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## 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”.<sup>1</sup> 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.<sup>2</sup> Sometimes referred to as the basic science in medicine,<sup>3,4</sup> epidemiology is founded on principles and methods (including methods of statistical analysis) that form the basis of clinical research<sup>3,4</sup> 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 will share a few examples to illustrate this point.

### Disease burden according to time: the importance of temporal trends

In a noted Shattuck lecture in the *New England Journal of Medicine*, Eugene Braunwald designated heart failure as a new epidemic of cardiovascular disease.<sup>5</sup> This eloquent statement generated thought-provoking questions: Was there indeed an “epidemic” of heart failure in the epidemiological sense of the word? If so, what the epidemic driven by increase in incidence, improvement in survival or both? These questions inspired epidemiologists to

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#### Conflict of Interest

None.

conduct the needed formal investigation of the heart failure epidemic, which meant bringing to bear rigorous epidemiologic 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 appreciably changed in the past two decades and that, while the outcomes remained quite poor, survival had improved.<sup>6, 7</sup> Substantial disparities were identified with a disproportionate burden of disease on the elderly and African-Americans.<sup>8, 9</sup> Thus, the investigation of the epidemic convincingly demonstrated that the incidence of heart failure was not increasing overall while survival was improving, creating an epidemic of hospitalizations among persons living longer with heart failure.<sup>10</sup> 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 persons living with heart failure was not directly related to heart failure<sup>10</sup> 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 HF. Indeed, to effectively diminish the massive burden of heart failure on patients and on the health care system, guided by the results of the investigation of the epidemic, we must reduce hospitalizations, realizing that most of these may not be due directly to heart failure. Hence, the results of the formal investigation of the heart failure epidemic have shaped more than a decade of outcome research focusing on the in-patient management of heart failure patients, relevant quality indicators and performance measures, and intervention studies. This line of work led to nation-wide strategies that are profoundly impacting the delivery of care and hence patients, providers and payors. The journey is far from being over and little if any progress has been made in addressing disparities in the disease burden. While the task at hand is immense, we however have a roadmap to move forward.

In 2010, *Circulation: Cardiovascular Quality and Outcomes* published an article on survival after myocardial infarction in the state of New Jersey.<sup>11</sup> Key findings were that patients hospitalized with myocardial infarction were less likely to die early after their event in contemporary times than twenty years ago. However, they are now more likely to die later and of non-cardiovascular 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 studies that, over the past year, have documented a major change in the epidemiology of myocardial infarction.<sup>12, 13</sup> in populations with a dramatic decline in the incidence of ST segment elevation myocardial infarction associated with an increase in the incidence of non-ST segment elevation myocardial infarction. This underscores the importance of focusing intervention on the care of non-ST elevation infarctions, which are less likely to receive evidence-based care compared to ST segment elevation infarctions and yet constitute the vast majority of myocardial information events.<sup>14</sup>

Taken altogether, these data on the epidemiologic of acute coronary syndromes are of utmost relevance to outcomes research for several reasons. Firstly, they indicate that progress has been made for the in-patient treatment of acute myocardial infarction as

illustrated by reductions on case fatality rates concomitantly to the gradual implementation of evidence-based therapies in acute myocardial infarction. Secondly, these findings underscore unambiguously that further progress will require focusing on non-ST elevation infarctions. Indeed, the presence or absence of ST-segment elevation on the initial electrocardiogram guides the acute management of myocardial infarction.<sup>15, 16</sup> As early reperfusion is critically important in ST-segment elevation myocardial infarction, systems that facilitate timely primary percutaneous coronary intervention have been the subject of intense efforts.<sup>17</sup> Yet, the incidence of ST-segment elevation myocardial infarction 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 towards comprehensive care approaches that consider the patient as a whole and not only 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 in Mississippi from the favorable mortality decline in cardiovascular disease among US whites. This trend was particularly alarming among black women in Mississippi where mortality is possibly increasing.<sup>18</sup>

Importantly, CVD trends in mortality show that trends among whites in Mississippi seemingly diverge from those among US whites, underscoring the complexity of disparities that reflect the interplay of race, geography, as well as socioeconomic status and education. Progressing in our understanding of the responsibility of each of these factors is at the same time complex and indispensable to intervene to reduce them. As the interventions, which are urgently needed, are deployed, surveillance of populations trends will be essential to assess their effectiveness. Importantly, it is clear from the review of trends such as these that disparities and outcomes research cannot be dissociated as disparities must be understood 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. While 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 “mega trials”, these concerns were seldom heard. More recently however, scientists and clinicians have underscored the importance of “studying the patients we are trying to treat”,<sup>19, 20</sup>

heralding a welcome awareness of the relevance of community studies to clinical practice.<sup>20</sup> Community-based research, thus, emerges as a strategy for research studies to anchor their results to clinical care.<sup>21</sup> Epidemiology cohorts constitute an attractive and still under-exploited resource for outcomes research, post marketing 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 is also 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 the elderly. Comparison of the Cardiovascular Health Study cohort to a national cohort of Medicare beneficiaries and to Medicare beneficiaries residing in the same geographic regions indicated that mortality in the Cardiovascular Health Study cohort was lower potentially reflecting participation bias. Importantly for health services research, the Cardiovascular Health Study cohort was comparable to the Medicare population for comorbidities and resource utilization.<sup>22</sup>

## 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."<sup>23</sup> Outcomes research and epidemiology are the compass and the roadmap to help us cross the quality chasm.

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