreement with observed data.

ICD-9

The 9th Revision of the International Classification of Diseases.

IMPACT ASSESSMENT

Simply stated, is the identification of future consequences of a current or proposed action.

INFORMED CONSENT

Voluntary consent given by a subject – i.e., person or a responsible proxy (e.g., a parent) – for participation in a study, immunization program, treatment regimen, etc., after being informed of the purpose, methods, procedures, benefits, and risks, and, when relevant, the degree of uncertainty about outcome. The essential criteria of informed consent are that the subject has both knowledge and comprehension, that consent is freely given without duress or undue influence, and that the right of withdrawal at any time is clearly communicated to the subject. Other aspects of informed consent in the context of epidemiologic and biomedical research, and criteria to be met in obtaining it, are specified in International Guidelines for Ethical Review of Epidemiological Studies (Geneva: CIOMS/WHO 1991) and International Ethical Guidelines for Biomedical Research Involving Human Subjects (Geneva: CIOMS/WHO 1993). A distinction is made between TACIT and EXPLICIT informed consent.

EXPLICIT INFORMED CONSENT

Usually secured by prior communication with the eligible potential participant and the procurement of a signature or mark of understanding on a document specially prepared for the purpose of recording that the process of obtaining informed consent as described above was adhered to.

TACIT (IMPLICIT) INFORMED CONSENT

Usually applies when a person volunteers their participation in a study by simply providing the information, action, or specimen needed in the absence of any formalised permission, but with due respect to the person's right to refuse to participate.

INTERVIEWER BIAS

Systematic error due to interviewers' subconscious or conscious gathering of selective data.

LATENT PERIOD

(Synonym: latency) Delay between exposures to a disease-causing agent and the appearance of manifestations of the disease. After exposure to ionizing radiation, for instance, there is a latent period of five years, on average, before development of leukemia, and more than 20 years before development of certain other malignant conditions. The term "latent period" is often used synonymously with "induction period," that is, the period between exposure to a disease-causing agent and the appearance of the manifestations of the disease. It has also been defined as the period from disease initiation to disease detection.

LITERATURE REVIEW
A critical analysis of peer-reviewed journals and relevant publications, systematically conducted to provide a synthesis of the state of knowledge as a basis for summarizing current research, or justifying further research.

LOG BOOK
A record of any deviances from the specified protocol of the study. This file is continually maintained and updated in order to provide a precise record of all changes or variations from the study protocol that are made. This record is very useful for evaluating the success of a study design or searching for potential errors in methods or procedures.

MAGNITUDE OF EFFECT
The actual size of the measure calculated to indicate the relationship between an exposure and an outcome.

MEASURE OF ASSOCIATION
A quantity that expresses the strength of association between variables. Commonly used measures of association are differences between means, proportions or rates, the rate ratio, the odds ratio, and correlation and regression coefficients.

MORTALITY:INCIDENCE RATIO (MIR)
One technique, among several, used to gain a sense of data quality, MIRs calculate a ratio of mortality (number of deaths) to the number of incident cases for a specific disease recorded in a particular region over a specified time period. Because not all incident cases die (from most diseases), one expects that the number of incident cases of a disease should always exceed the number of deaths from that disease in a given time period, and that the ratio between the two should be proportional to the known survival for that disease, if incidence and mortality are reported accurately (assuming stable levels of exposure to risk factors and a stable demographic structure). If one were to find an MIR to exceed unity, this would provide reason for concern about the quality of the data.

NATURAL EXPERIMENT
Naturally occurring circumstances in which subsets of the population have different levels of exposure to a supposed causal factor, in a situation resembling an actual experiment where human subjects would be randomly allocated to groups. The presence of persons in a particular group is non-random. The term derives from the work of John Snow (1813-1858), who investigated the distribution of cholera cases in London in relation to the source of their water supply. It would have been unethical for Snow to allocated subjects to groups exposed to a lethal infection, but tracing the source of their drinking water, using “shoe-leather epidemiology”, gave him the opportunity to make crucially important observations.

NULL HYPOTHESIS

The statistical hypothesis that one variable has not association with another variable or set of variables, or that two or more population distributions do not differ from one another. In simplest terms, the null hypothesis states that the results observed in a study, experiment, or test are no different from what might have occurred as a result of the operation of chance alone.

PARTICIPANTS (SUBJECTS)

Person upon whom research is conducted. The term research participant is suggested in preference to research subject on the grounds that subject is demeaning, but this can be ambiguous because members of research teams are also called participants.

PEER-REVIEW

Process of review of research proposals, manuscripts submitted for publication, abstracts submitted for presentation at scientific meetings, whereby these are judged for scientific and technical merit by other scientists in the same field. The term also refers to review of clinical performance when it is a form of medical audit.

PILOT STUDY (INVESTIGATION)

A small-scale test of the methods and procedures to be used on a larger scale if the pilot study demonstrates that these methods and procedures can work.

POINT ESTIMATE

A result statistic that does not take significance into account.

POISSON REGRESSION

A multivariate statistical modeling technique used to compare count data from independent populations. Output is a rate ratio.

POPULATION

1. All the inhabitants of a given country or area considered together; the number of inhabitants of a given country or area.
2. (In sampling) The whole collection of unites from which a sample may be drawn; not necessarily a population of persons; the units may be institutions, records, or events. The sample is intended to give results that are representative of the whole population.

POST-HOC ANALYSES

After the fact; a re-examination of the data after the data have been analyzed and the original hypothesis tested.

POWER

The ability of a study to demonstrate an association if one exists. The power of a study is determined by several factors, including the frequency of the condition under study, the magnitude of the effect, the study design, and sample size. Mathematically, power is 1-β (Type II Error). A characteristic of a statistical hypothesis test, denoting the probability that the null hypothesis will be rejected if it is indeed false. Resolving power is the comparable property of individual measurements.

PREVALENCE

The number of instances of a given disease or other condition in a given population at a designated time; sometimes used to mean prevalence rate. When used without qualification the term usually refers to the situation at a specified point in time (point prevalence).

PROBE

A tentative exploratory advance or survey.

PROPORTIONAL INCIDENCE RATIO (PIR)

The analogue to the PROPORTIONAL MORTALITY RATIO (PMR) using incidence, rather than mortality data.

PROPORTIONAL MORTALITY RATIO (PMR)

The proportion of observed deaths from a specified condition in a defined population, divided by the proportion of deaths expected from this condition in a standard population, either on an age-specific basis or after age-adjustment. Unlike the STANDARDIZED MORTALITY RATIO (SMR), it does not require data on the age composition of the population, but only on the deaths. The acronym, PMR, is preferably avoided because the same initial letters can stand for perinatal mortality rate.

PROSPECTIVE

With a view to the future.

PROTECTIVE FACTOR

An element that induces a level of protection as opposed to one that induces harm.

PUBLIC HEALTH

Public health is one of the efforts organized by society to protect, promote, and restore the people's health. It is the combination of sciences, skills, and beliefs that is directed to the maintenance and improvement of the health of all the people through collective or social actions. The programs, services, and institutions involved emphasize the prevention of disease and the health needs of the population as a whole. Public health activities chance with changing technology and social values, but the goals remain the same: to reduce the amount of disease, premature death, and disease-produced discomfort and disability in the population. Public health is thus a social institution, a discipline, and a practice.

P VALUE (PROBABILITY)

The probability that a test statistic would be as extreme or more extreme than observed if the null hypothesis were true. The letter P, followed by the abbreviation n.s. (not significant) or by the symbol < (less than) or > (greater than) and a decimal notation, such as 0.01, 0.05, is a statement of the probability that the difference observed could have occurred by chance if the groups were really alike, i.e., under the NULL HYPOTHESIS. Investigators may arbitrarily set their own significance levels, but in most biomedical and epidemiologic work, a study result whose probability is less than 5% ($P < 0.05$) or 1% ($P < 0.01$) is considered sufficiently unlikely to have occurred by chance to justify the designation "statistically significant." See also STATISTICAL SIGNIFICANCE.

QUALITY CONTROL

The supervision and control of all operation involved in a process, usually involving sampling and inspection, in order to detect and correct systematic or excessively random variations in quality.

RATE

A rate is a measure of the frequency of a phenomenon. In epidemiology, demography, and vital statistics, a rate is an expression of the frequency with which an event occurs in a defined population; the use of rates rather than raw numbers is essential for comparison of experience between populations at different times, different places, or among different classes of persons. The components of a rate are the numerator, the denominator, the specified time in which events occur, and usually a multiplier, a power of 10, which converts the rate from an awkward fraction or decimal to a whole number:

$$\text{Rate} = \frac{\text{Number of events in a specified period}}{\text{Average population during the period}} \times 10^n$$

All rates are ratios, calculated by dividing a numerator, e.g., the number of deaths, or newly occurring cases of a disease in a given period, by a denominator, e.g., the average population during that period. Some rates are proportions, i.e., the numerator is contained within the denominator. Rate has several different usages in epidemiology:

1) As a synonym from ratio, it refers to proportions as rates, as in the terms cumulative incidence ratio, prevalence rate, survival rate (cf. Webster's Dictionary, which gives proportion and ratio as synonyms for rate).

2) In other situations, rate refers only to ratios representing relative changes (actual or potential) in two quantities. This accords with the OED, which gives "relative amount of variation" among its entries for rate.

3) Sometimes rate is further restricted to refer only to ratios representing changes over time. In this usage, prevalence rate would not be a "true" rate because it cannot be expressed in relation to units of time but only to a "point" in time; in contrast, the force of mortality or force of morbidity (hazard rate) is a "true" rate for it can be divided by the total size of the population at risk.

RAW DATA

Data that have in no way been manipulated in preparation for their analysis.

REFERENCE GROUP (CONTROL GROUP)

The standard against which a population that is being studied can be compared.

RESEARCH DESIGN

The procedures and methods, predetermined by an investigator, to be adhered to in conducting a research project.

RESEARCH PROPOSAL

A document that lays out the full plan of action for addressing a particular research question.

RETROSPECTIVE STUDY

A research design that is used to test etiologic hypotheses in which inferences about exposure to the putative causal factor(s) are derived from data relating to characteristics of the persons under study or to events or experiences in their past. The essential feature is that some of the persons under study have the disease or other outcome of interest, and their characteristics and past experiences are compared with those of other, unaffected persons. Persons who differ in the severity of the disease may also be compared. There is disagreement among epidemiologists as to the desirability of using the term "retrospective study" rather than "case-control study" to describe this method.

RISK

The probability that an event will occur, e.g., that an individual will become ill or die within a stated period of time or age. Also, a non-technical term encompassing a variety of measures of the probability of a (generally) unfavourable outcome.

RISK ASSESSMENT

The qualitative or quantitative estimation of the likelihood of adverse effects that may result from exposure to specified health hazards or from the absence of beneficial influences.

RISK FACTOR

An aspect of personal behaviour or lifestyle, an environmental exposure, or an inborn or inherited characteristic, that, on the basis of epidemiologic evidence, is known to be associated with health-related condition(s) considered important to prevent. The term risk factor is rather loosely used, with any of the following meanings:

1. An attribute or exposure that is associated with an increased probability of a specified outcome, such as the occurrence of disease. Not necessarily a causal factor. A risk marker.
2. An attribute or exposure that increases the probability of occurrence of disease or other specified outcome.
3. A determinant that can be modified by intervention, thereby reducing the probability of occurrence of disease or other specified outcomes. To avoid confusion, it may be referred to as a modifiable risk factor.

SAMPLE

A selected subset of a population. A sample may be random or non-random and may be representative or non-representative.

SAMPLE, RANDOM

A sample that is arrived at by selecting sample units such that each possible unit has a fixed and determinate probability of selection.

SAMPLE, REPRESENTATIVE

The term "representative" as it is commonly used is undefined in the statistical or mathematical sense; it means simply that the sample resembles the population in some way.

The use of probability sampling will not ensure that any single sample will be "representative" of the population in all possible respects. If, for example, it is found that the sample age distribution is quite different from that of the population, it is possible to make corrections for the known differences. A common fallacy lies in the unwarranted assumption that, if the sample resembles the population closely on those factors that have been checked, it is "totally representative" and that no difference exists between the sample and the universe or reference population.

Kendall and Buckland comment as follows: "In the widest sense, a sample which is representative of a population. Some confusion arises according to whether 'representative' is regarded as meaning 'selected by some process which gives all samples an equal chance of appearing to represent the population'; or, alternatively, whether it means 'typical in respect of certain characteristics, however chosen'. On the whole, it seems best to confine the word 'representative' to samples which turn out to be so, however chosen, rather than apply it to those chosen with the object of being representative."

Kendall MG, Buckland WR: A Dictionary of Statistical Terms, 4th ed.
London: Longman, 1982.

SAMPLE SIZE CALCULATION

A mathematical method of determining the number of persons required in a sample to achieve a pre-specified level of statistical significance.

STABLE
Not subject to fluctuations from minor influences.

STAKEHOLDER
A person, group of people, or organization with an interest in the outcome being pursued.

STANDARDIZED INCIDENCE RATIO (SIR)
The ratio of the incident number of cases of a specified condition in the population to the incident number that would be expected if the study population had the same incidence rate as a standard or other population for which the incidence rate is known; this ratio is usually expressed as a percentage.

STANDARDIZED MORTALITY RATIO (SMR)
The ratio of the number of deaths observed in the study group or population to the number that would be expected if the study population had the same specific rates as the standard population, multiplied by 100. Usually expressed as a percentage.

STATISTICAL SIGNIFICANCE
Statistical methods allow an estimate to be made of the probability of the observed or greater degree of association between independent and dependent variables under the null hypothesis. From this estimate, in a sample of given size, the statistical "significance" of a result can be stated. Usually the level of statistical significance is stated by the P VALUE.

STEERING COMMITTEE
A group of stakeholders whose primary interest is in providing oversight to ensure that the project proceeds impartially to completion.

STOCHASTIC PROCESS
A process that incorporates some element of randomness.

VALIDITY, STUDY
The degree to which the inference drawn from a study, warranted when account is taken of the study methods, the representativeness of the study sample, and the nature of the population from which it is drawn. Two varieties of study validity are distinguished:

INTERNAL VALIDITY

The index and comparison groups are selected and compared in such manner that the observed differences between them on the dependent variables under study, may, apart from sampling error, be attributed to only the hypothesized effect under investigation.

EXTERNAL VALIDITY (GENERALIZABILITY)

A study is externally valid, or generalizable, if it can produce unbiased inferences regarding a target population (beyond the subjects in the study). This aspect of validity is only meaningful with regard to a specified external target population. For example, the results of a study conducted using only white male subjects might or might not be generalizable to all human males (the target population consisting of all human males). It may not be generalizable to females (the target population consisting of all people). The evaluation of generalizability usually involves much more subject-matter judgment than internal validity.

VARIABLE

Any quantity that varies. Any attribute, phenomenon, or event that can have different values.

CATEGORICAL

Nominal or ordinal variables.

DICHOTOMOUS (BINARY)

Categorical variables with only two possible values (e.g., yes/no, 0/1).

POLYTOMOUS

Categorical variables that can take three or more values
(e.g., age group: 0-4, 5-9, 10-14, …, 75+).

CONTINUOUS

Variables that can take any value within a predefined range of values
(e.g., height or weight).

Contacts:

World Health Organization

Francesca Racioppi
WHO Regional Office for Europe
European Centre for Environment and Health
World Health Organization
Via Francesco Crispi 10
00187 Rome Italy

Tel: + 39 06 4877 51 (switchboard)
Fax: +39 06 4877 599
http://www.euro.who.int/healthimpact/

University of Alberta

Professor Colin L. Soskolne
Department of Public Health Sciences
School of Public Health
University of Alberta
13-103 Clinical Sciences Building
Edmonton, Alberta
CANADA T6G 2G3

Tel: +1 780 492-6013
Fax:+ 1 780 492-0364
E-mail: colin.soskolne@ualberta.ca
http://www.ualberta.ca/~soskolne

United Nations Development Programme (UNDP)

Jamila Ibrahimova
UNDP Azerbaijan
3, UN 50th Anniversary str., Baku AZ 1001, Azerbaijan

Tel.: +99412 4989888
Fax: +99412 4922491
E-mail: jamila.ibrahimova@undp.org
http://www.un-az.org/undp/