

Appendix D. Stakeholder Partnership Council (SPC) Recommendations for Analyses

SPC RECOMMENDATIONS	QuintilesIMS RESPONSE
General	
Full and detailed summary of follow-up time in the cohort(s)—min, max, median, mean, <i>n</i> -tiles, % with 2, 3, 4, 5 years or more of follow-up—and examine 1 of the multivariable analyses on a different cohort defined by follow-up; i.e., follow-up time not equal to 2 years.	IMPLEMENTED: Per the committee recommendation, analyses were run both with follow-up time limited to 2 years and time to event analyses including all available follow-up time.
Breakdown of 18- to 40-year-old age group (e.g., 18–30 years old)	NOT IMPLEMENTED: This analysis was explored, but the numbers were small, with only 1% of women between 18 and 30 years of age.
Treatment Patterns	
Consider in plans for manuscript a table summarizing the characteristics of patients by black/white race, to help with any interpretation of racial differences in treatment patterns. This would be 1 of the potential themes of interest for the manuscript.	NOT IMPLEMENTED: It was decided that this topic will be reserved for a potential manuscript.
Confirm/explore whether a possible finding of more frequent, less invasive procedures among black women is true and holds up within age strata.	NOT IMPLEMENTED: Race was included as a covariate in the models; however, the sample size did not allow for stratification by race.
Include some detail on the distribution of subsequent procedures and/or treatment sequencing.	IMPLEMENTED: Treatment patterns and subsequent procedures were examined.
Provide more detail on patients receiving hysterectomies.	NOT IMPLEMENTED: It was felt that this request was beyond the scope of this study, which focuses on uterus-conserving procedures.
Hysterectomy is now mostly an outpatient procedure, so it would be interesting to look at time trends.	NOT IMPLEMENTED: Beyond the scope of the current study
Could be interesting to see if any of the myomectomy patients got pregnant, since	NOT IMPLEMENTED: Beyond the scope of the current study

that is the procedure recommended for those who still want to have a family.	
Symptoms/Procedures	
Recommended table structure: Create a table where rows are the covariates in the model and columns are symptoms and procedures.	NOT IMPLEMENTED: It was felt that this may be worthwhile for a publication, but there were other analyses/tables that were of greater priority.
Would it be interesting/feasible to use hysterectomy as the referent group for the models?	NOT IMPLEMENTED: We did not agree with this recommendation because hysterectomy would not make sense as there could not be any procedures or UF symptoms after hysterectomy.
Consider changing age to categorical.	IMPLEMENTED: We used age continuous where appropriate and age categorical when this helped to ensure the model fit.
Include Kaplan-Meier curves.	IMPLEMENTED: Per the committee recommendation, Kaplan-Meier curves were produced to further examine the time to event analyses.
Summarize the median, range, and <i>n</i> -tiles of days (not just mean) to subsequent symptoms or procedures, including patients who did not have the event of interest.	IMPLEMENTED: Additional information about follow-up time and time to event was provided.
New/recurrent symptom timing may just be the next annual check-up for patients—good to point out that these procedures are not resulting in women having to go back to the doctor before this annual check-up.	IMPLEMENTED: Kaplan-Meier curves were produced that reflect the time to new or recurrent symptoms.
A window of > 7 days for subsequent procedures may not be enough—30 or 60 would be preferable; could do further sensitivity analyses.	IMPLEMENTED: The time window was increased to 60 days per review of the data and clinician recommendation.
Look at the distribution of subsequent procedures by index procedure.	NOT IMPLEMENTED: Agree that this would be interesting to look at and may be appropriate to discuss in manuscript.
Consider restriction to patients who are nonobese and have no comorbidities at baseline as additional analysis—to address the point that it might not really be a “treatment failure” in complex patients with	NOT IMPLEMENTED: We adjusted for these variables in the model, but, given the sample size, stratified analyses for patients without comorbidities were not feasible.

multiple comorbidities to address their fibroids by multiple less invasive procedures in order to not put them at risk of a thrombotic event or other issues from more invasive procedures.	
Is there anything more we can do to describe the experience of patients with no recurrence?	IMPLEMENTED: Survival curves were produced and additional text added to the report to highlight these patients.