Understanding the Fundamentals of Epidemiology

an evolving text

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Preface

Introductory epidemiology courses are often referred to as "methods" courses, and many students come to them hoping to learn the methods that have made epidemiology so important. Certainly methods are an essential aspect of the field, and this text covers the usual complement. But especially for the newcomer, the critical need is to learn how epidemiologists think about health and the factors that affect it, and how epidemiologists approach studying them. Very few methods are unique to epidemiology. "Epidemiologic thinking" is its essence. Therefore, for me the central objective of an introductory course has been to explain the concepts and perspectives of the field.

For nearly 20 years I have had the privilege of teaching the introductory epidemiology course for epidemiology majors at the University of North Carolina School of Public Health and the special pleasure that derives from teaching students who have sought epidemiology out rather than come to learn it only as a school requirement. I have also had the honor of being entrusted by my colleagues with the responsibility for introducing our students to epidemiologic concepts and methods.

Over the years I have written out extensive lecture notes, initially in response to requests from course participants and subsequently to develop my own understanding. Not all course participants have appreciated them, but I have received sufficient positive feedback and expressions of interest from graduates who have gone on to teach their own epidemiology courses that I have decided to recast them as an "evolving text". I use the term "evolving" because I continue to clarify, develop, refine, correct, and, I hope, improve.

Regarding it as an evolving text is also my excuse for the fact that the material is not ready for formal publication. Moreover, unlike a published text, this volume does not claim to be authoritative – nor even thoroughly proofread. As an evolving work, its further development has always taken priority over appearance – and, it must be admitted, occasionally also over accuracy.[*]

Although the word processing is nearly all my own, the content is certainly not. Besides the extensive development and exposition of epidemiologic concepts and methods from courses and publications by others, I have had the good fortune to study with and learn from outstanding epidemiologists and biostatisticians, among them the late John Cassel, Gerardo Heiss, Barbara Hulka, Michel Ibrahim, Sherman James, Bert Kaplan, David Kleinbaum, Gary Koch, Lawrence Kupper, Hal Morgenstern, Abdel Omran, the late Ralph Patrick, Dana Quade, David Savitz, Carl Shy, the late Cecil Slome, H.A. Tyroler, and Edward Wagner.

[*] Important errata, as I learn about them, are posted on a site on the World Wide Web (http://www.epidemiolog.net/).

My thinking and this text have also greatly benefited from interactions with other colleagues and teachers, co-instructors, teaching assistants, collaborators, associates, research staff, fellows, and students. I must particularly acknowledge the assistance of Charles Poole, who has generously shared his expertise with me through his advanced methods course and frequent consultations. He has even made the ultimate sacrifice – reading this text and sitting through my lectures! The content (errors excepted!) and to some extent the exposition, therefore, represent the knowledge, ideas, examples, and teaching skills of many people, to a much greater extent than the specific attributions, citations and acknowledgements would indicate.

Acknowledgements are of greater interest to authors than to readers, and I ask your forgiveness for including several more. I received my own introduction to epidemiology from the late John Cassel -- intellectual pioneer, inspiring lecturer, and humanist -- and Bert Kaplan -- quintessential scholar, supporter, and friend, whose colleagueship, breadth of knowledge, depth of wisdom, dedication to the ideals of the academy, and personal warmth have enriched the lives of so many. I would also like to express my gratitude to colleagues, staff, secretaries (especially Pat Taylor, Edna Mackinnon Lennon, and Virginia Reid), students, administrators, and family for inspiration, stimulation, feedback, opportunity, advice, guidance, commitment, counseling, assistance, support, affection, and a good deal more.

Enjoy Epidemiology!

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Postscript: After the 20th anniversary edition of EPID 168 ("Fundamentals of epidemiology"), my teaching responsibilities have changed to its sister course, EPID 160 ("Principles of epidemiology for public health"). EPID 160 serves as the basic introductory course for all students, graduate and undergraduate, who are not majoring in epidemiology. Thus its audience is much more diverse in both interests and preparation. Time will tell if I am able to continue to refine the *Evolving Text*, but if so it will begin to move in the direction of making it more suitable for a general – and international – readership. I have been gratified by the expressions of interest in it in its present form and hope that it will continue to be of use to others.

March 9, 2001.

1. Epidemiology — Definition, functions, and characteristics

*Definition, characteristics, uses, varieties, and key aspects of epidemiology**

What to tell your family and friends

When your family or friends ask what you are studying, and you say "epidemiology", the response is often something like:

> "You're studying *what*?"
>
> "Does that have something to do with skin?"
>
> "Uh-huh. And what *else* are you studying?"

How should you reply? One possibility is to give a formal definition (e.g., "The study of the distribution and determinants of health related states and events in populations, and the application of this study to control health problems" [John M. Last, *Dictionary of Epidemiology*]). Another possible reply is, "Well, *some* epidemiologists study the skin. But epidemiologists study all kinds of diseases and other aspects of health, also. The root word is 'epidemic', rather than 'epidermis'." Another reply could be. "Epidemiology is the study of health and disease in populations. It's a basic science of public health.", though then be prepared to define "public health". And, if you're feeling erudite, you can follow-up with, "'Epidemiology' comes from the Greek *epi* (among, upon), *demos* (people), and *logy* (study)."

Epidemiology in transition?

The above should satisfy your friends, but what about yourself? Particularly if you are entering on the pathway to becoming an epidemiologist, do you know where it will lead you? According to Thomas Kuhn (1970:136-7), textbooks "address themselves to an already articulated body of problems, data, and theory, most often to the particular set of paradigms to which the scientific community is committed at the time they are written.…[They] record the stable *outcome* of past revolutions and thus display the bases of the current normal-scientific tradition". Raj Bhopal's review (1997), however, reports that recent epidemiology texts present a diversity of concepts and information, even in regard to the building blocks of epidemiology. Bhopal sees the fundamental question as "whether epidemiology is primarily an applied public health discipline…or primarily a science in which methods and theory dominate over practice and application". He predicts a lively discussion that will sharpen in the 21st century.

Indeed, in the leading commentary in the August 1999 issue of the *American Journal of Public Health*, three of my colleagues including our department chair seek to differentiate between epidemiology (a "science") and public health (a "mission"). They argue that the second half of Last's definition

* Dr. Raymond Greenberg wrote the original versions of the chapter subtitles.

(application and control) describes "the broader enterprise of public health" rather than epidemiology. Epidemiology "contributes to the rationale for public health policies and services and is important for use in their evaluation", but "the delivery of those services or the implementation of those policies" is not "part of epidemiology" (Savitz *et al.*, 1999: 1158-1159). Further, "the product of research is information, not, as has been argued, 'public health action and implementation' (Atwood et al., 1997: 693)." (Savitz et al.: 1160).

The article by David Savitz, Charles Poole, and William Miller might be regarded in part as a response to the charge made in an article by our previous chair, Carl Shy, that academic epidemiology has "failed to develop the scientific methods and the knowledge base to support the fundamental public health mission of preventing disease and promoting health through organized community efforts" (Shy, 1997). In making this charge, Shy builds on the contention in the Institute of Medicine report on *The Future of Public Health* (Committee for the Study of the Future of Public Health, 1988, which asserted that the U.S. public health system was in "disarray") that schools of public health are too divorced from public health practice. In that vein, in the editorial that precedes the Savitz *et al.* commentary, the previous Director of the Centers for Disease Control and Prevention (CDC) and two of his colleagues assert that, "[Epidemiologists] can make their goal journal publication, public interpretation of findings, or public health interventions", adding that "epidemiology's full value is achieved only when its contributions are placed in the context of public health action, resulting in a healthier populace." (Koplan et al., 1999).

These contrasting positions are not necessarily in conflict. To say that public health action is required to achieve epidemiology's full value does not imply that epidemiology or epidemiologists must launch that public health action, nor does appreciation of epidemiologists' contributions imply that those contributions are epidemiology (as opposed to good works that happen to be done by epidemiologists). But others have explicitly endorsed a diversity of roles for epidemiology. In a 2002 article, Douglas Weed and Pamela Mink provide a succinct and thoughtful discussion of this twenty-year long "remarkable disciplinary rift", concluding that "Science and policy walk hand-in-hand under the umbrella of epidemiology." (Weed and Mink, 2002: 70). They add that an epidemiologist can be a "full-fledged epidemiologist" whether s/he does etiologic research alone, combines public health practice and policymaking with research, or spends most of her/his time "making the public health system work". Perhaps influenced by the terrorism attacks of the previous autumn, the ensuing upsurge of concern about preparedness, and Internet dissemination of health information of highly variable reliability, Richard Kaslow in his 2002 Presidential Address to the American College of Epidemiology placed advocacy squarely within the epidemiology profession: "Individual epidemiologists may decline to 'get involved,' but I do not believe epidemiology without advocacy is any longer a viable option for the profession collectively. Through the College, our profession can speak with a compelling voice. It is no longer enough to serve the public simply by producing credible data, we must effectively translate those data into clear and balanced messages." (Kaslow, 2003: 547).

But whether we see ourselves first as scientists or first as public health professionals, our work takes place in a societal context, with resources and therefore priorities assigned by political and economic institutions that appear to serve the interests of some people and groups more than of others (Winkelstein, 2000). The research we do and our behavior in our other professional activities inevitably reflect our backgrounds and life experiences, our values and preconceptions, our personal ambitions and responsibilities. In that sense, what is epidemiology and what is not, and who is an epidemiologist and who is not, are determined in part by the custodians of curricula, hiring, research funding, and publication. Thus, you have an opportunity to make epidemiology what you think it should be. You may also acquire a responsibility:

> "Do epidemiologists and other public health professionals have a responsibility to ask whether the ways we think and work reflect or contribute to social inequality?
> "Proponents of socially responsible science would answer yes. What say you?"
> (Krieger, 1999: 1152)

Asking the right questions is fundamental, but you may also need to help develop the methods to enable epidemiologists to do what you think we should. In recent decades there have been great strides in the development and teaching of epidemiologic concepts and methods to study health problems of the individuals in a population, but these concepts and methods are less adequate for understanding population health (Koopman and Lynch, 1999), even in regard to epidemics – the origin of our discipline and its name. Indeed, Ollie Miettinen, a key thinker in defining the conceptual basis of modern epidemiology, does not even regard the occurrence of epidemics, "a focal concern of classical epidemiology", as "a problem of the form characteristic of modern epidemiologic research", because an epidemic is an affliction of a population in the aggregate, rather than of its individuals" (Miettinen, 1985:4). For Miettinen, the discipline of epidemiology is "the aggregate of *principles* of studying the occurrence of illness and related states and events." (Miettinen, 1985:4).

Advances in the methods for the study of health and disease in populations – epidemiology's calling card, as it were – may ease some of the apparent conflict between those who see epidemiology first as a scientific enterprise and those who see it foremost as a vehicle for solving major public health problems (Schwartz and Carpenter, 1999). Independent of whether epidemiologists are willing to study problems that cannot be solved within the prevailing paradigm and the conceptual and instrumental tools that it supplies (Kuhn, 1970), understanding those problems will require effective concepts and methods. Warren Winkelstein (2000) sees the need for a "more expansionist approach" in order to address disease problems arising from pollution, global warming, population growth, poverty, social inequality, civil unrest, and violence. Even without taking the further step of proposing that epidemiology should attempt to reduce these conditions themselves, the challenges for epidemiology are daunting.

Epidemiology functions and areas of application

The perspective in this text is that epidemiology is both a field of research to advance scientific understanding and also of application of knowledge to control disease and advance public health, a (primarily observational) science and a public health profession. Thus, epidemiologists conduct research and also work to control and prevent disease; they are scientists and engineers. Epidemiologic investigation is problem-oriented and tends toward applied research. Although it has a growing body of theory, the field is primarily empirically driven. Partly for these reasons, epidemiologists draw freely from other fields and gravitate towards multidisciplinary approaches.

Milton Terris, a leading exponent of close interrelationships among epidemiology, public health, and policy, has summarized the functions of epidemiology as:

1. Discover the agent, host, and environmental factors that affect health, in order to provide the scientific basis for the prevention of disease and injury and the promotion of health.
2. Determine the relative importance of causes of illness, disability, and death, in order to establish priorities for research and action.
3. Identify those sections of the population which have the greatest risk from specific causes of ill health [and benefit from specific interventions], in order that the indicated action may be directed appropriately. (targeting)
4. Evaluate the effectiveness of preventive and therapeutic health programs and services in improving the health of the population.

   (Milton Terris, The Society for Epidemiologic Research (SER) and the future of epidemiology. *Am J Epidemiol* 1992; 136(8):909-915, p 912)

To these might be added:

5. Study the natural history of disease from its precursor states through its manifestations and clinical course
6. Conduct surveillance of disease and injury occurrence in populations and of the levels of risk factors – passive (receive reports), active (poll practitioners, conduct surveys)
7. Investigate outbreaks (e.g., hospital-acquired infections, disease clusters, food-borne and water-borne infections) to identify their source and controlling epidemics (e.g., measles, rubella, coronary heart disease, overweight)

Classic and recent examples of epidemiologic investigation

Epidemiology has made significant contributions to the understanding and control of many health-related conditions, and epidemiologists are actively involved in studying many others. Some of the classic investigations and some areas of recent and current attention are listed below:

Scurvy (James Lind) - intervention trial, nutritional deficiency

Scrotal cancer (Percival Pott) - occupational health, carcinogens

Measles (Peter Panum) - incubation period, infectious period

Cholera (John Snow) - waterborne transmission, natural experiment

Puerperal fever (Ignatius Semmelweis) - hygienic prevention

Pellagra (Joseph Goldberger) - "epidemic" disease was not communicable

Rubella and congenital birth defects (Gregg) - prenatal exposure

Retrolental fibroplasia - iatrogenic disease

Lung cancer and smoking - coming of age of chronic disease epidemiology

Fluoride and dental caries - community epidemiology; environmental prevention

Poliomyelitis immunization trial - a massive experiment that demonstrated the effectiveness of the vaccine against this greatly feared virus

Cardiovascular disease - longitudinal community studies; community intervention trials

Breast cancer screening – a large-scale randomized trial of effectiveness of cancer early detection through screening

Reye's syndrome and aspirin - an epidemiologic success involving a rare but devastating disease brought on by a familiar and ubiquitous medicine

Toxic shock syndrome - an epidemiologic success in a "point-source" epidemic resulting from a new product introduction

Estrogens and endometrial cancer - controversies of case-control methodology and bias; pharmacoepidemiology

Psychiatric disorder - challenges in disease classification and assessment

Lead and cognitive development - a crucial role for a biologic marker

Electromagnetic fields - can an exposure be "exonerated"?

Legionnaire's disease - a newly recognized pathogenic bacterium foreshadows the resurgence of infectious diseases as a public health challenge in the U.S.

HIV - a new or newly-recognized virus that has transformed the public health and epidemiology landscape with respect to infectious diseases in general and sexually-transmitted infections specifically

Tuberculosis - reminding epidemiology of its roots; control of a pathogen is very different from its eradication

Injury - epidemiology without disease

Homicide - a behavioral epidemic or an environmental plague?

Varieties of epidemiology

As epidemiology continues to develop and to expand into new areas, the field has diversified into many forms:

Surveillance, "shoe-leather" epidemiology (outbreak investigations), and epidemic control

Microbial epidemiology – biology and ecology of pathogenic microorganisms, their lifecycles, and their interactions with their human and non-human hosts

Descriptive epidemiology – examination of patterns of occurrence of disease and injury and their determinants

"Risk factor" epidemiology – searching for exposure-disease associations that may provide insights into etiology and avenues for prevention

Clinical epidemiology* and the evaluation of healthcare – assess accuracy, efficacy, effectiveness, and unintended consequences of methods of prevention, early detection, diagnosis, treatment, and management of health conditions

Molecular epidemiology – investigate disease at the molecular level to precisely characterize pathological processes and exposures, to elucidate mechanisms of pathogenesis, and to identify precursor conditions

Genetic epidemiology – the confluence of molecular biology, population studies, and statistical models with an emphasis on heritable influences on disease susceptibility and expression

Big Epidemiology** – multisite collaborative trials, such as the Hypertension Detection and Follow-up Program (HDFP), Coronary Primary Prevention Trial (CPPT), Multiple Risk Factor Intervention Trial (MRFIT), Women's Health Initiative (WHI)

Entrepreneurial epidemiology – building institutions and careers by winning research funding and facilities

Testimonial epidemiology – giving depositions and testifying in court or in legislative hearings on the state of epidemiologic evidence on a matter of dispute

Social epidemiology – interpersonal and community-level factors influencing health at the population level

Global epidemiology – assessing the effects of human activity on the ecosystem that supports life on Earth.

Characteristics of epidemiology

With so many varieties of epidemiology, it is no wonder that confusion abounds about what is and what is not epidemiology. "Epidemiologic" research tends to:

be observational, rather than experimental;

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* In David Sackett et al.'s *Clinical Epidemiology*, 2nd ed, it is recounted that when one of the authors (P.T.), then a medical student in England "sought career guidance from a world-renowned London epidemiologist, he was informed that it was 'amoral' to combine epidemiology with clinical practice!"

** "Big" in epidemiology might be defined as upwards of $100 million for a study. To put these studies in perspective, the Human Genome Project cost $250 million in public funds, CERN (high energy particle physics research in Switzerland) $638 million/year, the Hubble Space Telescope $3 billion, and the Apollo Program $115 billion. (1999 dollars; data from the National Institutes of Health, the European Space Agency, and NASA, by way of Hannah Fairfield in the *New York Times* (Science Times, 6/27/2000).

focus on free-living human populations defined by geography, worksite, institutional affiliation, occupation, migration status, health conditions, exposure history, or other characteristics rather than a group of highly-selected individuals studied in a clinic or laboratory;

deal with etiology and control of disease, rather than with phenomena that are not closely tied to health status;

take a multidisciplinary, empirical approach directed at understanding or solving a problem rather than on advancing theory within a discipline.

However, not all epidemiologic studies have these characteristics.

So how then can you tell if someone is doing epidemiology or not? One wag suggested the following scoring system:

$$\text{score} = \frac{\ln(n^y)k^s d^2}{pc}$$

where:

n = number of subjects

y = number of years of follow-up

k = total direct costs (in $1,000,000)

s = sponsor (NIH=3, other public or foundation=2, corporate=1)

d = principal investigator's degree (EPID PhD=4, MD plus EPID MPH.= 3, MD w/o EPID MPH = 2, other health doctorate = 1)

p = number of first-authored publications that the PI will author

c = percent of the principal investigator's salary that will be covered

The higher the score, the more likely that the study is epidemiology.

Key aspects of epidemiology

A number of other fields – medicine, nursing, dentistry, pharmacy, demography, sociology, health psychology, health education, health policy, nutrition – share many common features and areas of interest with epidemiology (and with each other). Some of the key aspects of epidemiology are:

Epidemiology deals with ***populations***, thus involving:

- Rates and proportions
- Averages
- Heterogeneity within
- Dynamics - demography, environment, lifestyle

As other sciences, epidemiology involves ***measurement***, entailing the need for:

- Definition of the phenomena
- Spectrum of disease
- Sources of data
- Compromise

Most epidemiologic studies involve ***comparison***, introducing considerations of:

- Standards of reference for baseline risk
- Equivalent measurement accuracy
- Adjustment for differences

Epidemiology is fundamentally ***multidisciplinary***, since it must consider:

- Statistics, biology, chemistry, physics, psychology, sociology, demography, geography, environmental science, policy analysis, …
- Interpretation - consistency, plausibility, coherence
- Mechanisms - pathophysiology, psychosocial, economic, environmental
- Policy - impact, implications, ramifications, recommendations, controversy

Modes of investigation — descriptive vs. analytic epidemiology

Although the distinction is often difficult to draw, in part because of the greater valuation placed by many on the latter, epidemiologic investigations are sometimes usefully characterized as either ***descriptive*** or ***analytic***.

Descriptive epidemiology

Descriptive epidemiology describes the health conditions and health-related characteristics of populations, typically in terms of ***person, place, and time***. This information serves as the foundation for studying populations. It provides essential contextual information with which to develop hypotheses, design studies, and interpret results. Surveillance is a particular type of descriptive epidemiology, to monitor change over time.

Types of descriptive studies:

- Routine analyses of vital statistics (births, deaths), communicable disease reports, other notifiable events (outbreaks, induced abortions)
- Periodic surveys of health status, knowledge, beliefs, attitudes, practices, behaviors, environmental exposures, and health care encounters (e.g., National Center for Health Statistics surveys, Centers for Disease Control and Prevention Behavioral Risk Factor Surveillance System)
- Specialized surveys to establish prevalence of a condition, a characteristic, or use of a medical procedure

- Studies comparing information across geographical or political units, or between migrants and persons in their country of origin to look for differences and patterns

Analytic epidemiology

Analytic epidemiology involves the systematic evaluation of suspected relationships, for example, between an exposure and a health outcome. Because of their narrower focus, analytic studies typically provide stronger evidence concerning particular relationships.

Types of analytic studies:

- Case-control studies, comparing people who develop a condition with people who have not
- Follow-up (retrospective, prospective) studies, comparing people with and without a characteristic in relation to a subsequent health-related event
- Intervention trials (clinical, community), in which a treatment or preventive intervention is provided to a group of people and their subsequent experience is compared to that of people not provided the intervention

Analytic studies typically involve the testing of hypotheses, which in turn may arise from

- Case reports
- Case series
- Laboratory studies
- Descriptive epidemiologic studies
- Other analytic studies

The descriptive and analytic classification is more of a continuum than a dichotomy. Many studies have both descriptive and analytic aspects, and data that are collected in one mode may end up being used in the other as well. Whether a particular study is primarily "descriptive" or "analytic" may be a matter of the investigator's "stance" in relationship to the study question and the collection of the data. Since analytic epidemiology is often accorded a higher status than is descriptive epidemiology, with some regarding a study without a hypothesis as "not science", investigators sometimes feel constrained to come up with a hypothesis and present their work as "analytic", even if the hypothesis is contrived or is not the study's real focus.

Sources of data

Since epidemiology studies populations in their ordinary environments, there are many kinds of data that are relevant, and obtaining them can be logistically challenging and expensive. There is accordingly an interest in using data that are already available. Data for political and geographical aggregates are often more readily available than are data on individuals, a distinction referred to as the ***level of measurement***. Sources of data for epidemiologic studies include:

Aggregate data

Vital statistics (birth rates, death rates, pregnancy rates, abortion rates, low birth weight)

Demographic, economic, housing, geographical, and other data from the Census and other government data-gathering activities

Summaries of disease and injury reporting systems and registries

Workplace monitoring systems

Environmental monitoring systems (e.g., air pollution measurements)

Production and sales data

Individual-level data

Vital events registration (births, deaths, marriages)

Disease and injury reporting systems and registries

National surveys

Computer data files (e.g., health insurors)

Medical records

Questionnaires - in person, by telephone, mailed

Biological specimens (routinely or specially collected)

Sometimes a distinction is drawn between ***primary data*** (collected specifically for the study, which is generally advantageous) and ***secondary data*** (collected for some other purpose, and therefore possibly not as well suited for the question of current interest), though the former is not inevitably superior to the latter. Although data quality is always a paramount, compromises must often be made. Two examples are the use of a ***proxy informant*** when the person to be interviewed is ill, demented, or deceased and the use of a ***proxy variable*** when data cannot be obtained for the variable of greatest relevance.

Sources of error

The challenge of data quality in epidemiology is to control the many sources of error in observational studies of human populations. The best understood and most quantifiable is ***sampling error***, the distortion that can occur from the "luck of the draw" in small samples from a population. More problematic is error from ***selection bias***, where the study participants are not representative of the population of interest.

Selection bias can result from:

Self selection (volunteering)

Nonresponse (refusal)

Loss to follow-up (attrition, migration)

Selective survival

Health care utilization patterns

Systematic errors in detection and diagnosis of health conditions

Choice of an inappropriate comparison group (investigator selection)

Also highly problematic is ***information bias***, systematic error due to incorrect definition, measurement, or classification of variables of interest.

Some sources of information bias are:

Recall or reporting bias

False positives or negatives on diagnostic tests

Errors in assignment of cause of death

Errors and omissions in medical records

Observational sciences especially are also greatly concerned with what epidemiologists call ***confounding***, error in the interpretation of comparisons between groups that are not truly comparable. Differences in age, gender composition, health status, and risk factors generally must generally be allowed for in making and interpreting comparisons. A major theme in epidemiologic methods is the identification, avoidance, and control of potential sources of error.

Unique contribution of epidemiology

In an earlier era, epidemiology was characterized as "the basic science of public health work and of preventive medicine" (Sheps, 1976:61). Whether or not this claim was ever valid (i.e., whether "the" should be "a" and whether "basic" should be "applied"), epidemiology does have the advantage of a name that ends in "logy" (a factor not to be discounted in this "Era of Marketing" [George McGovern's apt phrase from the 1980's]) and remains a foundation for the practice of "evidence-based medicine" (definitely a term for the Era of Marketing). Moreover, epidemiology deals with the "bottom line", with the reality of human health. True, epidemiologic research suffers from many limitations. Indeed, in comparison to laboratory science, epidemiology may seem somewhat crude – akin to sculpting with a hammer but no chisel. But the limitations of epidemiologic research are largely a function of the obstacles epidemiologists must contend with, and both the obstacles and the limitations are inherent in the subject of study – free-living human populations. Laboratory studies provide better control of the confounding influences of genetic, environmental, and measurement variability. But the public health relevance of laboratory findings is often uncertain due to:

Differences between *in vitro* (test tube) and *in vivo* (whole animal) systems

Differences in susceptibility across species

Difficulty of extrapolating across dosages, routes of administration, cofactors, lifespans

Problems in generalizing results from highly controlled settings to free-living populations.

Exquisitely precise knowledge about what happens in cell cultures or experimental animals, while of great value in many respects, cannot tell us enough about human health. Ultimately, public health decisions require data from human populations. If we need to know what happens to people, we must employ epidemiology.

Bibliography

NOTE: In-depth reviews of epidemiologic knowledge in both topical and methodological areas can be found in the periodical *Epidemiologic Reviews*, published by the *American Journal of Epidemiology*. The first issue of the year 2000 (Armenian and Samet, 2000) features essays addressing the current state of epidemiology in a wide range of areas and provides an excellent overview of the field.

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Dimensions in the training of an epidemiologist

I. Epidemiologic perspective

1. Public health aspects: -- History of epidemiology, epidemiology as a public health science, clinical and public policy implications.
2. Scientific aspects: -- Problem conceptualization, philosophy of inference, study designs, interpretation of data, concepts of bias and multicausality.

II. Measurement and analysis: Measures of disease frequency and extent, study designs and strategies, control of sources of error, statistical inference, data analysis and interpretation.

III. Weighing epidemiologic evidence: Critical reading and synthesizing of information.

IV. Proposal development: Specification of research hypotheses, study populations, measurement tools, analysis strategies; human subjects protection; "grantsmanship".

V. Study design and execution: Protocol development, subject recruitment, instrumentation, data collection, quality control, reporting and communications collaboration and working with oversight bodies, presentation of findings.

VI. Data management: Manipulation and analysis of data using computers and statistical software packages.

VII. Substantive knowledge: General background in health-related sciences and multidisciplinary understanding of specific areas of research.

VIII. Epidemiologist roles: Development of skills for teaching, consultation, review of proposals and manuscripts, participation in professional meetings, leadership of multidisciplinary research teams, and continuing professional development.

(Used for a number of years by the UNC Department of Epidemiology as an outline of areas of required competencies)