MONASH University

AUSTRALASIAN PELVIC FLOOR PROCEDURE REGISTRY

ANNUAL REPORT 2023

Australasian Pelvic Floor Procedure Registry

This publication was produced by the Australasian Pelvic Floor Procedure Registry (APFPR) (the Registry) on behalf of the Steering Committee.

For all registry related enquiries regarding operational activities, including access to data, please contact Monash University APFPR team

Suggested citation: Ahern S, Lassetter C, Tapley K, Heriot N, Ruseckaite R, Hansen J, Kartik A, Merenda M, Jayasinghe R, Sharma M, King J, Yin J, Gallagher E, Short J, Keck J, Bach F, Daly O.J, Karantanis E, O'Connell H.E, Brennan P, Leslie J, Honardoost M.A. The Australasian Pelvic Floor Procedure Registry Annual Report 2023. Total pages 65. Monash University, School of Public Health and Preventive Medicine, February 2024.

APFPR COORDINATING CENTRE

School of Public Health and Preventive Medicine
Monash University
Level 3, 553 St Kilda Rd
Melbourne Victoria 3004

Telephone: 1800 571 093
Email: APFPR@monash.edu
Website: www.apfpr.org.au
LinkedIn: APFPR Pelvic Floor Procedure Registry
Twitter/X: @APFPR_AU

Unless otherwise stated, the data covered in this report refers to the period: 26th May 2022 to 26th September 2023 (the 12-month period since the 2022 APFPR report).

CONTENTS

FOREWORD

As clinical leads for the Australasian Pelvic Floor Procedure Registry (APFPR), we are pleased to present the 2023 APFPR annual report, relating to the activities and achievements over the twelve months prior to September 2023.

Highlights include increases in site and patient recruitment, allowing for additional breadth and depth of analyses of clinical data; reporting of initial Patient Reported Outcome Measures (PROMs) data; and the inclusion of Clinical Quality Indicators (CQIs), featured for the first time in this report.

During this time the APFPR completed a range of implementation and consolidation activities including: continuing the national rollout of both Stress Urinary Incontinence (SUI) and Pelvic Organ Prolapse (POP) modules, piloting and implementing PROMs, and expanding consumer involvement via the establishment of a Consumer Reference Group. We have also undertaken extensive user feedback in relation to the APFPR database.

We continue to engage with surgeons and their Colleges to encourage participation, through a range of College and Society meetings and conferences. The APFPR has also been accredited by both The Royal Australasian College of Surgeons (RACS) and The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) for continuing professional development programs, ensuring that clinicians are recognised for the time invested supporting the registry. A surgeon survey undertaken in late 2022 informed the scope and future direction for the registry, resulting in the recommendation to include native tissue SUI procedures. This will be implemented during the rollout of the updates to the database in 2024.

We would like to sincerely thank all those involved in the progress of APFPR for their commitment and collaborative efforts including our clinical specialists, consumers, representatives on the Steering Committee, clinician champions, the Consumer Reference Group, and the Registry team.

In december 2023, the APFPR provided its first set of benchmarked site reports to those hospitals that have provided a sufficient minimum number of recruited patients. As the registry grows, its impact will too, informing local clinical policy and practice changes, regulatory decisions on devices and the enhancement of the quality of care in women's health through robust data collection, monitoring and feedback.

We would like to acknowledge the efforts of our colleagues on the Steering Committee, as well as those of the APFPR registry team who have worked assiduously during the past year with exceptional commitment. We congratulate them on the quality of this 2023 report and ongoing efforts to foster improvements in patient care.

From the APFPR Clinical Leads:
Dr Jenny King, Associate Professor Jessica Yin, Dr Elizabeth Gallagher, Dr John Short, Dr James Keck, Dr Fiona Bach, Professor Helen O'Connell, Dr Jerome Melon.

CONSUMER UPDATE

Since joining the Australian Pelvic Floor Procedure Registry in March 2023 as the Consumer Representative with lived experience I have gained much insight into the amount of work required of all members of the Steering Committee and the Registry team to establish the Registry and lead it into its current stage of development. I appreciate the inclusion of the consumer's perspective during this time and the ongoing involvement with consumers that the APFPR has committed to.

The Consumer Reference Group held its first meeting in December 2022 and was a great success, providing for greater national consumer involvement and feedback. This enables further in-depth discussions to occur within the Steering Committee as we are able to put forward a detailed and informed consumer view of proposed registry developments. I would like to thank in particular Claudia Lassetter, the APFPR Communications Manager for her time and encouragement given to consumers.

In June 2023 the APFPR afforded me the opportunity to attend the Joint 31st National Conference on Incontinence and 4th Functional Urology Symposium which was held in Adelaide. I was able to gain further knowledge regarding pelvic organ prolapse procedures and stress urinary incontinence procedures currently being performed, treatment options and outcomes both nationally and internationally.

As the Registry matures through the next phase of developments, it is now collecting data for POP procedures; we hope hospital participation rates will continue to grow for all procedures performed that are currently in the APFPR's scope. It would be wonderful if the Registry was able to achieve a 90% or higher participation rate of all eligible procedures being performed for POP and SUI to align to consumer expectation.

I look forward to working alongside all members of the Steering Committee, Pip Brennan, the consumer representative and systemic advocate, the Consumer reference Group and being able to contribute to discussions in a valuable way.

I would like to acknowledge and extend gratitude to all the women who have worked tirelessly over the years in advocacy work for the support they have provided and still provide to women who have suffered complications from urogynaecological mesh procedures.

From Ms Jenny Leslie, Lived Experience Consumer

Over the last year, consumer involvement in the Australasian Pelvic Floor Procedure Registry has made solid progress. It has been wonderful to be joined by Jenny Leslie on the Steering Committee. In addition, the Consumer Reference Group has been formed and now constitutes an additional governance group alongside the Clinical Advisory Committee. It allows consumer issues to be presented at quarterly Steering Committee meetings, informed by a wider consumer voice. There have been webinars designed to raise community awareness of how registries work and why they are so important to monitor and communicate patient outcomes. We keep an eye on broader issues that sit outside the registry but which may impact community attitudes.

Opportunities the Registry offered us to learn and upskill have been very welcome. On 7 November 2022 I attended the Australian Clinical Registry Annual Scientific Meeting. I joined consumer advocate Shyam Muthuramalingam in the crowd, and we both agreed that we would love to have more company at future events. The AFPFR is really starting to gain momentum with a core number of sites onboard and hundreds of procedures captured; we hope to be part of the ongoing development of this Registry to track and improve women's health outcomes.

From Ms Pip Brennan, Systemic Advocate

On 13th December 2022 the Consumer Reference Group met for the first time with representation from New South Wales (NSW), Queensland (QLD), Victoria (VIC), South Australia (SA) and New Zealand (NZ). This group provided a broad perspective of views to inform the Steering Committee Consumer Representatives. Ms Kim Blieschke from South Australia and Ms Michelle Kennedy from Queensland were appointed as co-chairs of the Reference Group in 2023. Ms Kim Blieschke is a Paramedic and was involved in the co-design and setup of the Royal Adelaide Hospital Pelvic Mesh Clinic. Ms Michelle Kennedy was involved in the establishment of and continues to be involved with the Queensland Pelvic Mesh Clinic; both are strong advocates for mesh injured women. The inaugural Consumer Representative meeting was a great success. The Group met again in June 2023 and will continue to meet up to twice a year. During the June meeting it provided feedback on the proposed Clinical Quality Indicators and Patient Reported Outcome questionnaires. The feedback, covered in more detail later in the report, is currently being actioned by the Registry. Both Consumer Webinars have been a great success, and further Webinars are planned for 2024. We thank Professor Helen O'Connell and Dr Oliver Daly for their commitment and time invested in their presentations during the consumer webinars.

From the APFPR Consumer Reference Group

ACKNOWLEDGEMENTS

Steering Committee (Sept 2022 - 2023)

Professor Susannah Ahern Chair and Academic Lead

Pip Brennan Consumer representative, systemic health advocate

Amanda Craig Therapeutic Goods Administration (TGA) representative

Dr Oliver Daly Clinical Data Lead, urogynaecologist and obstetrician (until June 2023)

Professor Anne Duggan (until March 2023) Australian Commission on Safety and Quality in Health Care representative

Dr Elizabeth Gallagher Gynaecology representative

Gwili Holme Australian Government Department of Health and Aged Care representative (until May 2023)

Associate Professor Emmanuel Karantanis Gynaecology representative (until May 2023)

Dr James Keck Colorectal surgery representative

Dr Jennifer King Urogynaecology representative

Jenny Leslie Lived experience consumer representative (from February 2023)

Professor Helen O'Connell Urology representative

Sally Rayner Australian Government Department of Health and Aged Care representative

Dr John Short New Zealand Gynaecology representative

Kirstine Sketcher-Baker Jurisdictional representative

Jarrod Williams (until April 2023), **Dr Hamish Gray** (from May 2023) New Zealand jurisdictional representatives

Associate Professor Jessica Yin Urology and Private Hospital representative

Dr Fiona Bach Gynaecology representative

Dr Jerome Melon Urogynaecology representative (since November 2023)

Consumer Reference Group

Kim Blieschke Co-Chair Consumer Reference Group

Michelle Kennedy Co-Chair Consumer Reference Group

Pip Brennan Consumer representative, systemic health advocate

Jenny Leslie Lived experience consumer representative

Dora Vasiliadis Member

Nicolle Germano Member

Registry personnel (Sept 2022 - 2023)

The APFPR is managed by the Clinical Outcomes data Reporting and Research Program, School of Public Health and Preventive Medicine at Monash University:

Professor Susannah Ahern Academic Lead and Coordinating Principal Investigator

Kelly Tapley Project Manager (until September 2023)

Claudia Lassetter Communications Manager

Aruna Kartik Registry Coordinator

Dr Rasa Ruseckaite Senior Research Fellow

Jessy Hansen Data Analyst

John Liman Senior Software engineer

Michelle Merenda Research Assistant

Randi Jayasinghe Research Assistant

Mudit Sharma Data Support Officer

Natalie Heriot Senior Manager, Surgical Registries (from October 2023)

EXECUTIVE SUMMARY

Pelvic floor disorders continue to be an important women's health issue. Almost 50% of women in Australia are affected by the pelvic floor disorders of Stress Urinary Incontinence (SUI) and Pelvic Organ Prolapse (POP), with a 20% lifetime risk of requiring surgery[1-3].

The Australasian Pelvic Floor Procedure Registry (APFPR) is a Commonwealth Department of Health and Aged Care initiative established in 2019 to record information about the safety and effectiveness of procedures for Stress Urinary Incontinence (SUI) and Pelvic Organ Prolapse (POP) that involve the use of devices or prostheses including mesh[4]. It is a clinician-led, consumer-centred national Clinical Quality Registry (CQR) managed by Monash University. CQRs such as the APFPR are a critical component of Australia's efforts to continuously improve the nation's healthcare system, and are recognised as a vital tool to measure, analyse and report health outcomes for patients.

Specialist **Clinician** representatives inform all the activities of the APFPR via the Clinical Advisory Committee and Steering Committee. The APFPR engages with individual clinicians via site training and recruitment activities, including producing several site newsletters, a site visit program, and over 20 engagement and training sessions yearly, including presentations at scientific conferences. This has recently resulted in a total of **38 hospital sites participating and 943 patients** recruited into the registry (as at February 2024). However, this has followed a prolonged period of low levels of elective surgery during and subsequent to the pandemic, which has impacted the number of eligible procedures that could be entered into the registry. Updated analysis of publicly available data including the fiscal year 2021/2022 shows a continued reduction of SUI and POP procedures nationally. As a result, the APFPR conducted a survey of clinicians to identify the reasons for the decline and to inform the future scope of the registry. The results are outlined in this report.

Since its inception, the APFPR engaged **consumers** through representation on the Steering Committee, to ensure that the Registry was designed with active consumer engagement. In 2023 the APFPR went further, creating more consumer specific communication opportunities and significantly broadening engagement to include the creation of a **Consumer Reference Group**, comprising of consumers from all over Australia; the feedback from this group has been instrumental in the decision making about proposed PROMs questionnaires.

As at 10th October 2023 (when the clinical data analyses were undertaken), a total of 29 sites have contributed data to the registry. At the time of going to press there were 948 patient details captured in the APFPR, with an opt-out rate of less than 3%. The Registry continues to liaise with the Colleges and Surgical Specialist Societies and the State and Territory health authorities to emphasise that participation by surgeons is expected by those performing this surgery.

Clinical data reported by the APFPR for 2022-2023 relates **to 436 women who had their surgery performed,** almost equally across public and private hospitals. 78% of the procedures were for SUI, as this was the first procedure module that the registry commenced. The majority (between 80-90%) of procedures collected **are primary (first) procedures**, meaning that the entire patient journey from diagnosis can be captured by the registry. Subsequent procedures are those where a **revision** to a previous surgery was performed or a **particular complication was managed**. These records are especially important to understand the burden of ongoing care required for people impacted by adverse outcomes from previous surgery.

SUI procedures currently captured by the registry include **primary mesh slings** (177 procedures), **bulking agents** (98 procedures) and **revision/management of complications** (47 procedures). The median age of patients having these procedures for the first time was 60, 64, and 59 years respectively. A higher proportion of women undergoing subsequent procedures were current smokers (13%) and had diabetes (13%) compared to primary procedures (6%, 10% respectively). Most women with SUI procedures were post-menopausal. Over 80% of primary participants underwent urodynamic studies. Pelvic floor comorbidities were more common in patients with subsequent than primary procedures. For those having subsequent procedures, the most common comorbidity was **voiding dysfunction** (36%). Of the 177 primary sling procedures, 100% involved

a prosthesis implant, with a number also involving a concomitant non-mesh procedure, the most common being a non-mesh prolapse procedure. Of the 98 bulking agent procedures and the 47 subsequent SUI procedures, very few involved a concomitant procedure. For SUI sling procedures, nearly 80% of procedures used Gynaecare TVT Exact mesh. For SUI bulking agent procedures, the main device used was BULKAMID.

Efficacy outcomes at the **first post-operative visit** for 266 women following procedures for SUI were high, with **90% of mesh sling and 75% of bulking agent procedures resulting in improved status** at the time, with few reported complications. Improvement was more variable for those who had a subsequent procedure performed, with similar trends noted at the second post-operative visit.

POP procedures currently captured by the registry include POP procedures with mesh, as well as POP mesh procedures conducted with a native tissue SUI or other procedure. The median age of women undergoing a POP procedure was 68 years, with over 90% being post-menopausal. Clinical assessment showed that the most common pelvic floor comorbidity was **voiding dysfunction** (49%). Hysterectomy was the most common concomitant procedure (10.6%). **All women had improved POP status at their first post-operative visit**. The POP + SUI cohort was slightly younger with a median age of 65 years, and dyspareunia was the most common pelvic floor comorbidity for this cohort at 14%. **Over 30% had an associated hysterectomy**, and the most common SUI device used was Gynaecare TVT. **Over 90% of women reported an improvement in both SUI and POP status** at their first post-operative follow up visit. A small number of complications was observed.

The registry has reported **26 SUI mesh explantation procedures**. These are very early data but provide an indication of the potential of this specific registry data as the APFPR matures. The most common indication for mesh removal was **pain (37.1%)** followed by mesh exposure (34.3%) followed by voiding dysfunction (11.4%). The most common procedure was partial mesh removal (65.4%) followed by complete (26.9%) and extra-vaginal removal (7.7%). Over 50% of all presenting indications had improved at the first post-operative visit following surgical management.

The APFPR captures key performance measures (**clinical quality indicators**) in relation to key processes and outcomes of care. These include whether an objective clinical assessment and intra-operative cystoscopy were undertaken for primary SUI and POP procedures; whether the patient noted an improvement in their SUI or POP status after the procedure; and the proportion of procedures that have associated complications. These are presented on **page 45** and will be tracked over time with the aim of improving overall performance.

The APFPR commenced the collection of **Patient Reported Outcome Measures (PROMs)** in 2022, using the Australian Pelvic Floor Questionnaire (APFQ). The EQ5D general wellbeing survey, and a global improvement question have recently been included, but are not included in this report's analysis. Baseline and post-operative responses have been collected from **156 and 185 women respectively**, predominantly following SUI procedures. Response rates were 80% at baseline and 76.2% at 6 months. There were clinically significant improvements in mean scores associated with bladder and prolapse symptoms pre- and post-surgery. The APFPR will collect follow-up PROMs at 6, 12 and 24 months going forward.

To provide public recognition of clinicians and hospitals that have recruited significant numbers of women to the Registry, the APFPR launched the Health Service Awards in 2023. Two award categories were created: the *Best Contributor Award*, conferred to Monash Health, a public Health Service in Victoria, and the *Significant Contributor Awards*, conferred to two Victorian and two South Australian Health Services, two from the public and two from the private sector.

In June 2023 Dr Oliver Daly, founding member of the APFPR, stepped down from his role as the APFPR Clinical Data Lead. Dr Daly has been a faithful and tireless supporter of the registry since its inception. Steering Committee member Associate Professor Emmanuel Karantanis also recently concluded his 3-year term. Their commitment to the establishment of the APFPR, and their advocacy and support of the APFPR within the Royal Australian and New Zealand College of Obstetrics and Gynaecology had been instrumental in the registry's success. New clinician representatives to these positions are urogynaecolotists Dr Fiona Bach and Dr Jerome Melon, who are warmly welcomed to the registry.

Following a user review program, the APFPR is in the process of updating and modifying its dataset to reflect current user needs and make sure that it continues to capture items of most importance to women who have these procedures. The APFPR is also preparing its first benchmarked reports for sites that have undertaken a minimum number of procedures, and looks forward to increasing these reports as more sites continue to reach this milestone.

CHAPTER 1. BACKGROUND

Clinical Overview

Pelvic floor disorders, such as SUI and POP, are common disorders with prevalence increasing with the number of pregnancies, age and instrumented delivery. Almost 50% of women in Australia are affected by pelvic floor disorders including SUI and POP with a 20% lifetime risk of requiring surgery[1-3]. Pelvic floor dysfunction is a result of weakened, torn or overstretched pelvic floor structures, with the ongoing impact of aging, menopause, constipation, upright posture, heavy lifting in addition to previous birth and pregnancy related injury. When conservative treatments such as those suggested by the International Urogynecological Association (IUGA) below, result in unsatisfactory outcomes, patients consider surgical interventions.

Stress Urinary Incontinence (SUI)

SUI is the involuntary leakage of urine during activities such as coughing, sneezing, lifting, laughing or exercising. IUGA[5] advises that there are four methods to treat SUI:

- General lifestyle changes.
- Pelvic floor exercises.
- Continence devices.
- Surgery.
    - » Mesh midurethral sling – which involves the placement of a permanent monofilament polypropylene mesh sling under the middle section of the urethra. This has been the most commonly performed procedure however due to the concerns with mesh the other procedures are increasingly performed.
    - » Fascial sling – this procedure works in a similar fashion to the mesh slings however the sling material is the patients' own, harvested from the abdomen or thigh.
    - » Burch colposuspension – this is an open or laparoscopic procedure to elevate the periurethral tissues to treat incontinence.
    - » Periurethral bulking agents – bulking agents are injected using a cystoscope into the periurethral area.

Pelvic Organ Prolapse (POP)

POP refers to the bulging or herniation of one or more pelvic organs (uterus, cervix, bowel, and bladder) into or out of the vagina. POP occurs when the muscles, ligaments and fascia (a network of supporting tissue) that hold these organs in their correct positions become weakened.[5]

Treatment for POP may include:

- No specific treatment.
- Pelvic floor exercises (Kegel exercises).
- Pessaries (vaginal devices that come in various shapes and sizes). Pessaries help by providing mechanical support to the prolapsed organs, thus relieving symptoms.
- Surgery.

Historically vaginal surgery for POP has made use of the patients' own tissues (known as a fascial repair or colporrhaphy). Techniques generally involve surgical infolding of the prolapsed organ (e.g.

bladder and rectum) followed by excision of the excessive vaginal wall once the prolapsed organ is pushed back into a pelvic location.[5] Facial repair is effective for many patients. However, there are circumstances where mesh may provide stronger and more durable support, particularly for women with previous failed surgical repairs and complex comorbidities.

From a structural support standpoint, there are circumstances where mesh is recognised as a more reliable material than native tissue, particularly for women with more complex surgical needs such as after prior surgical failure for either SUI or POP.

Of the surgical interventions for SUI and POP, approximately 25% involved the use of a prosthesis/ prostheses with an estimated 150,000 mesh devices implanted in Australia[6] since 1998.

Establishment of the APFPR

In 2017 and 2018 an Australian Senate Community Affairs Reference Committee investigated the number of women in Australia who had transvaginal mesh, with its findings and recommendations being released in October 2018[6]. The Australian government supported the recommendations of the Senate Inquiry report and implemented a number of changes, including the cancellation by the Therapeutic Goods Administration (TGA)[7] of registration for transvaginal POP mesh devices and SUI mini-slings in November 2017. Further, during 2018 the TGA reclassified all surgical mesh products as class III devices. Concurrently the Australian Commission of Safety and Quality in Health Care developed clinical care pathways and credentialing of senior medical practitioners to undertake transvaginal mesh surgery; the purpose was to ensure that only specifically qualified surgeons could undertake this type of surgery[8,9].

One of the Senate review's recommendations was for a clinical registry to be established to monitor all implanted medical devices. In April 2019 the Australian Minister for Health announced funding for a registry to monitor prospective (i.e., going forward) outcomes of women who have surgery for pelvic floor disorders that include the insertion of mesh or a related device[4]. The APFPR was established in July 2019 with clinical leadership from several surgical specialty groups and operational management by Monash University, and commenced recruitment of its first sites and patients in January 2021.

Since its inception the APFPR was designed for participation by all sites and surgeons that undertake SUI and POP pelvic floor procedures in Australia and New Zealand. Participation is subject to relevant government and other agreements, ethics and governance requirements and in the case of surgeons in private practice, signing of a surgeon level agreement with the APFPR. At the time of going to press, the APFPR and the New Zealand Ministry of Health are in active discussions regarding supporting extension of the registry to New Zealand.

APFPR Aims

The APFPR was established in 2019:

- 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 Australian Commission on Safety and Quality in Health Care's Guidance for hospital credentialing of senior medical practitioners to implant and remove transvaginal mesh[8,9].
- 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 effectiveness.
- To provide feedback to clinicians, hospitals and the public on the effectiveness of pelvic floor interventions.

APFPR Procedures Captured

The APFPR captures the following SUI and POP procedures at the time of initial and subsequent surgeries, and collects follow up clinical and patient reported information for these procedures.

POP Procedures

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

SUI Procedures

- Mid-urethral Sling (synthetic mesh)
- Peri-urethral Bulking agent injections
- SUI mesh revision/explantation

The APFPR also captures whether one of the following procedures was performed at the same time (known as a concomitant procedure) as a core SUI/POP procedure, to understand how/if they may affect core procedure outcomes. Concomitant procedure outcomes are not specifically followed up in the APFPR.

Concomitant Procedures

- Anterior repair
- Posterior repair
- Sacrospinous fixation
- Hysterectomy
- Uterosacral plication
- Perineorrhaphy

Future inclusion of Native Tissue SUI Procedures in the APFPR

The APFPR collects information from surgeons regarding each patient's reason (indication) for surgery; specific comorbidities; and specific surgical/ procedure details including outcomes and complications related to the procedure/devices used. The APFPR now also collects women's perspectives through questionnaires at multiple time-points.

As part of its core procedures, from 2024, the APFPR will also capture the following surgeries that involve the use of native tissue:

- Autologous fascial sling
- Burch colposuspension

About devices/prostheses such as mesh

Therapeutic goods are required to be evaluated for quality, safety and efficacy and to be included in the Australian Register of Therapeutic Goods (ARTG) before they can be supplied in Australia. Therapeutic goods are included in the ARTG with either specific indication(s) or intended purpose(s) such as the use of transvaginal mesh. Where patients need access to therapeutic goods that are not on the ARTG, the TGA administers a Special Access Scheme[10] and other programs that provide access to those therapeutic goods. 'Off-label use'[10] generally refers to the use of a therapeutic good for an indication or intended purpose that is not specified in its ARTG entry. Off-label goods are provided at the discretion of the treating clinician who is responsible for obtaining informed consent from their patient and ensuring that the medical device is the appropriate treatment option and carries a positive benefit–risk profile. The APFPR records data on all implants used.

CHAPTER 2. REGISTRY METHODOLOGY

The APFPR is a population-based prospective, observational registry of patients undergoing SUI and POP pelvic floor procedures. The registry collects identifiable clinical data on key diagnostic, surgical, and clinical outcome information, and administers PROMs. Sites and surgeons undertaking these procedures are eligible to participate in the registry. The registry conforms to the national operating principles for clinical quality registries (CQRs) as set out by the Australian Commission on Safety and Quality in Health Care (ACSQHC).

The registry uses an opt-out model to recruit women undergoing pelvic floor procedures. The Australian Government's National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research 2023[11] determines that an opt-out approach to participant recruitment to research may be appropriate when it is feasible to contact some or all of the participants, but where the project is of such scale and significance that using explicit consent is neither practical nor feasible . Women are introduced to the registry by their clinician and are given an APFPR patient leaflet. Contact details of the patient are provided by the clinician so that the registry can send the patient an invitation and explanatory statement outlining the process to opt-out of the registry. Following an initial 2-week opt-out period, the patient is recruited into the registry, unless they have indicated otherwise. To date, the opt-out rate from the APFPR is below 3% which is consistent with Monash University's experience with opt-out registries. Utilisation of opt-out consent enables the possibility of near 100% data collection of all pelvic floor procedures occurring in Australia. Capturing as much of the impacted population is crucial to create representative and meaningful data. Recruited women may opt-out of the registry at any time by notifying the APFPR, or their clinician.

Ethical review

The ethical requirements of this registry have been approved by the Human Research Ethics Committee of Monash Health under the National Mutual Acceptance Scheme (NMA)[11]. The APFPR seeks further ethical approval if required and governance sign-off at participating hospitals (sites) prior to patient recruitment and data collection commencing. Additional ethics approvals are sought from participating sites that do not operate within the NMA. The registry is managed in accordance with the National Statement on Ethical Conduct in Human Research (2018)[9]. This statement has been developed to protect the interests of people who agree to participate in human research studies.

Surgeon recruitment & training

Identification of eligible hospitals occurs via recommendation from the APFPR clinical leads, publicly available information regarding clinicians who undertake pelvic floor procedures, as well as specialty conferences and meetings at which the APFPR present abstracts. In addition, sites or surgeons may also initiate contact with the registry to express interest in participating. Pelvic floor procedures are undertaken by urologists, gynaecologists, urogynecologists and colorectal surgeons in metropolitan and regional settings, and via public or private hospitals.

The APFPR welcomes the opportunity to attend hospital events or forums attended by surgeons from relevant specialist groups to introduce the registry and answer questions. Once the site has ethics and governance approval, the APFPR team provides database training and support. Each public hospital is enrolled as one entity, with the site Principal Investigator being the site contact person. In the instance of participating clinicians from private sites, the APFPR enters into an individual agreement with each individual clinician.

Patient eligibility

All patients undergoing a SUI and/or POP procedure and attending a participating site or having the procedure through a participating surgeon are eligible to participate. A list of sites that are contributing data is published at the end of this report.

Modules (SUI and POP) minimum datasets

The registry undertook a modular roll out, with the first clinical module to be implemented being the SUI module, followed by the POP module. The APFPR SUI and POP minimum data set (MDS) development consisted of a two-step e-Delphi process where Steering Committee clinical leads participated in an expert review panel to establish the minimum dataset considering the importance, feasibility and data burden of proposed data items.

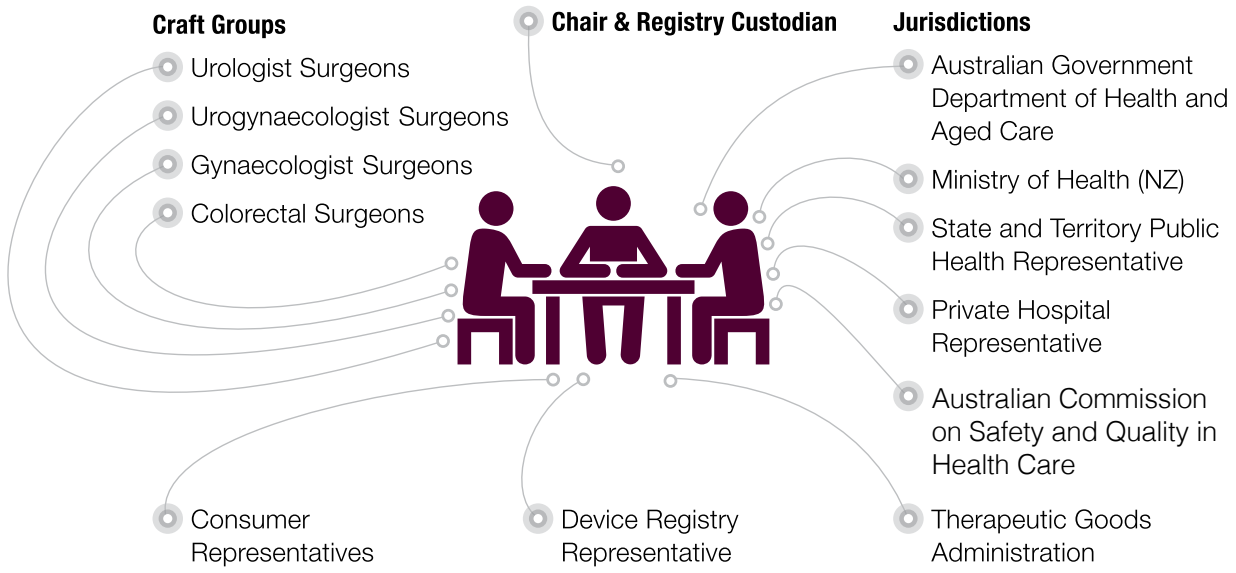
The APFPR dataset has been designed to support clinicians to meet any credentialing requirements of their institutions, based on the Australian Commission on Safety and Quality in Health Care transvaginal mesh credentialing guidance, and to do this in a manner that reduces data collection burden.

For more information please visit https://www.safetyandquality.gov.au/our-work/health-conditions-and-treatments/transvaginal-mesh. The APFPR data items can be found in Appendix I.

Registry governance

The APFPR Steering Committee drives the strategic direction and development of the APFPR, and benefits from representation from a broad group of stakeholders, which comprises:

Figure 2.1: Registry Governance



The Steering Committee (SC) is supported by two subcommittees that report to the Steering Committee:

i. A Clinical Advisory Committee (previously called the APFPR Management Committee), comprising the Steering Committee clinicians who meet quarterly to provide expert clinical advice to the registry.

ii. A Consumer Reference Group, the purpose of which is to provide feedback on how registry development initiatives meet consumer needs. The Group includes two Co-chairs with lived experience who lead discussions; the Consumer Representatives on the APFPR Steering Committee, two members from the APFPR team, and a number of lived experience consumers from all over Australia.

In December 2022, the Steering Committee conducted a self-evaluation of its performance to date, with recommendations implemented accordingly.

Data governance

The APFPR utilises a Research Electronic Data Capture (REDCap) database for data collection and storage. The database is hosted by Monash University. Study data was collected and managed using REDCap electronic data capture tool hosted and managed by Helix (Monash University).[12,13]

REDCap is a secure, web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for data integration and interoperability with external sources.

Monash University has established and managed clinical registries for over 20 years, currently operating 40 state and national registries including several large national ones. Monash University has the highest levels of data security and governance systems for sensitive data and complies with State, Territory and Commonwealth privacy laws. The registry retains participant contact details to enable contact for recruitment to the registry and for follow-up in relation to completion of PROMs survey questionnaires. The APFPR does not release identifiable information to any person or organisation, other than the treating clinician.

Each registry database user has their own username and password to access the database. In addition, during 2023, two-factor authentication was incorporated into database login, enhancing database privacy and security. Private hospital surgeons only have access to their own patients' data, that relate specifically to the treatment they have provided to them. All authentication and authorisation related information is encrypted and stored securely according to the Monash University Electronic Information Security Minimum Security Controls Procedure.

Data access requests

Researchers and medical professionals working at research institutes, hospitals, private entities, government or other health services within Australia and industry are eligible to request access to data held within the registry, once it reaches sufficient maturity. The APFPR has a Data Sharing/ Access Policy which describes the requirements and processes for researchers, patients and other agencies to request access to de-identified APFPR data or summary reports. The APFPR will only release the least sensitive level of data that is practicable to fulfil the uses identified in the research proposal submitted with the data request.

In 2023, the registry received and approved its first data access request from RANZCOG which requested early APFPR data in relation to mid-urethral slings and other continence procedures. The purpose of the request was to advise the NZ Ministry of Health of the future potential of APFPR data for monitoring pelvic floor procedure outcomes. The request was reviewed by the APFPR Steering Committee, and a summary report of the data was provided to RANZCOG with a clear caveat regarding the low numbers and inability to draw conclusions while the data is not yet representative. As APFPR data matures, safety outcomes regarding individual devices will be provided to the TGA, and industry may also request information regarding the safety and outcomes from their particular devices.

Data transparency

The APFPR Data Dictionary, which describes all the data items in the registry, was developed and uploaded to the APFPR website in April 2023. The data dictionary will be reviewed and updated annually as required.

Stakeholder engagement and communication

Stakeholder engagement is critical to ensure that the APFPR achieves its aims of high quality, meaningful nationwide data collection and reporting. Key APFPR stakeholder engagement activities over the previous 12 months have included:

- Invitations from government organisations such as the Therapeutic Goods Administration (TGA) to participate in consultations relating to pelvic floor procedures and the use of devices
- Meetings with key relevant Medical Colleges and Societies
- Invitation from Medical Colleges to partner and explore opportunities for interoperability
- Engagement with consumers, and subsequent demand from consumers Australia-wide for the APFPR to create more forums for knowledge sharing and consumer engagement
- The establishment of the Consumer Reference Group to support lived experience consumers to participate and share their views
- Interaction via the apfpr.org.au website
- Engagement with clinicians and sites on X (formerly Twitter)
- Growth in the APFPR's contact list of clinicians and other important stakeholders
- Engagement with jurisdictions
- Enquiries from consumers – expressing support for their surgeons to participate in the registry
- Liaison with international registries in a similar clinical domain

Consumer engagement

Building on a successful consumer engagement program which had previously consisted of a public facing website, several Communiques (newsletters), and customised consumer information, the APFPR conducted two consumer webinars during the past year. The webinars were well attended, attracting a number of consumer groups, including some of the mesh committees set up by health jurisdictions to advise on the deployment of services to women affected by mesh, as well as individual consumers.

Establishment of the Consumer Reference Group

Due to consumer demand and the advocacy efforts of APFPR Consumer Representatives, the APFPR held a Consumer Meeting in December 2022 to identify how the APFPR could further leverage consumer knowledge and lived experience to enrich the next stage of its development. Following positive feedback from participating consumers, all of whom have lived experience of pelvic floor disorders, the Steering Committee endorsed a proposal to create an ongoing Consumer Reference Group, comprising of lived experience consumers from all over Australia. The purpose of this group is to provide feedback and perspectives on how registry developments meet consumer needs. The Consumer Reference Group meets up to twice a year.

APFPR Health Services Awards

The importance of early adopting clinicians in the establishment of a registry cannot be overemphasised. During the 3rd quarter of 2022, the APFPR launched a number of Health Service Awards, an engagement tool to provide recognition and acknowledgment to the first participating sites. CQRs rely to a great extent on early adopter clinicians that contribute an initial critical mass of data in early stages of establishment, enabling representative and meaningful analysis. The awards recognise hospital sites that contributed their first 50 patients, as well as the APFPR's greatest contributor across Australia.

The Chair of the APFPR and other members of the registry team visited Health Services to present the awards and extend their gratitude to the hospitals and clinicians in person.

We are delighted to advise that in October 2023, APFPR awarded the following:

Best Contributor Award, recognising the highest contributor of individual patient data recruited up to 30 June 2023 in Australia. Monash Health recruited over 100 patients in 2023.

Public Health Services

Monash Health (Victoria)

Pictured, Monash Health Principal Investigator Professor Anna Rosamilia (far left) with Monash Health Staff and registry personnel.

Significant Contributor Awards for hospital sites that recruited at least 50 patient records up to 30 June 2023.

Private Health Services

Calvary North Adelaide (South Australia)

Pictured the urology team at Calvary North Adelaide Hospital, being conferred the award by Professor Susannah Ahern (fourth from right).

Private Health Services

Epworth Freemasons (Victoria)

Pictured: the registry team conferring the award to Principal Investigator and APFPR Clinical Lead Professor Helen O'Connell at the Epworth Freemasons Hospital in East Melbourne.

Private Health Services

Cabrini Health (Victoria)

Pictured: the Cabrini Hospital team being conferred the award by APFPR Chair Professor Susannah Ahern.

Public Health Services

The Queen Elizabeth Hospital (South Australia)

Pictured: the Queen Elizabeth Hospital (Adelaide), Professor Susannah Ahern conferring the award to the urology team.

Medical Colleges and Societies

A number of engagement meetings were conducted with the registry's key stakeholder group of Colleges and Societies. These included:

- The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG)
- The Urological Society of Australia and New Zealand (USANZ)
- Urogynaecological Society of Australasia (UGSA)
- The Colorectal Surgical Society of Australia and New Zealand (CSSANZ)
- Royal Australasian College of Surgeons (RACS)

Leveraging the Networks of Steering Committee Members

The Clinicians on the APFPR Steering Committee, Clinical Advisory Committee and Operations teams play a strategic role in the recruitment process. They assist the registry identify, contact and encourage individual clinicians to assume the role of Principal Investigators at their site and mobilise support from other clinicians.

Conferences

A clinician survey conducted in 2022 investigating surgeon preferences about how to best engage with the APFPR, identified conferences as a key channel to engage and recruit clinicians. The survey highlighted the importance of the APFPR's online presence in X (Formerly Twitter) and LinkedIn, specifically for the purpose of providing recognition to participating sites; however, it also illustrated the criticality of being present at conferences to raise awareness of the registry and its goals. Meetings and conferences have proven very successful at engaging existing clinicians and identifying potential Principal Investigators for new sites. We prioritise conferences organised by the Medical Colleges and Societies. The APFPR welcomes opportunities to present updates on the APFPR's progress at these events, to continue to raise the profile of the registry and keep our stakeholders engaged.

We thank the many organisations and individuals who support the APFPR's attendance at these events.

In 2022-3, the APFPR attended and/or presented at:

- UGSA 2022 Annual Scientific Meeting (ASM), September 2022.
- USANZ including the Australia and New Zealand Urological Nurses Society 27th Annual Meeting, February 2023. Presentation title: APFPR Open for business.
- RACS ASM, May 2023. Presentation title: Collecting Patient Reported Outcome Measures in the Australasian Pelvic Floor Procedure Registry.
- Australia's National Conference on Incontinence, sponsored by the Continence Foundation and USANZ, June 2023. Presentation title: Clinical practice trends in pelvic floor procedures: survey results from the Australasian Pelvic Floor Procedure Registry
- Urological Association of Asia Congress, September 2023. Presentation title: Update on the APFPR
- 2023 Australian Clinical Quality Registry ASM. Various presentations and posters.
- USANZ South Australian State Meeting, October 2023. Presentation title: Progress Update on the APFPR
- RANZCOG 2023 Annual Scientific Meeting, October 2023. Presentation title: APFPR PROMs Pilot update
- UGSA 2023 Annual Scientific Meeting, November 2023. Presentation title: Update on the APFPR: CQIs

The APFPR would like to acknowledge USANZ, the Continence Foundation of Australia and UGSA for their support in offering the APFPR a complimentary booth at their conferences.

Site and Clinician Newsletters

The APFPR engages with clinicians and sites via an operational newsletter, with four being issued during 2022/2023, in addition to several alerts. The newsletters cover training tips, updates on registry development, as well as the launch of the Health Service Awards. Our latest newsletter was focused on 'Target 1,000' in an effort to increase the number of procedures captured in the registry in 2023.

CPD Program

The APFPR has been accredited to provide continuing professional development (CPD) points for participating clinicians with both RANZCOG and RACs. The APFPR provides information regarding surgeon participation directly to the Colleges for the receipt of CPD points.

Database User Group Initiative

In recognition of the data collection burden and with a goal of identifying ways to reduce it, in late 2022 the APFPR embarked on a Database User Group review exercise where users provided feedback on the data set and the database. This informed a revision of the data variables and the way the database is presented, including an update of the Minimum Data Set. Opportunity areas were identified for streamlining data entry time points, and simplifying data collection to reduce the burden on clinicians. The new dataset will be live in early 2024.

Communicating to the public

The APFPR continued to update its consumer-friendly website, covering essential information about the scope of the registry, governance and ethics processes, and providing essential information for consumers. We also published three Communiques during the last 12 months.

Site Visits

As a matter of good practice, the APFPR attempts to combine conference travel with site visits whether possible. In the last 12 months, the following hospitals received a visit from APFPR personnel: Calvary North Adelaide, Epworth Freemason, Monash Health, Cabrini Hospital, St John of God Bendigo, and The Queen Elizabeth Hospital Adelaide. We always try to accommodate sites that request a visit.

Social Media

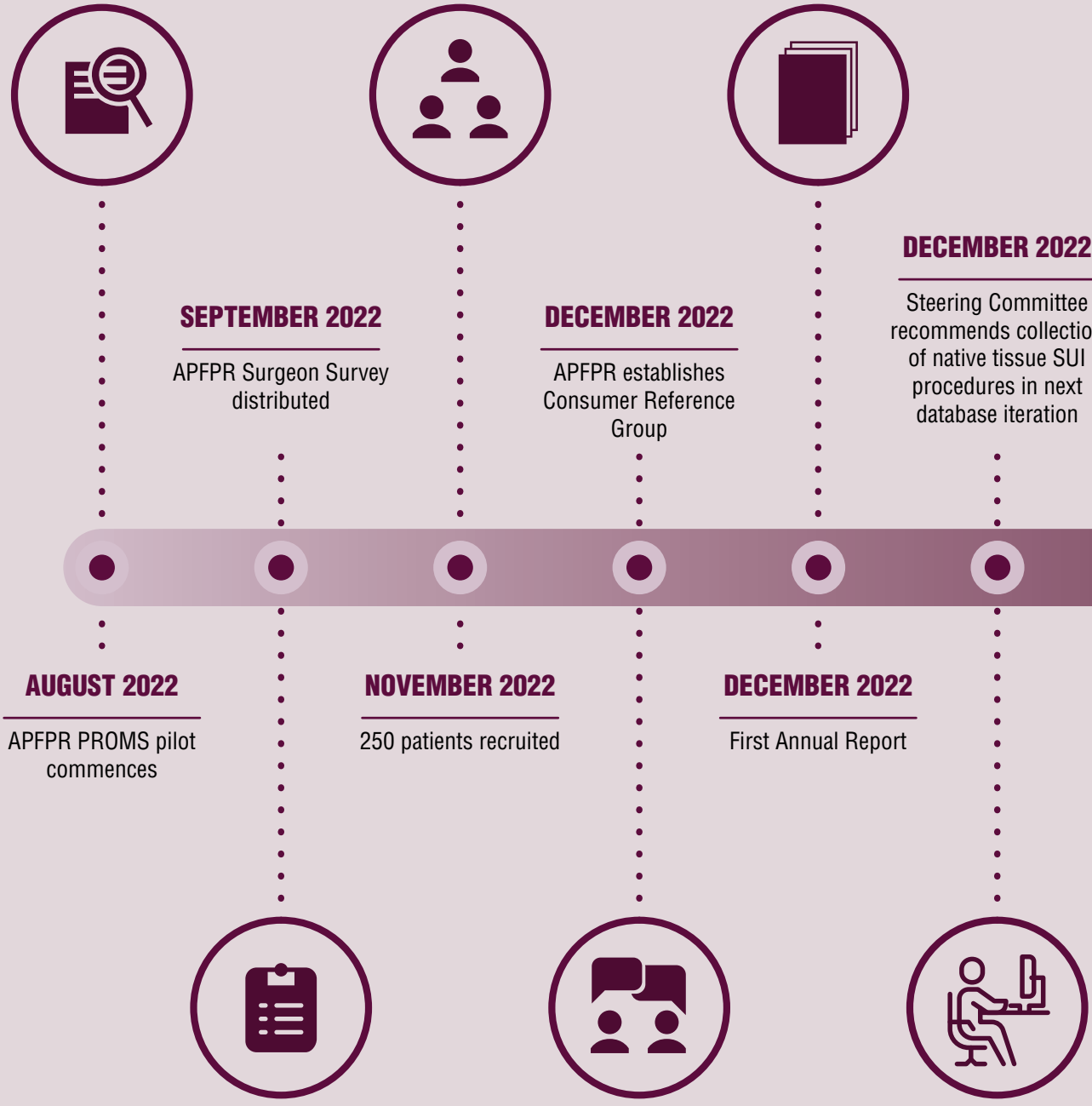
The APFPR has been active in connecting with clinicians and sites on X (formerly known as Twitter), and in 2023 further enhanced efforts to reach out via LinkedIn and increase engagement on that specific platform. Key highlights included the announcement of CPD points with RACS featuring over 1,000 impressions, and the publication of the 2022 Public Report which also attracted over 1,000 views across a few days. A similar spike in visitations was observed when we announced the RANZCOG CPD program.

Engaging with government stakeholders to achieve greater impact

The APFPR recognises its potential role in contributing to quality improvement at a systemic level, in the past year it contributed in the following ways:

- Providing feedback to the TGA on the Unique Device Identifier (UDI) development
- Submission to the TGA Consultation on the development of UDIs
- Submission to the TGA Consultation on recalls processes, preceded by meetings with the TGA to determine how the APFPR could best be of value in the process
- Submission to a sector consultation from the Department of Health and Aged Care into the Review into urogynaecological mesh (Mid-Urethral Slings)

KEY MILESTONES FROM THE PAST 12 MONTHS



AUGUST 2022

APFPR PROMS pilot commences

SEPTEMBER 2022

APFPR Surgeon Survey distributed

NOVEMBER 2022

250 patients recruited

DECEMBER 2022

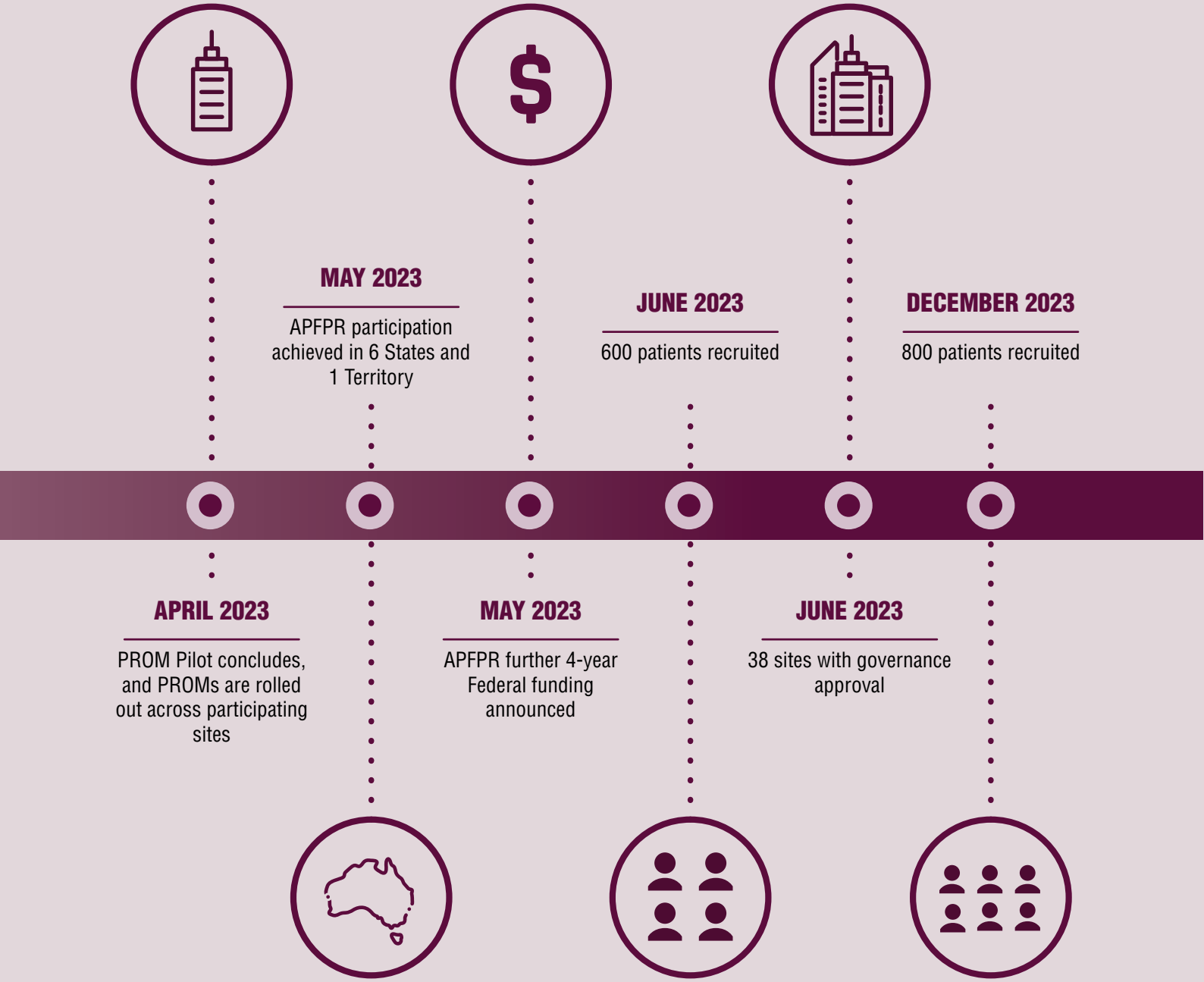
APFPR establishes Consumer Reference Group

DECEMBER 2022

First Annual Report

DECEMBER 2022

Steering Committee recommends collection of native tissue SUI procedures in next database iteration


APRIL 2023
PROM Pilot concludes, and PROMs are rolled out across participating sites
MAY 2023
APFPR participation achieved in 6 States and 1 Territory
MAY 2023
APFPR further 4-year Federal funding announced
JUNE 2023
600 patients recruited
JUNE 2023
38 sites with governance approval
DECEMBER 2023
800 patients recruited

CHAPTER 3. AUSTRALIAN DATA TRENDS

Procedure Trend Analysis

In 2022, the APFPR undertook analysis of publicly available data to identify the most recent trends in Australia in pelvic floor procedures involving implants such as mesh. The analysis was used to verify whether the assumptions made around procedures at the time of the APFPR's establishment were still relevant. The analysis was conducted using the following datasets:

1. **Australian Classification of Health Interventions (ACHI) codes**: are the Australian national standard for health intervention coding in Australian hospitals. ACHI classifies interventions (procedures) performed in public and private hospitals, day centres and ambulatory settings. These data are reported through Australian Institute of Health and Welfare (AIHW) Data Cubes, and are publicly available.

2. **Medicare Benefits Schedule (MBS)**: is a listing of the Medicare services that are subsidised by the Australian Government. MBS item reports include services that are performed by a registered provider for services that qualify for a Medicare Benefit. This provides the basis for billing in the private sector and in some instances in the public sector. These data are published by the Australian government and are also publicly available.

While the AIHW The National Hospital Morbidity Database (NHMD) and MBS reports provide the best available data informing procedure numbers in Australian Hospitals, there are some caveats to their use to analyse trends in pelvic floor surgery with or without the use of an implant such as mesh. Importantly, ACHI and MBS codes may not distinguish mesh from non-mesh procedures. For example, the code 35599-00 (ACHI) may be used for mesh or non-mesh (fascial) slings, and similarly for some POP procedures, e.g. anterior and posterior vaginal repairs, ACHI procedure codes do not distinguish procedures using mesh from native tissue procedures.

This is further complicated when using Medicare Item reports to analyse POP procedures over time, due to changes in the eligibility to claiming the MBS fee. For example, from 2018 following the Australian Senate Inquiry, the eligibility for claiming an anterior vaginal repair for POP, [item 35570 (MBS)], was restricted to "using native tissue without graft" procedures only, whereas it could be claimed for mesh procedures previously. As such, when using MBS data, item number statistics are not always reporting like-for-like procedures over time. However, using the available data, the registry has attempted to interpret what these trends mean with regards to contemporary clinical practice.

Trends in pelvic floor procedures from 2011-2023

These analyses were updated in 2023 specifically for this report. The most recent publicly available data continues to reflect trends reported in the 2022 APFPR Annual Report, namely:

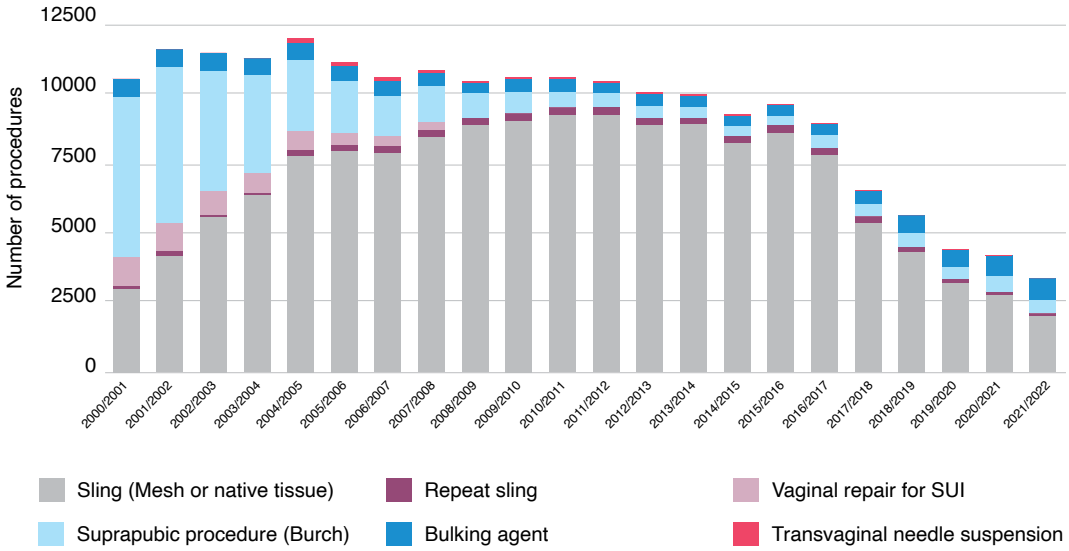
- A reduction in SUI procedures (in particular mesh slings)
- A reduction in POP procedures (in particular colporrhaphy), and
- An increase in the use of bulking agents.

These trends are shown and discussed in Figures 3.1-3.4.

SUI Procedures

The number of procedures for SUI has significantly decreased over time, from an average number of approximately 10,000 total SUI procedures prior to and including 2013-14, to only 3,363 total procedures in 2021-22 (Figure 3.1, AIHW data). Of these, in 2021-22 the number of sling procedures (mesh or fascial) for SUI was 2,022 procedures (40%), with bulking agents comprising 755 procedures (22.5%).

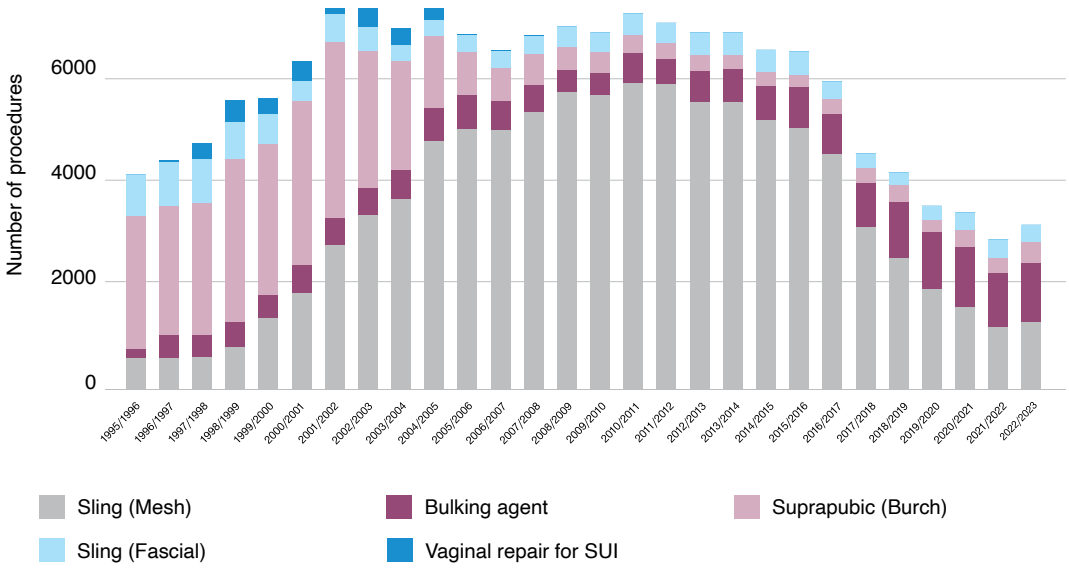
Figure 3.1: Number of SUI procedures over time (Source: AIHW)



MBS data describes procedures generally performed in private hospitals (a subset of the AIHW data), where approximately 70% of total gynaecological procedures are performed.

Figure 3.2 shows MBS data relating to 2,886 SUI procedures in 2021-22, and 3,175 SUI procedures in 2022-2023, perhaps reflecting a small post-COVID recovery. MBS data separates mesh and fascial slings (which is not the case in the AIHW data). MBS data also shows a significant reduction in mesh slings performed in private settings, from a peak of over 7,000 per year in 2010-11 to 1,307 in 2022-2023. In 2022-23 there were also 1,129 bulking agent procedures, 415 Burch colposuspensions and 324 fascial slings.

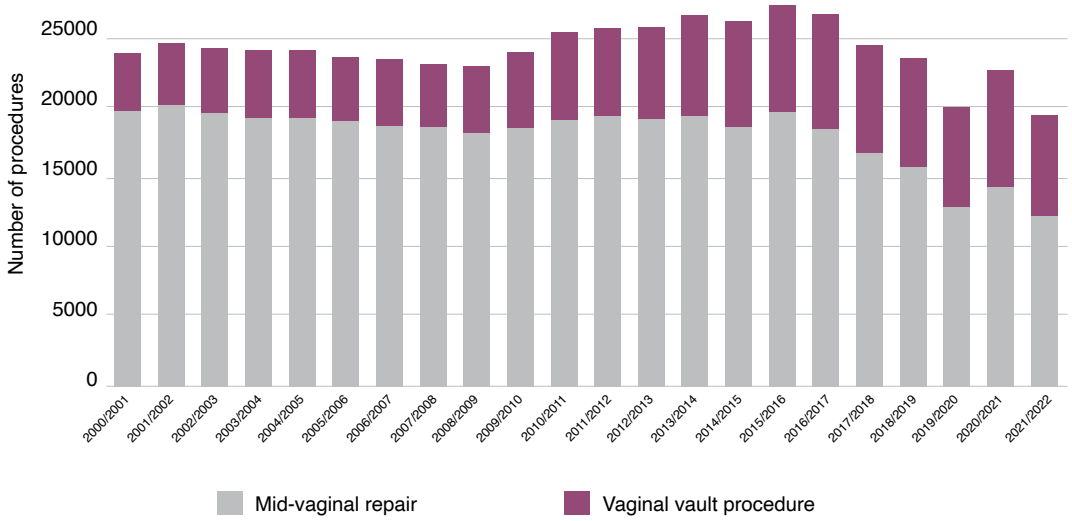
Figure 3.2: Number of SUI procedures over time (Source: MBS)



POP Procedures

Total numbers of procedures for POP have also declined during this period, although not as significantly as SUI procedures (Figures 3.3 and 3.4) Over the last 2 decades, total POP procedure numbers peaked at about 28,000 in 2015-16 and have declined to 19,674 procedures in 2021-22 (AIHW). This data does not distinguish between procedures undertaken with and without mesh implants. Similar numbers and trends are seen with the MBS data, with mesh versus non-mesh procedures not well delineated.

Figure 3.3: Number of POP procedures and repair type conducted in Australia (Source: AIHW)

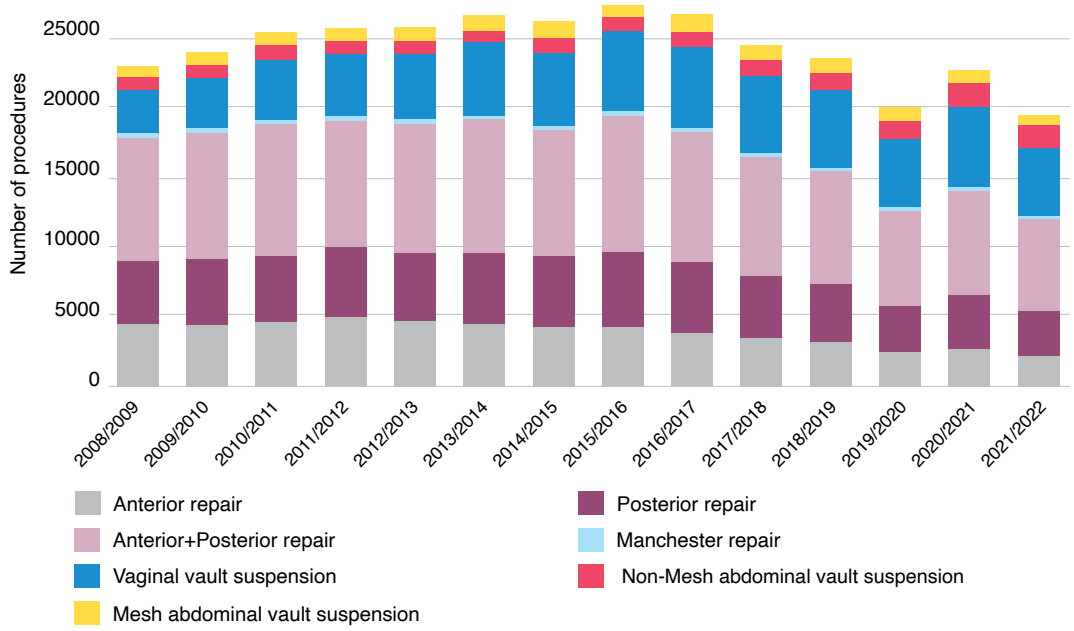


In 2008 there was a significant change in classification of prolapse procedures; as such Figure 3.4 shows a more detailed subdivision of POP procedures. The most commonly performed repairs in 2021-22 were anterior and posterior repairs, followed by vaginal vault suspension; posterior repair only; anterior repair only; non-mesh abdominal vault suspension and mesh abdominal vault suspension. The MBS classification does not specify all procedures which may use mesh thus it is difficult to determine a potential denominator for POP procedures available to be captured by the APFPR.

Table 3.1 Number of POP procedures in 2020-21 and 2021-22, by procedure type conducted in Australia (Source: AIHW)

	2020-21	2021-22
Sacral colpopexy	188	160
Anterior repair	2742	2171
Posterior repair	3853	3294
Anterior + posterior repair	7486	6587
Manchester repair	277	222
Vaginal vault suspension	5757	4913
Non-mesh abdominal vault suspension	1689	1613
Mesh abdominal vault suspension	934	714
Total	22926	19674

Figure 3.4: Number of POP procedures, by procedure type conducted in Australia (Source: AIHW)



Discussion

The decline in overall SUI procedures may suggest a reticence amongst patients to undergo surgery – for both native tissue and synthetic sling procedures. At this time, bulking agent injections are considered less invasive procedures, which originally had limited scope and were typically used after failure of other procedures. In more recent years they have been used as a primary procedure which is reflected in the rise in numbers. This is a new trend and it is important for the registry to gather prospective data on these outcomes. Whilst the placement of the bulking agent is a minor procedure, increasing tissue resistance under the urethra carries risk, just like any other surgical procedure. The APFPR will be monitoring the performance of this technique over time.

Additionally, the SUI data demonstrates that less effective treatments for SUI such as vaginal repair, have not recommenced despite the resurgence of native tissue repairs. Where repeat slings were not rare between 2004 and 2019, repeat slings are very rare now. As health services catch up on surgery delays brought about by the pandemic, the registry has observed a return to increased incidence of both mesh and fascial slings, Burch colposuspension and bulking agent injections.

Refinement of APFPR operations

Refining clinician credentialing for pelvic mesh procedures

In 2018 the Australian Commission for Safety and Quality in Health Care developed a set of guiding principles for the insertion and removal of pelvic floor implants such as mesh regarding the experience and qualifications[8,9] required by specialist surgeons who perform procedures involving implants such as pelvic mesh. Increasingly, hospitals are following these guidelines when recruiting surgeons to their hospitals. These are referred to as credentialing guidelines. This provides reassurance to consumers that clinicians who perform procedures with mesh have the recommended training and experience. The APFPR receives many queries from consumers on how to identify a credentialed surgeon. Contacting the hospital administration directly is the path to identifying whether a given surgeon is credentialed to perform a particular procedure. The Australian Commission for Safety and Quality in Health Care also provides clinical care pathways for referring doctors and consumer friendly information about each of the pelvic floor procedures[9].

Surgeon Survey 2022

Given changing clinical practice observed in the publicly available data, the APFPR developed and distributed a surgeon survey that aimed to:

- Confirm the clinical practice trends gained through MBS and AIHW data reported in 2022
- Understand reasons for the practice changes and how surgeons are responding to these factors
- Re-assess the scope of the registry in light of these practice changes

The survey was developed with input from the clinician representatives on the APFPR Steering Committee and underwent pilot testing by clinicians on the Clinical Advisory Committee. It was distributed via the clinical Colleges/Societies; key findings were presented at the National Conference on Incontinence in June 2023 – organised by the Continence Foundation of Australia in collaboration with the Urological Society of Australia. The survey is currently being drafted for publication.

Characteristics of the survey respondents included:

- 79 fully completed responses were obtained with an even representation of relevant surgeon groups
- Over 70% of respondents had a mixed public/private practice, with 20% practicing in non-metropolitan areas
- Representation from surgeons across all Australian jurisdictions, as well as New Zealand
- Approximately 50% of respondents had between 11-30 years of practice as specialist surgeons

Clinical procedural characteristics and trends identified in the survey included:

SUI Procedures

- Most commonly performed SUI procedure over the previous 5 years was mesh sling (performed by 87% of responding surgeons), followed by bulking agents (75%), autologous facial sling (62%) and Burch colposuspension (35%.). Approximately 75% of clinicians regularly undertook SUI mesh explantation procedures also.
- The most common procedure trends noted by clinicians were a reduction in mesh sling procedures (64%) and an increase in SUI mesh explantation (50%)
- The most common factors relating to the reduction in mesh sling procedures were considered to be patient preference (83%), followed by litigation concerns (59%)
- Clinicians responded to this trend by changing to other procedures (54%), non-operative management (17%), referral to others (15%) and upskilling (2%).

POP Procedures

- Most commonly performed POP procedure over the previous 5 years were anterior and posterior repair (86% and 82% respectively), with native tissue sacrocolpopexy and native tissue sacrohysteropexy the least commonly performed (15% and 16% respectively). Approximately 66% of clinicians regularly undertook POP mesh explantation procedures also.

- The most common procedure trends noted by clinicians were a reduction in mesh sacrocolpopexy and sacrohysteropexy procedures noted by 40% and 42% respectively) and an increase in these procedures without mesh (50% and 34% respectively). POP mesh explantation also increased (noted by 41%)

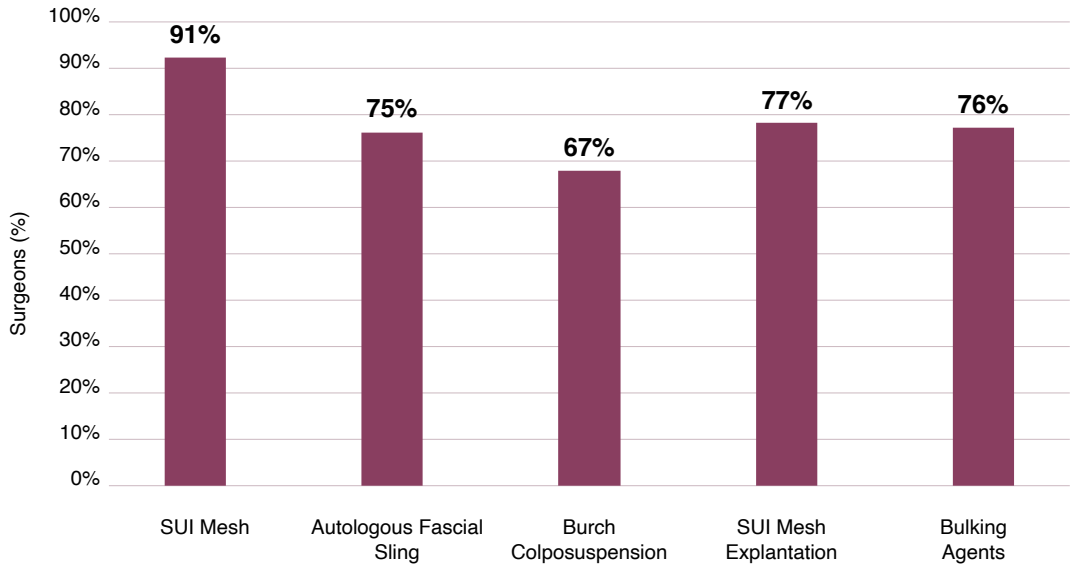
- The most common factors relating to the reduction in mesh POP procedures were considered to be mesh availability (81%), followed by patient preferences (62%)

- Clinicians responded to this trend by changing to other procedures (71%), upskilling (14%), referral to others (10%), and non-operative management (5%).

Recommendations for future procedures to be captured by the APFPR

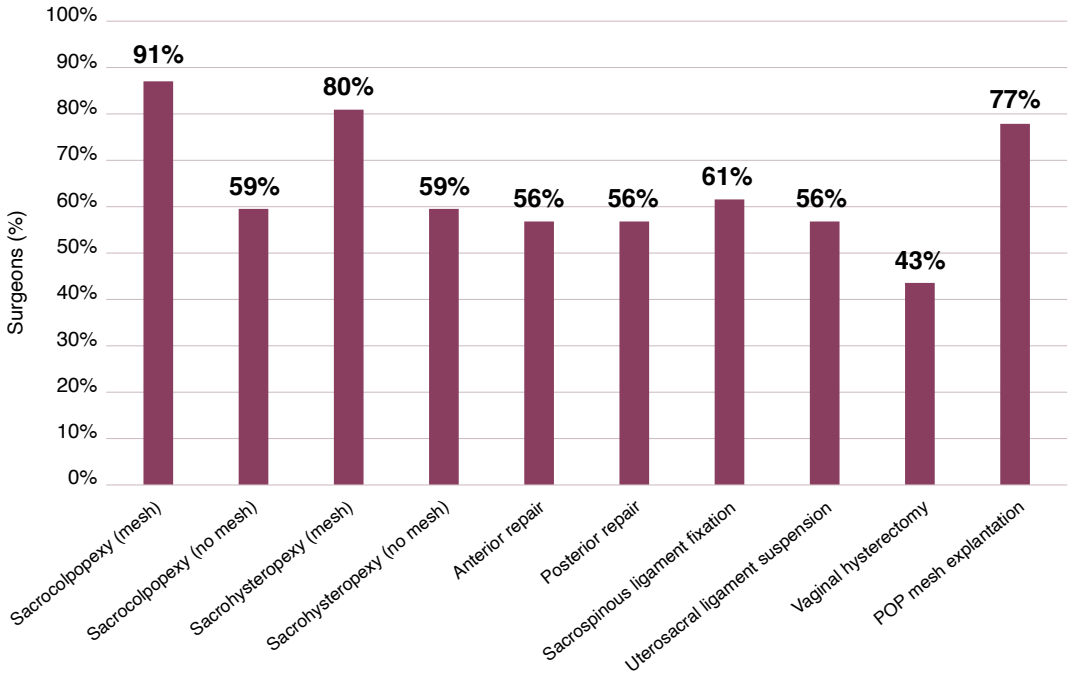
The clinician recommendations regarding POP procedures was that there should be no change (i.e. to continue to collect POP procedures involving mesh only i.e. sacrocolpopexy and sacrohysteropexy with mesh, and mesh explantation procedures).

Figure 3.5: Recommendation for inclusion of SUI Procedures



7 Source: Clinical practice trends in pelvic floor procedures: survey results from the Australasian Pelvic Floor Procedure Registry

Figure 3.6: Recommendation of inclusion of POP Procedures



CHAPTER 4. REGISTRY PARTICIPATION

The following section describes current hospital (site) and patient recruitment progress to date.

Hospital/site recruitment

Contributing data to registries, which is commonly known as participating, is voluntary in Australia. Registries engage in a number of engagement programs and activities to encourage participation. The first step is to recruit a hospital, in other words to obtain the necessary ethics and governance approvals for a hospital to take part. After this is obtained, clinicians can commence entering patient data. We refer to this as patient recruitment.

Ninety hospital sites have been identified across the 8 jurisdictions as suitable for participation. The map depicts the 38 sites that have obtained Ethics and Governance approvals as of 3/11/2023. Of these 38 sites, 29 are currently contributing data to the APFPR.

Figure 4.1: Number of hospital sites per state/territory that have obtained APFPR ethics and governance approvals as of 3/11/2023

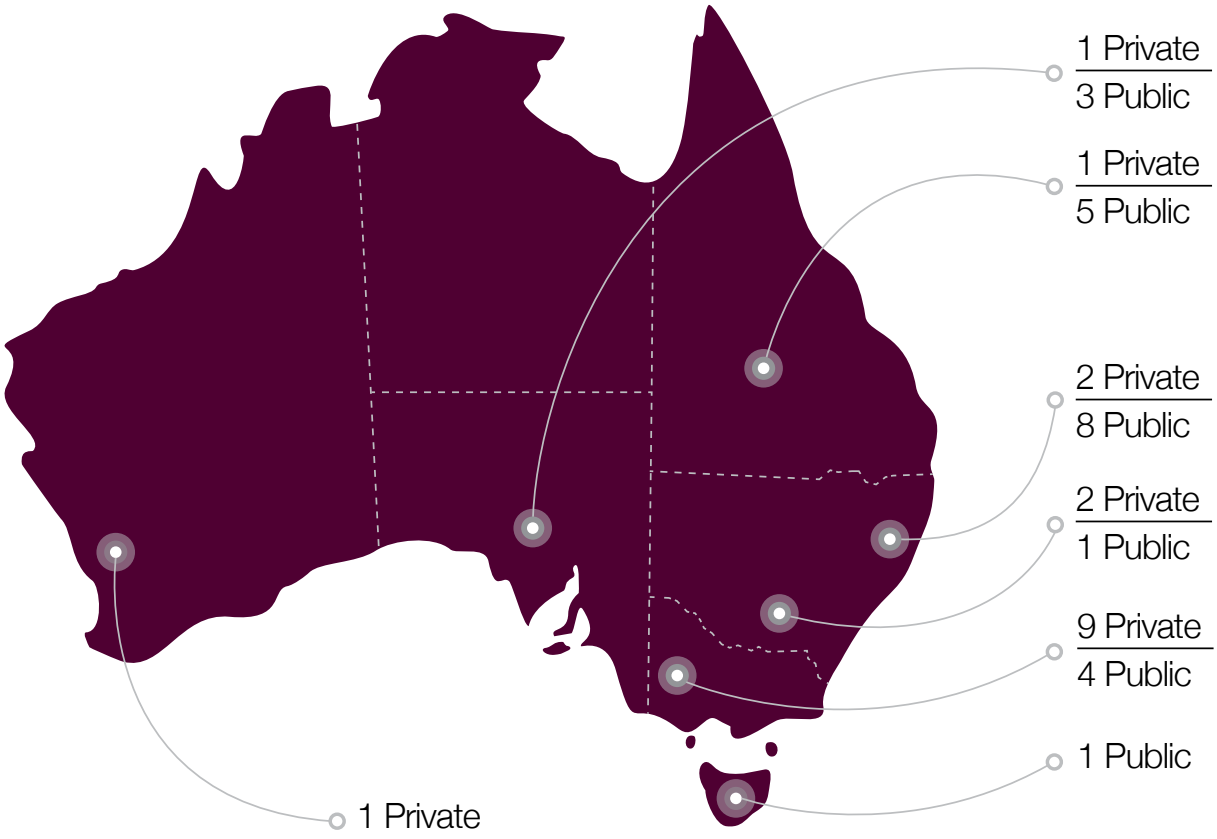


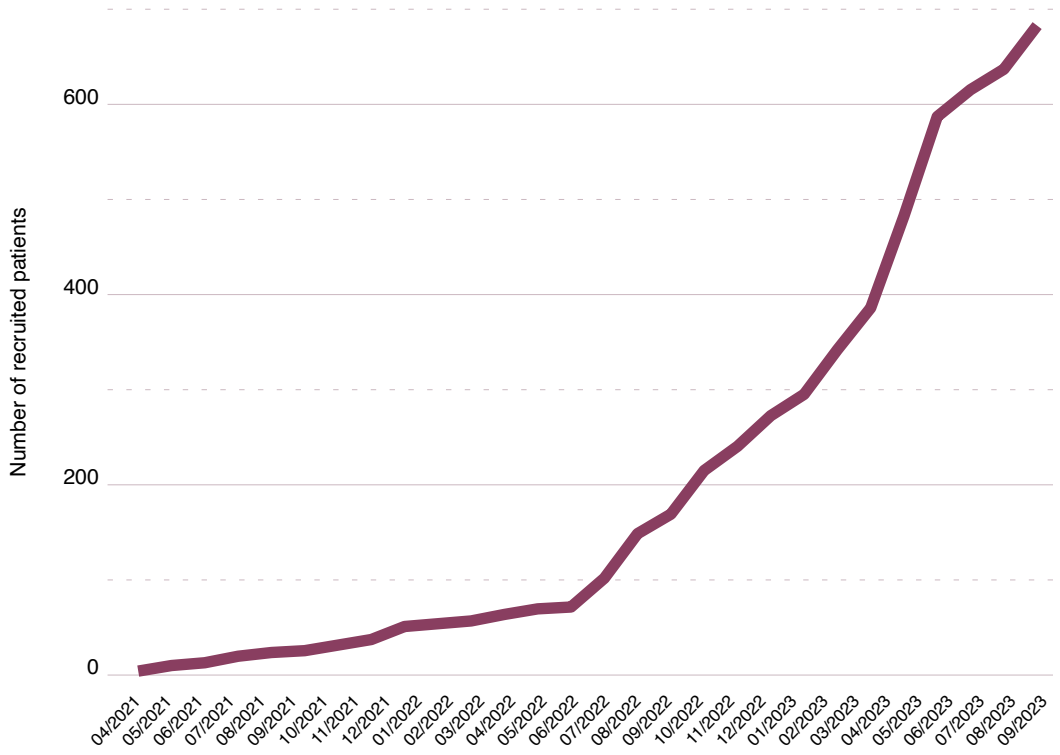
Table 4.1: Summary of hospital site recruitment progress

	N
Sites with approved governance	38
Governance application under review	2
In progress	12
Hospitals contacted	14
Hospitals identified	24
Total sites in current scope	90

Cumulative patient recruitment

As at 26 September 2023, 758 women were registered in the APFPR database, of which 696 (92.8%) have been recruited so far i.e. did not opt-out at the time of recruitment nor are currently in the 2-week opt-out recruitment period. A total of 22 women (2.9%) to date have chosen to opt-out of the registry completely, and 26 were partial opt-outs (PROMs only). The plateauing of growth over the last few months is likely associated with the move to multifactor authentication at individual sites, which required a lot of technical support for individual staff within the hospitals. Figure 4.2 shows cumulative participant recruitment over time.

Figure 4.2. Cumulative patient recruitment over time



Total Cohort (SUI, POP, SUI + POP procedures)

Summary information regarding the total APFPR cohort is provided in Table 4.2. Of the 696 women recruited to the registry to date, approximately half were recruited from public hospitals, and half from private hospitals. 436 of these women (63%) have had their surgery performed, with a slightly higher proportion of these performed in public versus private settings (reflecting the early involvement of public hospitals in the APFPR).

338 (78%) procedures captured relate to SUI procedures, 60 procedures (14%) are POP procedures, and 38 (9%) relate to SUI + POP procedures. Over 50% of procedures captured are from Victorian hospitals, followed by South Australia, public hospitals in NSW, and private hospitals in Queensland.

Table 4.2: Summary of surgery performed by hospital type

	All, N (%)	Public, N (%)	Private, N (%)
N recruited patients	**696**	**347**	**349**
Surgery performed	**436 (62.6)**	**222 (64.0)**	**214 (61.3)**
Surgery cohort			
Stress urinary incontinence (SUI)	338 (77.5)	158 (71.2)	180 (84.1)
Pelvic organ prolapse (POP)	60 (13.8)	37 (16.7)	23 (10.7)
SUI+POP	38 (8.7)	27 (12.2)	11 (5.1)
State			
Australian Capital Territory	5 (1.1)	<5+	<5+
New South Wales	70 (16.1)	54 (24.3)	16 (7.5)
Northern Territory	<5+	0 (0)	<5+
Queensland	32 (7.3)	8 (3.6)	24 (11.2)
South Australia	89 (20.4)	34 (15.3)	55 (25.7)
Tasmania	<5+	0 (0)	<5+
Victoria	234 (53.7)	125 (56.3)	109 (50.9)
Western Australia	<5+	0 (0)	<5+
Not stated	<5+	0 (0)	<5+

+Where numbers are small, the registry indicates <5 to protect patient confidentiality.

The APFPR reports whether a procedure for SUI, POP or SUI+POP was a primary (first) procedure, or a subsequent procedure, which may be a revision procedure or a procedure to manage a complication or adverse outcome (from a primary procedure).

Table 4.3 shows that of the procedures performed related to SUI, 85% were primary (first) procedures; for POP 78% were primary (first procedures) and for SUI+POP, 92% were primary procedures. This means that the registry will be able to provide greater information at this point on primary procedures than subsequent procedures (see following chapters). As the APFPR data grows and matures, more information will be able to be analysed relating to revisions and procedures undertaken to manage complications.

Table 4.3: Summary of surgical indication by cohort

	SUI only, N (%)	POP only, N (%)	SUI+POP*, N (%)
Surgery indication^	**338**	**60**	**38**
Primary	287 (84.9)	47 (78.3)	35 (92.1)
Subsequent	47 (13.9)	13 (21.7)	<5+
Not stated	4 (1.2)	0 (0)	0 (0)

* Refers to procedures recorded in the registry to treat both a SUI and POP diagnosis.
^ A primary surgery indication refers to a procedure a patient receives to treat a specific pelvic floor diagnosis (e.g. mesh sling implantation); a subsequent indication refers to any procedure to address recurrence, complication or patient request relating to a previous procedure that may or may not have been recorded in the registry, such as a revision or explant procedure. Such procedures might have occurred before the establishment of the APFPR.
+ Where numbers are small, the registry indicates <5 to protect patient confidentiality.

CHAPTER 5. STRESS URINARY INCONTINENCE (SUI) PROCEDURES

Demographics

This section provides data in relation to patients who had either a primary or secondary procedure for SUI. The primary procedure is the first procedure the woman has undergone to treat the SUI, and may be a mesh sling procedure or a bulking agent procedure, noting that fascial slings and Burch colposuspensions are not yet collected by the APFPR, but will be from 2024 onwards. A subsequent procedure for SUI may either be a revision procedure or management of a complication from a previous SUI procedure.

The characteristics of women having these procedures is similar. The median age of women having SUI procedures is 60 years for mesh sling, 64 years for bulking agents, and 59 years for a subsequent procedure (Figure 5.1 & Table 5.1).

Note: Primary SUI procedures are stratified by procedure type in following analyses with 177 mesh sling and 98 bulking agent procedures; 12 procedures with type 'Other' are not presented due to insufficient sample size.

Figure 5.1: Patient age at registration for SUI procedures (n=322)

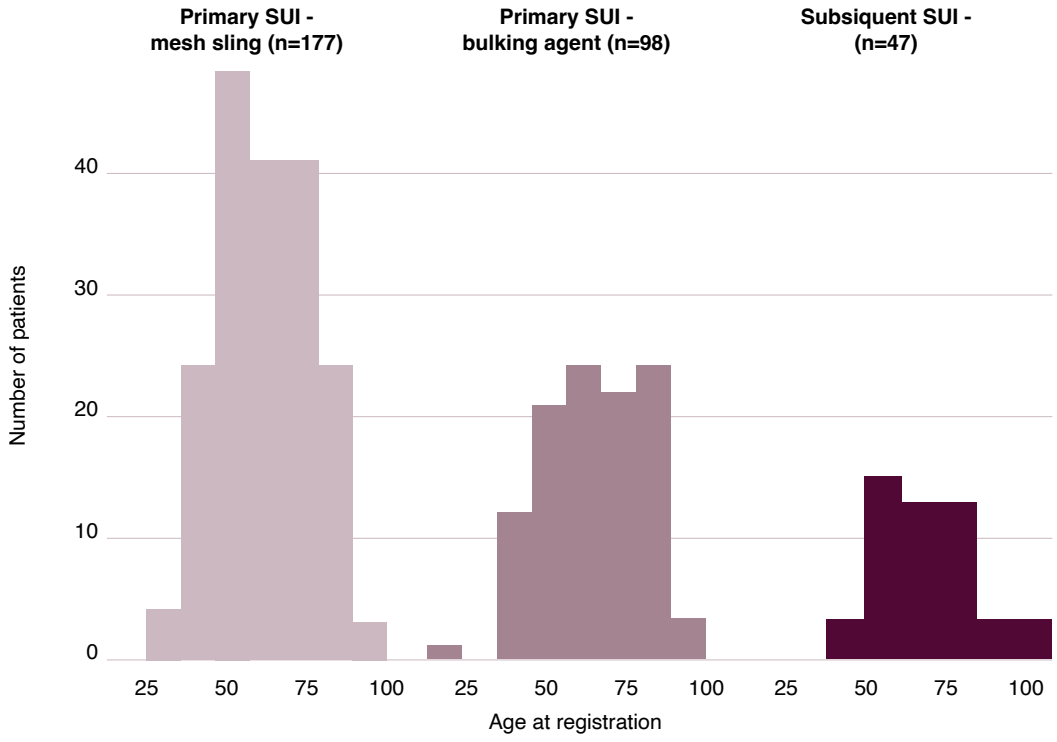


Table 5.1 presents the patient demographics. A higher proportion of women undergoing subsequent procedures were current smokers (13%) and had diabetes (13%) compared to primary sling procedures (6%, 10% respectively). Most women with SUI procedures were post-menopausal.

Table 5.1: Patient demographics for SUI procedures (n = 322)

Patient demographics	Primary SUI (sling), N (%)	Primary SUI (bulking), N (%)	Subsequent SUI, N (%)
N SUI surgery performed	**177**	**98**	**47**
Age at registration (years), mean (SD)	59.5 (13.7)	62.9 (14.6)	61.6 (12.3)
Age at registration (years), median (IQR)	60 (48, 71)	64 (54, 75)	59 (53, 70)
Patient risk factors*			
BMI, median (IQR)	28 (25, 32)	29 (26, 35)	29 (23, 34)
Current smoker	11 (6.2)	6 (6.1)	6 (12.8)
Diabetes	17 (9.6)	6 (6.1)	6 (12.8)
Post-menopause	106 (59.9)	69 (70.4)	31 (66.0)

*Note: Multiple responses allowed, row percentages shown

SUI clinical assessment

Clinical characteristics at the time of diagnosis for 322 women who underwent SUI procedures (mesh sling, bulking agents or subsequent procedure) are summarised in Table 5.2. Over 80% of primary participants underwent urodynamic studies, while a lower proportion was observed for subsequent procedures (32%). Pelvic floor comorbidities were more common in patients with subsequent than primary procedures. For those having subsequent procedures, the most common comorbidity was voiding dysfunction (36%). Fewer patients having a sling procedure reported a comorbidity compared to those having a bulking agent procedure. The most common comorbidity for those having sling procedures was dyspareunia, and the most common comorbidities for women having bulking agents were recurrent urinary tract infections and voiding dysfunction.

Table 5.2: Clinical characteristics for SUI procedures (n = 322)

Clinical characteristics at baseline	Primary SUI (sling), N (%)	Primary SUI (bulking), N (%)	Subsequent SUI, N (%)
N SUI surgery performed	**177**	**98**	**47**
Method of objective SUI assessment*			
Cough stress test	42 (23.7)	31 (31.6)	5 (10.6)
Urodynamic studies	154 (87.0)	83 (84.7)	15 (31.9)
Pad test	<5+	0 (0)	0 (0)
Other	<5+	<5+	<5+
Pelvic floor comorbidities*			
Recurrent urinary tract infections	10 (5.6)	16 (16.3)	13 (27.7)
Dyspareunia^	11 (6.2)	10 (10.2)	14 (29.8)
Pelvic pain	<5+	6 (6.1)	13 (27.7)
Voiding dysfunction/urinary retention	9 (5.1)	16 (16.3)	17 (36.2)
Catheter use	0 (0)	0 (0)	0 (0)

* Note: Multiple responses allowed, row percentages shown
^ Dyspareunia is a complaint of persistent or recurrent pain or discomfort associated with attempted or complete vaginal penetration[1]
+ Where numbers are small, the registry indicates <5 to protect patient confidentiality[1]

SUI procedure information

Table 5.3 provides the procedure information for the SUI cohort. Of the 177 primary sling procedures, 100% involved a prosthesis implant with a number also involving a concomitant non-mesh procedure, the most common being a non-mesh prolapse procedure. Of the 98 bulking agent procedures and the 47 subsequent SUI procedures, very few involved a concomitant procedure. 100% of mesh sling procedures included an intra-operative cystoscopy as well as 98% of bulking agent procedures and 96% of subsequent procedures. Very few intra-operative complications were reported.

Table 5.3: Procedure characteristics for SUI procedures (n= 322)

Procedure characteristics	Primary SUI (sling), N (%)	Primary SUI (bulking), N (%)	Subsequent SUI, N (%)
N SUI surgery performed	**177**	**98**	**47**
Surgical indication*			
Prosthesis implantation	177 (100)	0 (0)	<5+
Bulking agent	0 (0)	98 (100)	6 (12.8)
SUI complication	0 (0)	0 (0)	37 (78.7)
Asymptomatic SUI prosthesis removal (patient request)	0 (0)	0 (0)	<5+
Concomitant procedure*			
Native tissue	0 (0)	0 (0)	<5+
Prolapse	22 (12.4)	<5+	<5+
Hysterectomy	5 (2.8)	0 (0)	0 (0)
Perineorrhaphy	6 (3.4)	<5+	<5+
Additional POP procedure	10 (5.6)	<5+	0 (0)
POP complication	0 (0)	0 (0)	<5+
Other	<5+	<5+	<5+
Intra-operative cystoscopy			
Yes	177 (100)	96 (98.0)	45 (95.7)
No/not stated	0 (0)	<5+	<5+
Intra-operative complications*			
Blood loss >500ml	0 (0)	0 (0)	<5+
Other	<5+	<5+	0 (0)

+Where numbers are small, the registry indicates <5 to protect patient confidentiality
*Note: Multiple responses allowed, row percentages shown.

SUI implants: device information

Table 5.4 shows the prostethis type used in SUI procedures.

Table 5.4: Prosthesis type for SUI procedures (n=322)

Prosthesis type	Primary SUI (sling), N (%)	Primary SUI (bulking), N (%)	Subsequent SUI, N (%)
N SUI surgery performed	**177**	**98**	**47**
CT021 Supris Retropubic Sling	<5+	0 (0)	0 (0)
JJ070 Gynecare TVT Exact	139 (78.5)	0 (0)	0 (0)
MN039 Gynecare TVT ABBREVO Continence System	24 (13.6)	0 (0)	<5+
SC001 BULKAMID Urethral Bulking System	0 (0)	35 (35.7)	<5+
Other	12 (6.8)	63^ (64.3)	0 (0)
Not applicable	0 (0)	0 (0)	45 (95.7)

^Note: Prosthesis type data collection only recently made compulsory for bulking agent procedures, so historical entries have missing data and are listed as 'Other'
+Where numbers are small, the registry indicates <5 to protect patient confidentiality.

For SUI sling procedures, nearly 80% of procedures used Gynaecare TVT Exact mesh. For SUI bulking agent procedures, the main device noted was BULKAMID.

SUI outcomes

Of the participants with SUI surgery performed, 266 had a first post-operative visit recorded and outcomes are presented in Table 5.5. The median time to the first follow-up assessment was 44 days (approximately 6 weeks) for mesh sling, 39 days for bulking agents and 37 days (approximately 5 weeks) for subsequent procedures.

The majority of women with a primary procedure reported an improvement in their SUI status at the first post-operative visits (90% and 74%, respectively, for mesh sling and bulking agent), while only 41% with a subsequent procedure reported an improvement.

Low proportions of post-operative complication were reported at this follow-up visit. These included return to theatre, readmission to hospital, and being discharged with a catheter.

Table 5.5: Outcomes at first post-operative visit for SUI procedures (n=266)

Outcomes at first post-operative visit	Primary SUI (sling), N (%)	Primary SUI (bulking), N (%)	Subsequent SUI, N (%)
N SUI post-operative visit attended	**145**	**84**	**37**
Time to post-operative visit (days), median (IQR)	44 (40, 50)	39 (27, 46)	43 (30, 64)
SUI outcome status			
Improved	130 (89.7)	62 (73.8)	15 (40.5)
Same	7 (4.8)	19 (22.6)	9 (24.3)
Worse	<5+	<5+	9 (24.3)
Not evaluated	6 (4.1)	<5+	<5+
Complications*			
Return to theatre prior to discharge	<5+	0 (0)	0 (0)
Readmission within 30 days of surgery	8 (5.5)	<5+	<5+
Patient discharged requiring catheterisation	8 (5.5)	<5+	0 (0)
Other complication	5 (3.4)	0 (0)	<5+

*Note: Multiple responses allowed, row percentages shown
+Where numbers are small, the registry indicates <5 to protect patient confidentiality

A second post-operative visit was reported for 104 women who underwent an SUI procedure, and outcomes are noted in Table 5.6. The median time to the second follow-up visit was 197 days (6 - 7 months) for mesh sling, 140 days (4 - 5 months) for bulking agent and 115 days (3 - 4 months) for subsequent procedures. As for the first post-operative visit, an improvement in SUI status at the second visit was noted for most participants with a primary procedure (88% and 76%, respectively, for mesh sling and bulking agent) and a lower proportion of subsequent procedures reported an improvement (40%). There were few additional complications reported.

Table 5.6: Outcomes at second post-operative visit for SUI procedures (n=104)

Outcomes at second post-operative visit	Primary SUI (sling), N (%)	Primary SUI (bulking), N (%)	Subsequent SUI, N (%)
N second post-operative visit attended	**57**	**29**	**18**
Time to post-operative visit (days), median (IQR)	197 (155, 231)	140 (98, 176)	115 (44, 132)
SUI outcome status			
Improved	50 (87.7)	22 (75.9)	7 (38.9)
Same	7 (12.3)	7 (24.1)	7 (38.9)
Worse	0 (0)	0 (0)	<5+
Not evaluated	0 (0)	0 (0)	0 (0)
Complications*			
Return to theatre prior to discharge	<5+	<5+	0 (0)
Other complication	<5+	0 (0)	0 (0)

*Note: Multiple responses allowed, row percentages shown
+Where numbers are small, the registry indicates <5 to protect patient confidentiality

CHAPTER 6. PELVIC ORGAN PROLAPSE (POP), SUI-POP & EXPLANTATION PROCEDURES

Demographics

Age at registration for women with a primary POP procedure is presented in Figure 6.1, and patient demographics in Table 6.1. Median age was 68 years and over 90% of women were post-menopausal.

Figure 6.1: Patient age at recruitment for POP procedures

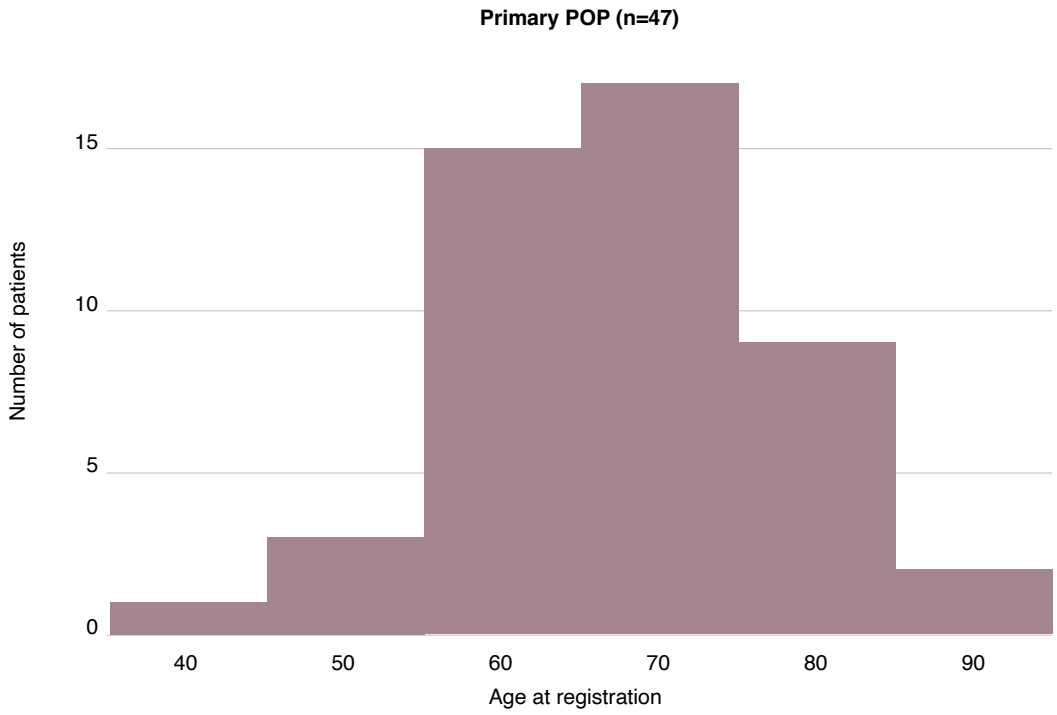


Table 6.1: Patient demographics for POP procedures

Patient demographics	Primary POP, N (%)
N SUI surgery performed	**47**
Age at registration (years), mean (SD)	67.6 (9.2)
Age at registration (years), median (IQR)	68 (63, 74)
Patient risk factors*	
BMI, median (IQR)	29 (26, 30)
Current smoker	<5+
Diabetes	<5+
Post-menopause	43 (91.5)

*Note: Multiple responses allowed, row percentages shown
+Where numbers are small, the registry indicates <5 to protect patient confidentiality

Clinical Assessment

Table 6.2 provides the clinical characteristics for the POP cohort; the POP Q was completed for most participants, and voiding dysfunction was the most common pelvic floor comorbidity (49%). Stage 3 presentation was the most common for all Anterior, Posterior and Apical stage presentations.

Pelvic Organ Prolapse Quantification (POPQ) Staging[14]:

0 - No prolapse is demonstrated

1 - Most distal portion of the prolapse is more than 1cm above the level of the hymen

2 - The most distal portion of the prolapse is situated between 1cm above the hymen and 1cm below the hymen

3 - The most distal portion of the prolapse is more than 1cm beyond the plane of the hymen but everted at least 2cm less than the total vaginal length.

POP procedure characteristics are presented in Table 6.3. Prolapse repair was the most common surgical procedure type (94%), with hysterectomy reported as a concomitant procedure for 11% of primary POP procedures. Intra-operative cystoscopy was performed for all participants.

Table 6.2: Clinical characteristics for POP procedures

Clinical characteristics	Primary POP, N (%)
N POP surgery performed	**47**
POP Q - Anterior Stage	
Stage 0/1	5 (10.6)
Stage 2	14 (29.8)
Stage 3	23 (48.9)
Stage 4	<5+
Not stated	<5+
POP Q - Apical Stage	
Stage 0/1	16 (34.0)
Stage 2	8 (17.0)
Stage 3	12 (25.5)
Stage 4	8 (17.0)
Not stated	<5+
POP Q - Posterior Stage	
Stage 0/1	12 (25.5)
Stage 2	13 (27.7)
Stage 3	15 (31.9)
Stage 4	5 (10.6)
Not stated	<5+
Pelvic floor comorbidities*	
Recurrent urinary tract infection	8 (17.0)
Dyspareunia^	5 (10.6)
Pelvic pain	<5+
Voiding dysfunction	23 (48.9)
Catheter use	0 (0)
POP symptoms*	
Bulge	39 (83.0)
Need to reduce	23 (48.9)

* Note: Multiple responses allowed, row percentages shown
^ Dyspareunia is a complaint of persistent or recurrent pain or discomfort associated with attempted or complete vaginal penetration[11]
+ Where numbers are small, the registry indicates <5 to protect patient confidentiality

Procedure Information

Table 6.3: Procedure characteristics for POP procedures

Procedure characteristics	Primary POP, N (%)
N POP surgery performed	**47**
Surgical indication*	
Prolapse repair	44 (93.6)
Additional POP procedure	<5+
POP complication	0 (0)
Asymptomatic POP prosthesis removal (patient request)	0 (0)
Concomitant procedure*	
Hysterectomy	5 (10.6)
Perineorrhaphy	<5+
Other	<5+
Intra-operative cystoscopy	
Yes	47 (100)
Intra-operative complications*	
Blood loss >500ml	<5+

* Note: Multiple responses allowed, row percentages shown
+ Where numbers are small, the registry indicates <5 to protect patient confidentiality

Of the women who underwent a primary POP procedure, 39 had a first post-operative visit recorded and these outcomes are summarised in Table 6.4. The median time to the first follow-up visit was 46 days (6 weeks). All participants had improved POP status at the first visit, and very few complications were reported.

Table 6.4: Outcomes at first post-operative visit for POP procedures

Outcomes at first post-operative visit	Primary POP, N (%)
N POP post-operative visit attended	**39**
Time to post-operative visit (days), median (IQR)	46 (40, 79)
POP outcome status	
Improved	39 (100)
Same	0 (0)
Worse	0 (0)
Not evaluated	0 (0)
Complications*	
Return to theatre prior to discharge	0 (0)
Readmission within 30 days of surgery	0 (0)
Patient discharged requiring catheterisation	0 (0)
Other complication	<5+

* Note: Multiple responses allowed, row percentages shown
+ Where numbers are small, the registry indicates <5 to protect patient confidentiality

SUI+POP cohort

Women who underwent both SUI+POP cohort procedures had a median age of 65 years, with 77% being post-menopausal (77%) (Figure 6.2).

Figure 6.2: Patient age at recruitment for SUI+POP procedures

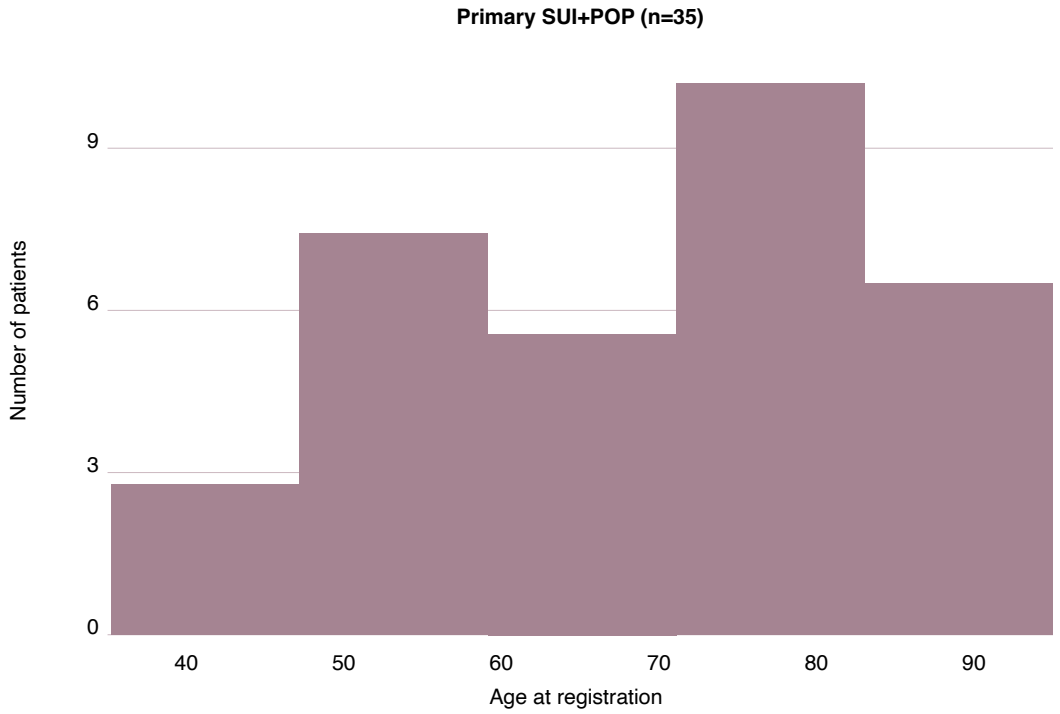


Table 6.5: Patient demographics for SUI+POP procedures

Patient demographics	Primary SUI + POP, N (%)
N SUI+POP surgery performed	**35**
Age at registration (years), mean (SD)	62.4 (13.2)
Age at registration (years), median (IQR)	65 (51, 72)
Patient risk factors*	
BMI, median (IQR)	27 (25, 34)
Current smoker	<5+
Diabetes	6 (17.1)
Post-menopause	27 (77.1)

* Note: Multiple responses allowed, row percentages shown
+ Where numbers are small, the registry indicates <5 to protect patient confidentiality

Clinical Assessment

The clinical characteristics for the SUI+POP cohort are presented in Table 6.6. Most women had urodynamic studies to assess SUI (77%), with the POP Q being reported in 86%. Dyspareunia was the most common pelvic floor comorbidity (14%), and women most commonly presented at Stage 3 (Anterior stage); Stage 0/1 (Apical stage) and Stage 2 (Posterior stage).

Table 6.6: Clinical characteristics for SUI+POP procedures

Clinical characteristics	Primary SUI + POP, N (%)
N SUI+POP surgery performed	**35**
Method of objective SUI assessment*	
Cough stress test	5 (14.3)
Urodynamic studies	27 (77.1)
Pad test	0 (0)
Cough test with prolapse reduction	0 (0)
Other	0 (0)
Not known/not done	0 (0)
POP Q - Anterior Stage	
Stage 0/1	6 (17.1)
Stage 2	11 (31.4)
Stage 3	13 (37.1)
Stage 4	0 (0)
Not stated	5 (14.3)
POP Q - Apical Stage	
Stage 0/1	21 (60)
Stage 2	<5+
Stage 3	5 (14.3)
Stage 4	0 (0)
Not stated	5 (14.3)
POP Q - Posterior Stage	
Stage 0/1	<5+
Stage 2	19 (54.3)
Stage 3	7 (20.0)
Stage 4	0 (0)
Not stated	5 (14.3)
Pelvic floor comorbidities*	
Recurrent urinary tract infection	<5+
Dyspareunia^	5 (14.3)
Pelvic pain	<5+
Voiding dysfunction	<5+
Catheter use	0 (0)
POP symptoms*	
Bulge	33 (94.3)
Need to reduce	7 (20.0)

* Note: Multiple responses allowed, row percentages shown
^ Dyspareunia is a complaint of persistent or recurrent pain or discomfort associated with attempted or complete vaginal penetration[11]
+ Where numbers are small, the registry indicates <5 to protect patient confidentiality

Procedure information

Table 6.7 provides the SUI+POP procedure characteristics, with prosthesis implantation and prolapse repair (94% and 83%, respectively) the most common surgical procedures. Over 30% had an associated hysterectomy. Intra-operative cystoscopy was performed for all women. The most common device used was Gynecare TVT mesh. Small numbers of intra-operative complications were noted.

Table 6.7: Procedure characteristics for SUI+POP procedures

Procedure characteristics	Primary SUI + POP, N (%)
N SUI+POP surgery performed	**35**
Surgical indication*	
Prosthesis implantation	33 (94.3)
SUI Complication	<5+
Prolapse repair	29 (82.9)
Additional POP procedure	5 (14.3)
Concomitant procedure*	
Native tissue	<5+
Hysterectomy	11 (31.4)
Perineorrhaphy	8 (22.9)
Other	<5+
Intra-operative cystoscopy	
Yes	35 (100)
SUI prothesis type	
CT021 Supris Retropubic Sling	0 (0)
JJ070 Gynecare TVT Single use device	25 (71.4)
MN039 Gynecare TVT ABBREVO Continence System	5 (14.3)
Other	<5+
Not applicable	<5+
Intra-operative complications (SUI)*	
Mesh Complication Classification Scale (MCCS~; coded)	<5+
Blood loss >500ml	0 (0)
Other	<5+
Intra-operative complications (POP)*	
Blood loss >500ml	<5+
Other	<5+

* Note: Multiple responses allowed, row percentages shown
+ Where numbers are small, the registry indicates <5 to protect patient confidentiality
~ https://www.ics.org/complication

Post-operative follow-up

Of the primary SUI+POP participants who had surgery performed, 31 had a first post-operative visit recorded and outcomes are summarised in Table 6.8. The median time to first follow-up visit was 46 days (approximately 6 weeks). Over 90% of women reported an improvement in both their SUI and POP status at this visit (94% and 90%, respectively), and few complications were reported.

Table 6.8: Outcomes at first post-operative visit for SUI+POP procedures

Outcomes at first post-operative visit	Primary SUI + POP, N (%)
N SUI+POP post-operative visit attended	**31**
Time to post-operative visit (days), median (IQR)	46 (40, 48)
SUI outcome status	
Improved	29 (93.5)
Same	<5+
Worse	0 (0)
POP outcome status	
Improved	28 (90.3)
Same	<5+
Worse	0 (0)
Complications*	
Return to theatre prior to discharge	0 (0)
Readmission within 30 days of surgery (SUI)	<5+
Readmission within 30 days of surgery (POP)	0 (0)
Patient discharged requiring catheterisation	<5+
SUI complication	<5+
POP complication	0 (0)

* Note: Multiple responses allowed, row percentages shown
+ Where numbers are small, the registry indicates <5 to protect patient confidentiality

Mesh Explantation Procedures

For the first time, the APFPR is presenting very early registry data regarding mesh removal (excision) procedures. Data as of September 2023 included 26 procedures related to mesh excision with 35 indications (reasons for excision), hence many procedures included more than one indication. The most common indications for mesh excision were pain (37.1%), mesh exposure (34.3%) and voiding dysfunction (11.4%) (Table 6.9).

Table 6.9: Indication for mesh excision (all types; n=26; multiple indications can be recorded per patient)

	% (of indications)
Pain	37.1%
Mesh exposure	34.3%
Voiding dysfunction	11.4%
Infection	5.7%
Other (haemorrhage, clinician-observed exposure, patient request)	2.9%
Total indications recorded	100.0%

Of the 26 procedures undertaken for mesh removal, the most common procedure was partial mesh removal (65.4%), followed by complete mesh removal (26.9%) and extra-vaginal mesh excision (7.7%; see Table 6.10).

Table 6.10: Mesh excision type (n=26)

	%
Complete	26.9%
Partial	65.4%
Extra-vaginal	7.7%
Total	100.0%

Twenty-six patients were reviewed at the first post-operative visit. The early post-operative outcomes are presented related to the indication for surgery. The data (see Table 6.11) suggests that at least 50% of presenting symptoms/issues either resolved or improved e.g. 50% of voiding dysfunction; 50% of infections; 67% of mesh exposures; 54% of pain presentations; and 75% of 'other'. There is some missing data noted where post-operative visit information is not reported. The APFPR acknowledges that this is very early data and is expected to change as it matures.

Table 6.11: First post-operative visit

	N	Resolved (%)	Improved (%)	Same (%)	Worse (%)	Not stated (%)
Pain	13	23.1%	30.8%	7.7%	23.1%	15.4%
Mesh exposure	12	66.7%	0%	0%	0%	33.3%
Voiding dysfunction	<5+	25%	25%	25%	0%	25%
Infection	<5+	50%	0%	50%	0%	0%
Other (haemorrhage, clinician-observed exposure, patient request)	<5+	50%	25%	0%	0%	25%

+ Where numbers are small, the registry indicates <5 to protect patient confidentiality

CHAPTER 7. CLINICAL INDICATORS AND PATIENT-REPORTED OUTCOMES

Clinical Quality Indicators

Clinical Quality Indicators (CQIs) are measures of performance, that capture how well the care provided aligns with best practice (process measures) as well as the clinical outcomes obtained (outcome measures such as efficacy/clinical improvement, or complications/adverse events). An initial set of clinical quality indicators were derived from the minimum data set and developed by the APFPR Steering Committee. They are reported for the first time publicly in this report. As the APFPR matures, less common complications and adverse events will also be reported.

The clinical quality indicators (CQIs) are summarised in Table 7.1. **Process indicators** include the presence of objective clinical assessment for both SUI and POP procedures (e.g. urodynamic studies for SUI or the POP Q score for POP). **Outcome indicators** include efficacy outcomes as well as complication rates for return to theatre, readmission within 30 days and discharge requiring catheterisation.

Regarding the process indicators, most primary participants underwent objective clinical assessment (90% and 92% for SUI and POP/SUI+POP, respectively). Intra-operative cystoscopy was performed in almost all women who underwent primary procedures (99% and 100% respectively). Efficacy was high for both SUI and POP procedures, with 84% of primary SUI participants and 96% of primary POP/ SUI+POP participants reporting improvement. Of the surgical complications, readmission within 30 days and discharged requiring catheterisation for primary procedures were the most common (4% and 5%, respectively). Return to theatre was very rare for primary and subsequent procedures (<1%).

Table 7.1: Summary of the clinical quality indicators

Type	Category	Name	Description	N Eligible	N (%)
Process Indicator	Objective clinical assessment	SUI urodynamics	Proportion of primary SUI patients who had urodynamics or cough stress test	287	257 (89.5)
		POP Q complete	Proportion of primary POP and SUI+POP patients who had POP Q completed	82	75 (91.5)
	Post-procedure assessment	SUI intra-operative cystoscopy	Proportion of primary SUI patients who had intra-operative cystoscopy	287	285 (99.3)
		POP intra-operative cystoscopy	Proportion of primary POP and SUI+POP patients who had intra-operative cystoscopy	82	82 (100)
Outcome Indicator	Efficacy	SUI outcome	Proportion of primary SUI patients with 'improved' SUI at the first post-operative visit	241	203 (84.2)
		POP outcome	Proportion of primary POP or SUI+POP patients with 'improved' POP at the first post-operative visit	70	67 (95.7)
	Return to theatre	Return to theatre prior to discharge (primary)	Proportion of primary patients with return to theatre prior to discharge	311	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	311	11 (3.5)
		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	311	15 (4.8)
		Patient discharged requiring catheterisation (subsequent)	Proportion of subsequent procedure patients discharged requiring catheterisation	51	0 (0)

Patient Reported Outcome Measures

The collection of patient-reported outcome measures (PROMs) is a critical registry activity that provides additional information regarding women's perspectives of their clinical outcomes from surgery.

Patient-reported outcome measures (PROMs) are standardised questionnaires that collect information on health outcomes directly from patients, including information related to symptoms, health related quality of life (HRQoL) and functional status.[15] PROMs collection by the Australasian Pelvic Floor Procedure Registry (APFPR) provides information about the effectiveness of pelvic floor procedures, as well as complications and mesh-related adverse events, to facilitate safety monitoring.

In 2022-23, the APFPR conducted a pilot PROMs study involving patients diagnosed with stress urinary incontinence (SUI) and pelvic organ prolapse (POP) recruited through certain sites. The aim of the study was to assess the feasibility of collecting PROMs, and the most effective methods of collection. Women recruited to the APFPR were invited to complete PROMs at baseline (before surgery) and at 6-months post-surgery for a period of approximately 9 months from July 2022 to March 2023. The results of the pilot were presented to the APFPR Steering Committee in June 2023 and it was agreed the APFPR should continue to collect post-operative PROMs for all women who participate, and who do not opt-out.

The Australian Pelvic Floor Questionnaire

Following a process that included qualitative feedback from women and clinicians, the Australian Pelvic Floor Questionnaire (APFQ)[16] was selected as the PROMs questionnaire to use for the APFPR PROMs pilot. The questionnaire was disseminated to participants through a combination of email, postal mail, SMS and on site (within a clinic). If no response was received within two weeks, patients were followed up by phone.

The APFQ was administered to 156 women at baseline and 185 at 6 months follow-up at 16 registry sites from 9 July 2022 to 15 September 2023 in New South Wales, South Australia, Queensland and Victoria (Table 7.2). This data collection included both collection of baseline (pre-operative) PROMs from the 156 women involved in the PROMs pilot, as well as PROMs at 6 months post-procedure from women involved in the PROMs pilot study, and others recruited through newer participating sites. This explains why there are more responses at 6 months than at baseline. The majority of PROMs were collected from women who had procedures for SUI.

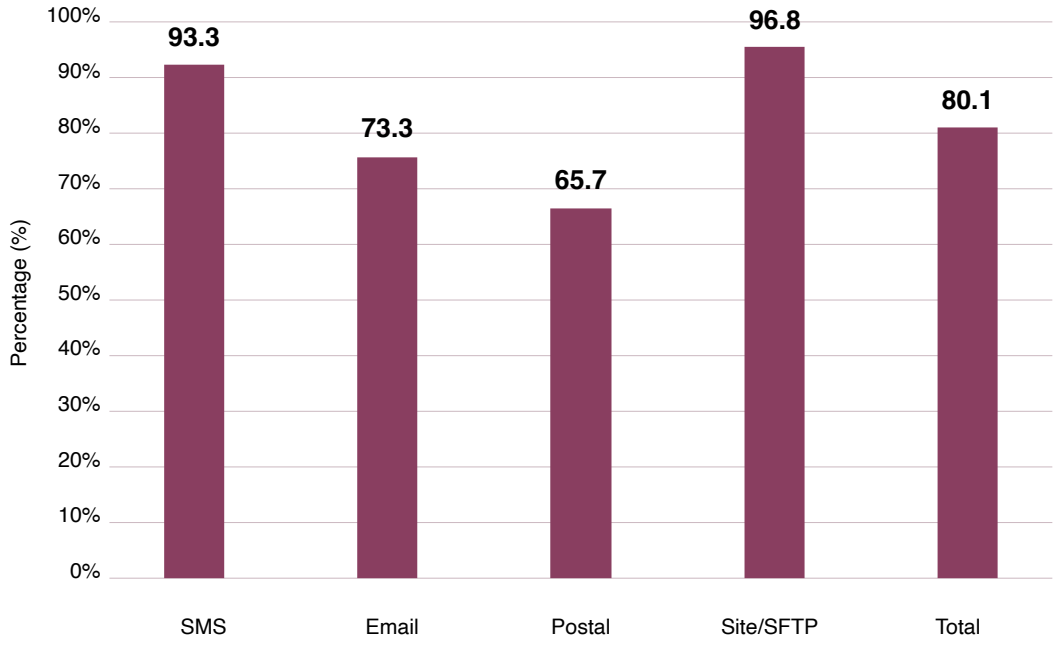
Table 7.2: Participant characteristics

Age category	Baseline (n, %) N - 156	6 months (n, %) N = 185
<35	3 (1.9)	4 (2.2)
36-45	17 (10.9)	27 (14.5)
46-55	41 (26.3)	44 (23.7)
56-65	27 (17.3)	38 (20.4)
66-75	44 (28.2)	51 (27.4)
76-85	22 (14.1)	17 (9.1)
>86	2 (1.3)	2 (1.1)
Age unknown	-	2 (1.1)
Surgery related to SUI	123 (78.8)	147 (79.5)
Surgery related to POP	15 (9.6)	22 (11.9)
Surgery related to both SUI and POP	18 (11.5)	16 (8.6)

PROMs Response Rates by Mode of Administration at Baseline

PROMs were collected initially via a variety of methods to determine which methods would result in the highest response rates. The overall response rate for baseline PROMs was 125 completed out of 156 (80.1%), with patients completing PROMs via email, postal or SMS mode of administration (see Figure 7.1).

Figure 7.1: PROMs response rate by mode of administration at baseline (n = 125)



The highest response rate was observed for the site (within a clinic) mode of administration. The site method comprised of three participating hospitals that sent PROMs to their patients, of which 30 out of 31 responded (96.8%). These hospitals then uploaded these results to the registry via Secure File Transfer Protocol (SFTP).

The next highest response rate was for PROMs that were administered to patients via SMS (text message). Twenty-eight of 30 patients completed PROMs via SMS with a response rate of 93.3%. PROMs were also administered via email to 60 patients with 44 of them completing (73.3% response). The lowest response rate was 65.7% which was observed in those who received the PROMs by post (see Table 7.3).

Table 7.3: PROMs response rate by mode of administration at baseline, rates and counts

	PROMs Sent (n)	PROMs Completed (n)	Response Rate (%)
Total	156	125	80.1
Site/SFTP	31	30	96.8
SMS	30	28	93.3
Email	60	44	73.3
Postal	35	23	65.7

PROMs Response Rates by Mode of Administration at 6 months

The PROMs response rate at 6 months decreased to 76.2% (see Figure 7.2), with 185 PROMs sent and 141 completed.

The number of PROMs sent and completed by mode of administration at 6 months is shown at Table 7.4. PROMs at 6 months were only collected by the registry; hospitals did not directly collect follow up PROMs. The highest response rate was observed in those who completed questionnaires by SMS with 127 of 162 completing their PROMs with the response rate of 78.4%. Lower response rates were observed for email (60%) and post (66.7%).

Figure 7.2: PROMs response rate by mode of administration at 6 months (n = 141)

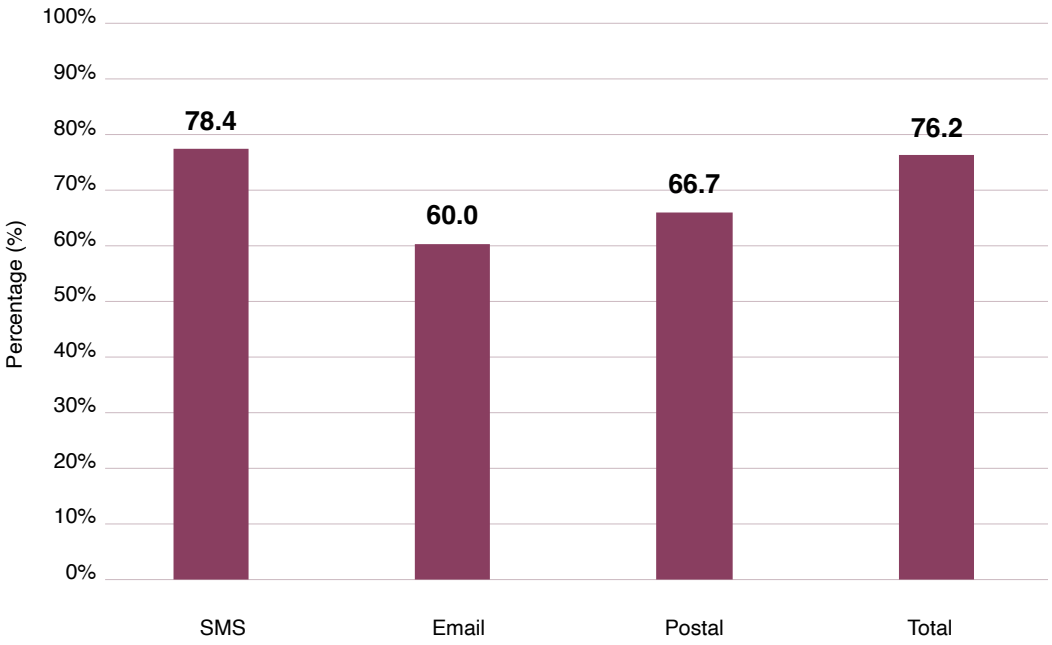


Table 7.4: PROMs response rate by mode of administration at 6 months

	PROMs Sent (n)	PROMs Completed (n)	Response Rate (%)
Total	**185**	**141**	**76.2**
SMS	162	127	78.4
Email	20	12	60.0
Postal	3	2	66.7

Following this initial study, PROMs for the APFPR continue to be collected via SMS (text message) where a mobile phone number is available, and by email or post when those contact details are available, at post-operative timepoints only: 6-, 12- and 24-months post procedure.

The APFQ scores

The APFQ is composed of 42 questions, divided into four independent domains: bladder function, bowel function, prolapse symptoms and sexual function. Each question in the APFQ is scored from 0 to 3, with the total possible bladder function score of 45, bowel function score of 34, prolapse symptoms of 15, and sexual function of 21[17]. Patient scores are divided by the number of questions within each domain and multiplied by 10, giving a value between 0 and 10 for each of the four domains, and a maximum total pelvic floor dysfunction score of 40.

The higher the score, the worse the symptoms/function i.e. a low score is 'good'. If women are not sexually active because of pelvic floor dysfunction, they will obtain a score of 8.5 (18/21) in the sexual domain.

Changes of approximately 1 in the appropriate pelvic floor domain can be considered clinically important differences. The average APFQ scores in those who completed PROMs at baseline and 6 months show clinically important differences in the domains of bladder and prolapse, with no difference in bowel domain and a slight increase in the sexual function domain (Table 7.5). The sexual domain scores are difficult to interpret due to potential changes in sexual activity and post-operative effects, and will be monitored.

Table 7.5: Mean (SD) scores at baseline and 6 months (PROMs)

Domain	Baseline (N=125)	6 months (N=141)	Difference
Total pelvic floor dysfunction	**14.47 (5.87)**	**12.12 (6.37)**	**-2.35**
Prolapse	2.74 (3.03)	1.09 (2.14)	-1.65
Bladder	4.16 (1.72)	2.95 (2.09)	-1.21
Bowel	2.41 (1.49)	2.41 (1.59)	0
Sexual dysfunction	5.17 (3.2)	5.66 (3.39)	0.49

The distribution of total pelvic floor dysfunction, prolapse, bladder, bowel, and sexual health dysfunction scores for all patients who completed the APFQ at baseline and at 6 – months post-op is shown in Figures 7.3-7.7. The higher proportion of women with lower scores at 6 months (i.e. a 'shift of the graph to the left') indicates better perception of their health when compared to before the procedure baseline (referred to as baseline).

These figures show results from the same survey that were given to patients before their operation and 6-months following. This survey asks questions about many specific pelvic floor symptoms/ problems that the surgery aims to improve.

By asking the survey pre-operatively and then 6 months later, we can see how much the initial symptoms/problems improved following the surgery.

The survey results in a higher score if the woman responds that she has lots of symptoms/ problems.

Figure 7.3 shows the APFQ Total pelvic floor dysfunction score distribution for all patients who completed the APFQ at baseline and 6-months post-op. (Note, the lower the score, the better the perception of overall health). Patient counts are shown in boxes next to each bar.

Figure 7.3: Patient distribution, Total pelvic floor dysfunction

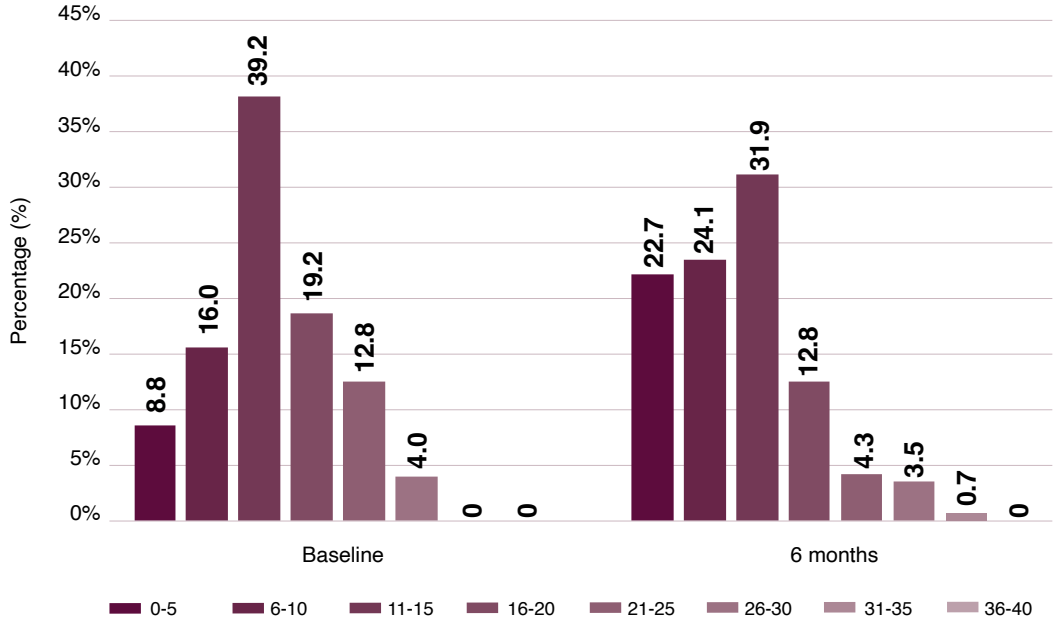


Figure 7.4 shows the APFQ Prolapse score distribution for all patients who completed the APFQ at baseline and 6-months post-op. (Note, the lower the score, the better the perception of overall health). Patient counts are shown in boxes next to each bar.

Figure 7.4: Patient distribution, Prolapse domain

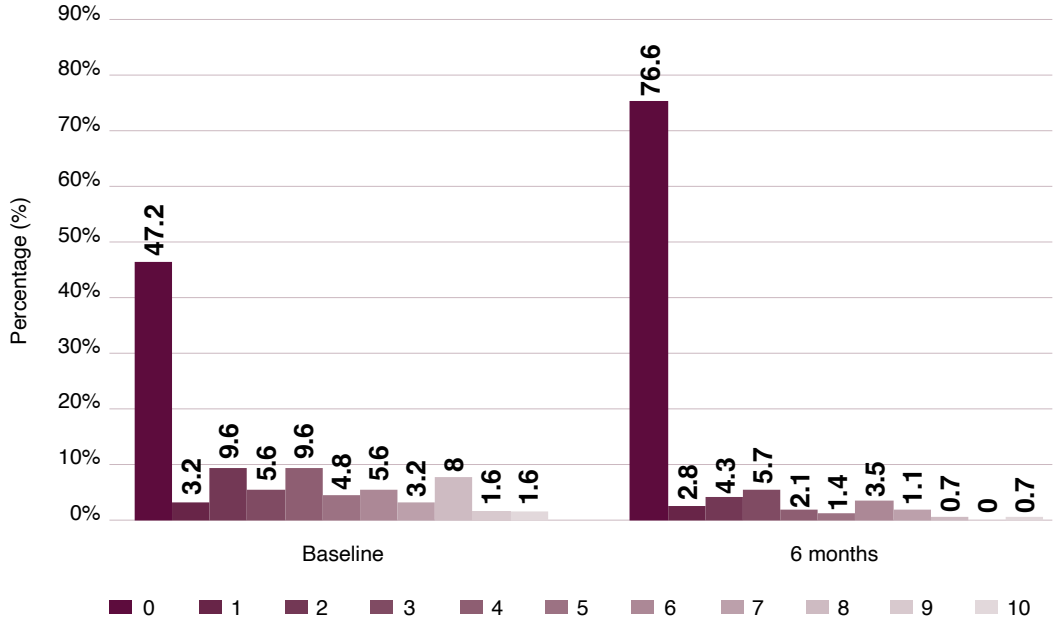


Figure 7.5 shows a higher proportion of women with scores of 0-2 post-operatively, compared with pre-operatively (a shift to the left). The figure shows the APFQ Bladder score distribution for all patients who completed the APFQ at baseline and 6-months post-op. (Note, the lower the score, the better the perception of overall health). Patient counts are shown in boxes next to each bar.

Figure 7.5:Patient distribution, Bladder domain

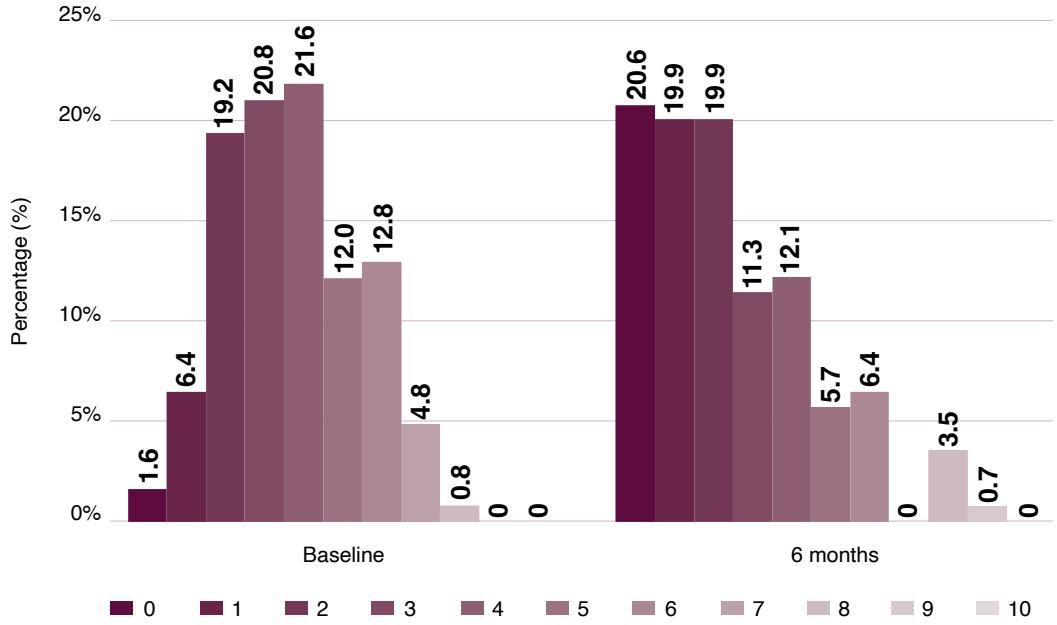


Figure 7.6 shows the APFQ Bowel score distribution for all patients who completed the APFQ at baseline and 6-months post-op. (Note, the lower the score, the better the perception of overall health). Patient counts are shown in boxes next to each bar.

Figure 7.6: Patient distribution, Bowel domain

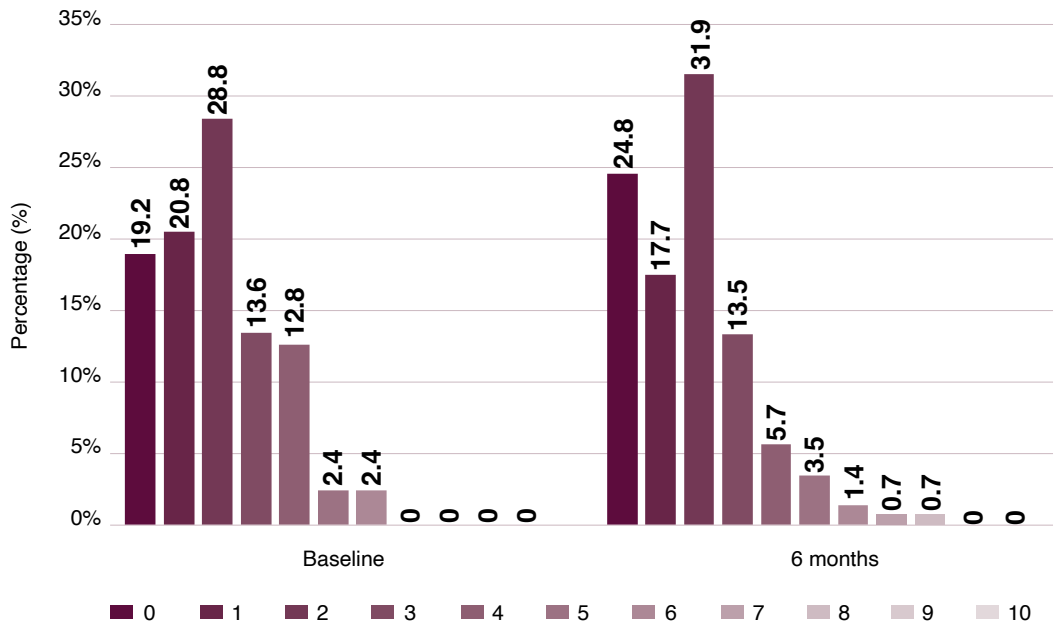
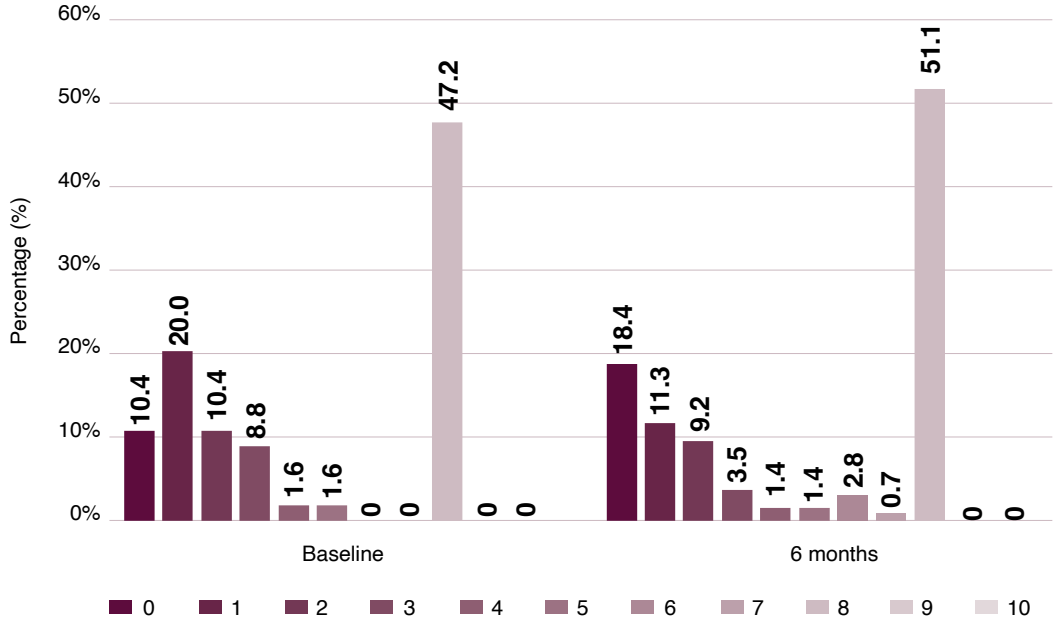


Figure 7.7 shows the APFQ Sexual dysfunction score distribution for all patients who completed the APFQ at baseline and 6-months post-op. (Note, the lower the score, the better the perception of overall health). Patient counts are shown in boxes next to each bar.

Figure 7.7: Patient distribution, Sexual dysfunction



The APFPR would like to acknowledge the contributions of APFPR Consumer Representatives and the APFPR Consumer Reference group, in providing detailed feedback about the choice of questionnaires adopted by the APFPR.

CHAPTER 8. ACADEMIC OUTPUTS

Publications

Ralphsmith M, Ahern S, Dean J, O'Connell HE, Ruseckaite R. Development of a conceptual framework for a new patient-reported outcome measure for pain in women following mesh surgery for pelvic floor disorders: a qualitative study. Int Urogynecol J. 2023 Jul;34(7):1541-1550. doi: 10.1007/s00192-022-05425-w. Epub 2022 Dec 20.

Jayasinghe RT, Ruseckaite R, Dean J, Kartik A, Wickremasinghe AC, Daly O, O'Connell HE, Craig A, Duggan A, Vasiliadis D, Karantanis E, Gallagher E, Holme G, Keck J, Williams J, King J, Yin J, Short J, Sketcher-Baker K, Brennan P, Rayner S, Ahern S. Establishment and initial implementation of the Australasian Pelvic Floor Procedure Registry. Int Urogynecol J. 2023 Jan 25. doi: 10.1007/s00192-022-05435-8. Epub ahead of print. PMID: 36695860.

Ruseckaite R, Jayasinghe RT, Bavor C, Dean J, Daly JO, Ahern S. Evaluation and acceptability of patient-reported outcome measures in women following pelvic organ prolapse procedures. BMC Health Serv Res. 2023 Jun 13;23(1):624. doi: 10.1186/s12913-023-09540-2.

Aruna K. Clinical Quality Indicators using Australasian Pelvic Floor Procedure Registry clinical data. Australian and New Zealand Continence Journal. 2023;29(4)

CHAPTER 9. FUTURE DIRECTIONS

In line with the completion of establishment phase activities, the upcoming program of work for the APFPR will focus on the refinement and improvement of the current dataset, ongoing recognition of participating sites and clinicians through awards and the provision of site reports, efforts to increase participation and site engagement, and future research activities.

Improvements

The APFPR will continue to review and reflect on database requirements and the minimum dataset. Currently, the Registry is working towards relaunching a more streamlined dataset with SUI native tissue procedures included.

Recognition and reporting

In recognition of the significant contribution made by our participating sites and clinicians to date, the APFPR will continue providing site reports in 2024, and more recognition awards going forward. In 2024, a greater number of sites with sufficient patient numbers as well as an increase in reported procedures is expected, enabling the development and distribution of more comprehensive reports. When PROMs data is sufficiently mature at a site level, these data will also be included.

Expansion

The APFPR is working with a public hospital in Western Australia to enable participation in line with Western Australia's patient consent regulations (opt-in). The APFPR hopes this will pave the way for participation for other public hospitals in the state. The APFPR also hopes to welcome New Zealand clinicians as participants to the registry during 2024.

PROMs and consumer engagement

The PROMs captured are expected to begin providing key insights into medium term clinical outcomes for women undergoing pelvic floor procedures, and PROMs collection will continue to be refined. The APFPR will also continue to pursue its commitment to further consumer engagement, specifically in producing a patient guide.

Research

As the number of patients recorded in the APFPR approaches the 1,000 mark (a target which is expected to be met in in the first quarter of 2024), the APFPR anticipates the ability to undertake more in-depth studies and will be encouraging clinicians and researchers to submit requests for data and/or collaborative research proposals.

ACRONYMS & ABBREVIATIONS

Abbreviation	Description
ACHI	Australian Classification of Health Interventions
AIHW	Australian Institute of Health and Welfare
APFPR	Australasian Pelvic Floor Procedure Registry
APFQ	Australian Pelvic Floor Questionnaire
ARTG	Australian Register of Therapeutic Goods
ASM	Annual Scientific Meeting
BMI	Body Mass Index
CPD	Continuing Professional Development
CSSANZ	Colorectal Surgery Society of Australia and New Zealand
CQR	Clinical Quality Registry
IQR	Inter-quartile range (Statistical measure)
IUGA	International Urogynecological Association
MBS	Medicare Benefits Schedule
MCCS	Mesh Complication Classification Scale
MDS	Minimum dataset
NHMD	National Hospital Morbidity Database
NMA	National Mutual Acceptance Scheme
NSW	New South Wales
NZ	New Zealand
POP	Pelvic Organ Prolapse
PROMs	Patient reported Outcome Measures
QLD	Queensland
RACS	Royal Australasian College of Surgeons
RANZCOG	Royal Australian and New Zealand College of Obstetrics and Gynaecology
REDCap	Research Electronic Data Capture
SA	South Australia
SD	Standard Deviation (Statistical measure)
SUI	Stress Urinary Incontinence
TGA	Therapeutic Goods Administration
UGSA	Urogynaecological Society of Australia
USANZ	Urological Society of Australia and New Zealand
UDI	Unique Device Identifier
UTI	Urinary Tract Infection
VIC	Victoria

REFERENCES

1 MacLennan AH, Taylor AW, Wilson DH, Wilson D. The prevalence of pelvic floor disorders and their relationship to gender, age, parity and mode of delivery. BJOG. 2000;107(12):1460-70.

2 Smith F, Holman C, Moorin R, Tsokos N. Lifetime Risk of Undergoing Surgery for Pelvic Organ Prolapse. Obstetrics & Gynecology. 2010;116(5):1096-100.

3 Deloitte Access Economics. Economic Impact of Incontinence in Australia. Canberra: Continence Foundation of Australia; 2011 Available from: https://www2.deloitte.com/content/dam/Deloitte/au/Documents/Economics/deloitte-au-economics-impact-incontinence-australia-190411.pdf

4 Ministers Department of Health. $2.3 million to improve safety of pelvic floor surgery (Media release). Canberra: Commonwealth of Australia; 2019 Available from: https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/ media/23-million-to-improve-safety-of-pelvic-floor-surgery.

5 International Urogynaecological Association. Your pelvic floor: Patient information Leaflets. 2022; Available from: https://www.yourpelvicfloor.org/leaflets/

6 Parliament of Australia The Senate Community Affairs References Committee. Number of women in Australia who have had transvaginal mesh implants and related matters: Report. Canberra: Commonwealth of Australia; 2018. Available from: https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/MeshImplants

7 Department of Health and Aged Care Therapeutic Goods Administration. Urogynaecological(transvaginal) surgical mesh hub. Canberra: Commonwealth of Australia; 2023.

8 Australian Commission on Safety and Quality in Health Care. Guidance for Hospital Credentialing of Senior Medical Practitioners to Undertake Transvaginal Mesh Surgery for Stress Urinary Incontinence: Patient Outcome monitoring and reporting. Sydney: AUSTRALIAN COMMISSION FOR SAFETY AND QUALITY IN HEALTH CARE ; 2018 Available from: https://www.safetyandquality.gov.au/sites/ default/files/migrated/Credentialing-of-Senior-Medical-Practitioners-to-Undertake-Transvaginal-Mesh-Implant- Surgery-forStress-Urinary-Incontinence.pdf.

9 Australian Commission on Safety and Quality in Health Care. Guidance for Hospital Credentialing for the Removal of Transvaginal TV Mesh. Sydney: AUSTRALIAN COMMISSION FOR SAFETY AND QUALITY IN HEALTH CARE ; 2018 Available from: https://www.safetyandquality.gov. au/publications-and-resources/resource-library/guidance-hospital-credentialing-removal-transvaginal-tv-mesh.

10 Prescribe an unapproved therapeutic good (health practitioners) | Therapeutic Goods Administration (TGA)

11 National Health and Medical Research Council, Australian ResearchCouncil and Universities Australia (2023). National Statement on EthicalConduct in Human Research. Canberra: National Health and MedicalResearch Council.

12 PA Harris, R Taylor, R Thielke, J Payne, N Gonzalez, JG. Conde, Research electronic data capture (REDCap) – A metadata-driven methodology and workflow process for providing translational research informatics support, J Biomed Inform. 2009 Apr;42(2):377-81.

13 PA Harris, R Taylor, BL Minor, V Elliott, M Fernandez, L O'Neal, L McLeod, G Delacqua, F Delacqua, J Kirby, SN Duda, REDCap Consortium, The REDCap consortium: Building an international community of software partners, J Biomed Inform. 2019 May 9 [doi: 10.1016/j.jbi.2019.103208]0

14 The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. Richard C. Bump (MD), Anders Mattiasson (MD), Kari Bø (PhD), Linda P. Brubaker (MD), John O.L. DeLancey (MD), Peter Klarskov (MD, PhD), Bob L. Shull (MD), Anthony R.B. Smith (MD), AM J Obstet Gynecol. DOI:https://doi.org/10.1016/S0002-9378(96)70243-0

15 US. Food and Drug Administration Guidance for industry: patient-reported outcome measures: use in medical product development to support labeling claims. (2006). Health Qual Life Outcomes, 4(1):79. doi: 10.1186/1477-7525-4-79.

16 Baessler K, O'Neill SM, Maher CF, Battistutta D. Australian pelvic floor questionnaire: a validated interviewer-administered pelvic floor questionnaire for routine clinic and research. Int Urogynecol J Pelvic Floor Dysfunct. 2009 Feb;20(2):149-58. doi: 10.1007/s00192-008-0742-4. Epub 2008 Oct 29. PMID: 18958382.

17 Baessler K, Mowat A, Maher CF. The minimal important difference of the Australian Pelvic Floor Questionnaire. Int Urogynecol J. 2019 Jan;30(1):115-122. doi: 10.1007/s00192-018-3724-1. Epub 2018 Aug 7. PMID: 30088031.

LIST OF FIGURES

LIST OF TABLES

APPENDICES

APPENDIX I. DATA ITEMS

Figure 1: Data items collected by the APFPR

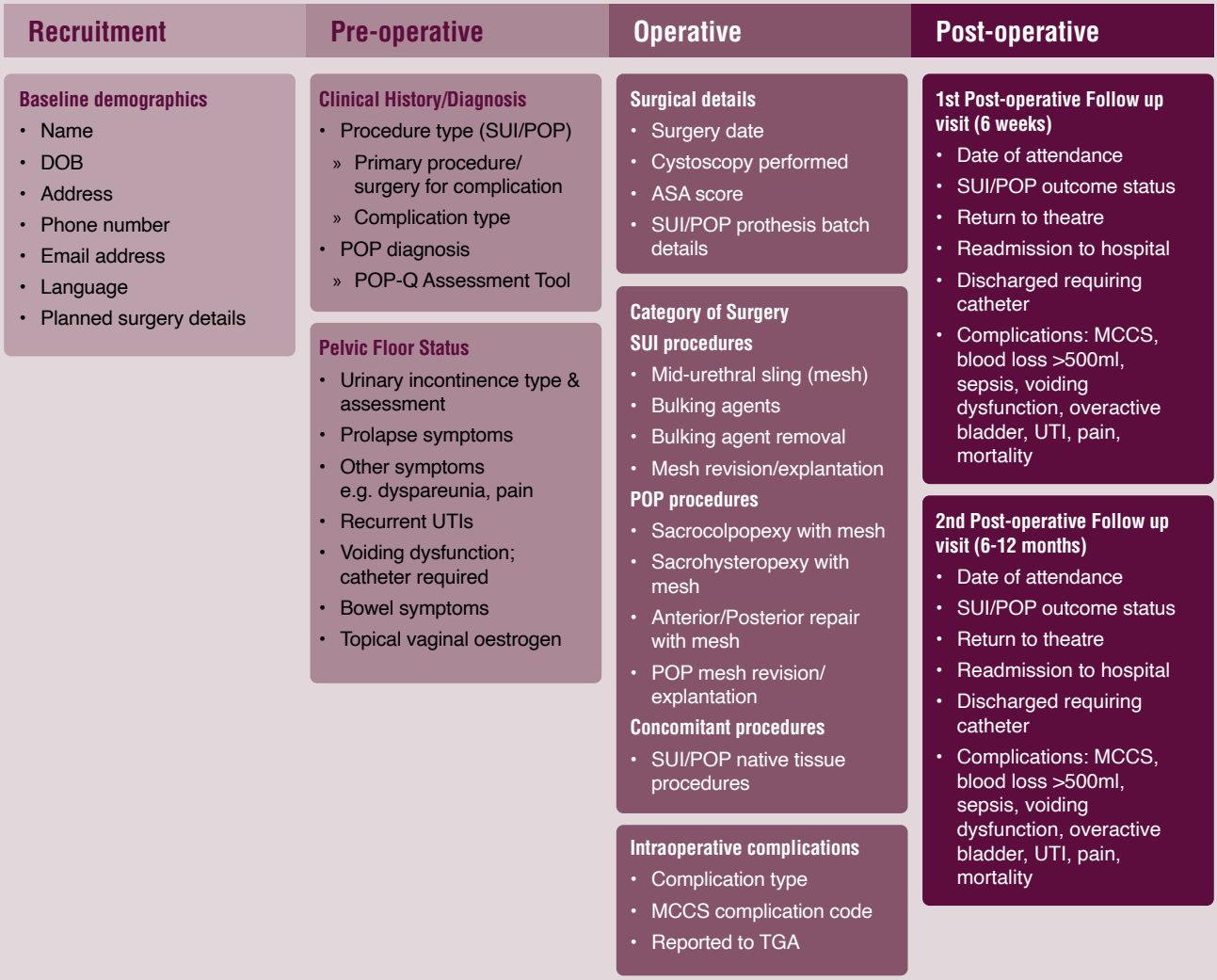
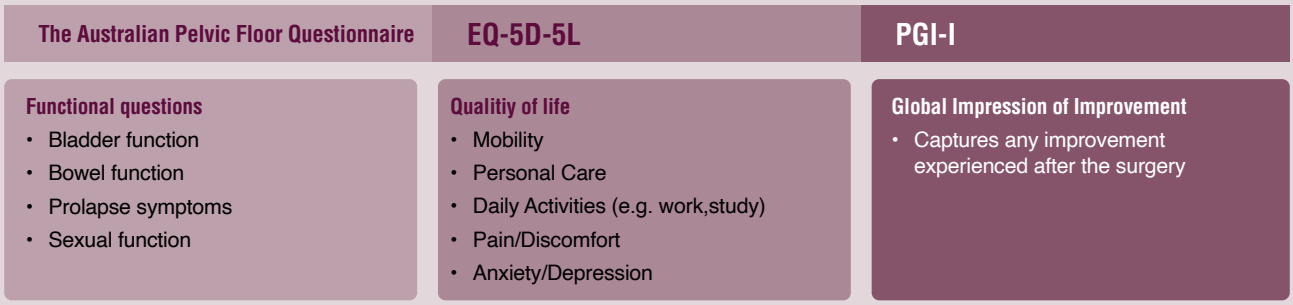


Figure 2: PROMs data Items collected by the APFPR



- The data items have been reviewed and will be streamlined in 2023.
- Autologous Fascial Sling and Burch Colposuspension procedures will be included in 2024.

APPENDIX II. DATA COMPLETENESS

Table 1: Data Field Completeness, by Data Collection Form

Variable	% Data Field Completeness
Registration form (cohort, N)	
DOB (all, n=758)	99.9%
Language (all, n=758)	99.5%
Postcode (all, n=758)	99.5%
Surgery form (cohort, N)	
Surgery type (SUI/POP) (all, n=436)	100%
SUI Surgery indication (SUI, n=338)	98.8%
SUI Surgery indication (SUI+POP, n=38)	100%
POP Surgery indication (POP, n=60)	100%
POP Surgery indication (SUI+POP, n=38)	94.7%
Cystoscopy performed (all, n=436)	99.3%
Objective evidence SUI (SUI, n=338)	81.7%
Objective evidence SUI (SUI+POP, n=38)	78.9%
POP-Q complete (POP, n=60)	75.0%
POP-Q complete (SUI+POP, n=38)	78.9%
First post-op visit form (cohort, N)	
SUI outcome status (SUI, n=280)	98.9%
SUI outcome status (SUI+POP, n=32)	96.9%
POP outcome status (POP, n=51)	98.0%
POP outcome status (SUI+POP, n=32)	93.8%
Return to theatre (all, n=363)	100%
Catheterisation (all, n=363)	100%
SUI Readmission (SUI, n=280)	99.6%
SUI Readmission (SUI+POP, n=32)	96.9%

APPENDIX III. PARTICIPATING SITES

Table 1. List of participating sites (as of 14/11/2023)

STATE	HOSPITAL NAME	SECTOR
ACT	The Canberra Hospital	Public
ACT	Canberra Private Hospital	Private
NSW	Nepean Hospital	Public
NSW	Royal Hospital for Women	Public
NSW	St George Hospital	Public
NSW	Westmead Hospital	Public
NSW	John Hunter Hospital	Public
NSW	Concord Hospital	Public
NSW	St George Private Hospital	Private
NSW	Westmead Private Hospital	Private
QLD	Sunshine Coast University Hospital	Public
QLD	Buderim Private Hospital	Private
SA	Flinders Medical Centre	Public
SA	Royal Adelaide Hospital	Public
SA	The Queen Elizabeth Hospital	Public
SA	Calvary North Adelaide Hospital	Private
TAS	Royal Hobart Hospital	Public
VIC	Bendigo Health	Public
VIC	Mercy Health	Public
VIC	Monash Health	Public
VIC	Western Health	Public
VIC	Cabrini Health	Private
VIC	Epworth Healthcare Freemasons	Private
VIC	Epworth Healthcare Geelong	Private
VIC	St John of God Bendigo	Private
VIC	St John of God Geelong	Private
VIC	St Vincent's Private Hospital (Melbourne)	Private
VIC	Waverley Private Hospital	Private
WA	Hollywood Private Hospital	Private

Table 2. List of approved sites where data entry has not yet commenced (as of 14/11/2023)

STATE	HOSPITAL NAME	SECTOR
ACT	Calvary John James Hospital	Private
NSW	Royal Prince Alfred Hospital	Public
NSW	Sutherland Hospital	Public
QLD	Gold Coast University Hospital	Public
QLD	Robina Hospital	Public
QLD	Varsity Lakes Day Hospital	Public
QLD	Townsville University Hospital	Public
VIC	Epworth Healthcare Eastern	Private
VIC	Epworth Healthcare Richmond	Private

MONASH
University