Outpatient Visits versus Telephone Interviews for Postoperative Care: A Randomized Controlled Trial (OPTIONs)

PROTOCOL TITLE:

Outpatient Visits versus Telephone Interviews for Postoperative Care: A Randomized Controlled Trial (OPTIONs)

PRINCIPAL INVESTIGATOR:

Name: Yuko Komesu, MD
Department: Urogynecology

VERSION NUMBER:

4

DATE:

2/10/17

REGULATORY FRAMEWORK:

Please indicate all that apply:

☐	DOD (Department of Defense)
☐	DOE (Department of Energy)
☐	DOJ (Department of Justice)
☐	ED (Department of Education)
☐	EPA (Environmental Protection Agency)
☐	FDA (Food and Drug Administration)
☐	HHS (Department of Health and Human Services)
☐	Other:

Is this a clinical trial under ICH-GCP E6? ☐ Yes ☒ No

If yes, please confirm that the research team is familiar with and agrees to comply with the investigator requirements cited in ICH-GCP E6. ☐ Yes ☐ No

ICH-GCP E6 can be accessed by copying and pasting this URL into your browser: http://www.fda.gov/downloads/Drugs/Guidances/ucm073122.pdf

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1. Objectives

1.1. Describe the purpose, specific aims, or objectives.

Healthcare in the United States is costly, does not result in high patient satisfaction and is in need of reform. It is well known that the current state of healthcare delivery is trapped in a paradox with higher spending and poorer outcomes compared to other countries.[1] To bring American healthcare back on course, the focus must shift to **value**. Health care value relies on quality and cost with the following equation: *value = quality ÷ cost*.[2] Quality incorporates clinical outcomes, safety, and patient satisfaction.[2] Routinely, hospitals and providers are rated on their postoperative care using the Consumer Assessment of Healthcare Providers and Systems (S-CAHPS) endorsed by the Agency for Healthcare Research and Quality (AHRQ). (https://cahps.ahrq.gov) In this equation, value increases by improving quality with increasing patient satisfaction and/or lowering costs without negatively impacting outcomes and maintaining safety. All healthcare stakeholders including patients, payers, providers, and suppliers benefit from working towards improving value.[3]

The value of routine, interval post-operative visits is unknown. Post-operative clinical visits are considered a "gold standard" based solely on tradition. Postoperative care of patients over the telephone has been utilized in place of traditional outpatient postoperative visits in the pediatric and adult surgery literature.[4-10] Retrospectively, this form of postoperative care has proven to be safe, effective, and reduces patients' nonmedical costs with improvements in patient satisfaction as measured on non-validated global scales.[5-10] However, a prospective trial evaluating patient satisfaction and the safety of phone call postoperative visits has not been undertaken. ***A key gap in assessing the value of Urogynecologic care is assessing the value of routine postoperative visits.***

Our specific aims for this study include the following:

1. Compare patient satisfaction with their postoperative care among women randomized to telephone calls versus routine outpatient visits at 3 months as measured by the postoperative domain of the S-CAHPS. *Hypothesis:* We hypothesize that patients receiving postoperative care with telephone calls will report non-inferior satisfaction on the S-CAHPS as women who have in-person postoperative clinic visits.

2. Compare adverse events at 3 months between patients randomized to telephone calls versus postoperative visits. *Hypothesis:* We hypothesize that adverse events will not differ between the two groups.

3. Determine the cost-effectiveness of postoperative care with telephone calls versus visits at 3 months using patient and societal perspectives.

Hypothesis: We hypothesize that postoperative care with phone calls is more cost-effective than in-person visits from both the patient and societal perspectives.

1.2. State the hypotheses to be tested.

Ultimately, our ***long-term goal*** is to institute novel approaches to postoperative care that adds value to healthcare delivery. Our ***overall objective*** here, which is the next step in pursuit of that goal, is to replace routine postoperative visits with telephone follow-up in a non-inferiority randomized controlled trial of postoperative patients after surgery for a pelvic floor disorders. Our ***central hypothesis*** is this novel use of telephone follow-up calls versus clinic visits in uncomplicated post-operative patients after surgery for pelvic floor disorders will result in non- inferior satisfaction for their care as well as significantly reduce patients' direct and indirect nonmedical costs for postoperative care. Our hypothesis has been formulated on the basis of other retrospective, observational studies in the pediatric and adult surgery literature.[4-10] The ***rationale*** for the proposed research is that, once it is established that postoperative care with telephone calls offers similar rates of satisfaction among patients for their postoperative care, that this new approach for healthcare will offer an alternative to routine postoperative care.

2. Background

2.1. Describe the relevant prior experience and gaps in current knowledge.

One in four women suffer from incontinence or prolapse and 1 in 5 women will undergo surgery for these disorders in their lifetime.[11] In the United States, more than 300,000 procedures are performed each year for pelvic organ prolapse with up to 25% undergoing reoperations.[12] The total annual medical cost for surgery alone is substantial, estimating more than one billion dollars.[13] Routine postoperative care visits consume health care resources as well as patients' time and their nonmedical cost. The contribution of the proposed research is expected to provide evidence for a new model of postoperative care with the potential to increase value in our health care delivery to women with pelvic floor disorders.

Based solely on tradition, physicians recommend routine, postoperative visits. The intervals of these visits vary depending on the type of surgery and by surgeon preference but have no real evidence indicating that these visits add value to postoperative care. While direct medical cost for a postoperative visit is covered through insurance since the 1992 National Global Surgery Policy, the patient still carries financial burdens and inconvenience to come to their postoperative visits.[14] Patients' nonmedical direct and indirect costs must be considered—examples of nonmedical direct costs include transportation and

childcare expenses and indirect cost includes income lost from time off work for either the patient themselves or for someone who accompanies them to their postoperative visit. This financial burden has a real impact from a societal perspective as low-income patients estimate spending nearly 10% of their monthly income for a postoperative visit.[15] Recognizing this burden and developing a new, convenient, safe approach to postoperative care has the potential to maintain patient satisfaction as well as decrease costs, thereby increasing value.

2.2. Describe any relevant preliminary data.

No preliminary data are currently available regarding patient satisfaction or cost effectiveness with postoperative care comparing clinic visits and telephone follow-up using standardized questionnaires.

A previous retrospective chart review of patients at the UNM Urogynecology office showed that patients travel 42.4 miles on average (SD +/- 91.5 miles) for their appointments. [16] In addition, Albuquerque is the only city in New Mexico with board certified Urogynecologists. Patients carry a significant burden of cost and time required for routine postoperative visits.

2.3. Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.

Retrospective studies have evaluated telephone evaluation in place of traditional outpatient visits in the pediatric and adult surgery literature including general surgery, urology, and orthopedic surgery.[4-10] Although validated measures were not used, global satisfaction scores were high, patients' indirect costs reduced, and, on the side of the providers, increased time available for new patients or other follow-up visits was created. Importantly, surgical outcomes were similar. These factors—outcomes and satisfaction improvement, cost reduction, clinical efficiency—have the potential to improve healthcare value in the postoperative setting and overall achieve the National Quality Strategy aims.

Telephone follow-up for postoperative care has not been evaluated using a randomized controlled study design with validated measures and has not been rigorously evaluated in the Urogynecologic literature. The British medical system has adopted the use of telephone follow-up by a clinical nurse after Urogynecologic procedures. One retrospective study using the British Society of Urogynaecology database showed 90% of women who underwent a midurethral sling received telephone follow-up and did not require an outpatient visit.[17] Using this same database, a retrospective observational study showed a trend toward self-directed care, in which patients self-present if complications occur.[18] These results along with the retrospective studies from other surgical

fields provide the rationale behind a randomized controlled study for postoperative telephone follow-up after surgery for pelvic floor disorders.

The contribution is significant because telephone follow-up has the potential to increase value in Urogynecologic postoperative care and meet the National Strategic Goals regarding quality. Presently no standard guidelines are available to recommend routine post-operative visits and this trial will allow us to evaluate the status quo—costly face-to-face visits versus inexpensive telephone calls. By minimizing patients' burden while delivering high quality care, we expect to maintain patient satisfaction as well as decrease cost. The Agency for Healthcare Research and Quality (AHRQ) through the U.S. Department of Health and Human Services sets the framework for providers and hospitals to assess value.[19] The AHRQ leads the National Quality Strategy which encompasses 3 aims: better care, healthy people, and affordable care.[19] The pursuit of improved healthcare value is the focus of this proposal and incorporates the aims of the National Quality Strategy.

The proposed research is innovative, in our opinion, because it represents a substantive departure from the status quo by replacing these postoperative visits with telephone calls. Telephone follow-up is a novel, simple, cost-reducing approach to postoperative care for women undergoing elective surgery for pelvic floor disorders. Currently, no randomized trials have evaluated satisfaction, safety and cost in an Urogynecology population using telephone follow-up for postoperative care. Evidence for this mode of postoperative care as safe and affordable with high satisfaction, will break down the barriers in reaching a new horizon for postoperative care with increased value. The establishment of phone calls as a safe, patient-centered way to conduct post-operative care would allow for a more efficient and effective healthcare delivery. This research may be generalizable to other surgical practices as well.

3. Study Design

3.1. Describe the study design (e.g., observational; randomized placebo-controlled clinical trial, etc.)

We will conduct a randomized trial to compare patient satisfaction between outpatient visits and telephone calls for post-operative care. We will recruit women pre-operatively at the UNM Urogynecology clinic who are undergoing surgery for pelvic floor disorders including urinary and/or anal incontinence and/or pelvic organ prolapse and/or pelvic pain, and/or mesh exposure/complications. All women will give written informed consent. Patients will be randomized at the time of discharge to either telephone follow-up or outpatient visits. Computer generated randomization will be assigned by research staff uninvolved with recruitment and will be stored in opaque,

sequentially numbered envelops. Follow-up for both randomization arms will be scheduled at 1-2 weeks, 6 weeks, and 3 months post-operatively, as these are common timeframes for routine postoperative visits in our practice.

3.2. Describe blinding, if applicable

Blinding is not applicable to this study.

4. Inclusion and Exclusion Criteria

4.1. Describe how individuals will be screened for eligibility.

Patients presenting to the UNM Urogynecology office who choose to undergo surgery for a pelvic floor disorder will be eligible for this study. These pelvic floor disorders include urinary and/or anal incontinence and/or pelvic organ prolapse and/or pelvic pain, and/or mesh exposure/complications .

4.2. Describe the criteria that define who will be included or excluded in your final study sample.

The inclusion criteria are the following:

1. Subjects ≥ 18 years of age
2. Women undergoing surgery for a pelvic floor disorder
3. Able to give informed consent
4. Has a reliable phone number for contact postoperatively
5. Able to speak and understand English or Spanish. Spanish forms will be submitted after initial review of English materials.

The exclusion criteria are the following:

1. Any patient whose physician decides medical necessity for the patient to have postoperative follow-up in the clinic
2. Unable to give written informed consent
3. Does not have a reliable phone number
4. Inability to speak and understand either English or Spanish. As noted above, Spanish forms will be submitted after initial review of English materials.
5. Those who specifically request postoperative clinic visits
6. Pregnant patients

4.3. Indicate specifically whether you will include each of the following special populations: (You may not include members of the above populations as subjects in your research unless you indicate this in your inclusion criteria.)

- *Adults unable to consent*

- *Individuals who are not yet adults (infants, children, teenagers)*
- *Pregnant women*
- *Prisoners*

Special populations such as adults unable to consent, individuals who are not yet adults, pregnant women, and prisoners will not be included in this study.

4.4. Indicate if you excluding any particular populations (e.g., women, children, persons not fluent in English, a particular racial or ethnic group, etc.) and provide justification.

We will be excluding women who are unable to speak and understand either English or Spanish. The justification for this is the satisfaction surveys (S-CAHPS by the U.S. Agency for Healthcare Research and Quality) are only available in English and Spanish. And because this is our primary objective, it is important to use these standardized surveys.

5. Number of Subjects

5.1. If this is a multicenter study, indicate the total number of subjects to be accrued across all sites.

This is a randomized controlled trial at a single site—the University of New Mexico's Urogynecology department.

5.2. Indicate the number of subjects to be recruited at this site.

The recruitment goal for this study is 120 patients to allocate 60 patients in the clinic visit group and 60 patients in the telephone follow-up group.

5.3. Provide sample size justification

The sample size for this study is determined by our primary objective, patient satisfaction measured by the Consumer Assessment of Healthcare Providers and Systems (S-CAHPS) survey. We will conduct a non-inferiority patient satisfaction study comparing postoperative care with clinic visits versus telephone calls.

We have been able to identify two publications that have used the S-CAHPS; both of these reported scores for individual items, as well as composites of "top box" responses for individual items. For example, responses for the question, "After your surgery did the surgeon listen carefully to you?" has three responses: 1. Yes, definitely, 2. Yes, somewhat, and 3. No. A top box response is "Yes, definitely". The global satisfaction with their surgeon is a single item, ranging from 0 (worst surgeon possible) to 100 (best surgeon possible), with "top" box responses of 100. "Top" box responses in prior studies ranged from 56-100% with the majority of responses about 90%. Assuming both the control and experimental groups are equivalent in patient satisfaction, a non-inferiority calculation can be applied using 90% as the percentage "success" in the control group and experimental groups with 80% power, an alpha of 0.05, and 15% non-

inferiority limit. In this equation, if there is truly no difference between the control and experimental groups, then 100 patients for total sample size are required to be 80% sure that the upper limit of a 90% two-sided confidence interval will exclude a difference in favor of the control group of more than 15%. Our primary outcome measure is the global composite for the surgeon rating, which has been used in the previous studies. This sample size will provide similar power for comparison of other items and scale of the S-CAHPS between groups. We anticipate that up to 10% of women who are recruited will have complications that preclude them from participation after consent and prior to randomization, such as poorly controlled pain, complications or surgeon concerns. In addition, we anticipate that 10% of women will be lost to follow-up. Therefore we plan to recruit a total of 120 women, 60 per group.

6. Study Timelines

6.1. Describe:

- *The duration of an individual subject's participation in the research*
- *The duration anticipated to enroll all subjects*
- *The expected duration for the investigators to complete the study (complete analysis)*

It is anticipated that approximately two years will be needed to complete this entire project. We expect that patients will be enrolled starting in August 2016. We anticipate recruitment to take one year and be complete by August 2017. Data entry will be ongoing during this time and should also be complete by November to December of 2017 (or 3 months after last patient is enrolled). Data analysis will be completed by February 2018. Our final goal is to submit the abstract for the AUGS 2018 fall meeting.

Timeline	**August 2016- Sept 2016**	**Aug 2017-Dec 2017**	**Jan 2018-Feb 2018**
Subject recruitment, surgery, through 3 month follow up			
Data analysis		◄——►	
Manuscript preparation		◄	——►

7. Study Endpoints

7.1. Describe the primary and secondary study endpoints.

The **primary endpoint** of our study is to compare patient satisfaction between postoperative follow-up with clinic visits versus telephone calls in a randomized, non-inferiority controlled trial.

7.2. Describe any primary or secondary safety endpoints.

The **primary safety endpoint** of our study is to determine the difference in adverse events, emergency room visits, primary care physician visits between patients with postoperative follow-up in the clinic versus telephone calls.

Our **secondary endpoint** is to compare the patients' nonmedical costs (gas money, time from work, child care, etc) between those who follow-up postoperatively in the clinic versus telephone calls.

7.3. Describe any exploratory endpoints.

Our **exploratory endpoint** is to determine if there is a difference in pain and pelvic floor symptoms in patients with follow-up with clinic visits versus telephone calls. The pain assessment will be measured by the Surgical Pain Scales. The pelvic floor symptoms will be measured by the Pelvic Floor Disorder Inventory (PFDI-20).

8. Research Setting

8.1. Describe the sites or locations where your research team will conduct the research.

The study will be performed at the University of New Mexico Hospital (UNMH), Sandoval Regional Medical Center (SRMC), and the associated Urogynecology clinics.

8.2. Identify where your research team will identify and recruit potential subjects.

Potential subjects will be recruited in the UNM, SRMC, and Westside Urogynecology clinics. All patients planning to undergo surgery will have a complete history and physical taken and undergo a pelvic exam, as is standard practice. After written consent to participate in the study, women will complete initial questionnaires in the outpatient offices.

8.3. Identify where research procedures will be performed including any laboratory analytics

Surgeries will be undertaken in either UNMH, the Outpatient Surgery and Imaging Services (OSIS), or SRMC hospital. All other follow up after surgery will be performed again in the above mentioned outpatient clinics.

There are no laboratory tests in this trial other than what would routinely collected prior to surgery.

8.4. Describe the composition and involvement of any community advisory board

NA. There will be no involvement of a community advisory board.

8.5. For research conducted outside of UNM HSC and its affiliates describe:

NA. No research will be conducted outside of UNMHSC and its affiliates.

9. Resources Available

9.1. Describe the qualifications of the PI and study staff (e.g., training, experience, oversight) as required to perform the research. When applicable describe their knowledge of the local study sites, culture, and society.

9.2. When applicable, describe which licensed physicians/providers will be responsible for medical decision-making and ordering and evaluation of necessary diagnostics and therapeutics.

9.3. Describe other resources available to conduct the research: For example, as appropriate:

- *Justify the feasibility of recruiting the required number of suitable subjects within the agreed recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?*
- *Describe the time that will be devoted to conducting and completing the research.*
- *Describe the facilities available to conduct the research.*
- *Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated consequences of the human research.*
- *Describe the process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.*
- *If CTSC resources are being accessed, the signed CTSC resources attachment must be uploaded on the CTSC Submission page in Click.*

Dr. Rebecca Rogers and Dr. Yuko Komesu are board certified subspecialists in urogynecology and will serve as the PI for this study. They are experienced researchers at UNM. They have been the PI on multiple research trials and have successfully completed randomized control trials as senior faculty members at UNM.

The University of New Mexico (UNM) urogynecology division operates at two main locations. *UNM Women's Health Urogynecology Center (UNMH)* located in downtown Albuquerque provides a full range of services for women with pelvic floor disorders. At UNM, the clinic at University of New Mexico's Health Sciences Center consists of 8 exam rooms, 2 treatment rooms and 3 consult rooms with a separate entrance for Urogynecology patients. Our second location is at *Sandoval Regional Medical Center (SRMC),* a community based facility located in Rio Rancho, New Mexico, a large suburb located outside of Albuquerque. The UNM Westside clinic is located in the western side of Albuquerque where there are 3 examination rooms devoted to Urogynecologic patients.

Based on the current surgical volume in the UNM division of Urogynecology, there are approximately 400-500 surgeries performed each year for pelvic floor disorders. Hence, assuming 25% recruitment, it will take 12 months to recruit the

120 patients necessary. Additionally, they are going to be followed for 3 months after surgery, so in total, to recruit subjects, perform their surgery and to collect all 3 month follow up data, we expect this will take 15 months. Then, for data analysis and composition of the manuscript, we estimate that this will take 6 months.

Clinical Research Nurse Coordinator/Research Staff**:** The Urogynecology Division employs 5 research coordinators, two student research assistants and a full time research administrative assistant. We also employ one research nurse through our NIH-funded Clinical and Translational Research Center and one nurse directly through the Department. Our research staff has extensive experience conducting multi-center investigations and recruiting patients to clinical studies, with special expertise in community-based research and quality of life studies.

Research Experience: The Urogynecology Division at UNM has a strong history of conducting high quality research and collaboration with other investigators in the US and abroad, and had consistently met or exceeded recruitment goals on time. We are currently members of the NICHD-sponsored PFDN, and have met recruitment goals with high rates of follow-up and accurate data collection. In addition to PFDN research, Dr. Rebecca Rogers and Dr. Yuko Komesu have mentored and have been the PI on multiple clinical trials and contribute multiple publications in peer-reviewed journals. Their Curriculum Vitaes are attached. Our group is well versed in the importance of adherence to protocols, timely completion of regulatory requirements, effective recruitment strategies, and the importance of the inclusion of minority subjects. Research is integral to all aspects of Divisional work; importantly, all members of the clinical team participate in research efforts. There are weekly research meetings to discuss the progress of the ongoing studies within the department, and it is an excellent forum to ensure that all involved are adequately informed of their duties, of the protocol, and of the procedures.

We do not anticipate that emergency care will be needed for this study, however as the patients are getting surgery, the Urogynecology physicians are available on a 24 hour basis, 7 days per week for their patients requiring emergency care.

10.Prior Approvals

There will not be any approvals obtained prior to commencing the research. The study was presented for approval by Dr. Yuko Komesu, and the signed Departmental Review Form can be found in the “supporting documents” section.

This study does not include any ionizing radiation, biological specimens, or drugs.

11. Multi-Site Research

NA. This is not a multi-site study.

12. Study Procedures

This is a randomized non-inferiority controlled clinical trial to determine the value of postoperative care by measuring patient satisfaction, safety, and cost-effectiveness. Patients will be randomized postoperatively to either follow-up in the clinic or with telephone calls at 1-2 weeks, 6 weeks, and 3 months. The target population is women with a pelvic floor disorder (urinary and/or anal incontinence and/or pelvic organ prolapse and/or pelvic pain, and/or mesh exposure/complications) who are planning surgical management.

Before Surgery:

Patients who meet inclusion criteria will be invited to participate in the study. All patients who agree will give written consent prior to their surgery. All patients will complete baseline questionnaires including the following: Surgical Pain Scales, Pelvic Floor Disorder Inventory (PFDI-20), the Preoperative S-CAHPS questionnaire, and the European Quality of Life-5 Dimensions (EQ-5D). Data collected in addition to the above outcome measures will include *Patient Demographics:* age; self-reported race and ethnicity; primary language, marital status, education, health insurance, annual income estimate, and living arrangements. Also, *Medical/Surgical History:* medical comorbidities; prior surgeries for pelvic floor disorders. The physician's physical exam will include the following: Pop-Q stage, height, weight, and pelvic floor disorder diagnoses. The *Patient Contact* form will be completed for all patients enrolled.

Day of Surgery:

On the day of the patient's surgery, the operation that was decided between the patient and her physician will be performed. Information including the indications for surgery, procedures performed, length of surgery, and any intraoperative adverse events will be collected. This information will be recorded by the surgeon immediately postoperative in the *Surgeons Report* form.

Immediately Postoperative:

The Immediately Postoperative S-CAHPS questionnaire will be completed before discharge. If the patient stays overnight in the hospital after surgery, the S-CAHPS questionnaire will be completed on postoperative day #1. For women

undergoing day surgery the form will be completed in the postoperative holding area.

Randomization:

Computer generated randomization will be assigned by research staff uninvolved with recruitment and will be stored in opaque, sequentially numbered envelops. On the day of the patient's discharge following surgery, the Urogynecology team will call the research coordinator and the patient will be randomized to either clinic visits or telephone calls for postoperative follow-up. Both the clinic visits and telephone calls will be scheduled with specific dates and times. These intervals are at 1-2 weeks, 6 weeks (+/-2 weeks), and 3 months (+/-3 weeks) as this is our current practice. See table 1.

Patients randomized to telephone calls:

Patients will be scheduled to receive a telephone call from qualified medical staff from the Urogynecology office at 1-2 weeks, 6 weeks (+/-2 weeks), and 3 months (+/-3 weeks). A scripted interview (See forms: *1-2 Week Interview, 6 Week Interview, and 3 Month Interview*) will be conducted to evaluate the patient's postoperative status. The information gathered from the telephone interview will be entered into their medical record. If the medical staff person has any concern regarding a patient's postoperative status, the patient will be called by one of the Urogynecology physicians and/or a clinic visit will be scheduled immediately, as is standard practice for patients who are called postoperatively. If the patient requests a postoperative appointment in the clinic, this will also be scheduled immediately. This process is already a standard practice for patient phone calls to our clinic.

In addition to evaluating the patient's postoperative status, the *Patient Cost Survey* will evaluate primary care and emergency room visits, new prescriptions, hospital admissions, estimated travel time, and nonmedical costs.

After the 3 month phone call, each patient will return to the Urogynecology office and meet with a research assistant for a research visit. The patient will then complete the following questionnaires: PFDI-20, EQ-5D, Surgical Pain Scales, and the Postoperative S-CAHPS questionnaire.

Patients randomized to clinic visits:

Patients will be scheduled to receive clinic visits with a physician at the Urogynecology office at 1-2 weeks, 6 weeks, and 3 months. The same scripted interview (See forms: *1-2 Week Interview, 6 Week Interview, and 3 Month Interview*) will be obtained to evaluate the patient's postoperative status. This clinical encounter will also be entered into the medical record. The *Patient Cost Survey* will be completed by the patient at each postoperative visit as well.

These patients will have physical exams performed. The *Adverse Events Physical Exam* form will be completed by the physician performing the postoperative exam.

After the 3 month clinic visit, the patients will meet with the research assistant for a research visit. At this time, the PFDI-20, the EQ-5D, the Surgical Pain Scales, and the Postoperative S-CAHPS questionnaire will be administered. After completion, the patient will be compensated $50.

Figure 1:

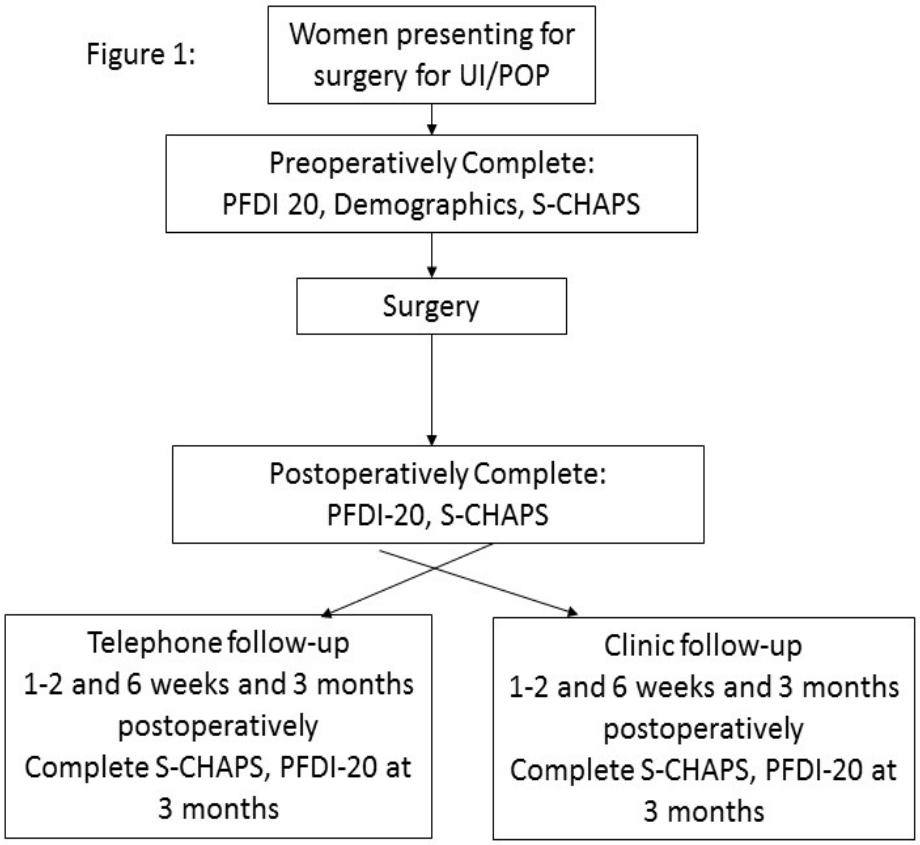

Table 2: Study forms at each interval

	Pre-op	Immediately post-op	Time of Discharge	1-2 weeks post-op	6 weeks post-op	3 months post-op
Demographics	X					
S-CAHPS	X		X			X
EQ-5D	X					X
PFDI-20	X					X
Physical Exam	X					
Surgeons Report		X				
Patient Cost	X			X	X	X

Adverse Events			X	X	X	X

For Clinic Phone Calls other than the calls scheduled at 1-2 weeks, 6 weeks and 3 months:
At the time of discharge, patients receive the contact information for the Urogynecology clinic and on-call staff for after-hours concerns. These calls may be patients from both arms of this study. The qualified medical staff receiving these calls will have a scripted form (the *Interview form)* to complete and added to the medical record, as is standard practice in our clinics. The number of additional phone calls will be calculated. The medical staff will determine if the treatment plan is sufficient over the phone or if a clinic visit is necessary. This process is already standard practice in the Urogynecology clinic.

If a patient randomized to the telephone calls requires a clinic visit, the *Interview, Patient Cost survey, Adverse Events Physical Exam* forms will be completed.

Outcome Measures:

1. Surgical-Consumer Assessment of Healthcare Providers and Systems (S-CAHPS) survey: The "gold standard" for healthcare quality, developed by the Surgical Quality Alliance including the American college of Surgeons and overseen by the U.S. Agency for Healthcare Research and Quality (AHRQ). Incorporates six composites: information to prepare for surgery, communication before surgery, attentiveness on the day of surgery, information to help recovery, communication after surgery, staff at surgeon's office and the overall surgeon rating. [19]
2. Adverse Events: Using a Clavien-Dindo scale, a validated measure of the severity of adverse events associated with surgery. [20]
3. European Quality of Life-5 Dimensions (EQ-5D): Preference-based utility index algorithm used to calculate each subject's utility index and compare change in QALYs between the two treatment groups. [21]
4. Pelvic Floor Distress Inventory (PFDI-20): This is a validated, reliable and responsive 20-question form with 3 scales (Urinary Distress Inventory, Pelvic Organ Prolapse Distress Inventory, and Colorectal-Anal Distress Inventory) assessing women with pelvic floor disorders. [22]
5. Surgical Pain Scales: Four visual analog scales that measure pain at rest, pain during normal activities, pain during work or exercise, and pain unpleasantness. [23]

13.Data Analysis

Data Analysis: Between and within group differences will be evaluated using Fisher's exact test for categorical variables and t-tests for continuous variables.

If there are any baseline differences between groups, and multivariate analysis will determine the contribution of these differences to observed differences (if any) between groups.

Power Analysis: Our power calculation is based on our primary outcome—patient satisfaction. We have been able to identify two publications that have used the S-CAHPS; both of these reported scores for individual items, as well as composites of "top box" responses for individual items. For example, responses for the question, "After your surgery did the surgeon listen carefully to you?" has three responses: 1. Yes, definitely, 2. Yes, somewhat, and 3. No. A top box response is "Yes, definitely". The global satisfaction with their surgeon is a single item, ranging from 0 (worst surgeon possible) to 10 (best surgeon possible), with "top" box responses of 10. "Top" box responses in prior studies ranged from 56-100% with the majority of responses about 90%. Assuming both the control and experimental groups are equivalent in patient satisfaction, a non-inferiority calculation can be applied using 90% as the percentage "success" in the control group and experimental groups with 80% power, an alpha of 0.05, and 15% non-inferiority limit. In this equation, if there is truly no difference between the control and experimental groups, then 100 patients for total sample size are required to be 80% sure that the upper limit of a 90% two-sided confidence interval will exclude a difference in favor of the control group of more than 15%. Our primary outcome measure is the global composite for the surgeon rating, which has been used in the previous studies. This sample size will provide similar power for comparison of other items and scale of the S-CAHPS between groups. We anticipate that up to 10% of women who are recruited will have complications that preclude them from participation after consent and prior to randomization, such as poorly controlled pain, complications or surgeon concerns. In addition, we anticipate that 10% of women will be lost to follow-up. Therefore we plan to recruit a total of 120 women, 60 per group. All data will be entered into REDcap and undergo data cleaning. Data analysis will be performed as instructed by the CAHPS Analysis Program using the CAHPS41.SAS macro program provided by the AHRQ. Analysis will be performed using Fisher's Exact test for categorical variables, t-tests for continuous variables, and Wilcoxon Rank test for ordinal variables with significance set at $P<0.05$. Evaluation of potential confounders (e.g. age, baseline questionnaire) will be performed using regression methods, if, by chance there are differences between groups.

Cost-Effectiveness Analysis

The cost-effectiveness analysis will be conducted from a societal and patient perspective and will be expressed as incremental cost required to produce one additional unit of quality-adjusted life year (QALY). Data on each subject's use of medical and non-medical resources related to postoperative care will be collected during the follow up period. Direct and indirect costs of postoperative care with telephone calls compared to in-person visits and women's preference will be estimated.

We plan to capture incremental direct health care, direct non-medical, and indirect resource use related to study interventions and postoperative complications. Costs will be estimated using the resource costing method. Direct medical service use collected from each study case report form and direct non-medical and indirect costs collected from patient questionnaires are monetized by multiplying the number of units of each resource use by the average unit cost of this item in dollars. Detailed individual cost data will not be collected. This method allows a consistent capture of resource use when costs are incurred across multiple health systems or payers. Detailed case report forms, that include the interventions performed (e.g. phone calls, in-person visits) and clinical events (e.g. complications) will be completed at study calls and visits. Patient questionnaire on direct non-medical costs (e.g. transportation) and indirect costs (e.g. time, lost productivity) will be completed at study calls and visits. Data from medical resource types (physician visits, medications, hospital admissions and emergency room visits) will be collected. Cost for each direct medical service use, direct non-medical items, and indirect items will be assigned based on national Medicare reimbursement rates or other standardized unit costs as indicated in Figure 3.

Figure 3: Resource Utilization Data Collection and Price Data Source, By Utilization Category

Service	**Source Documentation**	**Price Weight**
Medication	Case Report Form	Drug Red Book
Physician visit	Case Report Form	Medicare reimbursement
Complication: surgery	Case Report Form	Medicare reimbursement
Complication: hospitalization	Case Report Form	Medicare reimbursement
Complication: ER visit	Case Report Form	Medicare reimbursement
Time	Questionnaire	Average cost
Lost Productivity	Questionnaire	Average cost

Rationale for using the EQ-5D to measure Utility Values

The European Quality of Life-5 Dimensions (EQ-5D) (EuroQol Group, http://www.euroqol.org), preference-based utility index algorithm will be used to calculate each subject's utility index. [21] This instrument will be collected at baseline and 3 months. The EQ-5D has 5 attributes (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) with 3 levels each for a possible 243 unique health states. The EQ-5D scoring Function is based on the time-tradeoff method with UK Scores ranging from -0.59 to1.00 and US Scores from -0.11 to 1.00. This instrument has been previously validated in women with pelvic floor disorders. [24, 25] These data will be used to compare change in QALYs between the two treatment groups. We are choosing to use a general

scale to calculate change in utilities (rather than condition-specific) to allow for comparison of cost-effectiveness results with other interventions and diseases.

Statistical Analysis: Differential mean costs and differential mean QALYs between the two treatment groups will be estimated using multiple regression analysis. Specifically, a generalized linear model with appropriate link function (e.g., log-link) and response probability distribution (e.g., gamma distribution) will be used to analyze costs due to the potential skewness and heteroscedasticity of medical expenditure data, while an ordinary least squares regression will be used for analyzing QALY data. The models will account for treatment group, stratification factors, as well as other characteristics of the subjects that are found to differ significantly between the groups.[26] When estimating QALYs, we will also adjust for subjects' baseline utility scores to account for potential imbalance in baseline utility between the two treatment groups. [26] We will calculate the incremental cost-effectiveness ratio (ICER), which is the differential mean costs divided by the differential mean QALYs between the two groups, to assess the additional costs associated with each additional QALY gained. Our base case analysis will be conducted based on subjects with complete data. Sensitivity analysis will be conducted to include subjects with incomplete data using the multiple imputation method. Non-parametric bootstrapping resampling technique will be used to derive the 95% confidence interval for the ICER. In addition, cost-effectiveness acceptability curve (CEAC) will be generated to illustrate the likelihood that one treatment is more cost-effective than the other with various ceiling cost-effectiveness ratios. The cost-effectiveness evaluations will be conducted as within-trial comparisons. We plan to conduct supplemental analyses using other outcome measures including incremental cost per patient satisfaction.

14. Provisions to Monitor the Data to Ensure the Safety of Subjects

We have formed a DSMB of individuals not participating in the study but expert in pelvic surgery. The DSMB chair is Dr. Sara Popek, MD and members are Drs. Rameet Singh, MD and Dr. Nathan Blue, MD. Biannually, the board will meet and discuss study recruitment, attrition, and adverse events that have occurred. The intervention in this study is low risk and although surgery is inherently risky, surgery is not part of the intervention of this study, as women have already decided to proceed with surgery for their pelvic floor dysfunction apart from the interventions of this trial. The DSMB will determine whether or not adverse events are related to the intervention in this study or not related, and determine if it is safe to continue recruitment of patients.

The DSMB will review the adverse events forms that are collected with each patient encounter for both the telephone follow-up and outpatient visit groups. This adverse events form includes queries for emergency room visits or primary care physician office visits since the last postoperative encounter. If a serious adverse event is identified, the DSMB will be notified immediately to meet and review the case. In addition to asking the patient during the encounter, the

patient's chart will be reviewed at each follow-up interval (1-2 weeks, 6 weeks, 3 months). If the patient received care at an outside facility, records will be requested.

Privacy concerns are taken into account with every patient seen at the UNM or SRMC clinics. Participants approached and/or interviewed in the clinic setting will be in private offices or examination rooms in the UNM, Westside, or SRMC clinics, where all staff, including research staff, are well-versed in sensitive health care discussions and procedures. Telephone interviews for recruitment and study data gathering are conducted in the research staff area or private physician offices, where all staff have received CITI Training. The office area designated for the entire Urogynecology research staff is isolated from the clinical administrative staff area, providing protection for participants and potential participants during screening, recruitment, study-designated calls, and data entry.

Additionally, the operating rooms at UNM and SRMC are places where patient privacy is respected and observed. All study sheets used to collect patient information will be de-identified.

At all times throughout the clinical investigation, confidentiality will be observed by all parties involved. All data will be secured against unauthorized access. Privacy and confidentiality of information about each subject will be preserved in study reports and in any publication. Each subject participating in this study will be assigned a unique identifier. An IRB-approved HIPAA authorization is required to be signed. All documents containing personal health information (screening logs, consent documents, data forms) are maintained in locked file cabinets with access available only to research staff and investigators. Data is entered into a password protected system. No individual identifiers are entered into the system. The sole link with personal information is maintained by the research team in locked files with access limited to authorized research staff and investigators. This information is only to be used at the study center.

15. Withdrawal of Subjects

15.1.

Any participant may withdraw from the study at any time without penalty and will continue to receive the clinical standard of care. A subject may be withdrawn from the study without her consent at the discretion of the physician and study staff if they believe she no longer meets study inclusion criteria or if she meets exclusion criteria, or if they believe that it is not in her best interest to continue study participation. Investigators may withdraw a subject if the subject is not following the study protocol. If a woman is withdrawn from the study either at her

own discretion or that of the research staff, she may continue with the planned surgical procedure performed in the usual fashion.

To minimize withdrawal from the study, patients will be randomized discharge from the hospital following their surgery. According to the 2010 CONSORT guidelines, we will analyze all participants assessed for eligibility within the study. We will document reasons for withdrawal from the study including failure to meet eligibility criteria or participant declining enrollment into the study. We will report eligibility criteria not met or reasons for declining participation in the study. The withdrawal procedure is clearly documented in the study consent.

16.Data Management/Confidentiality

16.1.

Randomization assignment will be generated by computer based randomization table and assigned by a research coordinator not otherwise involved in the study. Assignments will be kept in sealed opaque envelopes numbered sequentially, and on the day of the patient's surgery, the surgeon will call a research coordinator who will open the next envelope in the sequence. This de-identified study subject number will then be assigned to the patient. All data collection sheets and questionnaires will contain the subject number and day of the hospital or clinic visit. No other patient identifiers will be collected. PHI including patient name, date of birth, phone number, medical record number will need to be collected to track for appointments.

The data collection, HIPAA and consent forms will be maintained in a locked file cabinet in the OBGYN administrative area. A separate folder will be designated for each participant. The offices have the additional security of being badge-access only for OBGYN department employees. A key matching study number to subject's name will be secured in a locked file cabinet in the OBGYN research administrative area.

The only PHI collected will be patient name, date of birth, medical record number and telephone number for site use only and to ensure patient follow up. This will not be entered into the database, but it will be kept with the other identifying information.

The data does not include sensitive information or information requiring additional protection.

All data will be kept in a locked file cabinet in the research administrative area. In order to further ensure patient confidentiality, the identifying information will be kept separately from the numbered study files in a locked cabinet.

Electronic data entry will be performed in the OBGYN administrative offices, using the de-identified subject study number. The electronic data will be encrypted, password protected, and stored on the secure UNM OBGYN department server. This server's electronic security is monitored / maintained by the Health Sciences Library and Informatics Center (HSLIC). A REDCap database will be created to collect, store and manage the data. REDCap databases are reposed securely. The REDCap database is only accessible using a individual unique login and password and access is only provided to co-investigators. Access is restricted to co-investigators and will be protected using the unique REDCap login and password provided to each co-investigator.

Access to the files and REDCap will be restricted to research personnel and Investigators and will be locked or protected using the unique REDCap login and password provided to each co-investigator. The data will be stored for 5 years after completion of analysis and then will be destroyed.

A Certificate of Confidentiality will not be used to protect data from forced release. No data will be transported to outside locations. There will be no audio or video recordings or photographs taken.

17.Data and Specimen Banking

As stated above, the data collection, HIPAA and consent forms will be maintained in a locked file cabinet in the OBGYN administrative area. A separate folder will be designated for each participant. A key matching study number to subject's name will be secured in a locked file cabinet in the OBGYN research administrative area. In order to further ensure patient confidentiality, the identifying information will be kept separately from the numbered study files in a locked cabinet. All data will be entered into REDCap which is password protected and will only be accesed by investigators. The data will be maintained for 5 years after completion of the study and then destroyed.

No specimens will be archived for future use. Additionally, this is neither a multi-center study nor will any information be banked or archived elsewhere.

18.Risks to Subjects

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Risks of enrollment in the study include the risk of breach of confidentiality. We will take every measure to try to ensure the security and confidentiality of participants. Participants will be recruited in a private room and will have ample time to consider whether they want to participate in the study. Also, locked filing cabinets will be used to protect patient consent information and collected data.

The link identifying patients and their study numbers will be also stored in a locked cabinet.

Additionally, each patient who will be offered enrollment will already have agreed to surgery for one or more pelvic floor disorders. There are risks inherent to these surgical procedures including bleeding, risk of infection, injury to surrounding organs, especially if an intraperitoneal surgery is performed (bowel, rectum, bladder, ureters, nerves vessels, vagina, uterus, cervix). We attempt to minimize the possibility of unrecognized injuries by performing cystoscopy with all of these procedures to ensure bladder integrity and to note efflux from each ureteral orifice. If the patient opts for a surgery that involves mesh, she will be made aware of the risks of transvaginal mesh included in the FDA warning (e.g. mesh erosion, pelvic pain, and pain with intercourse). Each patient will be provided with informed consent regarding these risks and offered a blood transfusion in the event of life-threatening blood loss. Giving informed consent for these procedures is our practice's standard of care and will not be altered in the study population.

The risk of not presenting for postoperative checks are small, and include that the patient may have problems that are not recognized by the patient or medical staff during phone calls, and could potentially lead to delay of diagnosis. We believe that these risks are small, as women do not routinely undergo a physical exam at all in person postoperative visits if she does not express having any specific problems. In addition, if concerns are raised during calls, women will be scheduled to be seen in the clinic as is our current practice.

Questionnaires will be provided preoperatively, immediately postoperative, and 3 months postoperatively. There is a risk of patient discomfort with completing these questions.

There are no known additional risks to the form of postoperative care. Each patient will receive instructions and contact information prior to discharge. This contact information will include after-hours phone numbers, so a member of the Urogynecology team may be contacted at any time postoperatively. The patients who are randomized to the telephone follow-up will be asked at every interval if they feel a postoperative clinic visit is necessary. This question will be asked regardless if the patient is asymptomatic. If the patient desires a clinic visit, an appointment will be scheduled as soon as possible. ALL patients, regardless of their randomization visits are also welcome to call the clinic if they have any questions or concerns regarding their postoperative care. If the medical staff decides a follow-up appointment is necessary, an appointment will be made as soon as possible. These measures are already part of our clinical practice

There are no additional risks to those who are not subjects of this study.

19. Potential Benefits to Subjects

The patients enrolled are already opting for surgical correction of their pelvic floor disorder. Participation in this study may help to increase the value of postoperative care by utilizing telephone follow-up instead of clinic visits, and decreasing the time and hassle of presenting for in person postoperative care. Participation in this study may show an increase in patient satisfaction and a decrease in patients' nonmedical indirect costs. There is no guarantee that any individual will personally benefit by participating in this research study. Participation in this study may provide information that may help improve our postoperative care for other women who have surgery for pelvic floor disorders in the future.

20. Recruitment Methods

We will both recruit women from our Urogynecology clinical practice we do not plan to advertise for this study as only women already desiring surgery for a pelvic floor disorder will be recruited.

The Urogynecology clinic at UNMH, Westside, and at SRMC has a large referral population of patients with pelvic organ prolapse. Subjects will be identified in the clinics at UNM/HSC and Sandoval Regional Medical Center by investigators. The patients will be counseled about their chosen surgery as well as their postoperative follow-up. Subjects are encouraged to consult with family, friends, and primary health care providers, as well as communicate any questions they may have before beginning the written consent process.

If a woman is withdrawn from the study either by her desire or that of the research staff, or does not desire to participate, she will be offered the same treatment options instead of undergoing randomization. She will have her postoperative follow-up in the clinic. Her follow up times for after surgery are the same regardless of participation in the study.

A flyer with the study plan and outline will be given to each patient considering surgery for her pelvic floor disorder(s) evaluated in the Urogynecology clinic. This will allow patients time to consider enrollment before the surgery date.

21. Provisions to Protect the Privacy Interests of Subjects

21.1. .

Privacy concerns are taken into account with every patient seen at the UNM or SRMC clinics. Participants approached and/or interviewed in the clinic setting will be in private offices or examination rooms in the UNM, Westside, or SRMC clinics, where all staff, including research staff, are well-versed in sensitive health care discussions and procedures. Telephone interviews for recruitment and study data gathering are conducted in the research staff area or private physician offices, where all staff have received CITI Training. The office area designated

for the entire Urogynecology research staff is isolated from the clinical administrative staff area, providing protection for participants and potential participants during screening, recruitment, study-designated calls, and data entry.

Additionally, the operating rooms at UNM and SRMC are places where patient privacy is respected and observed. All study sheets used to collect patient information will be de-identified.

At all times throughout the clinical investigation, confidentiality will be observed by all parties involved. All data will be secured against unauthorized access. Privacy and confidentiality of information about each subject will be preserved in study reports and in any publication. Each subject participating in this study will be assigned a unique identifier. An IRB-approved HIPAA authorization is required to be signed. All documents containing personal health information (screening logs, consent documents, data forms) are maintained in locked file cabinets with access available only to research staff and investigators. Data is entered into a password protected system. No individual identifiers are entered into the system. The sole link with personal information is maintained by the research team in locked files with access limited to authorized research staff and investigators. This information is only to be used at the study center.

22.Economic Burden to Subjects

Research Procedures	Number of Samples/Procedures	Responsible Party	
		Study	3rd Party Payer or Participant
Consent	1	☒	☐
Preoperative EQ-5D Questionnaire	1	☒	☐
Demographics Form	1	☒	☐
Preoperative S-CAHPS Questionnaire	1	☒	☐
Preoperative PFDI Questionnaire	1	☒	☐
Preoperative Pain scale	1	☒	☐
Immediate Postoperative S-CAHPS Questionnaire	1	☒	☐
Cost Survey at 1-2 weeks, 6 weeks, 3 months	3	☒	☐
Adverse Events Physical Exam Form at 1-2 weeks, 6 weeks, 3 months	3	☒	☐
3 Month Postoperative S-CAHPS Questionnaire	1	☒	☐
3 Month Postoperative Pain Scale	1	☒	☐
3 Month Postoperative PFDI-20	1	☒	☐
3 Month Postoperative EQ-5D	1	☒	☐

Questionnaire			
Standard of Care Procedures	**Number of Samples/Procedures**	**Responsible Party**	
		Study	**3rd Party Payer or Participant**
Surgery for Pelvic Floor Disorder	1	☐	x
Preoperative visit	1	☐	x
Urodynamics (bladder study)	1	☐	x
1-2 week postoperative visit	1	☐	x
6-8 weeks postoperative visit	1	☐	x
3 month postoperative visit	1	☐	x
_____	_____	☐	☐
_____	_____	☐	☐

There are no study related costs to the participants. Whether enrolled in the clinic visit or the telephone follow-up arm of the study, participants will not be billed for the study materials. They have already chosen to undergo surgery, and they will receive prior authorization from their 3rd party payers, or they will have worked out financial assistance, if needed, with the hospital prior to their surgical date. These costs will be billed to their insurance provider and costs may range from copay only to full cost of treatment. The postoperative follow-up is included in the patients' surgical package for 90 days after surgery. Therefore, the clinic visits do not pose any additional medical costs to the patients.

23.Compensation

For enrollment in the study, each patient will be compensated $50 in the form of two gift cards. This payment is reasonable compensation for the inconvenience of participating in a research study due to the multiple questionnaires evaluating the importance of attempting to show any benefit in conducting postoperative care with telephone calls.

The compensation of study subjects will be prorated. Prior to discharge home, the patient will be compensated $20. After the 3 month encounter, $30 will be compensated. These payments will be provided as gift cards. The clinic visits are the standard of care for our postoperative patients. Therefore, these visits will not be compensated. In addition, the telephone calls are the intervention to determine the value of postoperative clinic visits. These telephone calls will not be compensated, because that would require the patient to return to the office which would defeat the purpose of the study.

24.Compensation for Research-Related Injury

If participants are injured or become sick as a result of this study, UNMHSC will provide emergency treatment at the study participants' cost. No commitment is made by the University of New Mexico Health Sciences Center to provide free medical care or money for injuries to participants of the study. Reimbursement for treatment for all related costs of care will be sought from the participant insurer, managed care plan, or other benefits program. The participant will be responsible for any associated co-payments or deductibles required by the insurance. Participants will be encouraged to report any illness or injury they believe to be related to the study to the investigator or research staff. Participants will be given telephone contact information for the Urogynecology office for the purpose of asking any questions or stating any concerns about the study or treatment as a research subject. They may also be directed toward the HRPO. This language will be stated in the written consent document, and reviewed during the informed consent process. Again, the patient undergoes an informed consent process for the surgical procedure regardless of enrollment in the study; hence, there is no additional risks to participate in this study.

25.Consent Process

Patients will be approached about the research study at the Urogynecology clinic at UNM, Westside and at SRMC during a discussion for the management of pelvic organ prolapse. Each patient undergoes counseling in a private room with a closed door to ensure privacy. All of the physicians and research staff involved with this study will be responsible for obtaining written consent. Those recruited will have already decided to undergo surgery for a pelvic floor disorder at the discretion of the surgeon. Hence, they will not be coerced into performance of any "extra" procedures. Additionally, care will not be withheld if they decide not to participate. Study consent will be obtained by one of the research team members.

The patients who would like to participate in the study will be consented prior to their surgery. There is a variable amount of time between the decision to undergo surgery and their next visit for their pre-operative assessment, but it ranges from a few days to months. Hence, the patient will be counseled on the study upon the decision to undergo surgery, during their pre-operative visit, and again at the time of discharge. They will have these multiple opportunities to ask any questions that they may have, and they will also be provided with the clinic's contact information to get in touch with research investigators to address any additional questions or concerns.

Subjects will be reassured that participation is completely voluntary and does not affect their treatment, their relationship with their providers, or the university to minimize the possibility of coercion or undue influence. The patients will be asked that they understand the opportunity to participate and their complete freedom to decline. This will also be asked if they understand and if they have any questions. There is no minimum time period needed between informing the

patient of the study and time of consent. Subject will all be encouraged to take as much time as they need.

This study will obtain HIPAA authorization prior to enrollment. HIPAA authorization is imbedded within the study consent form which will be reviewed with all participants by the physician obtaining consent. Specific information that will be obtained includes prior medical history, surgical history, reproductive health history including child bearing, drug allergies, age, ethnicity. This information will obtained by health care providers, not research coordinators, as deemed necessary for a more complete and accurate medical history of the patient.

The HIPAA form is included with the study consent form which is also included in this submission.

Subjects not fluent in English

The primary outcome of this study is patient satisfaction measured by the Agency for Healthcare Research and Quality (AHRQ) surgical survey entitled, "Consumer Assessment of Healthcare Providers and Systems" (S-CAHPS). This questionnaire is provided in both English and Spanish. Therefore, the inclusion criteria states both English and Spanish speakers will be eligible for participation. The consent, demographics, and postoperative surveys will be available in both English and Spanish. Non-English and non-Spanish speakers will be excluded. If the person obtaining consent does not speak Spanish, then a certified interpreter via in-person or telephone service will be available.

Cognitively Impaired Adults/Adults Unable to Consent/Use of a Legally Authorized Representative

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NA. Cognitively impaired subjects will not be included in this study.

Subjects who are not yet adults (infants, children, teenagers)

NA. Only subjects ≥ 18 years of age will be included in this study.

Waiver or Alteration of Consent Process (consent will not be obtained, required element of consent will not be included, or one or more required elements of consent will be altered)

NA. There will be no waiver or alteration of the consent process.

26.Documentation of Consent

We plan to document consent, and the consent form is attached. We do not plan on collecting/storing tissue samples.

27.Study Test Results/Incidental Findings

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We do not intend to share study test or procedure results with study participants. Additionally, we do not anticipate that the research being conducted will result in incidental findings. Every patient will receive the practice's standard of care regarding a pre-operative work up, which may include different laboratory tests and imaging studies, as determined by their other active medical issues. These results are not directly a part of the research being conducted, and will hence be disclosed to the patient. They will not, however, affect randomization.

28.Sharing Study Progress or Results with Subjects

The patients will not be masked to their study arm. We do not intend to seek out study participants to disseminate information once the study is complete. Women who are interested in the results will be provided the information where to read the manuscript once it is published. Study results for individual participants will not be shared. Once the study is complete if the patients desire they will be informed of what arm they were randomized to.

29.Inclusion of Vulnerable Populations

There will not be any vulnerable populations included in this study. Those electing for surgery will not be coerced into doing so, nor will they be coerced into participating in this trial.

30.Community-Based Participatory Research

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NA. There will be no involvement of the community in this research.

31.Research Involving American Indian/Native Populations

NA. This research does not specifically target this population. If a Native American woman is a candidate for this study she will be offered participation.

32.Transnational Research

NA. This study is not transnational.

33.Drugs or Devices

NA. This research does not involve drugs or devices.

Checklist Section

This section contains checklists to provide information on a variety of topics that require special determinations by the IRB. Please complete all checklists relevant to your research.

NA. None of the checklists were applicable to this study.

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