Study Title: Impact of Decision Aids in Urogynecology

Document Title: Design and Analysis plan for a study examining the impact of decision aids in Urogynecology

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Background:
Pelvic floor disorders including pelvic organ prolapse (POP), stress urinary incontinence (SUI), and overactive bladder (OAB) are significant source of impaired quality of life, psychosocial distress, and financial burden. Patients with these conditions broadly desire symptom improvement and a better understanding of their condition and treatment options.

Purpose:
To examine the efficacy and acceptability of decision aids (DAs) in counseling urogynecology patients with prolapse, stress urinary incontinence, or refractory overactive bladder.

Design
A before-after study first enrolled patients into a control group that underwent usual care without a DA. Then, the study enrolled patients in the intervention group, where providers utilized a DA for counseling. Post-visit patient surveys assessed treatment preference, knowledge, and patient-physician collaboration using SURE, CollaboRATE, and Shared Decision Making (SM) Process scales. Post-visit provider surveys assessed perception of the decision-making process and visit length. Independent t-tests were used for continuous variables (Knowledge and SDM Process scores) and Chi-square for categorical variables (treatment preference, SURE, and CollaboRATE.

Materials:
The three decision aids used for this study focused on POP, SUI, and OAB. The DAs were created by the Health Decision Sciences Center (HDSC) and Female Pelvic Medicine and Reconstructive Surgery (FPMRS0 faculty at Massachusetts General Hospital (MGH). These DAs were reviewed by experts at the Blum Family and Learning Center at MGH for plain language and clarity. The DA worksheets are short, paper-based forms designed to support SDM in a clinical encounter to present treatment options, and to discuss risks and benefits of each treatment option. The main feature of these one-page worksheets is the decision matrix in the middle of the page, listing four common treatment options down the left-hand side, s well as a brief explanation of the treatments' benefits, risks, and next steps. This format allows patients to visually see the pros and cons of each treatment and allows them to select an option that most closely aligns with their values.

Sample:
We conducted a before-after pilot study enrolling patients from the FPMRS division of the Obstetrics and Gynecology department at MGH, located in Boston, Massachusetts. Eligible patients were 18-95 years old, with POP, SUI, or OAB, and preferred language English. Patients were ineligible if they had prior surgery for POP or incontinence or if they did not attend the visit.

Intervention:
The intervention group, providers had access to the DA worksheets for their routine office visits and utilized the DA with the patient. In the control arm, the providers did not utilize the DAs.

Survey protocol:
The survey was given between February 2019 and April 2019. Participants were asked fi they would be interested in participating in a research study. Then, they reviewed an information sheet that described the study and had to acknowledge that they read it and were willing to continue to the survey. Then, they continued to the survey. Thy were asked to complete the survey either after the visit in the waiting area or returning it in a self-addressed envelope to the research team.

Risk and Adverse Events:
No diagnosis or treatments were offered or administered as part of this study. The standard of care is that physicians discuss appropriate treatment options, including their benefits and risks. There are minimal risks associated with participating in the survey. No confidential or PHI was collected as part of this study.

There are no adverse events expected for this minimal risk survey study. Study staff will review the completed data set and will notify the site PI about any serious or moderate potential adverse events (AEs) immediately and any minor or potential ones at weekly meetings. The PI will review AEs individually real-time and in aggregate on a weekly basis at team meetings. The PI and clinician co-investigators will review potentially serious adverse events (SAEs), as soon as they are discovered. The PI ensures all protocol deviations, AEs, and SAEs are reported to the IRB according to the standard requirements.

There are no formal stopping rules for this minimal risk study.

Outcomes: The survey collected the following information:

Measures:
Patient Post-Visit Survey: the patient post-visit surveys aimed to capture several key parameters regarding the treatment choice and decision-making process between the patient and provider:

- *Knowledge questions*: Four to five multiple choice questions about the condition, treatment options, benefits, and harms. One point was given for each correct item. A total knowledge score was calculated for all respondents who completed at least half of the items. The knowledge questions on each DA were tailored to each specific condition of either POP, SUI, or OAB.
- *Treatment preference*: One items assessed the patient's preferred treatment
- *SURE scale*: A 4-item short form of the Decisional Conflict Scale measures patients' internal beliefs about (1) feeling informed, (2) clear about personal values, (3) sure about the best choice, and (4) supported in decision making. A top score is defined by responding yes to all four items.
- *CollaboRATE*: A three-item process measure of patient's perceptions of the quality of their provider's communication. The three items address whether the patient's provider understands their health issue, listens to them, and includes what matters most to them in choosing what to do next. Each item is scored on a scale of one to ten with one indicating

no effort was made by the provider and ten being every effort was made by the provider. A top score is defined by scoring ten on all three questions on the survey.

- *SDM Process scale*: A four-item measure that assess discussion of options, pros, cons, and preferences. A total score is calculated according to established scoring guides and ranges from 0-4, with higher scores indicating more shared decision making. Scores have been related to increased patient satisfaction with treatment outcomes and current symptoms, decreased decisional regret, and higher quality of life and symptoms scores.

Provider Post-Visit Surveys: Assessed clinicians' perceptions of patient knowledge, involvement in the decision-making process, length of visit, perception of patient satisfaction, and each provider's own satisfaction with the visit.

Sample Size: There was no formal power calculation done for this pilot study.

Statistical Methods:
This pilot study assessed the feasibility of incorporating DAs into the clinical visit and differences in the decision-making metrics between the groups. We examined efficacy by comparing the intervention and control groups on measures of knowledge scores, SURE top cores, CollaboRATE top scores. We examined acceptability of the intervention by looking at the usage of the DAs, clinicians' satisfaction with the visit, and perceptions of length of visit. Differences between cohorts were examined using independent t-test (2-sided) for continuous variables and Fisher's Exact (2-sided) test for categorical variables. The data from the intervention group was analyzed with an intention-to-treat analysis.

Data Sharing:
We are committed to making resources and data from the proposed research available to other investigators in the research community. The study team will create a complete, cleaned, de-identified copy of the final data set. We will also make information necessary to interpret the data, such as study protocols, data dictionaries, decision aid worksheets, and surveys available to interested investigators. Information for investigators interested in using this data will be made available on the Health Decision Sciences Center website and in publications of the data or by contacting the PI. The PI will share a de-identified data set with outside investigators at no cost, according to approved Mass General Brigham policies for data sharing. Investigators from other sites will be able to request the data and will be required to complete a data use agreement that ensures that all local IRB requirements are met before using the data, that they will not attempt to identify any data in the dataset, and that they will not share the data set with anyone outside their project team.