Australasian Pelvic Floor Procedure Registry (The APFPR)

Consumer-Led Information session 6th 12 2022



www.apfpr.org.au

Email us: apfpr@monash.edu

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Acknowledgement of Country





We acknowledge that we are meeting (virtually) on many lands. I, Pip Brennan am dialing in from the traditional country of the Whadjuk people of the Noongar Nation. We pay respect to Elders past and present and acknowledge that they have occupied and cared for this country over countless generations. We extend respect to all Aboriginal and Torres Strait Islanders and celebrate their continuing contribution to the life of this country we get to call home.

Image courtesy of Narelle Henry

Recognition of Lived Experience



- We recognise the importance of the Lived Experience voice to be at the health and medical research decision-making table
- We recognise the value consumers bring to how our health services and research initiatives are designed, delivered and evaluated.
- We thank those that have come before us to pave the way for the health consumer movement and all those who have shared personal stories and partnered to create positive change



Our panel today



Ms Pip Brennan

- Independent lived experience consultant
- APFPRConsumerRepresentative



Dr Oliver Daly

- Urogynaecol ogist
- APFPR Clinical Data Lead

Professor Helen O'Connell AO

- Urological Surgeon
- APFPR Urology lead



Professor Susannah Ahern

- MedicalAdministration
- PreviousDirector MedicalServices
- APFPR Chair

Ms Kelly Tapley

- 20 years
 experience in
 health project
 management
- APFPR ProjectManager





APFPR Consumer-led information sessions



Chaired by APFPR consumer representative/s

- Based on consumer demand, and preferred topics
- Topics covered in Session #1
 - Clinical overview
 - How and why the APFPR was established
 - Presentation available on the website under the Publications tab
 - Australasian Pelvic Floor Procedure Registry (The APFPR) Information session 26th July 2022
- Consumer questions/suggested topics for Session #2
 - Where to find more information on revision surgeries and implantation
 - What information can we expect to see from the APFPR in the future
 - How is the APFPR progressing
 - Why we need PROMs and what is their purpose
- We welcome your suggestions for **Session #3**, please email them to apfpr@monash.edu

What information do hospitals capture?



Health Information (hospital administrative data) for funding, or reporting

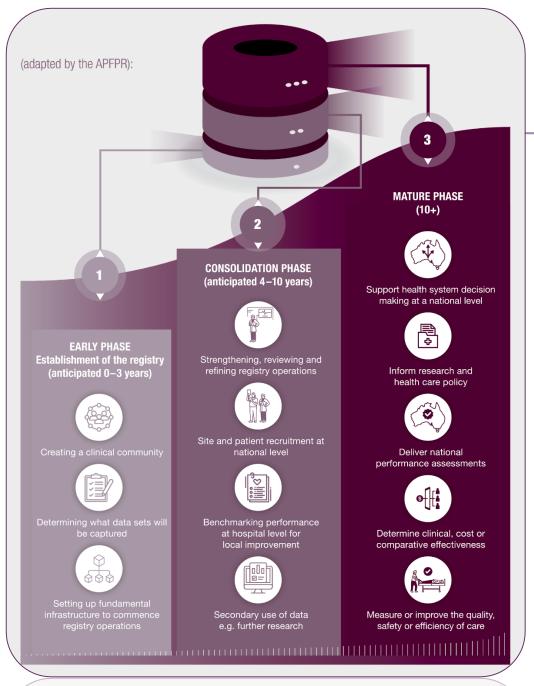
Health information

- about the quality of care provided
- If treatment successful or led to harm
- improvements to health conditions over time
- whether patient outcomes meet the minimum standards of care

- This more detailed information is captured by Clinical Quality Registries
- The combined data is useful to determine best practice
- CQR Participation is voluntary

The potential of CQRs - examples from other registries





Clinical Quality Registry – Maturation Framework



- Long term observational studies
- A comprehensive set of critical data, patient demographics, programs of care provided over several years – resulting in reliable data that enables data driven health policy making
- Marathons not sprints

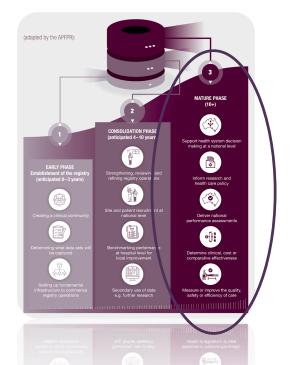
Clinical Quality Registries at various stages of development



Australian Cystic Fibrosis Data Registry

Chronic disease registry since 1998

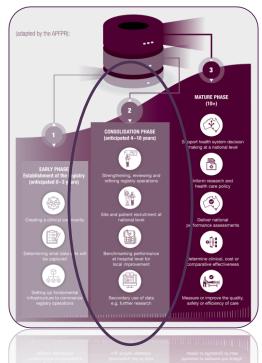




Australian Breast Device Registry

Device safety registry since 2015

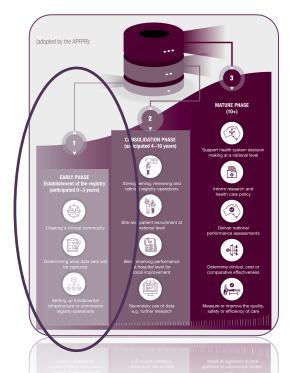




Australian Pelvic Floor Procedure Registry

Device/procedure registry since 2019

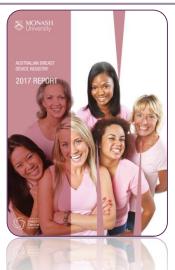




The Australian Breast Device Registry











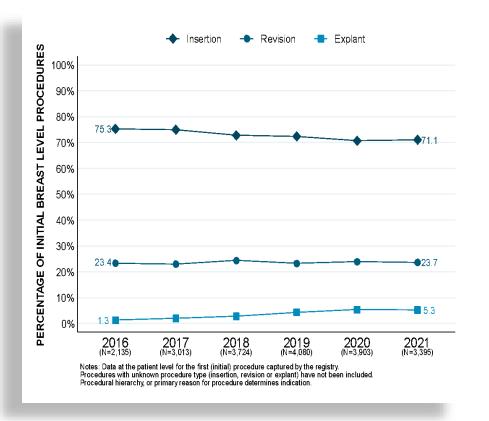


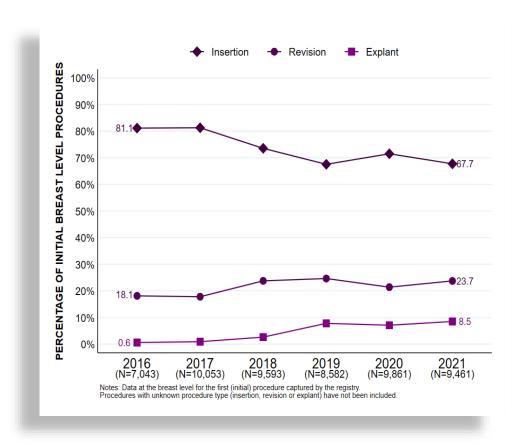


- National rollout from 2015 with funding from the Australian Commonwealth Government Department of Health.
- Working in partnership with Australian patients, public and private healthcare sites, surgeons and clinical craft groups.

The Australian Breast Device Registry

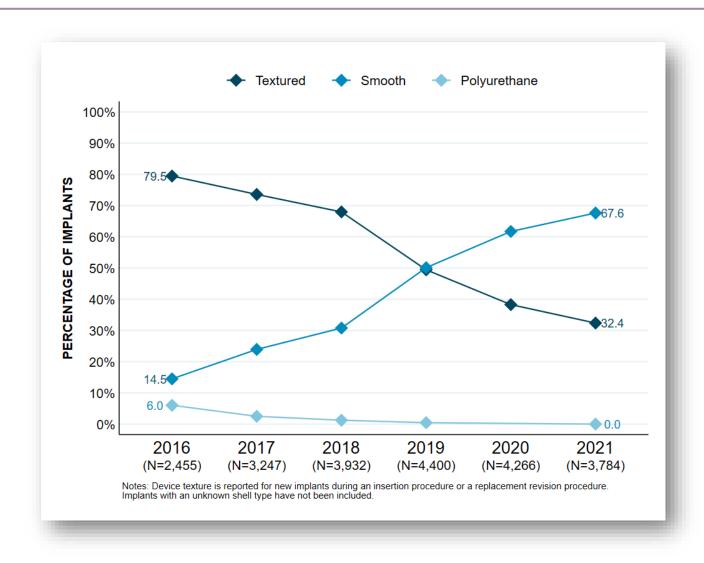






The Australian Breast Device Registry

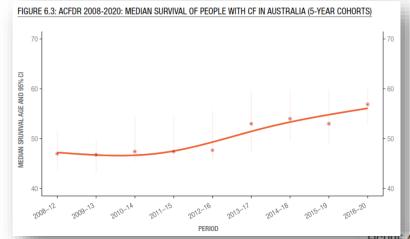


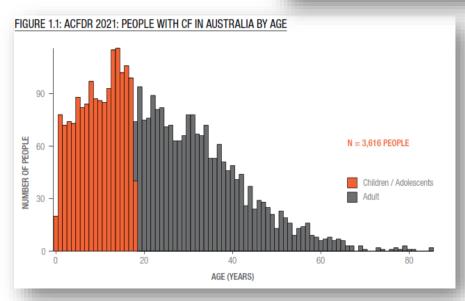


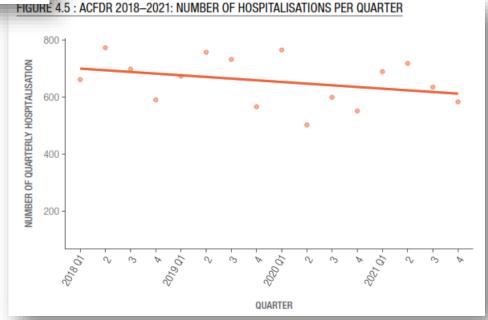












Why we need the APFPR



- High volume (000s) of pelvic floor procedures in Australia
- No reliable source of data to monitor their outcomes
- Routine administrative data collection of pelvic floor procedures does not necessarily distinguish native tissue from other implants
- No previous routine collection of clinical information to analyse and report on to improve quality of care

The APFPR is a Department of Health and Aged Care funded **quality improvement initiative** resulting from recommendations of the 2017-2018 Australian Senate inquiry into *Complications from procedures involving transvaginal mesh*

Monash University was contracted to set up The APFPR in mid 2019 to prospectively capture procedure data, has just completed its establishment activities, and is capturing patient and procedure data from several participating hospitals

The APFPR's objectives





To **monitor safety and quality of care** in SUI and POP pelvic floor procedures involving prostheses, including revision and explantation.



To align with and support health service implementation of the ACSQHC's Guidance for hospital credentialing of senior medical practitioners to implant and remove transvaginal mesh.



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



To create meaningful population-level prospective longitudinal health outcome information to inform women considering or undergoing pelvic floor procedures regarding the risks and efficacy.



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

What type of data the APFPR captures



- Demographic data
- Clinical history (including comorbidities)
- Details relating to the procedure
 - Including other procedures that are carried out at the same time but for which outcomes are not captured
- Information relating to any medical device used
- Clinical Quality Indicators Captured by the clinician
 - These are based on recommendations made by the Australian Commission on Safety and Quality in Health Care
- Patient Reported Outcome Measures (PROMs) Reported by the patient)



Recruitment (via surgeon)





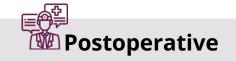


Baseline demographics

- Name
- DOB
- Address
- Phone number
- Email address
- Language
- Planned surgery details







Clinical History/Diagnosis

- Procedure type (SUI/POP)
 - Primary procedure/surgery for complication
 - Complication type
- POP diagnosis
 - POP-Q Assessment Tool

Pelvic Floor Status

- Urinary incontinence type & assessment
- Prolapse symptoms
- Other symptoms e.g. dyspareunia, pain
- Recurrent UTIs
- Voiding dysfunction; catheter required
- Bowel symptoms
- Topical vaginal oestrogen

Risk factors/Comorbidities

- Height/Weight/BMI
- Smoking
- Diabetes
- Post-menopausal/Hormone replacement









Surgical details

- Surgery date
- Cystoscopy performed
- ASA score
- SUI /POP prothesis details

Category of Surgery

SUI procedures

- Mid-urethral sling (mesh)
- Bulking agents
- Bulking agent removal
- Mesh revision/explantation

POP procedures

- Sacrocolpopexy with mesh
- Sacrohysteropexy with mesh
- Anterior/Posterior repair with mesh
- POP mesh revision/explantation

Concomitant procedures

Other selected procedures

Intraoperative complications

- Complication type
- MCCS complication code
- Reported to TGA









Postoperative

1st Postoperative Follow up visit (6 weeks)

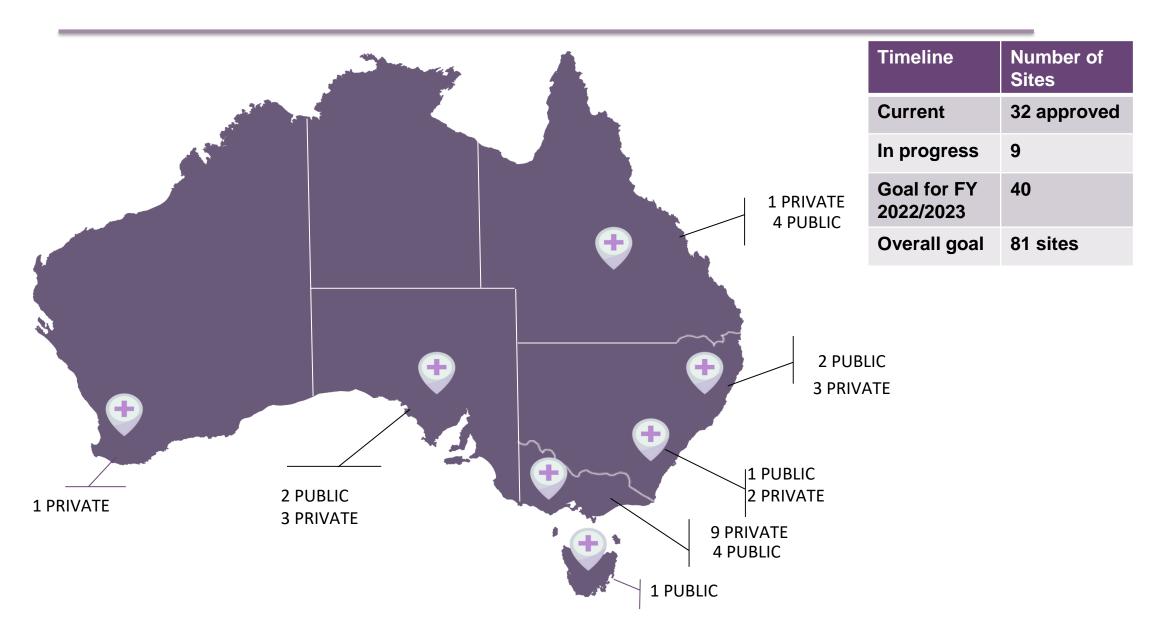
- Date
- SUI/POP outcome status
- Return to theatre
- Readmission to hospital
- Discharged requiring catheter
- Complications MCCS, blood loss >500ml, sepsis, voiding dysfunction, overactive, bladder, UTI, pain, mortality

2nd Postoperative Follow up visit (6-12 months)

- Date
- SUI/POP outcome status
- Return to theatre
- Readmission to hospital
- Discharged requiring catheter
- Complications MCCS, blood loss >500ml, sepsis, voiding dysfunction, overactive, bladder, UTI, pain, mortality

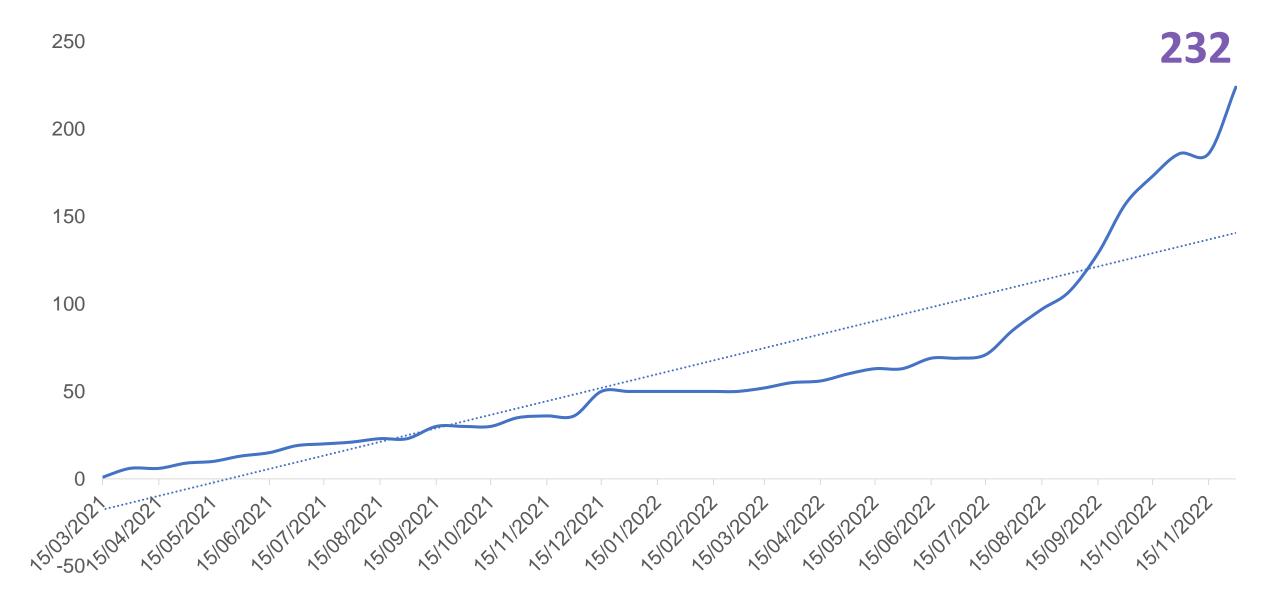
Site recruitment update





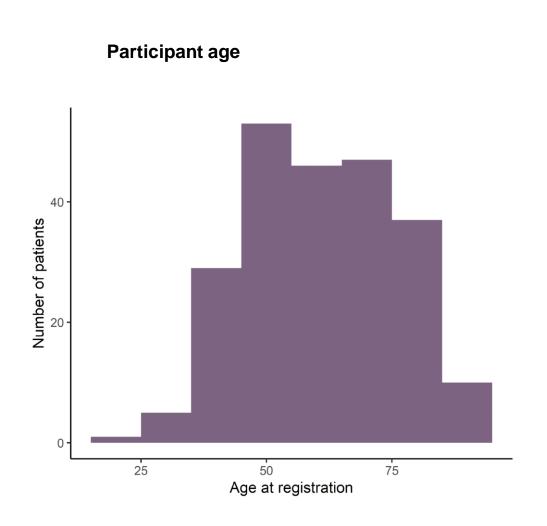
APFPR Running Recruitment 2/12/2022





PARTICIPANT DEMOGRAPHICS





Mean age = 61 years

7% have a LOTE

75% had surgery planned for SUI*

16% had surgery planned for SUI & POP

9% had surgery planned for POP only

100% had phone numbers provided

63% had email provided

PARTICIPANT COHORTS (GROUPS)



	SUI only	POP only	SUI and POP*
	N (%)	N (%)	N (%)
N participants	175	20	37
Surgery performed	89 (50.9)	10 (50)	16 (43.2)
Attended first post-operative visit	65 (37.1)	7 (35)	11 (29.7)
Attended second post-operative visit	24 (13.7)	0 (0)	0 (0)
Surgery indication (if performed)	89	10	16
Primary (implantation)	75 (84.3)	3 (30)	16 (100)
Legacy (complication/revision)	13 (14.6)	6 (60)	0 (0)

Note: Analyses on following slides present data for cohorts with sufficient sample size

CLINICAL ASSESSMENT – SUI GROUP



Clinical characteristics	Primary, N (%)	Legacy, N (%)
N SUI surgery performed	75	13
Method of objective SUI assessment*		
Cough stress test	20%	7.7%
Urodynamic studies	88%	46.2%
Pad test	1.3%	0%
Pelvic floor status*		
Recurrent UTIs	4%	7.7%
Dyspareunia	2.7%	30.8%
Pelvic pain	1.3%	23.1%
Voiding dysfunction	6.7%	7.7%
Patient risk factors*		
BMI median	27	24
Current smoker	12%	7.7%
Diabetes	12%	15.4%
Post-menopause	61.3%	76.9%

PROCEDURE CHARACTERISTICS – SUI



Procedure characteristics	Primary N (%)	Legacy N (%)
N SUI surgery performed	75	13
Category of surgery*		
Prosthesis implantation	84%	15.4%
SUI Complication	0	69.2%
Asymptomatic SUI prosthesis removal (patient request)	0	1 (7.7%)
Native tissue	4.0%	0
Prolapse	10.7%	0
Hysterectomy	1 (1.3%)	0
Perineorrhaphy	1 (1.3%)	0
Additional POP procedure	2 (2.7%)	0
Bulking agent	12%	15.4%

Devices	Total N (%)
SUI prothesis type	
CT021 Supris Retropubic Sling	2 (2.7)
JJ070 Gynecare TVT Single use device	52 (69.3)
MN039 Gynecare TVT ABBREVO Continence System	3 (4.0)
SC001 BULKAMID Urethral Bulking System	2 (2.3)
Other	6 (6.8)
Not applicable	23 (37.5)
Total	88

POSTOPERATIVE OUTCOMES (1st visit) – **S**SUI cohort



Outcomes at first post-operative visit	Primary, N (%)
N SUI post-operative visit attended	55
Time to post-operative visit (days) median	42
SUI outcome status	
Improved	81.8%
Same	16.4%
Worse	1.8%
Complications*	
Return to theatre prior to discharge	0%
Readmission within 30 days of surgery	1.8%
Surgical treatment required	0%
Patient discharged requiring catheterisation	3.6%
SUI complication	0%

PROMs Update



Executed

 Evaluation of PROMs in Patients following SUI and POP Procedures - Acceptability study. March 2022

In progress

- 1. Pilot of APFQ Questionnaire and methods of administration. Ends May 2023 ••••
- 1. Development of a pain specific PROM questionnaire. Ends Feb 2024.

1. PROMs Research - selection of questionnaire



To determine whether selected instruments were acceptable by assessing

- Relevance of questions
- Clarity of wording
- Ease of use
- Clinical applicability
- Validated in the Australian population
- Well accepted by patients and surgeons
- Result: the APFQ selected for a pilot
 - APFQ integrates 4 domains to assess bladder, bowel, prolapse & sexual symptoms, their severity, bother & impact on QoL. It contains 43 questions asking patients to describe theirs experience during the last month.





AUSTRALIAN PELVIC FLOOR QUESTIONNAIRE		Patient's Name: Date of Birth: Date completed:		
Please circle your most a	pplicable answ	er. Consider your experier	nce during the last month.	
BLADDER FUNCTION			(145)	
Q1. How many times do you pass urine in a day? 0 Up to 7 1 Between 5-10 2 Between 11-15 3 More than 15 Q4. Do you need to rush/hurry to pass urine when you get the urge? 0 Can hold on 1 Cocasionally have to such – less tran-orcelveek. 2 Requirily have to rush – orce or morelveek. 3 Daily	might to pass to 0 0-1 1 2 2 3 3 More th hurry to the to time? On the total 1 Occasion 1 Occasion 1 0 0-1 1 0 0 0 1 1 1 1 1 1 1 1 1 1 1 1	on 3 times e leak when you rush or illet or can't you make it in	Q3. Do you wet the bed before you wake up at riight? 0 Never 1 Occasionally - less than once per week 2 Frequently - once or more per week 3 Always - every night Q6. Do you lesk with coughing, sneezing, laughing or exercising? 0 Not at all 1 Occasionally - less than once per week 2 Frequently - once comore per week 2 Frequently - once comore per week 3 Dally	
Q7. Is your urinary stream (urine flow) weak, prolonged or slow? Never Consistently – less than crop per week Frequently – ense or more per week Daily Q16. Do you have to wear pads because of urinary leakage?	bladder empty 0 Never 1 Occal 2 Fi 3 Sa 1 D vid B d vide a uring		OB. Do you need to strain to empty your bladder? Never Onessionally – less than oxos per week. Frequently – oxos or most per week. Daily Otto you have frequent bladder infections?	
0 None - Never 1 As a precaution 2 When exercising / during a cold 3 Daily	Never Before Modera 3 Always	going out tely	0 No 1 1-3 per year 2 4-12 per year 3 More than one per month	
Q13. Do you have pain in your bladder or urethra when you empty your bladder?		ne leakage affect your les like recreation.	Q15. How much does your bladder problem bother you?	
0 Never Cocasionally – less than once per week Prequently – once or more per week Deity	routine activities like recreation, socializing, sleeping, shopping etc? 0 Not at at 1 Sightly 2 Moderately 3 Greatly		0 Not at all 1 Sightly 2 Moderately 3 Greatly	
Other symptoms (heematuria, pain etc.)				
BOWEL FUNCTION		_	(/34)	
Q16. How often do you usually open your bowels? 0 Ever other day or daily 1 Less than every 3 days Less than once a week 0 More than once per day	usual stool? 0 Soft 0 Firm 0 Hard (p 1 Variable		Q18. Do you have to strain to empty your bowels? 0 Never 1 Occasionally – less ten once per week 2 Frequently – orce or more per week 3 Daily	
Q19. Do you use laxatives to empty your bowels? 1 Occasionally – less transres per week. 2 Frequently – once or more per week. 3 Daily	0 Never 1 Occasio	eel constipated? onally – less franchica per week rifly – ance ar mare per week	Q21. When you get wind or flatus, can you control it, or does wind leak? 0 Neiver Occasionally - less tran once per week Prequently - once or more per week Bally Daily	

AUSTRALIAN PELVIC FLOOR QUESTIONNAIRE		Patient's Name: Date of Birth: Date completed:	
Q22. Do you get an overwhelming sense of urgency to empty bowels? Never Never Cossionally – less train once per week. Frequently – once or more per week. Daily Q25. Do you have a feeling of incomplete bowel emptying? Never Cossionally – less train once per week. Trequently – once or more per week. Daily	don't mean to? 0 Never 1 Occasions 2 Frequently 3 Delty Q26. Do you use empty your bowe 0 Never 1 Occasions	k watery stool when you sily – less than orco per week – once or more per week finger pressure to help 17 By – less than or or week – onch an only in welk	Q24. Do you leak normal stool when you don't mean to? 0 Never 1 Occasionally – less than once per week. 2 Frequently – once or more per week. 3 Daily Q27. How much does your bowel problet bother you? 0 Not at all 1 Slightly Moderately 3 Greatly
PROLAPSE SYMPTOMS			(/!!
Q28. Do you have a sensation of fissue protrusion/lumpbulging in your vagina? Never Occasionally – isss francrus per week Finquently – once or more per week Daily Q31. Do you have to push back your prolapse to empty your bowels? Never Never ONEVER	0 Ner 1 Occasiona 2 Frequently 3 Daily	wese or a dragging kess or a dragging kly – less trac orce per week – orce or mos per week does your prolapse	G30. Do you have to push back your prolapse in order to void? 0 Never 1 Occasionally – less then once per week 2 Frequently – once or more per week 3 Daily Other Symptoms: (problems: walking / sitting pain, vagnat bleeding)
2 Frequently – once or more per week. 3 Daily	 Moderately Greatly 	*	
SEXUAL FUNCTION			<u></u>
Q33. Are you sexually active? No Less than once per week Conce or more per week Daily or most days If you are not sexually active, please continue to answer questions 34 & 42.	please tell us why Do not han Do not han Do I am not in Do My partner Do Vaginal dry Too painful Do Embarrass	e a partner terested is unable yness if unent due to the ncontinence	Q35. Do you have sufficient vaginal lubrication during intercourse? O Yes No
Q36. During intercourse vaginal sensation le: 0 Normal / pleasant 1 Minimal 1 Paintul 3 None	Q37. Do you feel loose or tax? 0 Never 1 Occasions 2 Frequently 3 Always	that your vagina is too	Q38. Do you feel that your vagina is too tight? 0 Never
bother you?	1 At the entr 1 Deep insid	r? sble, I do not have pain ance to the vagina ie, in the pelvis entrance & in the pelvis stoms?	Q41. Do you leak urine during sexual intercourse? O Never 1 Occasionally 5 Frequently 3 Always
Q42. How much do these sexual issues bother you? Not applicable Not at all Slightly Moderately			

References: 1 Baessler, Kaven, O'Neill, Sheila, Maher, Christopher, & Battistutta, Diana (2010) A validated self-administered female pelvic floor questionnaire. International Urogynecology Journal, 21(2), pp. 163-172. 2 Baessler, Kaven, O'Neill, Sheila, Maher, Christopher, & Battistutta, Diana (2009) Australian pelvic floor questionnaire:: a validated interviewer administered pelvic floor questionnaire for routine clinic and research. nternational Urogynecology Journal, 20(2), pp. 149-158

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2. PROMs Research – Administration





PROMs Pilot – Timing and Method of administration

- Intention to collect responses to APFQ before surgery and 6 months after surgery
- Commenced in July 2022, ends May 2023
- SUI & POP included
- Patients who are enrolled in the registry are eligible
- Disseminated via email, mail or telephone
- Completed across several hospitals public and private
- A study evaluation will be conducted at the end of the pilot to understand/compare response rates, barriers and enablers for survey completion, data entry; use for reporting.

3. PROMs Research – PAIN PROM





Pelvic Floor procedure PAIN PROM (Monash Uni)

- To assist with the development of a Pain specific PROM tool
- Researching a pain specific measure for women with a pelvic floor disorder
- This interview is designed to understand and obtain your perspective on what you think or feel is important and what you feel should be included in the new pain questionnaire.
- Project Title: Developing a new pain specific patient-reported outcome measure in women with a pelvic floor disorder. Project Number: 35901.

To participate, please email:

sheymonti.hoque@monash.edu

Review of scope



A review of which procedures the APFPR should capture going forward, informed by:

- 1. Analysis of current clinical practice in Australia
- 2. Study of what international PFP registries collect
- 3. Survey of surgeons who perform these procedures
- 4. Consultation with the Steering Committee (including clinical leads & consumer rep)
- Consultation with new APFPR Consumer Reference Group regarding outcomes
- 6. Consultation with the Medical Colleges/Societies (eg USANZ)

What's next for the APFPR?



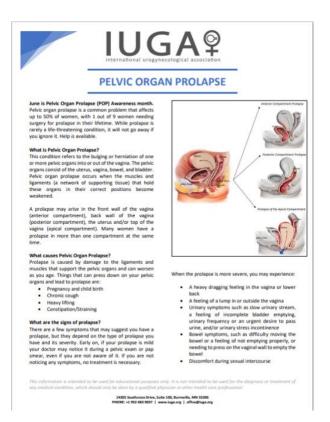
- Public Report 2022
 - Progress report of the APFPR activities since its establishment
- Communique #5
- PROMS Pilot results due June 2023
- Annual Report 2023
- 1,000 patient milestone, enabling individual hospital reports (benchmarked for improvement purposes)
- More Consumer-led information sessions



Where to find more information about pelvic floor procedures



- International Urogynaecological Association
- Yourpelvicfloor.org (Patient information sheets)





IUGA is pleased to offer Patient Information Leaflets in pdf format for convenient download. For optimal viewing, please download o

roviders:

IUGA patient education leaflets are also available in printed brochure format. To order, visit our Online Store at www.iugastore.com.

Please Note: Brochure format is not available in every language.

Leaflets (downloadable pdfs) in foreign languages will be added periodically. If you are interested in volunteering to translate a brochure into your native language, please contact office@iuge.org.

The content of the IUGA Patient Information Leaflets reviewed every three years at a minimum

Disclaimer:

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Dutch:

Danks] het werk van de 100A leden en vele vrijwilligers zijn wij in staat om deze informatie in een groot aantal talen beschikbear te maken. De kwaliteit van de vertalingen wordt gecontroleerd om ervoor te zorgen dat deze zo nauwkeurig mogelijk is, maar er is ablijd een risloo op onnauwkeurigheden en op een andere (of zelfs verkeerde) interpretatie van bepaalde informatie vertaald vanuit het Engels. Voor de meest actuele versie van de patienteninformatie en -foldera verwijzen wij altijd naar de Engelse tekst en versies omdat de vertalingen minder vaal en soms later worden bijgewerks dan de originelle Engelse versies.



- Each hospital responsible for credentialing surgeons
- Recommended credentialing requirements (Australian Commission on Safety and Quality in Health Care)
- RANZCOG Sub-specialist Urogynaecologist / General Gynaecologist + Pelvic floor module + 1 year of audited practice OR
- RACS Urologist + 1 year of female urology training including prolapse surgery / General Surgeon with 1 year in pelvic floor surgery (rectocoele)
- Ongoing continuing professional development in mesh removal surgery and tracking of outcomes for at least 6 months, monitored through audit or registry.
- Access to multi-disciplinary expertise (Medical, Physio, Investigations, Pain management, Mental Health)

Based on Guidance for Hospital Credentialing for the Removal of Transvaginal TV Mesh | Australian Commission on Safety and Quality in Health Care



- (i) familiarity with the clinical care pathways guidance issued by the Commission;
- (ii) the ability to diagnose and select patients who are appropriate to undergo the procedure;
- (iii) the ability to explain the procedure, potential outcomes and potential complications at the time of obtaining the patient's informed consent, including the ability to clearly and accurately explain and document the alternative treatments available;
- (iv) the knowledge of appropriate pelvic anatomy and potential areas of safety/risk associated with the procedure;
- (v) the ability to perform the actual procedure safely and efficiently; and
- (vi) the capacity to track outcomes and complications.



- (i) the results of post-operative monitoring of the patient over a <u>minimum</u> 6 month period including:
 - Documentation of residual mesh erosion, extrusion or exposure and level of retained mesh
 - patient reported level of improvement and satisfaction
 - Persisting groin or pelvic pain.
- (ii) any of the following events, at whatever point they come to the medical practitioner's attention:
 - Injury to the pelvic organs or major blood vessels
 - Injury to the gastro-intestinal tract
 - Blood loss > 500 ml for procedure
 - New or worsening vaginal, pelvic or groin pain
 - New onset or worsening dyspareunia
 - Persistent neurologic injury.
 - Readmission/re-operation for complications related to removal surgery
 - Sepsis
 - Death from any cause, with cause recorded.

Based on Guidance for Hospital Credentialing for the Removal of Transvaginal TV Mesh | Australian Commission on Safety and Quality in Health Care





Based on Guidance for Hospital Credentialing for the Removal of Transvaginal TV Mesh |

Australian Commission on Safety and Quality in Health Care

General questions to ask your surgeon



General questions:

- 1. Do I really need this procedure?
- 2. What are the risks?
- 3. Are there simpler, safer options?
- 4. What happens if I don't do anything?
- 5. What are the costs?

Mesh revision questions to ask your surgeon



- Is the surgeon credentialed to treat mesh complications?
- How likely are my problems to be fixed by surgical revision of the mesh?
- What kind of mesh do I have and where it is located?
- Which of my problems are likely to be related to the mesh?
- Is the aim to cut, partially or completely remove the mesh?
- What are the potential complications and side effects of mesh revision?
- Chance that pelvic floor problems (SUI/POP) will return?
- What are the non-surgical alternatives and how likely are these to work
 Who else will be involved in my care?
- How many mesh revision procedures like mine have you performed?
- How do you monitor and audit your outcomes e.g. APFPR
- What are the outcomes success, persistent and new problems
 - O Pain, Bladder, Bowel, Prolapse and sexual function

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Thank you!

Keen to keep in touch? Email us!

We only use email addresses to share useful information about the Registry and send invitations to events.

You can opt out at any time