Outcomes research is distinct in its focus on the patient’s experience. Ideally, our research should illuminate key determinants of successful prevention, diagnosis, or treatment of disease, with an emphasis on outcomes that patients will recognize as important.

Some of the studies in our pages, however, use biomarkers or surrogate end points. These measures reflect biological processes that are related to risk of meaningful patient outcomes. For example, low-density lipoprotein (LDL) is a marker of risk and the outcome for many studies that assume that lowering LDL is equivalent to reducing risk. Other studies with similar assumptions have used glucose control as an outcome; even the Food and Drug Administration has approved drugs using the assumption that change in a marker of adverse outcomes is also associated with changes in outcome.

In fact, these markers are not equivalent to patient outcomes. Although they may be good predictors of outcomes and even play a role in the pathophysiological processes that increase risk, their modification by intervention does not always change patient risk in predictable ways. The Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial presents a recent example of a successful modification of a risk factor that does not translate into the expected change in patient risk. Yet, many of our articles—and several in this issue of the journal—use biomarkers as outcomes. Maddox et al focus on blood pressure levels, and Dai et al focus on autonomic function. In prior issues, Angell et al, Rinfret et al, Laclaustra et al, and Kressin et al have studied blood pressure control; Groom et al examined microemboli during cardiopulmonary bypass; Steiner et al, Lopez-Jimenez et al, Marma et al, and Wilson et al assessed risk of cardiovascular disease; Nasir et al assessed coronary artery calcium; and Kallio et al evaluated endothelial function.

Despite their limitations, there are reasons to use biomarkers or other surrogates in studies. For example, in the Kallio study of exposure of adolescents to tobacco smoke, the measurement of clinically relevant outcomes would require decades. Thus, the focus on intermediate end points adds evidence to the literature and contributes to our understanding of how tobacco exposure in youth may lead to high risk of cardiovascular disease later in life. The hypertension studies can provide insights despite their lack of information about clinical events. In particular, they can determine the success of strategies to reduce blood pressure and identify differences in success between groups or settings as well as promote innovations to improve these strategies. The ultimate question, however, will be whether the strategies actually improve patient outcomes.

Notable in our pages and at the core of our field is the focus on studies that use outcomes that reflect the patient’s experience. Through this type of research, we seek to understand the determinants of outcomes experienced by patients as well as develop and test interventions to improve quality and quantity of life—or the quality of death. In this issue of the Journal, articles by Spencer et al, Fosbøl et al, and Pottala et al have included mortality among other outcomes. In the study by Amin et al, bleeding is an outcome. Sørensen et al studied the incidence of amyotrophic lateral sclerosis and other motor neuron disorders. In each case, patients would recognize these outcomes as important end points—events that are experienced.

Each issue of the Journal since its inception in 2008 has featured such articles; mortality has been a frequent but by no means sole focus. For example, Keenan et al assessed readmissions; Arnold et al, Norris et al, and Venkitachalam et al assessed health status and quality of life; Gullikson et al studied recurrent acute myocardial infarction; Lewsey et al assessed stroke; Flaker et al studied cognitive function; and Girard et al focused on complications after surgery.

Articles that investigate outcomes from the perspective of the health care system hold a place of similar importance. Although not directly experienced by patients, these outcomes affect society and represent meaningful end points to patients collectively. Such articles that explore the issues of cost, efficiency, and value can frequently be found in our pages, including the investigation by Reed et al in this issue. Past issues featured cost-effectiveness studies and commentaries and cost studies. To publish content of consequence—new knowledge that will advance the field and ultimately lead to better practice and policies—continues to be our goal. Articles that can satisfy our criteria come in many forms, with varied designs and focused on distinct outcomes. Contributions that reflect outcomes in terms of the patient experience or the health care
system remain an important component of this diverse palette.

Disclosures

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References


30. Reed SD, Whellan DI, Li Y, Friedman JY, Ellis SJ, Pina JF, Selles SJ, Davidson-Ray L, Johnson JL, Cooper LS, O’Connor CM, Schulman KA; HF-ACTION Investigators. Economic evaluation of the HF-ACTION (Heart Failure: A Controlled Trial Investigating Outcomes of Exercise Training) randomized controlled trial: an exercise training study of


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