AUSTRALASIAN PELVIC FLOOR PROCEDURE REGISTRY

COMMUNIQUE #2 – February 2021

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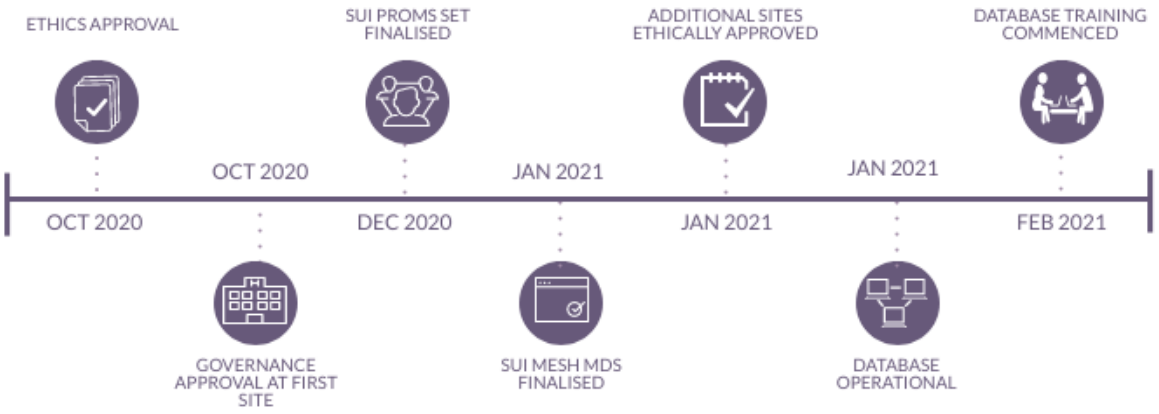
This Communique outlines the progress of the Australasian Pelvic Floor Procedure Registry (APFPR). The APFPR is a clinician-led national clinical quality registry, with the primary aim of monitoring the safety of stress urinary incontinence (SUI) and pelvic organ prolapse (POP) procedures involving mesh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

APFPR NOW OPERATIONAL

In January, the APFPR transitioned from the development phase to being operational. On 29th January training capability was opened for participating sites that had governance approval, and as of the 15th February, the APFPR was able to commence recruitment and receive data for the first module involving SUI mesh/prosthetic procedures including implantations, revisions and explantations. To acknowledge the significance of the registry's commencement, an official launch will occur in the next couple of months.

July 2020-February 2021 IN REVIEW



MINIMUM DATASET DEVELOPMENT

The finalised minimum dataset for the rollout of the first module is an evidence and consensus-based set of data items, supporting the collection and reporting of clinical outcomes of SUI procedures involving prostheses and associated complication procedures.

An initial data set was proposed following a systematic review of data items collected from international female pelvic floor surgical procedure registries and databases clinician nominated data items and reporting recommendations. Through a modified Delphi process involving a 14-member expert review panel composed of urologists, general gynaecologists and urogynaecologists, the initial dataset was refined to 42 clinically important data items related to device and procedure safety and efficacy that were feasible to collect.

In addition to the collection of patient and device data for safety tracking purposes, presurgical pelvic floor related items such as urinary incontinence type, and the presence of dyspareunia, persistent pelvic and associated pain, recurrent urinary tract infections and voiding dysfunction provide a baseline upon which to gauge surgical effectiveness and associated complications post procedure. Risk factors considered to have important modifying effects on surgical outcomes such as BMI, smoking, diabetes and menopausal status are also included.

Clinical information is collected pre-operatively, at operation and post operatively. Complications are classified according to the ICS-IUGA Mesh Complication Classification Scale using the online calculator: https://www.ics.org/complication . For those complications not collected using this scale, the registry has listed common ones for selection and there is the ability to add further complications by free text.

Clinicians will be able to access their registry patient data via the database. In addition, once clinician and site volumes are sufficient, the APFPR will provide reports to participating sites and clinicians. The APFPR encourages requests to access data from clinicians and researchers.

PATIENT REPORTED OUTCOME MEASURES (PROMs) ACCEPTABLITY STUDY

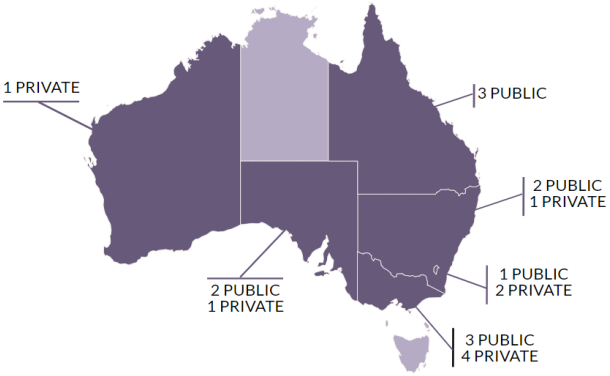
The registry team conducted qualitative interviews with women with a history of SUI surgery or SUI surgical complications and treating clinicians to determine the feasibility of incorporating PROMs into the APFPR. Based on the study and further consultation with clinicians and consumers, the following instruments were selected for use by the registry:

- The Patient Global Impression of Improvement (PGI-I) instrument
- ICIQ-FLUTS, a questionnaire for evaluating female lower urinary tract symptoms and impact on quality of life
- PISQ-IR to assess female sexual function
- SF 12-assessing impact of health on everyday life

PROMs will be collected at baseline (before the surgical procedure), and then followed up at six and 12 months post-operatively. Administration of the PROMs will be undertaken via multiple mechanisms (including email, paper-based and phone call) and is the responsibility of the APFPR team. If clinicians already administer PROMs they are welcome to discuss with the APFPR team how this process can be streamlined via the APFPR.

ETHICS and GOVERNANCE

On October 1st 2020, the APFPR received Human Research Ethics Committee approval through Monash Health under the National Mutual Acceptance (NMA) Scheme. Currently 20 sites have either ethics approval or, approval is pending. Both ethics and site governance approvals need to be in place prior to contributing patient data to the registry. Three sites: Monash Health and Cabrini in Victoria and St George Hospital in Sydney currently have governance approval.



Sites with ethics approval/ethics pending

VIC: Monash Health, Western Health, Bendigo Health, Cabrini Health, Mercy Health, St Vincent's Private Hospital Melbourne, Epworth Health
NSW: Westmead Hospital, St George Hospital, St George Private Hospital
QLD: Gold Coast University Hospital, Robina Hospital, Varsity Lakes Hospital
ACT: The Canberra Hospital, Canberra Private Hospital, Calvary John James Hospital
WA: Hollywood Private
SA: Royal Adelaide Hospital, The Queen Elizabeth Hospital, Calvary North

RECRUITMENT and DATA COLLECTION

Recruitment is a shared responsibility between the site/surgeon and the APFPR. The surgeon will introduce the participant to the registry, provide them with an information leaflet and register them on the APFPR database. Participants are then sent an introductory letter and explanatory statement by the APFPR team. Recruitment occurs through an opt-out process whereby consent is assumed 14 days following dispatch of recruitment material unless the participant contacts the registry to opt out. To accommodate the varied work flows and practices of hospitals and clinics, data capture for the registry is supported either via a web-based database or paper case report forms. Paper collection forms will be uploaded using a secure link. Training for recruitment and data collection has commenced at participating sites.

APFPR WEBSITE

The APFPR website apfpr.org.au has been updated with additional information of interest for clinicians and patients.

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