Study Recruitment

<u>Study Topic</u>: Patient Reported Outcomes after Ventral Hernia Repair with Mesh
<u>Institution</u>: The U.S. Food and Drug Administration

Who can join?

Do you want to improve quality for hernia treatment? Would you like to share your experiences about hernia? Does this flyer seem interesting to you? If any of these are true to you, *and* if you have had a hernia surgery and you are over 18 years of age, you are invited to participate!

Goal of the study

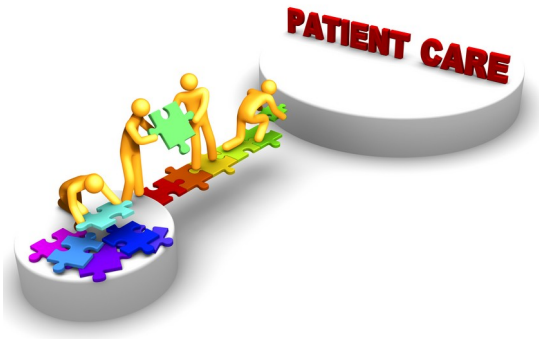
- Learn about patient outcomes to improve quality treatment for hernia patients
- Understand the experience of people with hernia during or after treatment
- Build a good tool (survey) that can reflect health outcomes for hernia patients over a long period of time

Background

The Americas Hernia Society Quality Collaborative (AHSQC) was established in 2013 as a quality improvement program to study and improve health outcomes for hernia patients. This will be accomplished through patient-centered data collection into a registry. Over 150 hospitals currently contribute data to the registry, which has a portal that allows patients to enter data directly into the survey. However, the frequency of data collection, and the appropriateness of the content of the survey is unknown. This study will evaluate the content of this tool for regulatory use, determine the value of the data captured by the tool to be used for device surveillance and regulatory decision making. This study will contribute to the quality improvement process for stakeholders participating in the AHSQC.

Study procedure

You will be part of a focus group of 5-8 people. You will be asked about experiences of your hernia treatment and outcomes. Each focus group will take 1.5 to 2 hours. The researcher will take notes during the interview and focus groups, and may audio record the discussion for note taking purposes.



Risk and Benefits

We do not anticipate that taking part in this research study will put you at risk or discomfort. 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 without penalty. Personal identifiable information you provide will be kept secure by the research team.

There are no direct benefits in participating in the study, yet your participation will contribute to the quality improvement effort for hernia treatment, and the generalizable knowledge in the field of ventral hernia.

Compensation

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

Contacts

If you would like to know more about this study, or have any questions or concerns about participation in this study, you can contact the study researcher *Joyce Lee* at MedSunHernia@fda.hhs.gov or by phone at 240-402-0716.

Confidentiality

Efforts will be made to keep study participant's personal information confidential. Personal identifiers will be replaced with unique ID numbers, and the interview and focus group transcripts will be de-identified. Participant's name will not be used in the written reports or publications which may result from this research.

Subject identifiers such as consent forms will be stored in secure file cabinets, or encrypted with a password if it is an electronic document, and can only be accessed by the project team. Identifiable information will be kept confidential unless required by law. The recordings of the interview and focus group discussions will be deleted after transcribing. Data will be analyzed and securely stored in the FDA White Oak Campus.