FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF FOCUS GROUPS (0910-0497)

Focus groups do not yield meaningful quantitative findings. They can provide public input, but they do not yield data about public opinion that can be generalized. As such, they cannot be used to drive the development of policies, programs, and services. Policy makers and educators can use focus groups findings to test and refine their ideas, but should then conduct further research before making important decisions such as adopting new policies and allocating or redirecting significant resources to support these policies.

TITLE OF INFORMATION COLLECTION:

Feasibility Study Using Hospitals Participating in the American Hernia Society Quality Collaborative (AHSQC) to Assess Patient Reported Outcomes after Ventral Hernia Repair with Mesh: Focus group protocol

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Statement of need:

Anecdotal evidence suggests that ventral hernia repairs depending on patient factors, surgical technique, and type of mesh used can result in dysfunction of the abdominal wall. This effect can greatly impact quality of life and basic physiological functions (such as respiratory and bowel function). Ventral hernia repairs with mesh can result in chronic debilitating pain, and mesh infections.

As part of the patient engagement effort in the FDA Center for Devices and Radiological Health (CDRH), the primary goal of this project is to work collaboratively with the clinical community to identify, understand, and solve problems with the use of medical devices. In our relationship with AHSQC, the project seeks to enhance the current patient reported outcome (PRO) tool that is used to capture patient health outcomes after hernia repair. One hundred fifty hospitals nationwide currently contribute data to the AHSQC hernia registry. The registry contains a patient portal that allows patients to enter data directly into the PRO tool, however the content appropriateness of the PRO tool is unknown.

In preparation for this study, we will conduct two rounds of focus groups to gain understanding of the collective views from the patient population. Conducting focus groups is a validated method for content generation and enhancement for PRO instruments (Rothman, 2009), and the findings from the focus groups will help further develop the current PRO tool and contribute to the quality improvement process for stakeholders participating in the AHSQC.

2. Intended use of information:

The aim of the focus groups is to 1) generate evidence on the current PRO tool capture of clinically important items relevant to this patient population; 2) evaluate the frequency with which the assessment should be administered based on recall period; and 3) evaluate patient understanding of each of the items in the tool, determine the preferable scale to capture PRO, determine if the registry patient access portal is the preferred method of data entry.

Findings from the focus groups will be used to further enhance the content of the existing PRO tool for regulatory use, determine the utility of the data captured by the PRO tool as real world evidence (RWE) for device surveillance and regulatory decision making, and contribute to the quality improvement process for stakeholders participating in the AHSQC.

3. Description of respondents:

There will be 2 focus groups each in the two round data collection, a total of 4 focus groups. Each focus group will consist of 5-8 patients. Inclusion criteria are patients with ventral hernias including umbilical, epigastric, Spiegelian, lumbar, incisional, and parastomal hernias who are over 18 years of age (AHSQC, 2016).
Research participants (patients) will be recruited from the hospitals that have contributed to the registry. Recruitment forms will be provided to hernia patients during their visit to the hospital, and announcements of the recruitment will be shown on the AHSQC website and patient portal.

4. Date(s) to be conducted and location(s):

Dates: February 2017-May 2017
Location: The focus groups will be conducted remotely through the online software WebEx, or in selected hospitals, depending on scheduling of patients and the researcher.

5. How the Information is being collected:

Each focus group will consist of 5 to 8 participants. There will be one researcher facilitating the discussion on a semi-structured guideline (see Appendix), and one note-taker to observe and help document the discussion through notes and audio recording. The current or updated PRO tool will be given to the participant to facilitate discussion during the focus group. Informed consent for the study will be obtained from each participant before the focus group begins. The estimated duration of the focus group is 1.5 to 2 hours.
The first round of data collection will consist of 2 focus groups. In this round we aim to understand the clinically important items and themes that are relevant for the population, appropriate endpoints, and adequate length of recall periods for patients.

After the first round of focus groups, content for the survey will be generated from the patient's perspective and the research team will incorporate the findings into an updated PRO tool. To further enhance the content of the tool, we will conduct a second round of focus groups that includes the pilot test of the updated tool. Such debriefing discussions were accomplished and recommended in other PRO instrument development studies (Leidy, et al., 2010; Rothman, 2009), and include recognizing patient understanding of the instrument, as well as the appropriateness of response options and data entry methods. This round will consist of 2 focus groups with different patient participants of the same target population.

6. Number of focus groups:

4

7. Amount and justification for any proposed incentive:

No compensation will be provided to participants in taking part in the study.

8. Questions of a Sensitive Nature:

There will be no questions of any sensitive nature.

9. Description of Statistical Methods (I.E. Sample Size & Method of Selection):

Four focus groups with 5-8 participants each will be recruited from the hospitals that have contributed to the hernia registry. We strive to conduct random sampling by providing recruitment forms to hernia patients during their visits to the hospital, and announcing the recruitment on the AHSQC website and patient portal.

Patients who are interested in the study will go through a simple screening process through the phone or email to check for inclusion eligibility (see Appendix). We will answer patients questions, if any, during the phone call. If they meet the inclusion criteria, we will allocate their participation to round one or round two focus groups randomly, as well as based on their availability.
The number of focus groups is intended to reach the point of data saturation, where no new themes emerge (Rothman, 2009). A documentation system will be used to keep track of emerging themes.

BURDEN HOUR COMPUTATION *(Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours):*

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden Hours (rounded)
Focus Group Participants Round I	16	120	32
Participant Screening Round I	16	5	1
Focus Group Participants Round II	16	120	32
Participant Screening Round II	16	5	1
Total	32	250	67

REQUESTED APPROVAL DATE:

NAME OF PRA ANALYST & PROGRAM CONTACT:

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Leidy, N. K., Wilcox, T. K., Jones, P. W., Murray, L., Winnette, R., Howard, K., et al. (2010 Dec). Development of the EXAcerbations of Chronic Obstructive Pulmonary Disease Tool. *Value in health*, 13(8):965-75.

Rothman, M. e. (2009). Use of Existing Patient-Reported Outcome (PRO) Instruments and Their Modification: The ISPOR Good Research Practices for Evaluating and Documenting Content Validity for the Use of Existing Instruments and Their Modification PRO Task Force Report. *Value in Health*, 12(8):1075-83.

APPENDIX

Screening Questions

1. Are you over 18 years old?
2. Have you had hernia treatment?
3. What type of hernia do/did you have?
4. Which hospital did you go to for treatment?
5. Are you willing to participate in the focus group?
6. What is your availability for the next month?

Focus Group Script

(Investigator will hand out and collect consent forms before beginning the interview.)

Introduction: Hello, my name is _____. I am a researcher in the FDA, and am working with the Americas Hernia Society Quality Collaborative (AHSQC) on a quality improvement program to study and improve patient outcomes in hernia patients. The purpose of this study is to gather the right information to build a database about hernia outcomes. This database will help us understand the outcomes of hernia repair treatments, and eventually predict the recurrence rate of hernia. We would like to understand your experience after hernia repair, and what has been important to you before, during, or after treatment.
This is an interactive discussion, everyone's input is appreciated. There are no right or wrong answers, and you may skip through any questions you don't want to answer. Participation is voluntary; you may choose to withdraw from the study at any time. I will also digital record our group discussion for note-taking purposes, so I don't miss or change something that you said. The record will be kept confidential, and will only be used within our research team. If any time during the interview you'd like to turn the recorder off, just let me know.
Also, to protect the privacy of the focus group members, we ask that you do not discuss the sensitive topics or identify other members outside the group. Do you have any questions before we begin?

Questions: (round 1)

1. Can you tell me about what it is like living with hernia or recovering from hernia treatment?
2. What did you feel about your treatment?
3. Did your hernia recur? Do you know why that might have happened?
4. How was each time different?
5. How do you think your experiences could be improved?
6. What was your experience in talking with your clinician/surgeon about the procedure?
7. What is the most important thing you will consider when making a treatment decision?
8. Are there other items or questions that should have been in the survey?
9. Any phrasing or wording of the questions that was confusing or hard to understand?

Questions: (round 2)

1. What did you think about the survey in general?
2. Let's discuss each question. What did you think was the best about this survey? What was the worst?
3. Was there any phrasing or wording of the questions that was confusing or hard to understand?
4. Are there other items or questions that should have been in the survey?
5. Would you purpose to answer the questions on a different scale? Example: 5 options instead of 4

6. Would another kind of data entry method be more preferable?

Closing Statements

I think we are reaching the end of our discussion. Are there any last comments or thoughts? I really appreciate your time, and would like to thank you for providing me and our team valuable information on this topic, and we will try to use this information to improve the quality of care in hernia treatment. If you have any questions or comments, feel free to email me at ting-hsuan.lee@fda.hhs.gov. Thanks again!