

AUSTRALASIAN PELVIC FLOOR PROCEDURES REGISTRY

COMMUNIQUE #1 – July 2020

Title: Australasian Pelvic Floor Procedures Registry (APFPR)
Coordinating Principal Investigator: Professor Susannah Ahern

This Communique outlines the progress of the Australasian Pelvic Floor Procedures Registry (APFPR). The APFPR is a clinician-led national clinical quality registry, with the primary aim of monitoring the safety of stress urinary incontinence (SUI) and pelvic organ prolapse (POP) procedures involving mesh and other implantables.

BACKGROUND

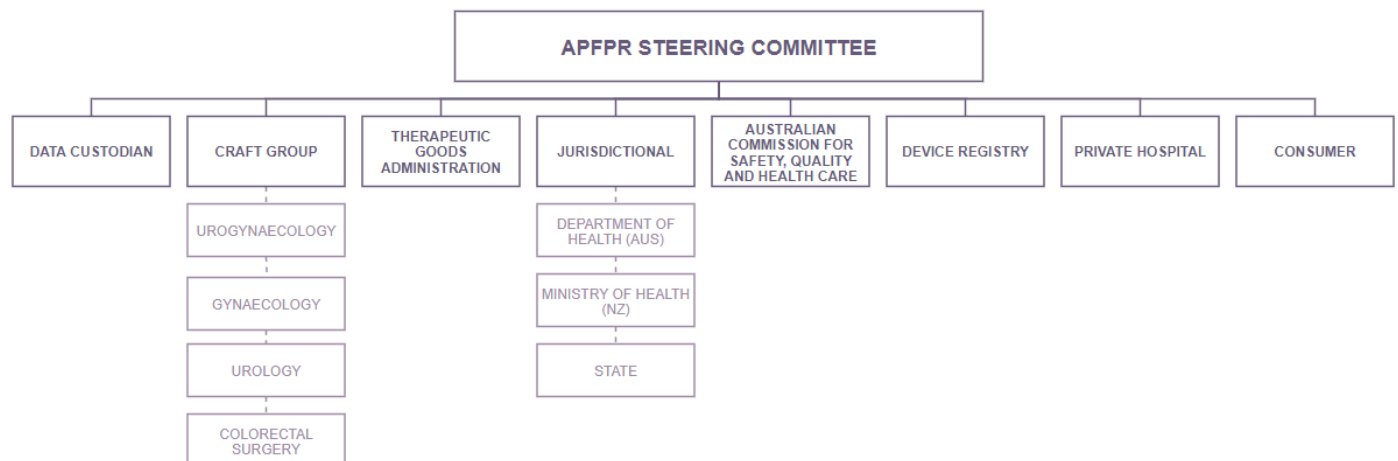
The APFPR is a Department of Health, Government initiative following the recommendations of the Australian Senate enquiry into complication arising from procedures involving transvaginal mesh. The registry will prospectively collect health data on SUI and POP procedures including those involving repeat surgery, revisions and explantations from participating hospitals and surgeons. To monitor safety and quality of care, details on the procedures undertaken, mesh implant used, clinician and patient reported outcomes of surgery as well as parameters to adjust for the presence of modifying factors will be collected.

SCOPE

The registry will be rolled out utilising a phased modular approach commencing with procedures involving SUI mesh, followed by POP mesh. For each module a minimum clinical dataset will be developed and appropriate patient reported outcomes will be identified through a consultation process involving a broad range of stakeholders that include surgeon craft groups, consumers, regulatory bodies such as the TGA and the Australian Safety Commission (ACSQHC).

GOVERNANCE

STEERING COMMITTEE

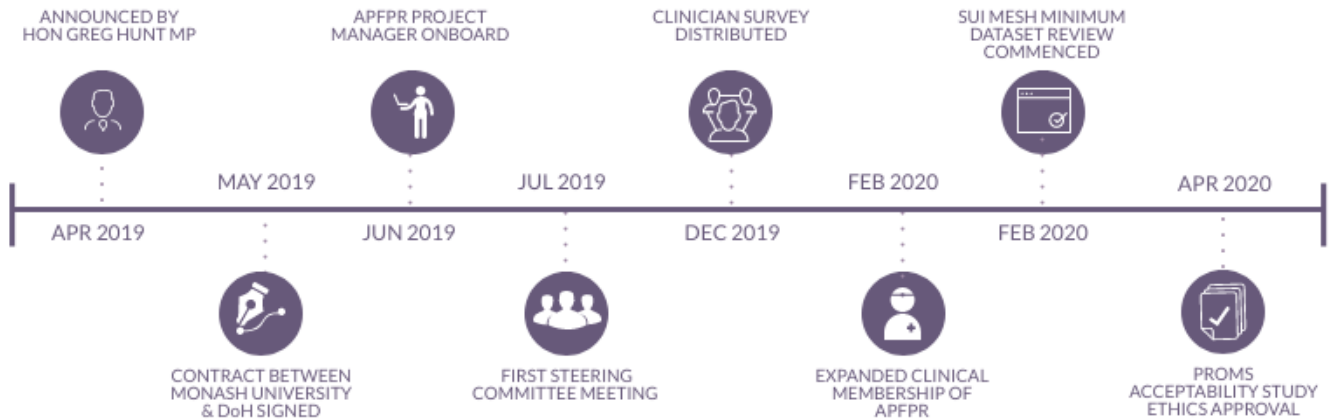


The APFPR Steering Committee oversees corporate and clinical governance and promotes activities within the registry. For a list of members, please click [here](#).

COORDINATING CENTRE

The Monash University development team has expertise in registry design, and works closely with both the Steering and Management committees to develop processes and activities that the registry will undertake. The team is led by Professor Susannah Ahern (Data Custodian and Steering Committee Chair) and Ms Joanne Dean (Project Manager), and includes professional, academic and clinic staff.

2019-2020 YEAR IN REVIEW



REGISTRY ACTIVITIES

Steering Committee Membership – The steering committee recently expanded membership increasing craft group representation and includes specialties from Urogynaecology, Urology, General Gynaecology and Colorectal Surgery. The registry is currently finalising a process to expand consumer representation.

Clinician Survey - Surgeons undertaking SUI and POP procedures were recently invited to complete a survey seeking feedback on the scope of the registry and potential barriers and enablers to registry participation. We would like to thank both the surgeons that provided their feedback as well as RANZCOG and USSANZ who kindly distributed the survey on behalf of the registry. Preliminary results were presented to the APFPR Steering Committee and have informed APFPR activities. The surgery is being prepared for journal publication.

Systematic Review - To support the minimum clinical dataset and the development of patient reported outcome measures, one of APFPR's first activities was to undertake a systematic review of all registries and databases involved in the collection of data involving SUI and POP procedures.

Minimum Dataset- SUI Mesh - The collation of an extensive dataset specific to SUI procedures utilising guidelines and existing international registry datasets was the starting point for development of a minimum dataset. Via a Delphi process, data items categorised for safety, effectiveness, or risk adjustments purposes are currently being evaluated for importance and feasibility through a series of rounds utilising an expert review panel.

PROM Acceptability Study - An important aspect to the APFPR's monitoring of safety and quality of care capability is to obtain patient derived outcomes following SUI and POP procedures. The registry has investigated the most commonly used health-based questionnaires (or patient reported outcome measures -PROMS) and is currently undertaking an acceptability study to determine feasibility, relevance, clarity and usefulness of the chosen PROMS. Qualitative interviews are currently being conducted with women who have undergone a SUI procedure and surgeons who perform these procedures. A similar approach will be repeated for POP mesh procedures module later in the year.

SA Pelvic Mesh Parliamentary Inquiry - The APFPR was invited to the South Australia Parliamentary Inquiry into pelvic mesh. Professor Susannah Ahern and Professor Helen O'Connell represented the registry and provided an update on the registry's progress.

TGA Engagement - The APFPR has teamed up with the Therapeutic Goods Administration (TGA) to support their current device reporting procedures. Both the surgical and patient derived outcomes collected by the registry will provide additional information to the TGA to support their safety notification and recall processes.

COMMUNICATION

The APFPR Website has been launched (apfpr.org.au). A comprehensive version of the website is under development and will be launched prior to the start of recruitment, in a few month's time.

ENQUIRIES If you would like further information about the APFPR or participating in the registry, please email the APFPR Coordinating Centre, apfpr@monash.edu