

## Commentary



The difference between statistical and clinical significance is subtle but important. A result that we identify as statistically significant (usually defined at the 5% level, with  $P \leq 0.05$ ) may not be clinically significant (usually defined as an effect size, or difference between treatments, of  $\geq 10\%$ ). The P-value, though readily attainable through any standard statistical software program, may not be very meaningful in real life. What we really want to know is the probability that an observed outcome is of clinical or practical significance. To this end, we have to use our experience and understanding of a clinical situation to define a threshold of clinical significance, which is often defined as a difference  $\geq 10\%$ . An alternative to the P-value is the confidence interval, which defines a range, in the same terms by which the data were measured, within which the true value probably (95% probability) resides. The confidence interval also provides information about statistical significance, the strength and direction of the effect, and enables us to consider the clinical relevance of the outcome. To make these points clear, authors and editors should make an effort to report confidence intervals about their point estimates. In the following editorial, Dr. Joseph explains the importance of reporting confidence intervals in the context of health care reform.

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## Health Care Reform, Statistical Significance, Effect Size, and the Future of the Profession

Health care reform is transforming the medical landscape for clinicians, patients, and administrators alike, with initiatives that strive to maximize health care access and quality while containing expense. The theme of “reform culture” is that of evolving processes of measurement, analysis, and change that are not unique to medicine but rather are a component of a new global economy. Research and analytics have never been so pervasive throughout industries ranging from communications and manufacturing to finance. Outside the health care sector, the vernacular of Six Sigma, Fair Market Valuation, and even Google Analytics are all hallmarks of a culture geared toward analytics. In health care, we have come to recognize this culture in the form of Pay for Performance, Physician Quality Reporting Initiative (PQRI), and Evidence-Based Medicine. No matter what the industry, society now expects greater clarity, transparency, justification, and accountability through analytics.

Reform culture has had an impact on all aspects of the profession of foot and ankle surgery, from the way we evaluate patients

and render care, to the finer details of practice management. Although the means of health care reform are controversial, the unifying message is that reform must be justified by *significant* discrepancies in our health system that can be changed to cause the *greatest impact* on improving the balance between health care quality, access, and cost. As a college of surgeons, the concept of *significance* is well known to us as we use statistical calculations every day to report the *P* values described in our research. We are comfortable with this statistical measurement. At its core, the *P* value merely tells us that a measured difference between 2 treatments was probably attributable to the intervention rather than chance. The new demands of reform, however, call for accountability beyond a simple claim of statistical significance. To meet this higher degree of accountability, a more meaningful and robust measurement is needed.

Outcomes research is one of the fundamental ways by which we demonstrate the importance of our interventions. *Large effects* are a critical component in establishing the practical significance and