

Deciding Our Future: Consensus Conference Summary Report

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Urogynecologic Society (AUGS) Scientific Committee

Objectives: There are few quality measures that allow for optimization of care for pelvic organ prolapse (POP). In coordination with the American Urogynecologic Society (AUGS), a prior group agreed upon health care provider–reported data elements that are important for large-scale quality measurement. The primary objective was to review existing patient-reported outcome (PRO) measurement tools for POP and consider where improvements are needed for inclusion in a quality measurement tool. A secondary objective was to discuss enhanced strategies to improve the quality of care for women with mesh complications.

Methods: The AUGS Scientific Committee convened a 1-day meeting titled “Deciding our Future: Consensus Conference on Prolapse Outcomes and Best Practices for Mesh Complications.” Speakers discussed the current state of POP outcome measurement and meaningful ways of measuring and improving quality. Furthermore, past and future work for standardization of care regarding mesh complications was discussed.

Results: Conference participants included invited speakers, representatives from AUGS and partner societies, 5 patient representatives from the AUGS Patient Advisory Committee, and 38 registered participants from academic institutions, community practices, and industry. Participants developed a roadmap for incorporating PROs into a national POP quality improvement registry. Participants also discussed important gaps in our knowledge of treatment of mesh complications and previewed proposed terminology and treatment algorithms.

Conclusions: Using appropriate methodology, existing PRO measurement tools can be collapsed into one concise tool for POP quality measurement. Over the next year, work will continue toward this goal. Proposed updates to mesh terminology and treatment algorithms will be published separately.

Key Words: consensus report, patient-reported outcomes, prolapse quality measurement, mesh complications

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In the United States alone, approximately 300,000 surgeries for pelvic organ prolapse (POP) are performed annually.¹ When framed from an individual woman’s perspective, she has a 12.6% risk of undergoing surgery for POP by age 80 years.² To contrast

this risk with other women’s health issues, it is only slightly less than the 14.8% lifetime risk of developing breast cancer.³ Despite this high number of surgeries and large impact of POP on women’s health, there are few existing metrics that allow clinicians to optimize care for POP. Few patient-reported outcomes (PROs) are tracked by clinicians in a systematic fashion, although POP is a quality of life condition that can recur, requiring reoperation in approximately 17% of cases.⁴ Furthermore, few quality measures that specifically aim to track and improve POP treatment outcomes exist. Because of this lack of focus on quality, treatment plans may not only fail to adequately consider conservative therapies but also fail to highlight areas of improvement for surgery. In addition, unexpected complications may occur when outcomes are poorly tracked, such as the recent series of adverse events linked to surgical mesh used in urogynecologic procedures,^{5–7} which only came to light after serious events were reported.^{5–8}

Because POP continues to require a high number of surgeries and has a large impact on women’s health, it is imperative that we improve our methods of monitoring and improving the quality of care provided. The Women’s Health Technologies Coordinated Registry Network (WHT-CRN) previously coordinated with the American Urogynecologic Society (AUGS) to develop a large-scale registry for POP quality measurement.⁹ A consensus group that comprised individuals from multiple societies used a modified Delphi method to determine the health care provider–reported data elements that would be incorporated into the registry. However, PRO measurement is an important component of gauging quality for surgical treatments that are commonly performed and inherently low risk. The currently proposed registry data elements do not yet include any PRO measurement tools. Therefore, on September 23, 2019, the AUGS Scientific Committee convened a conference titled “Deciding our Future: Consensus Conference on Prolapse Outcomes and Best Practices for Mesh Complications.” The primary objective was to review existing PRO measurement tools and consider where improvements are needed for quality measurement. A secondary objective was to discuss enhanced strategies to improve the quality of care for women with mesh complications.

CONFERENCE PARTICIPANTS

- AUGS representatives and planning committee:

Geoffrey W. Cundiff, MD (AUGS President)
Charles R. Rardin, MD (AUGS Board of Directors)
Catherine S. Bradley, MD, MSCE
Christopher J. Chermansky, MD
Gena C. Dunivan, MD
Nazema Y. Siddiqui, MD, MHSc

- Invited Speakers:

Matthew Barber, MD, MHS
Sarah H. Boyles, MD
Nancy Gretzinger, PhD (Patient Representative)

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 Daniel M. Morgan, MD
 Kevin P. Weinfurt, PhD
 Malka S. Zeefe, JD (Patient Representative)

- Partner Society Representatives:
 - American Association of Gynecologic Laparoscopists (AAGL); Andrew Cassidenti, MD
 - American College of Obstetricians and Gynecologists (ACOG); Renee M. Ward, MD
 - International Urogynecological Association (IUGA), Douglas Tincello, Professor of Urogynaecology
 - Society of Gynecologic Surgeons (SGS); Danielle Antosh, MD
 - Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU); Jennifer T. Anger, MD, MPH
- AUGS Patient Advisory Committee (2 speakers above and 3 additional patient representatives)
- 38 registered participants from academic institutions, community practices, and industry

DETAILS OF MEETING

Part I: Measuring Quality and Outcomes of Prolapse Treatment

Kevin Weinfurt, PhD, discussed general methodology of how to develop rigorous tools to measure quality. He focused on outcome measurement, which is one component of quality measurement (different from structure or process measurement). He stated that an *outcome* may be a symptom (eg, depression), whereas an *outcome measure* is a standardized way to measure this symptom (eg, Patient Health Questionnaire), and an *outcome performance metric* is something that is created to measure quality of care (eg, percent of patients with the diagnosis of major depression and initial Patient Health Questionnaire score >9 with a follow-up score <5 in 6 months). To create an outcome performance metric, the context of use must be considered. We also need to have a good outcome measurement tool. To create this tool, we need to understand which effects are important to the person with a condition. This includes understanding many aspects of physical, mental, and social functioning, as well as the modification of activities that may ultimately dilute the effects of a biologic intervention such as surgery. To develop a good PRO measurement tool, we should do the following: (1) collect qualitative data to understand the meaning of the PRO concept, (2) write items that we think will measure the concept, (3) test items for understanding (cognitive interviews), (4) administer items to a large sample of people, (5) use analyses to see how well the items are working and develop a scoring method, (6) evaluate the reliability and validity of the tool, and (7) adapt the measure for other cultures or languages if needed.

Next, Daniel Morgan, MD, discussed the current state of quality measurement for POP. He discussed the background of how quality measurement emerged in our health care system and reviewed the financial implications. He also reviewed some of the unintended consequences of quality measurement, including the time and resources spent as well as the level of usefulness. For POP care, we have “process” measures that have been accepted by the National Quality Forum and incorporated into registries like the AQUIRE Urogynecology Quality Registry.¹⁰ For “outcome” measurement, none of the measures currently meet National Quality Forum benchmarks; however, there are a few measures in the AQUIRE registry: intraoperative bladder, ureter, or bowel injury. He discussed the issues with using rare surgical outcomes as an overall measure of quality and how there is poor

resolution in distinguishing quality with this method. He also discussed the concept that an outcome measure essentially measures if a problem was fixed and managed well. For high caseload/low-risk surgeries, like hysterectomy and prolapse surgery, quality is best measured using a combination of process measures (which we currently have) and functional health measures, such as PROs.

Next, there were a series of presentations about existing focus group work and patient-perspectives on POP outcome measurement. Prior qualitative studies by Sung et al¹¹ and Dunivan et al¹² were presented and reviewed. The AUGS Patient Advisory Committee had previously reviewed these articles, and Malka Zeefe, JD, served as spokesperson for this committee. She presented compiled patient comments about these focus group studies and existing literature.

Finally, there were a series of presentations reviewing the current state of prolapse outcome measurement. These presentations included the following: (1) the proposed data elements for a large-scale prolapse registry (WHT-CRN Core Data Element List, to be incorporated into the AUGS AQUIRE POP module), (2) a review of major questionnaires currently used for POP outcome measurement and how items from these questionnaires map to patient-important elements from qualitative studies, and (3) a discussion of the gaps that exist. The group discussed an overall roadmap to development of enhanced PRO tools for POP outcome measurement.

Part II: Building Consensus Around the Approach to Mesh Complications

The second half of the conference began with AUGS’ outgoing president, Geoffrey Cundiff, MD. He provided an update from the AUGS Board of Directors regarding the use of mesh in treatment of pelvic floor disorders. He summarized that AUGS supports evidence-based medicine, informed consent, and patient autonomy. The Board of Directors would like to identify research related to the management of mesh complications, gaps in known research, the role of registries, and the concept of “Centers of Excellence” in the management of surgical mesh complications.

Nancy Gretzinger, PhD, a spokesperson for the Patient Advisory Committee, then provided the patient perspective on mesh complications as well as sharing her personal journey with mesh complications. She eloquently described the agony felt by women who have suffered from mesh complications, and she illustrated how mistrust has developed between some women with mesh complications, medical societies, and health care providers. She emphasized that patients struggling with mesh complications want to be acknowledged and desperately desire a list of health care providers who can provide evidence-based medical care.

Dr Pamela Moalli reviewed the objectives and timeline for the Pelvic Floor Disorders Registry (PFDR). She discussed overall challenges with the registry, patient and health care provider perspectives, and an update on the information collected. The rate of patient participation with completion of questionnaires and a 12-month visit was only 13.7%. Dr Catherine Bradley then reviewed POP registries, including the PFDR, WHT-CRN Core Data Element List, and the AQUIRE POP Module. Overall, the WHT-CRN POP working group incorporated experience from the PFDR, and determined the importance of rating the severity of a complication and the need to capture quality outcome measures. The next steps are to incorporate the WHT-CRN Core Data Element List into a prolapse module in the AUGS AQUIRE Quality Improvement registry.

Dr Douglas Tincello, from IUGA, reviewed the ICS/IUGA terminology on mesh complications, which is a standardized definition of complications relating to mesh and native tissue repairs. It was created by 16 experts and underwent 11 rounds of peer review. It provides a consistent and standardized record of complications but has been criticized for being overly complex. However, the

online calculator helps significantly with its use. In follow-up, Dr Charles Rardin reviewed the limitations of the ICS/IUGA terminology. These included complexity of the system, limited emphasis on the grading of severity, and poor interrater reliability. He then presented a proposed AUGS Consensus Statement on Management of Mesh Complications. This consensus statement is under development and describes standardized terminology for procedures to treat mesh complications, as well as treatment algorithms based on symptoms and presence or absence of mesh exposure.

Conference participants split into groups for a session moderated by Dr Matthew Barber. The groups were asked to address two questions: (1) what is the most important gap that we need to fill in the treatment for women with mesh complications and (2) What is the best step forward to fill this gap? From the group sessions, the following items were identified:

- Preoperative prediction of mesh complications
- Standardized patient education
- Patient access to timely data and high-quality care
- Understanding the minimal amount of treatment needed to resolve symptoms
- Assessment of patient-reported adverse events
- Explore patient concerns about systemic responses and other types of symptoms that health care providers do not usually attribute to mesh (eg, “mesh belly”)
- Raise awareness on issues of trust between patients, health care providers, and societies.

Finally, the day concluded with a panel discussion including representatives from AUGS and partner societies. Panel members responded to questions from moderators and the audience regarding the aforementioned items and the concept of “Centers of Excellence” for treatment of mesh complications.

MAIN OUTCOMES AND NEXT STEPS

With regard to POP outcome measurement for quality registries, a good amount of work has already been performed. This includes the creation of validated questionnaires, initial PRO item development, and focus group work to understand patient perspectives. The major limitations of existing work are the following:

1. The majority was performed in white women with higher socioeconomic status, and we need to assess generalizability in broader populations.
2. To address major concepts that are important to patients (ie, all of the themes brought forth in focus group studies), we would need to administer a battery of questionnaires. This is not feasible in clinical practice, and one condensed measurement tool is desired for outcome measurement in registries or for quality metric development.
3. For maximal clinical utility, technology should be leveraged so that any POP outcome measurement tool should interface with existing electronic medical records. Patient-reported outcomes that are used for quality measurement would ideally be built electronically to facilitate embedding these questions into an overarching system.

To move forward, we will first need to propose a recommended POP outcome measurement tool that encompasses all of the important concepts that patients identify (eg, not only bulge but also other physical function measures, sexual function, and pain). To accomplish this goal, we need to do the following:

- Review, assess, and rank all existing items from multiple questionnaires to find a smaller subset that are relevant and nonredundant.

- Test these questions in cognitive interviews using appropriate methodology.
- Include women of color, women of different socioeconomic status, and women with lower literacy levels in cognitive interviews.
- Propose a subset of items to be incorporated in evidence-based quality measurement tools. Propose a method of testing validity and reliability in the future.

The AUGS Scientific Committee has begun the work outlined previously. The committee will host another conference to present and discuss a proposed subset of items for inclusion as patient-reported data elements in the AUGS ACQUIRE prolapse module. This conference is planned for March 2020, in Jacksonville, Florida. Broad participation in this meeting is welcomed.

Regarding mesh complications, we discussed challenges with existing registry data capture and terminology. A proposed algorithm for evaluation and management of mesh complications was discussed; standard terminology for inclusion in operative notes was also discussed. Proposed terminology and treatment algorithms will be published separately in a planned AUGS-IUGA Position Statement on Management of Mesh-Related Complications.

In conclusion, a consensus meeting was held to discuss how we measure and report on the quality of POP care, as well as mesh complications. Conference goals were achieved, and a roadmap for future work was developed.

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