

Editorial

CLINICAL EPIDEMIOLOGY*

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I DEFINE clinical epidemiology as the study of determinants and effects of clinical decisions. Clinical epidemiology is not merely epidemiology done by clinicians. Nor does it pertain to the clinical activities of medically-trained epidemiologists. Clinical epidemiology is not a clearly demarcated field. As many other scientific pursuits that concern more than one discipline, clinical epidemiology is best characterized by its spans, its overlaps, its gates and even by its incursions rather than by its borders.

It is more difficult to define a field with multiple components than to do so for a single or "purer" area of endeavour. Yet the challenge is not unique: Consider these descriptions in the biomedical sciences: "clinical pharmacology", "bio-statistics", "community health", "environmental toxicology", "family medicine", "clinical psychology" and "health economics"; and in other sciences, "electrical engineering", "physical chemistry", "experimental psychology" and "marine geology".

Such double designations are a taxonomic accommodation to the real world. Our interest in chemistry may require more specificity than the unmodified term depending on the relevance (biochemistry or physical chemistry) or depending on applications (chemical engineering or clinical chemistry).

Curiously, the term clinical epidemiology causes resistance; it even raises eyebrows. Among those having adverse reactions, the phrase evokes, at worst, suggestions of unworthy compromise or some sort of dilution of pure epidemiology. At best, clinical epidemiology is regarded as unnecessary, unusual or even bizarre. I am of the opinion that *clinical epidemiology* is a sensible way to describe a distinctive area of activity within a very heterogeneous discipline. I maintain that its two-word identification, far from bizarre, is the conventional way of designating a bridge science. In the applied sciences, the joining of two or more methods or fields is less likely to be a sign of compromised rigour than the mark of judicious focusing.

In what way is clinical epidemiology distinctive? To develop an answer, I considered taxonomy first. That, in turn, took me to standard definitions:

"Epidemiology is the study of the distribution and determinants of disease frequency in man" [1].

"Epidemiology is the study of disease occurrence in human populations" [2].

"... the study of the distribution of a disease or a physiologic condition in human populations and of the factors that influence this distribution" [3].

"Clinical" is used in endless ways. It can be a modifying adjective that downgrades a rank, as in clinical professor. It is used to describe the research that a clinician does,

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without regard, necessarily, of the methods, content or study subjects of the research. It can be employed simply to identify the setting where patient-activity takes place. Some schools for health administrators, for example, refer to the postings of their trainees in hospitals as "clinical". Some consensus about the meaning of clinical can be distilled from standard sources:

"having to do with medical study or practice based on actual treatment and observation of patients, as distinguished from experimental or laboratory study" [4].

"... denoting the symptoms and course of a disease as distinguished from the laboratory findings of anatomical change" [5].

"... qui observe directement (au lit des malades) les manifestations de la maladie" [6].

Feinstein [7] extends the principle of direct observation to that of direct responsibility as he defines *clinician*:

"Let me define a clinician as a member of one of the healing professions—such as medicine, osteopathy, and clinical psychology—who takes direct responsibility for the care of living patients, or who has spent substantial amounts of postgraduate time in developing his skillful knowledge of such activities. The clinician may be in private practice, academic research, or administrative work, but his distinguishing characteristic is a background of observational and therapeutic experience in dealing with sick people."

The definitions emphasize *direct*: *direct* examination, *direct* observation, *direct* responsibility for living patients. Such direct bedside and consulting room activities then become the ultimate frame of reference for the science of clinical epidemiology because such are the activities to be guided.

What then is the distinctive mark of clinical epidemiology? In my view, it is epidemiologic research oriented to the improvement of clinical decisions. My own definition is:

Clinical epidemiology is the study of determinants and effects of clinical decisions.

In contrast, *classical* epidemiology is oriented to the elucidation of cause. Many examples of classical epidemiologic work demonstrate that such research can also affect and does affect clinical decisions. I shall cite only one example, the Framingham study [8]. But the questions and hypotheses of clinical epidemiology arise more directly and *immediately* from the daily problems of clinical practice. The resulting research is planned to provide clinicians with answers they can apply directly and *readily* at the bedside or in the consulting room. From question to application the loop is tight. These are some questions that could concern the clinical epidemiologist:

- (1) What is the frequency of application that promotes maximum benefit of Papanicolaou smears in the prevention of cancer of the cervix?
- (2) Which subgroups of patients with diabetes mellitus are most susceptible to the benefits of the insulin pump?
- (3) Does spirometry have any role in early detection of chronic obstructive pulmonary disease or in the management of early manifest chronic obstructive lung disease?
- (4) Is there any difference in the effectiveness of home dialysis compared to more conventional renal dialysis?
- (5) Under what circumstances do management decisions of gastroenterologists improve with use of endoscopic devices?
- (6) What is the mix and what is the working relationship of health professionals that enables the most effective primary health care to a defined population?
- (7) Can one develop valid measures of quality of life that permit a scientifically admissible evaluation of palliative care services?

One landmark definition of clinical epidemiology was proposed by Sackett in 1969:

“Clinical epidemiology is the application of epidemiologic biometric methods to the study of diagnosis and therapy by a clinician who provides direct patient care.”

I cannot accept the constraint that clinical epidemiology is done or can only be done by “a clinician who provides direct patient care.” I do not believe it matters *who* does the study as long as the problem concerns the clinical decision-making process and as long as the results of the research are immediately useful to a clinician who provides direct patient care. Non-medical biostatisticians, for instance, can initiate and conduct clinical epidemiologic research and do so in relevant and elegant ways. I am concerned that Sackett’s definition sets aside disease aetiology which may affect clinical decisions (communicable diseases still involve clinicians) and it overlooks prevention in the context of clinical practice. The few available effective measures of secondary prevention or early detection of pre-symptomatic chronic disease are undertaken almost exclusively by clinicians.

The list of authorities invoked in this discussion would be incomplete without reference to John R. Paul, who I believe was the first to combine the terms in a 1938 paper.

“Epidemiology is concerned with measurements of the circumstances under which diseases occur, where diseases tend to flourish and where they do not” [10].

In Paul’s 1938 definition, the word *epidemiology* was not modified or qualified, but the context and the concepts of his paper were entirely consistent with his own later better developed ideas. He wrote, for instance, that the clinical epidemiologist may have similar interests to those of the health department epidemiologist, but “he is to the statistical epidemiologist what a gardener is to a farmer” [11].

In a recent editorial Holland records his opinion, “that the term clinical epidemiology has served its purpose but is now no longer of any use” [12]. He marshals two main arguments to support his rejection. He is against the idea that clinical epidemiology is an undertaking restricted to *clinicians who provide direct patient care* (Sackett’s phrase). “It is not helpful”, he writes, “to describe specifically a small group who practices both epidemiology and medicine” [12]. He also argues that while ward rounds can be a highly appropriate medium for teaching epidemiology, that fact provides insufficient grounds to add “clinical” as a means to partition a part of the field which is specifically important to practising doctors or which is best studied by clinicians as investigators or collaborators. Historically, he showed that the origin of the term in the United Kingdom was little more than an expedient administrative ploy.

I agree with Holland’s arguments and concern but not with his conclusions. The specificity of clinical epidemiology is not determined by the clinical background of the investigator. Nor should it be influenced by paedagogic strategies that can be used to sensitize medical students and physicians to the proper place of epidemiology in the array of relevant biomedical sciences. The specificity of clinical epidemiology is determined largely by the category of problems under study, *clinical decisions*, and by unique methodological challenges.

The main challenges include difficulties of linking numerator clinical events or patients with corresponding denominators, the critical choice of proper comparison groups for *observational* clinical studies, and the calibration of precise, valid useful measures of exposure and outcome for use both in experiments and observational studies. Consider again the seven research questions set forth earlier in this paper. They do suggest distinctive turf and distinctive technique. Neither the turf nor the technique are likely to be of priority to the classicist whose skills and interest have prepared him to study aetiology.

Holland dismisses the need for clinical epidemiology to define a distinctive area of activity. Semantics and expediency are not enough, he argues, and I agree. Yet the purpose of this position paper is to show that the rationale goes much beyond semantics or expediency.

I now turn to some practical considerations. Operationally, research and teaching in clinical epidemiology can be done by establishing a university department of clinical epidemiology, as Sackett did at McMaster University in 1968. Alternatively, clinical epidemiology programmes within more traditional departments of epidemiology can be organized. In another model, teaching hospitals of medical schools can create clinical epidemiology divisions such as those organized at the Royal North Shore Hospital of Sydney, Australia in 1979 or more recently, in 1983, at my hospital, the Montreal General Hospital of McGill University. Such units maintain vital links with a clinical department, usually a department of medicine *and* a university department of epidemiology. Dual academic accountability can be accomplished smoothly with simultaneous appointments of key investigators and teachers in the department of epidemiology *and* a clinical department. The precise administrative arrangements vary from faculty to faculty and hospital to hospital.

Ideally, to achieve fruitful investigation with effective diffusion of research findings to the clinical community, a clinical epidemiology unit or programme should have a critical mass of methodologists who spend the majority of their time in epidemiologic research working on projects with latent clinical objectives. Preferably, the methodologists should spend a meaningful proportion of time in clinical practice, within a discipline in which they are formally trained, but I do not believe such a requirement is essential.

In the clinical environment where they work there should be a substantial number of academic clinicians, whose primary role is patient care and clinical teaching but who have formal training in epidemiology to the point that they can function as investigators for an important proportion of their time. The clinically-based colleagues can be principal investigators, collaborators or sophisticated consumers of epidemiologic research. A fertile research programme in clinical epidemiology depends on two solid bridgeheads; the span which creates the bridge occurs naturally when each side is competent, credible and well-trained in the specialty of the opposite side.

C. M. Fletcher (cited by J. R. Paul) wrote, "If the work of clinicians and epidemiologists is indeed in continuity then it is essential that they should be in continuous professional contact" [11]. I believe that the lack of many functional bridges between clinical disciplines and epidemiology reflects inadequate contact frequently reinforced by physical barriers in medical campuses. The result is a very limited understanding of relevant research questions on the part of epidemiologists and not even awareness of the methodological armamentarium of the epidemiologist on the part of clinicians. Important research questions cannot fail to arise when frequent contact is promoted. Diffusion and application of useful findings is facilitated when there is close interaction among methodologists and clinicians. The impact of epidemiologic inquiry on decision-making for the patient then approaches efficiency.

Clinical epidemiology is unlikely to be a passing fad that competes unfairly in the short run with other worthy pursuits of the epidemiologist for resources and which puts other time-tested strategies in jeopardy. Traditional public health and occupational health still need classical epidemiology as their basic science. Epidemiological methods and statistical methods must continue to be developed. Knowledge in the realm of infectious diseases needs to have the frontiers pushed back further with epidemiology in a strategic role. The search for cause through population studies should never be encumbered.

All strategies of sound epidemiologic research need no further justification than as an expression of human creativity. Einstein wrote, "Do not stop to think about the reasons for what you are doing, about why you are questioning. . . Curiosity has its own reason for existence. Never lose a holy curiosity" [13]. Even though my personal commitment is to research and practice in clinical epidemiology, I can support and will support the pursuit of holy curiosity in any of the subdisciplines of epidemiology, not for any particular pragmatic reason but because it seems right. But I would like to express a concern that we as epidemiologists reach out to the clinician less reluctantly and more effectively than we have done in rheumatology, in family medicine, in nephrology, in neurology and in several other critically important clinical disciplines. I will use one last definition by Thomas Addis, a giant among clinicians.

“A clinician is complex. He is part craftsman, part practical scientist, and part historian. . . . It is only if we look at him when he is working with his patients that we find him single-minded. Then he is a wholly pragmatic and utilitarian. His only design is to bring relief, and he is not at all scrupulous about how he does it” [14].

Let the designs of some of us in epidemiology, some of the time, be also directed to bring relief to the patient and even to the clinician. In so doing, we need not surrender our scientific scruples.

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