The Australasian Pelvic Floor Procedure Registry (APFPR): Monitoring device safety for women

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Background

- Pelvic floor disorders such as stress urinary incontinence (SUI) and pelvic organ prolapse (POP), are common disorders with prevalence increasing with parity and age.[1-3]
- The APFPR is a national clinician led Clinical Quality Registry (CQR) that was established following the recommendations of the 2018 Senate Committee Inquiry into transvaginal pelvic mesh complications in women.
- The APFPR monitors the safety and effectiveness of pelvic floor procedures (PFP) involving mesh/other prostheses by ongoing systematic collection, analysis and reporting of outcomes to improve quality of care.

Objectives of the APFPR

To monitor safety and quality of care in both SUI and POP pelvic floor procedures, with a focus on those involving mesh, including revision and mesh explantation

To address the deficits in the systematic collection, analysis and reporting of pelvic floor procedures, and to establish early warning systems

To provide feedback to clinicians, hospitals and the public on the safety & effectiveness of pelvic floor interventions

The APFPR has been developed to align with and support health service implementation of the ACSQHC's credentialing guidelines

Designed with consumer involvement; the APFPR will provide meaningful prospective longitudinal health outcome information for women undergoing pelvic floor procedures

Aim

To describe the aim, development and implementation of the APFPR

Methods

Governed by a **Steering Committee** with representation by consumers, clinicians and government departments; managed by Monash University

Dataset determined using Delphi process; **Clinical Quality Indicators (CQIs)** have been derived from the dataset

Collects **pre-operative, operative, post-operative clinical data** for women undergoing SUI and POP procedures:
- Mid-urethral slings
- Bulking agents
- POP mesh procedures
- Revisions and explantations

Data reporting: providing customised reports to
- Hospitals
- Clinicians
- Public

Targeting high volume sites performing **SUI and POP procedures** or via expression of interest

Eligible patients recruited by surgeon/site using an **opt-out approach** or single waiver of consent

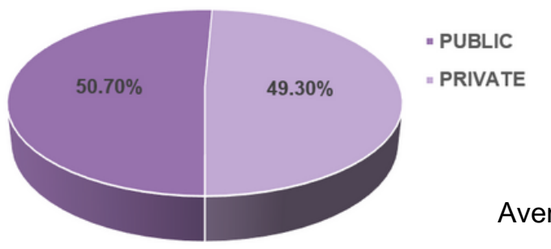
Collects **Patient Reported Outcome Measures (PROMs)** at 6, 12 and 24 months following surgery

Results

As of 14/9/2023,

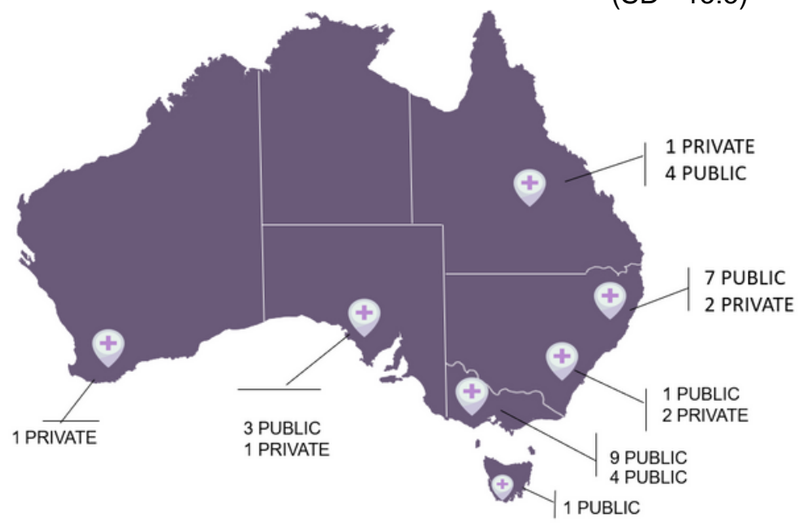
Total patients recruited = 702
Opt out rate= 2.7%

Public-Private split of recruited patients



Average age = 62 years
(SD= 13.5)

36 hospitals with ethics and governance approvals of which **30 are contributing data**



452 SUI and POP procedures have been recorded
380 primary surgeries and **72 surgeries to manage complications**

Cabrini Health is a proud contributor to the APFPR and has won a Health Service award for its significant contribution.

Results (continued)

Patient Reported Outcome Measures (PROMs)

The **Australian Pelvic Floor Questionnaire** is the tool being used for PROMs.[4] Initial implementation has shown good response rates (approx 70%) using multimodal administration with mail, email, sms and telephone.

Clinical Quality Indicators

Process Indicators

Category	Name	Description	N Eligible	N (%)
Objective clinical assessment	SUI urodynamics	Proportion of primary SUI patients who had urodynamics or cough stress test	274	248 (90.5)
	POP Q complete	Proportion of primary POP and SUI+POP patients who had POP Q completed	77	71 (92.2)
Procedure assessment	SUI intraoperative cystoscopy	Proportion of primary SUI patients who had intraoperative cystoscopy	274	272 (99.3)
	POP intraoperative cystoscopy	Proportion of primary POP and SUI+POP patients who had intraoperative cystoscopy	77	77 (100)

Outcome Indicators

Category	Name	Description	N Eligible	N (%)
Efficacy	SUI outcome	Proportion of primary SUI patients with 'improved' SUI at the first postoperative visit	234	195 (83.3)
	POP outcome	Proportion of primary POP or SUI+POP patients with 'improved' POP at the first postoperative visit	68	65 (95.6)
Return to theatre	Return to theatre prior to discharge (primary)	Proportion of primary patients with return to theatre prior to discharge	302	1 (0.3)
	Return to theatre prior to discharge (subsequent)	Proportion of subsequent procedure patients with return to theatre prior to discharge	51	0 (0)
Readmission	Readmission within 30 days (primary)	Proportion of primary patients with hospital readmission within 30 days	302	10 (3.3)
	Readmission within 30 days (subsequent)	Proportion of subsequent procedure patients with hospital readmission within 30 days	51	1 (2.0)
Catheterisation	Patient discharged requiring catheterisation (primary)	Proportion of primary patients discharged requiring catheterisation	302	15 (5.0)
	Patient discharged requiring catheterisation (subsequent)	Proportion of subsequent procedure patients discharged requiring catheterisation	51	0 (0)

CQI data presented as of 4/9/2023

Conclusion

From 2023, the APFPR will produce benchmarking reports incorporating CQIs, PROMs and clinical outcomes to provide feedback to hospitals and surgeons thereby highlighting the potential of CQRs to monitor device safety and clinical practice to support quality improvement.

References

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The Australasian Pelvic Floor Procedure Registry (APFPR) is supported by funding from the Australian Government, Department of Health and Aged Care, under the National Clinical Quality Registry Program.