How Many Patients Do We Need? Simple Classification to Use In Study Planning

Meghan Wally, PhD, MSPH*; Rachel Seymour, PhD; Tamar Roomian, MPH, MS; Christine Churchill, BA; Nikkole Marie Haines, MD; Joseph R. Hsu, MD, FAAOS; Michael J. Bosse, MD, FAAOS; Madhav A. Karunakar, MD, FAAOS; EMIT*
Atrium Health, Charlotte, North Carolina, UNITED STATES

Purpose: High-level research is a difficult undertaking in orthopaedic trauma, often requiring multicenter studies and years of data collection to reach the necessary sample size for statistical power. The feasibility of enrolling the required sample size is often a guessing game, which presents challenges for planning. This study seeks to characterize the recruitment rates at a Level I trauma center enrolling for multiple prospective orthopaedic trauma research studies and identify patient and study-related predictors of consent.

Methods: This analysis includes data from 10 federally funded studies conducted as part of a large, national consortium that were enrolling patients in 2013 and 2014 (n = 334 patients; 444 patient-study dyads). We received IRB approval to collect minimal demographic and process variables about all eligible patients. The authors conceptualized a simple classification scheme for research studies based on intensity of the study intervention, and categorized studies prior to analysis. "Low" is defined as no or minor change to the patient's care based on participation (randomized studies cannot be defined as "low"). "Intermediate" was defined as significant change to patient's care based on participation (eg, different medication/dose, different surgical technique, participation in a program). Finally, "high" was defined as major change to patient's care based on study participation (eg, additional procedures) and any study including experimental medication. The percent of eligible patients who consented to participate was calculated and described for each study. A 2-level generalized linear model with random intercept for study was used to predict study consent.

Results: A total of 315 patients consented to be in a study (71% of approached patients). Consent rate varied by study (45% to 95%). No patient characteristics (race, age, or gender) were associated with consent. Consent rates decreased as intensity increased (93% for low intensity, 71% for intermediate, 57% for high). Patients approached for studies of intermediate intensity were 83% less likely to consent (odds ratio [OR] = 0.17; 95% confidence interval [CI]: 0.04, 0.67), and those approached for studies of high intensity were 99% less likely to consent (OR = 0.09; 95% CI: 0.03, 0.32).

Conclusion: Patient factors were not associated with consent in this population. Study intensity is a major driver of consent rates and enrollment. Studies of higher intensity will require the study team to approach up to twice as many patients as the target enrollment. This study provides a framework that can be used in study planning and determination of feasibility.