AUGS
PELVIC FLOOR DISORDERS REGISTRY

MDEPINET

OCTOBER 2, 2015

Agenda

- PFDR Origins and Design
- Obstacles and Challenges
- Barriers of Implementation
- Funding and Potential Stakeholders
- Areas for Future Growth
- PFDR and the National Medical Device Evaluation System

PFDR Origins and Design

- In 2012, the FDA issued 522 Orders for transvaginal mesh products for Pelvic Organ Prolapse (POP).
- In support of the FDA's recommendations, AUGS developed the Pelvic Floor Disorders Registry (PFDR) to collect comparative effectiveness, quality of life and safety data associated with surgical and non-surgical treatments for POP, to ultimately to improve the quality of care for women.
- AUGS collaborated with clinical and industry representatives to create, refine and implement the PFDR.
- In addition to fulfilling the FDA's requirement for monitoring of vaginal mesh outcomes, the PFDR is also a research and quality improvement registry for AUGS' participants.

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Pelvic Floor Disorders Registry PFDR

Obstacles and Challenges

- Development timelines and evolving research needs
- Inflexible system architecture
- Governance and partnering with diverse, competing stakeholders
- “Dual Purposing” the PFDR: 522 studies, additional research, and quality improvement functionality
- Meeting evolving regulatory requirements: PQRS, Meaningful Use, Merit-Based Incentive Payment System (MIPS), etc.
- Escalating costs

Barriers of Implementation

- Establishing core minimum data elements
- Interoperability
- Patient participation – informed consent
- Physician participation – increased workload versus benefits of participating
- Research funding

Registry Funding and Potential Stakeholders

- Industry Partners include ACell, AMS, Boston Scientific and Coloplast
- Stakeholders include Industry Partners, FDA, NICHD, NIDDK, NIA, CDC, ACOG, AUA, ABOG, ABU, SUFU
- Additional Industry Partners are welcome
- Potential to seek PCORI, NIH, FDA funding

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Areas for Future Growth

- Expanding beyond POP
- Interoperability
- Maintenance of Certification
- Meeting CMS Regulatory Requirements

PFDR in the National Post-Market Surveillance System

- PFDR lessons learned may contribute to more strategically coordinated registry networks in the future
  - PFDR has engaged multiple competing stakeholders successfully
- PFDR can share reusable tools at the systems level per the Medical Device Registries Task Force (MDRTF) recommendation
- PFDR will benefit from MDRTF advances in interoperability, more flexible architecture, standardized structured data, and data portability solutions.


Pelvic Floor
Disorders
Registry
PFDR