One Key Question: Pilot Study at NorthShore

Statistical Analysis Plan

Clinicaltrials.gov (NCT03947788)

11/17/2020

Patients were excluded from analysis if they reported experiencing menopause or having a hysterectomy or sterilization. Since OKQ is a practice-level intervention, we used intention-to-treat analysis and calculated each practice's rate for each outcome, regardless of whether patients' individual physician had participated in the OKQ training. In each group of patients (baseline time point in control and intervention practices, and post-intervention time point in control and intervention practices), we calculated the percentage receiving reproductive counseling and the percentage who were extremely or very satisfied.

We used chi square tests to compare rates across the two time points within each practice. We also used multivariable logistic regression with an intervention time point interaction (difference-in-differences) term to assess intervention efficacy independent of differences across sites and time trends unrelated to the intervention, controlling for practice type (ob/gyn vs. primary care), patient age, race/ethnicity, and reason for visit. Results are reported as adjusted odds ratios (aOR) and 95% confidence intervals (CI). All analyses were conducted using SAS 9.4 (SAS Inc., Cary, NC).

We calculated a minimum sample size of 260 was needed to observe a 15% between-group difference in the pre-to-post change in counseling rates with 80% power. The statistical significance level for all tests was <0.05.

This research was registered on clinicaltrials.gov (NCT03947788) and approved by NSUHS Institutional Review Board (IRB). Analysis of de-identified data was exempted by the University of Chicago IRB (The University of Chicago, 19-0149;
NSUHS, 18-343).