Outcomes Research and Epidemiology
The Synergy Between Public Health and Clinical Practice

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Outcomes research was defined in 1998 as “the study of the end results of health services that takes patients’ experiences, preferences, and values into account … intended to provide scientific evidence relating to decisions made by all who participate in health care.” Inherent to this definition is the fact that outcomes research is multidisciplinary and relies on diverse domains of expertise, with an explicit goal of direct relevance to the care delivered to patients. Within this multidisciplinary framework, epidemiology is one of the disciplines related to the field of outcomes research. Epidemiology is the study of distribution and determinants of disease frequency in human populations, with a particular focus on the occurrence of disease as categorized by time, place, and persons. Sometimes referred to as the basic science in medicine, epidemiology is founded on principles and methods (including methods of statistical analysis) that form the basis of clinical research. The fundamental constructs that epidemiology embraces are key to the conduct of outcomes research today. Indeed, envisioning the burden of disease through the lenses of the traditional epidemiological constructs of time and person can provide powerful guidance to shape the direction of outcomes research and assess its impact. This Editor’s Perspective shares a few examples to illustrate this point.

Disease Burden According to Time: The Importance of Temporal Trends

In a Shattuck Lecture published in the New England Journal of Medicine, Eugene Braunwald designated heart failure as a new epidemic of cardiovascular disease. This eloquent statement generated thought-provoking questions: Was there, indeed, an epidemic of heart failure in the epidemiological sense of the word? If so, is the epidemic driven by increase in incidence, improvement in survival, or both? These questions inspired epidemiologists to conduct the needed formal investigation of the heart failure epidemic, which meant bringing new epidemic of cardiovascular disease. This eloquent statement of the heart failure epidemic, which meant bringing epidemiologists to conduct the needed formal investigation of the heart failure epidemic, which meant bringing to rigorous epidemiological methods to the analysis of trends in incidence and survival according to person, time, and place. This formal investigation convincingly demonstrated that the incidence of heart failure had not changed appreciably in the past 2 decades, and that, although the outcomes remained quite poor, survival had improved. Substantial disparities were identified with a disproportionate burden of disease on elderly and black people. Thus, the investigation of the epidemic convincingly demonstrated that the incidence of heart failure was not increasing overall, whereas survival was improving, creating an epidemic of hospitalizations among persons living longer with heart failure. These findings focused attention on understanding the burden of hospitalizations in heart failure. Of direct importance to outcomes research was the finding that a large proportion of hospitalizations among people living with heart failure is not directly related to heart failure, but, rather, reflects the plurality of comorbid conditions that trigger an inordinate number of hospitalizations. These conclusions in turn provide a roadmap for the management of heart failure. Indeed, to effectively diminish the massive burden of heart failure on patients and on the healthcare system, guided by the results of the investigation of the epidemic, we must reduce hospitalizations, realizing that most of these may not be directly due to heart failure. Hence, the results of the formal investigation of the heart failure epidemic have shaped more than a decade of outcomes research, focusing on the inpatient management of patients with heart failure, relevant quality indicators and performance measures, and intervention studies. This line of work led to nationwide strategies that are profoundly affecting the delivery of care and, hence, patients, providers, and payers. The journey is far from being over, and little if any progress has been made in addressing disparities in the disease burden. Although the task at hand is immense, we do have a roadmap to move forward.

In 2010, Circulation: Cardiovascular Quality and Outcomes published an article on survival after myocardial infarction (MI) in the state of New Jersey. Key findings were that patients hospitalized with MI are less likely to die early after their event in contemporary times than 20 years ago. However, they are now more likely to die later and of noncardiovascular conditions (respiratory or kidney diseases or cancer). These epidemiological findings document a change in outcomes that only studies focusing on populations, as epidemiological studies do, can detect.

Another example of the clinical importance and relevance of epidemiological studies of acute coronary syndromes are those that have documented over the past year a major change in the epidemiology of MI in populations with a dramatic decline in the incidence of ST-segment elevation MI (STEMI) associated with an increase in the incidence of non-STEMI. This underscores the importance of focusing intervention on the care of non-STEMIs, which are less likely...
to receive evidence-based care compared to STEMI events and yet constitute the majority of MI events.

Taken together, these data on the epidemiology of acute coronary syndromes are of utmost relevance to outcomes research for several reasons. First, they indicate that progress has been made for the inpatient treatment of acute MI as illustrated by reductions in case fatality rates concomitant to the gradual implementation of evidence-based therapies in acute MI. Second, these findings underscore unambiguously that further progress will require focusing on non-STEMIs. Indeed, the presence or absence of STEMI on the initial ECG guides the acute management of MI. Because early reperfusion is critically important in STEMI, systems that facilitate timely primary percutaneous coronary intervention have been the subject of intense efforts. Yet, the incidence of STEMI has dramatically declined, a fact that should foster a discussion about the population impact of early reperfusion efforts and shape the design of future interventions to broadly improve outcomes. Finally, these epidemiological data should encourage clinicians to direct efforts toward comprehensive care approaches that consider the patient as a whole and not only as the heart, as the impact of conditions not related to the cardiovascular system emerges as increasingly important.

**Disease Burden According to Persons: Surveillance of Health Disparities**

As an illustration of the relevance of epidemiological studies to the delivery of care, the analysis of disease patterns according to persons is crucial to detect health disparities in the population. For example, in Mississippi, recent trends in cardiovascular mortality revealed profound disparities, with a divergence of the trends among blacks from the favorable mortality decline in cardiovascular disease among the US white population as a whole. This trend was particularly alarming among black women in Mississippi, where mortality is possibly increasing. Importantly, cardiovascular disease trends in mortality show that among whites in Mississippi, the trend seemingly diverges from that of the US white population as a whole, underscoring the complexity of disparities that reflect the interplay of race, geography, socioeconomic status, and education. Progressing in our understanding of the responsibility of these factors is at the same time as complex and indispensable as intervening to reduce them. As the interventions, which are urgently needed, are deployed, surveillance of populations trends will be essential to assessing their effectiveness. Thus, it is clear from the review of trends that disparities and outcomes research cannot be dissociated because disparities must be understood in order to understand outcomes and their determinants.

**Epidemiology Cohorts as Resources for Outcomes Research**

Large-scale randomized clinical trials have been the trademark of clinical research in cardiovascular diseases over the past 3 decades. Life-saving treatments have been unambiguously and rigorously identified as efficacious and have been gradually implemented into clinical practice. Although these major changes were occurring, epidemiologists had conversations about participation bias, generalizability, and external validity, all constructs near and dear to them, but in the golden days of the cardiology megatrials, these concerns were seldom heard. More recently, however, scientists and clinicians have underscored the importance of “studying the patients we are trying to treat,” heralding a welcome awareness of the relevance of community studies to clinical practice. Thus, community-based research emerges as a strategy for research studies to anchor their results to clinical care. Epidemiology cohorts constitute an attractive and still-underexploited resource for outcomes research, postmarketing surveillance of drug therapy, and health services evaluation. Such cohorts are characterized by rigorous case ascertainment and validated follow-up data, thereby providing a unique opportunity to couple the surveillance of a disease to the care delivered to persons living with that disease for a comprehensive appraisal of health and health care. These distinct advantages notwithstanding, external validity also is a potential concern when turning to epidemiology cohorts for health services research. This concern can be addressed by comparing data from administrative databases and epidemiological cohorts as exemplified in the Cardiovascular Health Study. The Cardiovascular Health Study is a population-based prospective cohort study focusing on risk factors associated with cardiovascular disease in elderly persons. Comparison of the Cardiovascular Health Study cohort to a national cohort of Medicare beneficiaries and to Medicare beneficiaries residing in the same geographic regions indicates that mortality in the Cardiovascular Health Study cohort is lower, potentially reflecting participation bias. Importantly for health services research, the Cardiovascular Health Study cohort is comparable to the Medicare population for comorbidities and resource utilization.

**Summary**

As illustrated by these few examples, outcomes research and epidemiology are complementary disciplines. When applied in synergy, they can provide unique and powerful insights into the effectiveness of care and the response to interventions designed to improve the quality of care in populations. As defined by the Institute of Medicine, quality of care is “the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.” Outcomes research and epidemiology are the compass and roadmap to guide us across the quality chasm.

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**References**


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