MONASH University

AUSTRALASIAN PELVIC FLOOR PROCEDURE REGISTRY

PUBLIC REPORT 2022

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.

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Unless stated otherwise, the data covered in this report refers to the period: 1 January 2021 to 30 September 2022.

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FOREWORD

FROM THE STEERING COMMITTEE CLINICAL LEADS: PROFESSOR HELEN O'CONNELL, DR ELIZABETH GALLAGHER, ASSOCIATE PROFESSOR EMMANUEL KARANTANIS, MR JAMES KECK, DR JENNIFER KING, MR JOHN SHORT, ASSOCIATE PROFESSOR JESSICA YIN

As clinical leads for the Australasian Pelvic Floor Procedure Registry (APFPR), we are pleased to present its first Public Report. This report describes the registry's activities and achievements to date, including the commencement of data collection for both Stress Urinary Incontinence (SUI) and Pelvic Organ Prolapse (POP) procedures involving mesh and other devices. The report also provides an overview of the changing clinical, regulatory and consumer preference landscapes related to the safe and effective treatment of pelvic floor disorders, which continue to represent a major women's health issue in Australia.

This registry is an important national quality and safety women's health initiative with significant consumer and public interest. The APFPR has support from the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), the Urogynaecological Society of Australasia (UGSA), the Urological Society of Australia and New Zealand (USANZ), the Colorectal Surgical Society of Australia and New Zealand (CSSANZ) and the Royal Australasian College of Surgeons (RACS).

The APFPR has faced a number of challenges over the last 3 years directly related to COVID-19 that impacted its ability to recruit hospitals and women to participate. Despite this, the registry has been successful in delivering on many key project outputs and is currently progressing well with recruitment activities.

The APFPR understands it has been an extremely trying time for those working in health services over the last 3 years. We would like to sincerely thank all those involved in the APFPR to date for their commitment including: clinical craft groups, consumer representatives, government agency representatives on the Steering Committee, and the operations team, and congratulate them on their work and the quality of this report.

As the registry matures, we look forward to seeing it provide feedback to hospitals and clinicians on their procedures and outcomes to influence best clinical practice at a local level, and more broadly to support the enhancement of quality of care in women's health through robust data collection, monitoring and reporting.

MESSAGE FROM THE CONSUMER REPRESENTATIVE

Pip Brennan

There is no more important role for a consumer representative than to contribute to safety and quality initiatives. Registries are not well understood in the general population, but they are one of the most important safety and quality activities we have. The APFPR is unique in that it represents the implementation of a recommendation from a Senate Inquiry to help drive safety and quality in pelvic floor procedures. I am personally pleased to see a reduction in pelvic mesh implants since the Inquiry and welcome the role of the registry in identifying complications early on. Tracking mesh removal and revision procedures via the registry will be another important outcome, and I am pleased that already quite a few mesh clinics in South Australia, Victoria and New South Wales are contributing data.

It is also positive that the registry has a strong focus on Patient Reported Outcome Measures (PROMs), including the development of a pain-specific pelvic floor procedure PROM. There has also been important work done on developing a consumer participation statement. We are executing our plans for ongoing, wider consumer involvement in 2022-23: an important part of its development. This includes regular consumer webinars, the creation of consumer reference groups to gain feedback on important developments, a public facing report, and the creation of more content specifically catering to consumer needs.

As a systemic advocate I do not have lived experience of pelvic floor procedures and I pay tribute to the consumer networks and champions across the nation who have done so much over the years to bring this issue to light. I feel honoured to be a part of the APFPR Steering Committee and I also acknowledge the important efforts and contribution of the APFPR's founding Consumer Representative Dora Vasiliadis over the last three years. I look forward to including a wider consumer voice into the registry's activities in 2023 and beyond.

EXECUTIVE SUMMARY

Almost 50% of women in Australia are affected by pelvic floor disorders including Stress Urinary Incontinence (SUI) and Pelvic Organ Prolapse (POP) with a 20% lifetime risk of requiring surgery for childbirth related issues[1-3].

The APFPR is an Australian Government health initiative established to record information about surgeries for SUI and POP procedures that involve the use of devices including pelvic mesh. The former Minister for Health on 5 April 2019 announced the establishment of the registry to monitor health outcomes for women undergoing pelvic floor surgical procedures[4], as part of a broader response by the Commonwealth and State governments to support women who were negatively affected by the implantation of pelvic mesh. The creation of the APFPR was one of a number of key recommendations resulting from the Inquiry: 'Senate Community Affairs References Committee - Number of women in Australia who have had transvaginal mesh implants and related matters' in March 2018[5]. The APFPR is funded by the Australian Government Department of Health and Aged Care and is a clinician-led 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: they are now recognised as a vital tool for measuring, analysing and reporting health outcomes for patients. Participation from hospitals and clinicians in CQRs is voluntary. The APFPR has undertaken significant work to gain the buy-in of the key clinical craft groups to support the registry, and engaged consumers to ensure that the registry has been designed with active consumer engagement. Currently, clinicians from over 40 hospitals have committed to lead their site's participation in the APFPR.

The APFPR experienced significant delays in hospital and patient recruitment over 2020-21, mainly due to COVID-19 restrictions on elective surgery as well as a redirection in hospital activities away from non-COVID related initiatives. The registry is also noting changes in the external environment relating to pelvic floor procedures. Analysis undertaken by the registry has shown a significant reduction in pelvic floor procedures involving mesh across Australia over the last decade, and increases in native tissue and other non-mesh procedures, including bulking agents. This is similar to international procedure trends, and reflected in the scope of international registries.

Nevertheless, as at 1 December 2022 Australia-wide thirty-two hospitals have been approved to commence recruiting women undergoing pelvic floor procedures, with a further 9 hospitals in advanced stages of progress towards approval. Fifteen sites have contributed data to the APFPR to date. As at 15 November 2022, the APFPR recorded data from 167 women who have undergone either a SUI procedure or a POP procedure involving mesh, despite a backdrop of a significant decline of pelvic mesh procedures overall. The opt-out rate is low, with 2.4% of patients choosing to opt out of participating in the APFPR, demonstrating that the vast majority of women approached support this initiative.

FUTURE DIRECTIONS

The APFPR's priority over the next 2-3 years is the continued national rollout of the registry to ensure that as many clinicians and women as possible have the opportunity to participate in this national quality and safety activity. To that end, the APFPR is working towards onboarding 50% of eligible hospitals (those that undertake pelvic floor procedures) by mid-2023. The APFPR will evaluate the initial implementation of PROMs to understand and compare response rates from different methods of delivery, barriers and enablers for survey completion. The APFPR looks forward to producing its first hospital-specific comparative reports, and to provide feedback to individual hospitals on their outcomes relative to their peers.

The APFPR is currently undertaking a survey of Australian and New Zealand clinicians who undertake pelvic floor procedures to better understand contemporary trends in clinical practice, and to consider whether the current scope of procedures for the APFPR should be reviewed to better reflect this. The dataset is also being reviewed to ensure that it captures the minimal information required to support best practice, while minimising the data collection burden for clinicians and patients. The datasets will be reviewed by the consumer representatives as well as an additional group of lived experience consumers.

Dialogue is ongoing with New Zealand to facilitate potential participation in the APFPR. The APFPR also looks forward to an expanded program of consumer engagement including increasing involvement of consumers in APFPR activities, regular consumer webinars and continuing to update the information available on the APFPR website in alignment with consumer needs.

As the number of patients recorded in the database increases, it will enable the APFPR to share deidentified data (i.e. aggregated data that does not share the patient's identity) with clinicians and researchers to further investigate which specific factors lead to better patient outcomes. Beyond the next few years, the APFPR's core purpose will be to capture as much high quality information regarding pelvic floor procedures as possible, with which to inform clinical practice, regulatory decisions and health policy.

The Monash School of Public Health and Preventive Medicine, has extensive experience in the establishment and maintenance of clinical quality audits and registries: among these are the Australian National Diabetes Audit (ANDA), the Australian Breast Device Registry (ABDR), the Victorian State Trauma Registry (VSTR) and many more. There are currently forty-five CQRs under Monash leadership, the largest number managed by one single entity in the whole of Australia.

EVENTS LEADING UP TO THE ESTABLISHMENT OF THE APFPR

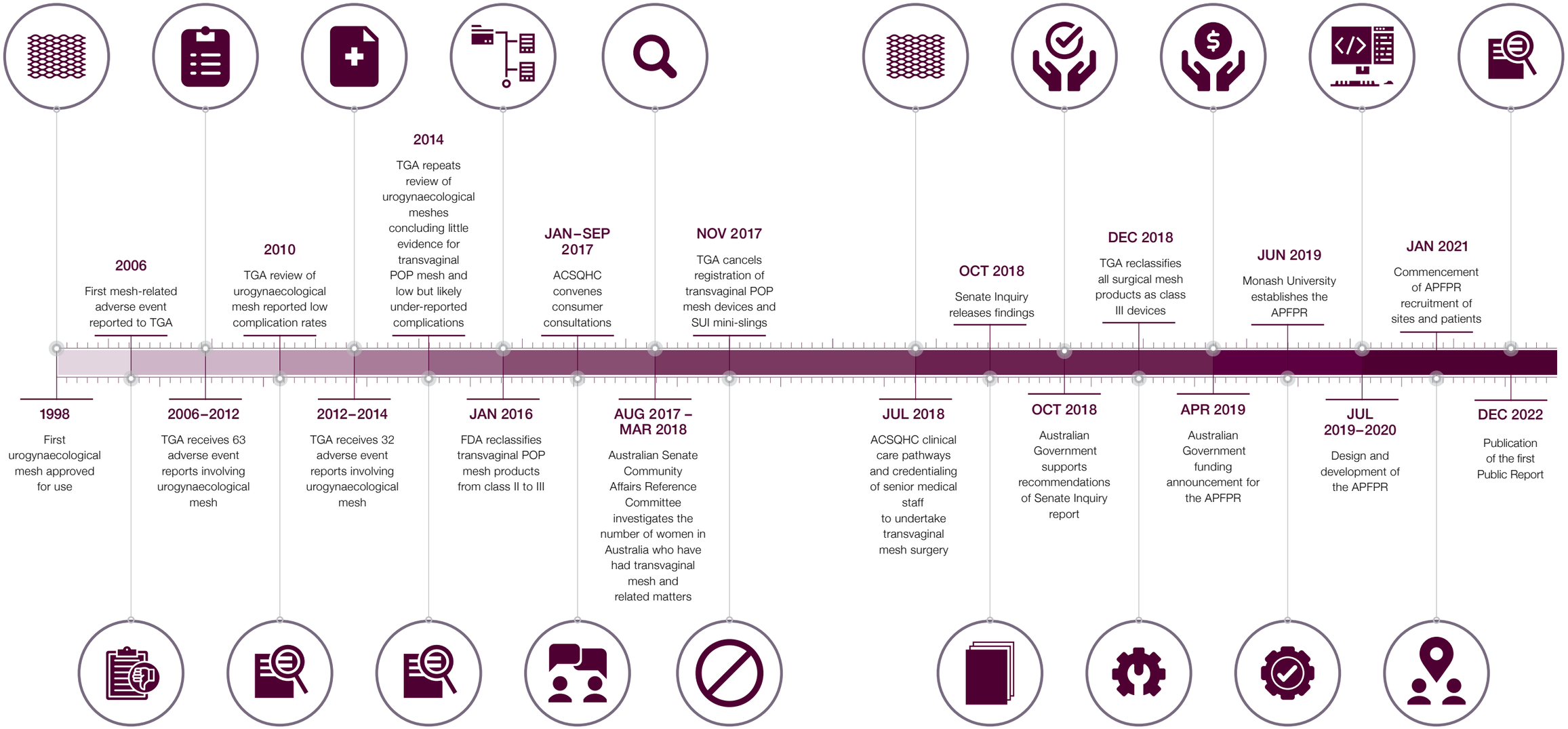


Table adapted from Daly. O, et.al 2019[6]

PURPOSE

The APFPR monitors the safety and quality of care and outcomes for women undergoing procedures to treat pelvic floor disorders related to SUI and POP that include devices, grafts and/or prostheses.

The APFPR currently captures outcome data on the following pelvic floor procedures:

Stress Urinary Incontinence

- Mid-urethral sling (synthetic mesh)
- Peri-urethral bulking agent
- Bulking agent removal
- SUI mesh revision/explantation

Pelvic Organ Prolapse procedures

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

The APFPR also captures whether one of the following procedures was performed at the same time as a specific SUI/POP procedure, to understand how/if they may contribute to the overall procedure outcomes:

- SUI native tissue procedure
- Hysterectomy
- Perineorrhaphy
- Prolapse surgery
- Additional POP procedure

The APFPR collects information from surgeons and women regarding their reason for surgery, particular co-morbidities, and specific surgical procedure details including any complications or adverse events related to the procedure/device. Prior to the establishment of the APFPR, there was no systematic process to monitor the outcome of these procedures. The initial capture and monitoring of pelvic floor procedures involving the use of mesh devices and their health outcomes provide an early detection system for investigation of device performance and to inform best clinical practice.

APFPR OBJECTIVES

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

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

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

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

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

CLINICAL OVERVIEW

Pelvic floor disorders such as SUI and POP, are common disorders with prevalence increasing with parity (number of births), age and lifestyle-related risk factors.

Almost 50% of women in Australia are affected by pelvic floor disorders including SUI and POP, with a 20% lifetime risk of requiring surgery for childbirth related issues[1-3]. Over the last 20 years, almost 200,000 women have had SUI procedures, with more than 70% involving the use of a mesh or other implantable prosthesis[6]. Significant but unquantifiable numbers of women have also had transvaginal mesh procedures performed for prolapse, as reported in the Australian Government, Senate Community Affairs References Committee, Number of women in Australia who have had transvaginal mesh implants and related matters, 2018[5].

Traditionally vaginal surgery for prolapse makes use of the patient's own tissues (known as a fascial repair or colporrhaphy). Techniques generally involve either support of the vaginal vault or uterus, or surgical plication "infolding" of the connective tissue layers that support the prolapsed organ (e.g. bladder and rectum) followed by excision of the excess vaginal skin once the prolapsed organ is pushed back into a well-supported pelvic location. However pelvic floor dysfunction is a result of weakened, torn or overstretched pelvic floor structures, with the ongoing impact of aging, menopause, upright posture, heavy lifting, in addition to previous birth and pregnancy related injury. It is not surprising that recurrent problems can occur and it has been known for well over 100 years that repair procedures have a significant failure rate. As a result, vaginal mesh use became widespread initially for incontinence surgery following the development of the mid-urethral sling. From a structural support standpoint, mesh has been used to provide more durable support than already-damaged native tissue particularly for women with prolapse recurrence, or a higher risk of recurrence. Most current pelvic floor mesh products are composed of lightweight, monofilament polypropylene mesh which is incorporated into the pelvic floor connective tissue[7].

Since the Australian Senate Inquiry into the Number of women in Australia who have had transvaginal mesh implants and related matters[5], there has been greater awareness of the risks of surgical management of SUI and POP, particularly with mesh, and the need to reserve its use for when conservative treatment does not sufficiently address symptoms that impact quality of life. In the wake of consumer concerns about permanent, life-altering consequences some women experienced post-implantation, the use of mesh for SUI and POP has significantly decreased.

CLINICAL QUALITY REGISTRIES (CQRs)

Clinical Quality Registries collect, analyse and report on health data from individuals with a specific medical condition, disease or undergoing a specific procedure, enabling analysis on the effectiveness of treatment by systemically comparing the outcomes of hundreds if not thousands of procedures. Over time, via regular feedback and review, CQRs contribute to improvements in clinical practice.

Information collected through CQRs helps to systematically monitor the appropriateness and effectiveness of healthcare provided to individuals. Information is routinely collected, analysed and then reported back to patients, clinicians, hospitals and government. It is used to identify variations in treatment; compare the outcomes achieved between procedures, providers and devices, and highlight areas for potential improvement in the overall quality of care. The feedback loop shown below is critical to drive improvements in quality, safety and appropriateness of care. As such, CQRs are supported by the Australian Commission on Safety and Quality in Health Care (ACSQHC), Australia's peak healthcare safety and quality organisation[8].

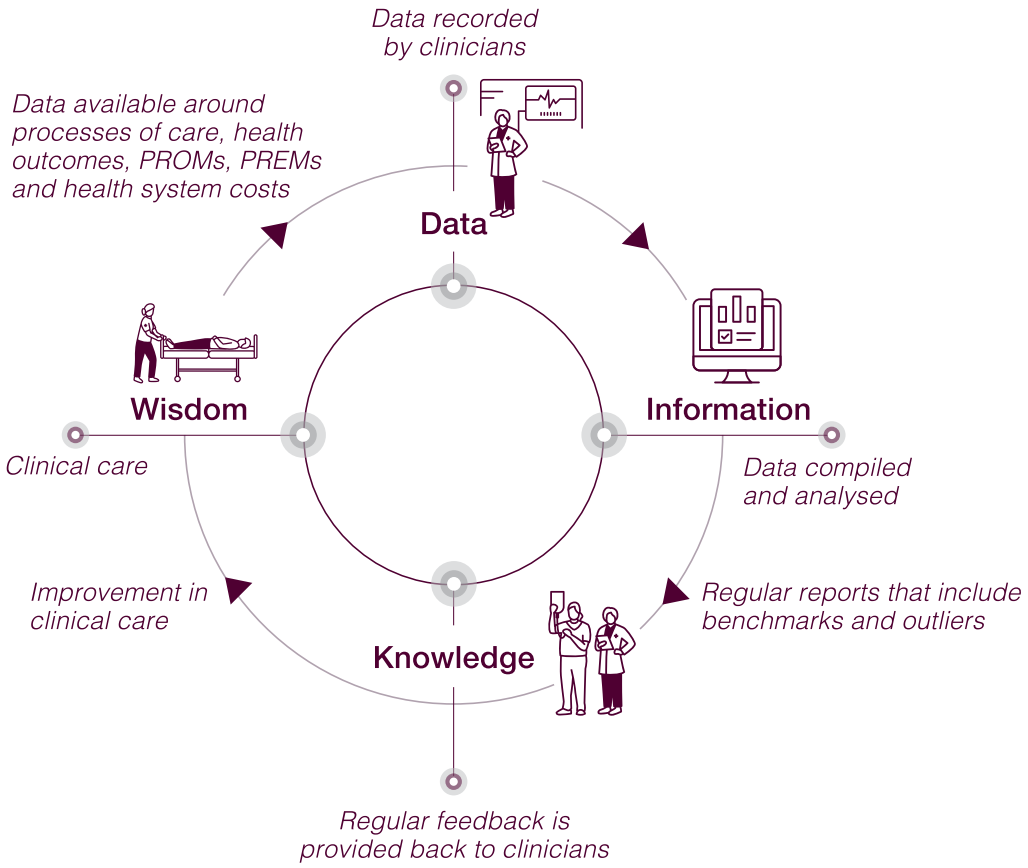


Figure 1: *Adaptation of The Australian Commission on Safety and Quality in Health Care (ACSQHC) Clinical Outcome Feedback Loop*

HOW CQRs ADD VALUE AS THEY EVOLVE

Registry maturity phases: The APFPR – an early phase registry

In general, the major benefits of CQRs may take up to 10 years to achieve due to the requirement for long term follow up and the evaluation of procedure performance over time, CQRs also add value as soon as they commence engaging with the relevant clinical community and involving them in registry activities. Early stage registries add value in the following ways:

CQRs such as the APFPR encourage clinician participation across multiple craft groups and specialties. The **collaboration** that arises in the establishment and ongoing activities of the registry supports harmonisation of clinical practice across these different specialties. The collaboration also enhances broader clinical practice through information sharing between different professional groups.

Evidence-based **guidelines** are reviewed to inform the development of the registry datasets and to align with clinician expectations regarding what effective contemporary clinical practice looks like. These data sets are also informed by international data collections, to allow future international harmonisation where possible.

Creating **standardised** datasets that allow comparison of practice and outcomes within and across specialties, across public and private, metropolitan and rural settings, and across jurisdictions. This regular comparison of clinical practice amongst peers is an important part of the quality improvement cycle and an essential part of the health learning system. Data comparison can be reassuring especially for new specialists and those working in smaller communities.

Patients are **empowered** to encourage or seek out clinicians that participate in registries. Patients are able to provide feedback regarding their experience via PROMs collected by the registry, and can access their clinical data to be more informed on the procedures and devices that have been used.

When mature, CQRs can improve the quality of care by:

- Providing timely, credible risk adjusted data back to clinicians about how their outcomes benchmark with others, both locally and internationally
- Identifying and investigating variations in clinical practice and outcomes; and
- Acting as an early warning system of device/procedure performance.

CQRs are critical in ensuring clinicians receive accurate and timely information to inform their ongoing practice. Ultimately, the success of CQRs is dependent upon the engagement of clinicians to participate.

COVID-19 IMPACTS ON REGISTRY DEVELOPMENT

The timing of the APFPR site recruitment and data collection directly coincided with the onset of the COVID-19 pandemic. The registry commenced in mid-2019 and was in the process of establishing the SUI dataset, developing the processes and data systems required, when COVID-19 reached Australia in March 2020. For much of 2020, hospital approval applications for projects unrelated to COVID-19, such as the APFPR, were de-prioritised, and health service clinicians in non-critical care areas were redeployed to manage patients affected by COVID-19. Additionally, the number of eligible procedures available for data capture dramatically decreased due to delays and cancellations of elective surgery, especially in Victoria and New South Wales - which had initially been selected as pilot states for the APFPR as they have the largest populations. This resulted in significantly slower than expected recruitment for the APFPR between 2020-2022. Despite this, the APFPR accelerated other activities such as creating training documents, developing Standard Operating Procedures, and undertaking historical and international reviews to better understand the contemporary context for these procedures.

ESTABLISHING A REGISTRY AT A TIME OF EVOLVING CLINICAL PRACTICE IN AUSTRALIA

Reduction in pelvic floor procedures involving pelvic mesh

A reduction in pelvic floor procedures due to COVID-19 related factors was expected in 2020, as these are classified as non-urgent category three surgeries. The APFPR undertook additional analyses on publicly available data going back as far as twenty years, to identify trends in pelvic floor procedures, including those using mesh, using the following datasets:

Medicare Benefits Schedule (MBS) Item Statistics Reports: These reports include procedures that qualify for a Medicare Benefit, performed by a registered provider, and with a request for reimbursement. They provide the basis for billing in the private sector, and therefore indicate the number of procedures performed in those settings, but do not include patient activity in the public sector.

Australian Institute of Health and Welfare National Hospital Morbidity Database (AIHW NHMD): The AIHW NHMD data is comprised of admitted patient procedures reported by Australian Hospitals, coded using the Australian Classification of Health Interventions (ACHI), the national standard for intervention coding. This dataset captures procedures performed in public and private hospitals, day centres and ambulatory settings. While based on MBS items, they may have definitions different to the eligibility criteria for claiming an MBS item, or in some cases there may not be an equivalent ACHI code.

While the **AIHW 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 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 previously it could be claimed for mesh procedures. As such, when using MBS, 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 changes in clinical practice.

Trends in pelvic floor procedures from 2000-2020

Figures 2 and 3 below shows a reduction in total numbers of SUI procedures (particularly mesh sling procedures - Fig 2) with a >50% reduction in overall procedures from 2016 to 2020, but a slight increase in bulking agent procedures for SUI.

Figure 2 *Number of SUI procedures over time (Source: AIHW [9])*

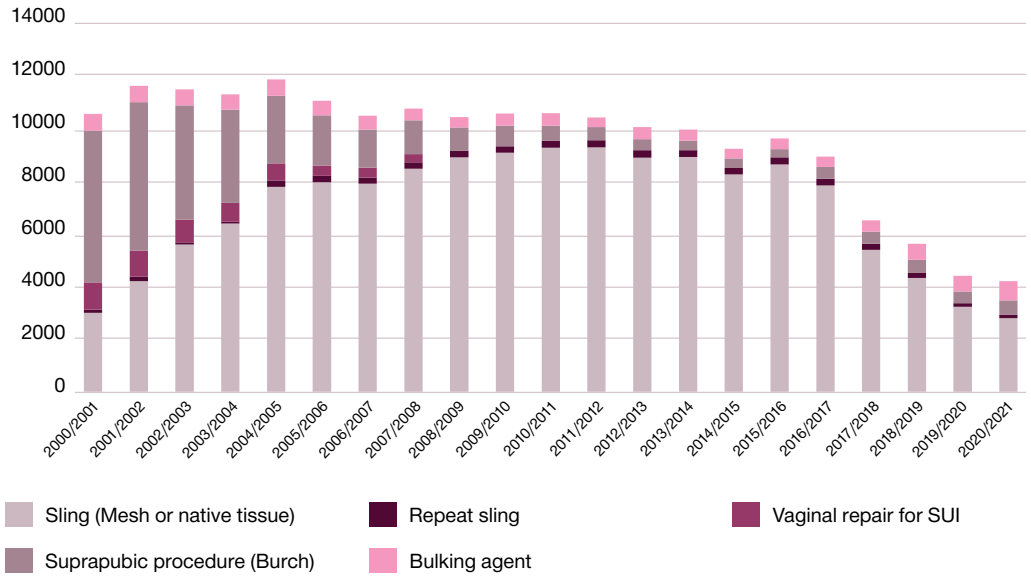
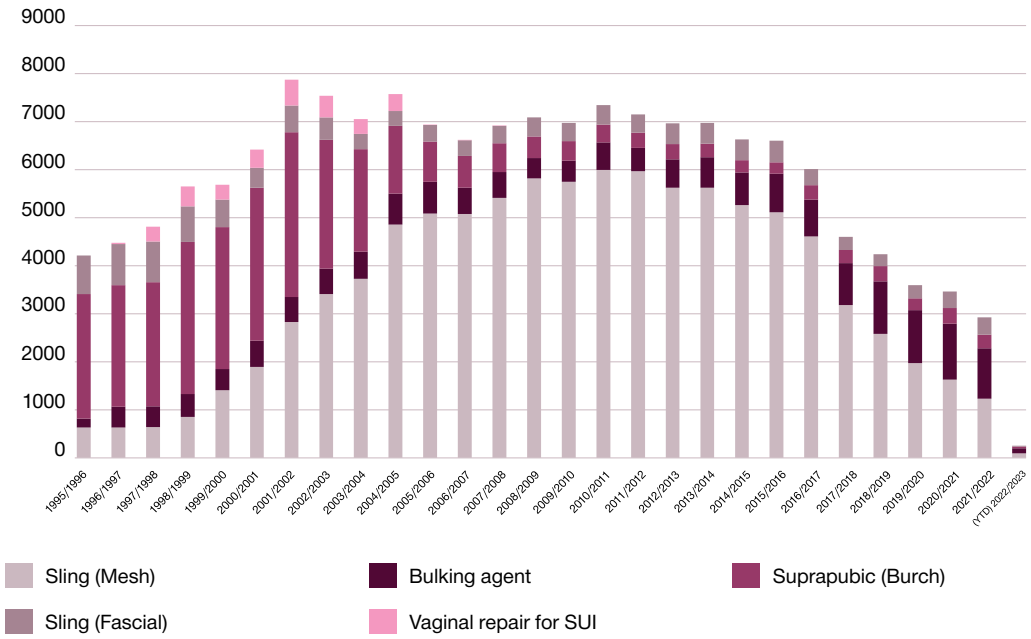


Figure 3 *Number of SUI procedures over time (Source: MBS[10])*



For POP procedures treating lower-mid vaginal (anterior and/or posterior) or apical (vaginal vault and Manchester) prolapse, with or without mesh, an average of 25,000 procedures were performed annually until 2016, after which there was >20% reduction in volume, predominantly related to fewer lower-mid vaginal colporrhaphy procedures (Figure 4). In 2008, there was a significant change in classification of prolapse procedures, hence the later time series in figure 5 showing a more detailed subdivision of procedures. Apart from 35597-00/01 – mesh sacrocolpopexy , 35595-00/01 – non-mesh pelvic floor repair using abdominal approach, and 35577-00 – Manchester repair, the other procedures may or may not have used mesh. Numbers of mesh sacrocolpopexy procedures have remained stable over this time.

Figure 4 *Number of POP procedures and repair type conducted in Australia (Source: AIHW[9])*

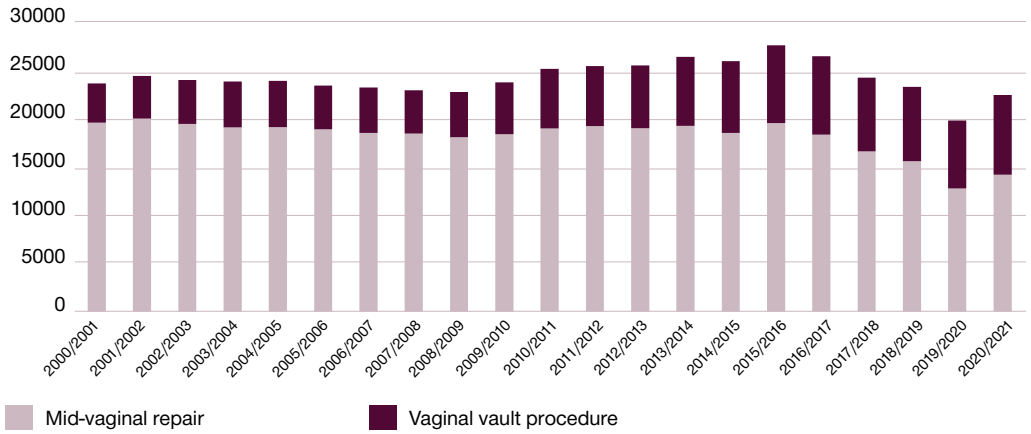
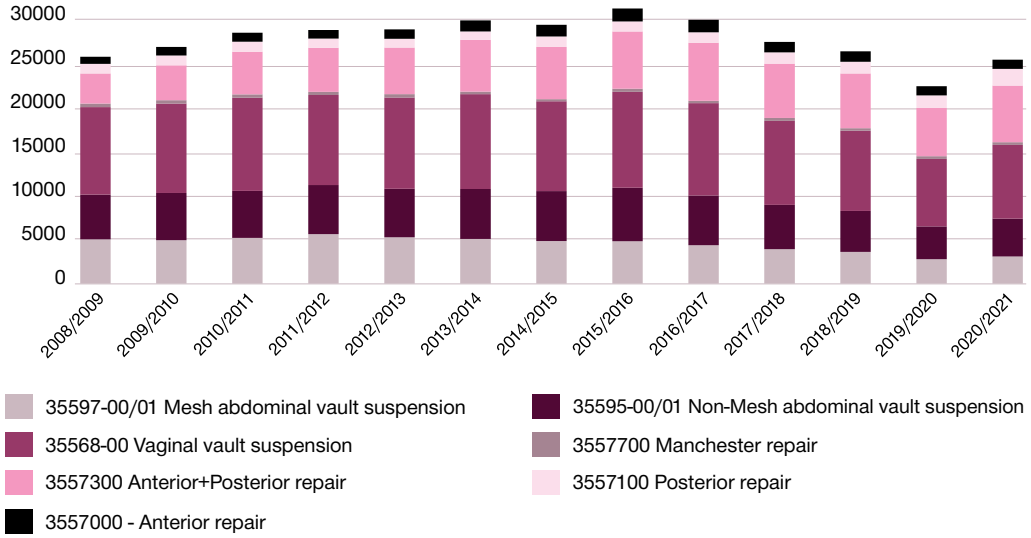


Figure 5 *Number of POP procedures, by procedure type conducted in Australia (Source: AIHW[9])*



These trends coincide with the following factors:

- Changes in clinician and consumer sentiment towards the use of prosthetics, in the wake of some women experiencing permanent and life-altering consequences from certain types of implants, as reported by consumers during the Australian Senate Community Affairs References Committee Inquiry into the number of women in Australia who have had transvaginal mesh implants and related matters (a consumer-led initiative).
- Federal Court class actions and negative media coverage, leading to a reduction in consumer demand.
- The introduction of ACSQHC care pathways and credentialing guidance for pelvic mesh procedures in 2019, which may have changed practice and/or number of clinicians performing mesh procedures.
- Impact of COVID-19 on health service capacity to assess women and perform SUI and POP procedures.
- TGA regulatory changes reducing the number of SUI/POP devices approved for use in Australia[11]
- SUI/POP implant manufacturers withdrawing their products from the international and Australian market for commercial reasons, limiting supply of products.
- Greater access to consumer information, and consumer awareness, in light of the above factors

Other potential factors affecting consumer demand may include:

- Reduced prevalence of SUI and POP
- Women coping longer with SUI and POP symptoms, delaying treatment
- Seeking non-surgical alternative treatments e.g. pelvic floor physiotherapy
- A higher threshold of symptoms tolerated before seeking surgical treatment

These trends have also been observed in international registries such as The British Society of Urogynaecology (BSUG) registry[12]. The longer-term outcome of these trends is not known and will be monitored by the APFPR.

MAPPING PROCEDURES CAPTURED BY INTERNATIONAL REGISTRIES

The APFPR recently engaged with over ten international registries to ascertain the breadth of the procedures they currently capture, such as the UK's Pelvic Floor Registry and the German Surgical Registry, identifying that many registries have a broader scope than the APFPR. This information has been useful in illustrating the potential opportunities in the ongoing development of the APFPR, and also informed a survey that is currently being conducted amongst surgeons to determine their recommendations with regards to which procedures could be captured going forward.

Table 1: *Procedures Captured by Pelvic Floor Registries Internationally*

	Pelvic floor Procedures																								
	SUI									**POP**															
Name of registry	Mid-urethral sling – retropubic	Mid-urethral sling – TOT	Mini-sling#	Bulking agent injections	Colposuspension incl Burch	Marshall Marchetti Krantz	Vaginal urethrocystopexy	Autologous fascial sling	Artificial urinary sphincter	Sacrocolpopexy	Sacrospinous colpopexy	Uterosacral colpopexy	Hysterectomy	Abdominal sacrocolpopexy	Vaginal sacrospinous hysteropexy	Sacrohysteropexy	Anterior colporrhaphy	Paravaginal repair	Posterior colporrhaphy	Manchester repair	Enterocoele repair	Perineorrhaphy	Colpocleisis	Rectopexy
APFPR Australia	✔	✔	✔	✔						✔			✔ Concomitant surgery	✔		✔	✔		✔					
British (BSUG)	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔
UK pelvic floor registry	✔	✔	✔	✔	✔	✔		✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔
Danish (DugaBase)	✔	✔	✔	✔	✔	✔	✔	✔		✔	✔	✔		✔			✔		✔	✔	✔	✔	✔	
France Vigi-mesh registry	✔	✔	✔		✔	✔	✔	✔		✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔
Norwegian (NFIR)	✔	✔	✔	✔	✔	✔	✔	✔	✔															
German surgical registry	✔	✔	✔						✔	✔		✔	✔	✔		✔	✔		✔					
Swedish GynOp	✔	✔	✔	✔	✔	✔	✔	✔		✔	✔	✔	✔	✔ Concomitant POP surgery			✔		✔		✔	✔	✔	
IUGA (International)	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔
AQUIRE (AUGS) SUI module (US)	✔	✔	✔	✔	✔	✔		✔		✔ Concomitant POP surgery														
US PFDR	✔ Concomitant SUI surgery, no bulking agents									✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	

Information mapped by the APFPR

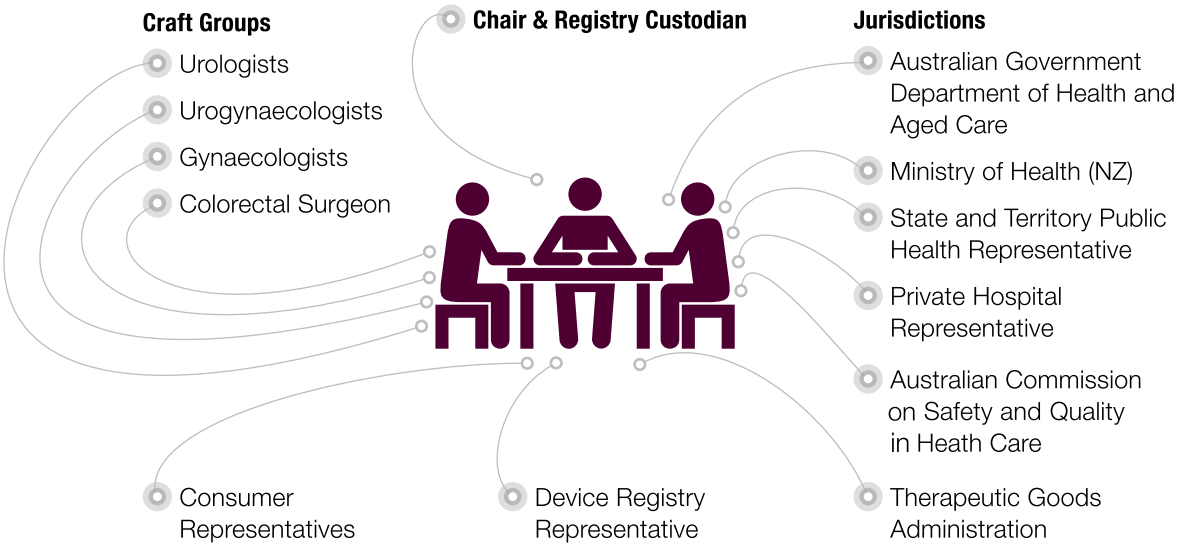
APFPR - primarily mesh-related, though it includes a question related to native tissue repair and concomitant procedures
 # Revision and Explantation only

KEY REGISTRY ESTABLISHMENT ACTIVITIES

Registry Governance

The APFPR Steering Committee benefits from representation from a broad group of stakeholders, which comprises:

Figure 6 *Registry Governance*



The strategic direction and development of the APFPR is overseen by a Steering Committee that includes broad stakeholder representation from the Australian Government Department of Health and Aged Care; Therapeutic Goods Administration; Australian Commission on Safety and Quality in Health Care; consumers; academics; and senior clinicians from key medical specialist societies and medical colleges who carry out pelvic floor procedures. A unique characteristic of the APFPR's Steering Committee is that it brings together the expertise of four different specialist groups to collaborate on this important initiative: urologists, urogynecologists, gynaecologists and colorectal surgeons, all of whom perform pelvic floor procedures. The Steering Committee meets quarterly. The Management Committee (the clinical specialists) also meet with the coordinating centre each quarter to discuss specific clinical issues.

Data Governance

Monash University has established and managed clinical registries for over 20 years, currently operating 45 registries including several large nationwide ones. Monash University has the highest levels of data security and governance systems for sensitive data. The APFPR complies with state, territory and Commonwealth privacy laws.

All personnel at sites involved in providing data to the registry undertake training by Monash University to ensure that they understand their obligations in regard to data confidentiality and privacy relating to this quality assurance activity. Each registry database user has their own username and password to access the database. Private surgeons only have access to their 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. Currently the APFPR uses a Redcap Database for data collection and management.

The registry retains clinician and participant contact details so that a patient can be contacted if required, such as for completion of a follow-up questionnaire, to track additional related procedures over time, and to provide information to the consumer regarding their data on request.

Data Access

As a general rule, the APFPR does not release identifiable information to any person or organisation, other than participating clinicians and hospitals. To ensure patient privacy, any external access to information from the APFPR must adhere to strict protocols and procedures.

Researchers and medical professionals working at research institutions, hospitals, private entities, industry, government or other health services within Australia can request access to data held within the registry, once the APFPR reaches sufficient maturity.

In general, individually identifiable data in respect of patients, contributing clinicians, or hospitals is not provided to third parties and will normally only be available to authorised APFPR personnel in the course of operating the registry. Exceptions may include data linkage where the APFPR is collecting follow-up information from jurisdictional or national datasets. Patient requests for access to their data will be managed according to the APFPR Data Access Policy. Patients will need to provide identifying information before the data is released to them.

STAKEHOLDER ENGAGEMENT

The APFPR's strategic focus to date has been:

- determining the clinical and patient-reported minimum data sets for the APFPR
- recruiting sites, clinicians and patients into the registry

Clinician Survey

In line with best practice, surgeons undertaking SUI and POP procedures completed a survey in 2019 regarding their preferences of what the registry should capture, and potential barriers and enablers to registry participation. Results were presented to the APFPR Steering Committee and have informed APFPR establishment activities.

Systematic Review

To support the minimum clinical data set and the development of PROMs, one of the APFPR's first activities was to undertake a systematic review of the data sets used by international registries and databases involved in the collection of data about SUI and POP procedures.

National roll out

Engagement of jurisdictions has been via meetings with the APFPR coordinating centre and development of a letter and briefing document for dissemination to the eligible health department within each jurisdiction, to promote participation in the registry. The ACSQHC is also supporting the registry via its Inter-Jurisdictional Committee.

Clinician Engagement

Participation in registries is voluntary in Australia. Key clinician engagement activities have included: participating in key clinical conferences, and communicating via Twitter and LinkedIn. The APFPR engaged in a number of conferences throughout 2022: using these, the APFPR was able to identify a number of new sites to target, bringing the total number of potential eligible sites to approximately 80 across Australia.

The Registry published four public newsletters (the APFPR Communique), since its inception which have been distributed to over 1,000 contacts, and a fifth one is planned before the end of 2022. The focus of these has been providing updates on recruitment activities across Australia and reporting on the APFPR's other awareness building initiatives, particularly among health services, clinician organisations and participating clinicians.

Consumer Engagement

During the early stages of development, the APFPR appointed Ms Dora Vasiliadis as consumer representative. Dora brought a wealth of lived and learned experience to the registry and provided extensive input into the development of the minimal clinical data sets for both SUI and POP modules. Dora completed a three-year term in April 2022. The APFPR would like to acknowledge her commitment and significant contribution to the development of the registry. A recruitment process is currently underway to identify a new consumer representative with lived experience to join the Steering Committee.

In June 2021, Ms Pip Brennan was appointed as Consumer Representative and Systemic Advocate. Pip brings a wealth of systemic health advocacy experience. Both Pip and Dora were involved in the development of the PROMs for both modules (which are currently being piloted), and also provided extensive feedback on the APFPR's external communications.

In March 2022 the Steering Committee endorsed a Consumer Participation Statement that is based on guiding principles endorsed by the Australian Research Healthcare Alliance (ARHA) and the Consumer Health Forum of Australia (CHF).

The purpose of consumer participation in the APFPR is to:

- Incorporate the consumer voice into the APFPR goals and strategy
- Support translation and communication of key messages to consumers
- Liaise with consumer forums and bring in a wider consumer voice
- Support and raise awareness of the APFPR
- Ensure patient safety and quality is always at the centre of discussions

Concurrently, following consumer demand, the APFPR is establishing a consumer reference group to provide further consumer input on specific issues such as the outcomes captured. Terms of reference for the group have been developed and recruitment will take place in November 2022.

At the suggestion of the APFPR's consumer representative, the APFPR ran its first public webinar in July 2022, and the second is planned for December 2022. The July webinar was well received and generated varied questions from consumers. This information, in turn, has been used to update the website.

APFPR Website

In 2020 the APFPR developed a consumer-friendly website, covering essential information about the scope of the registry, newsletters and information for health professionals. As the registry matures and evolves, the website will become a key resource for women following a pelvic floor procedure or considering one.

REGISTRY METHODOLOGY

The APFPR is a population-based prospective, observational registry of patients undergoing SUI and POP pelvic floor procedures involving mesh or other prostheses. The registry collects identifiable clinical data on key diagnostic, surgical, and complication details, and administers PROMs both prior and post-procedure. All hospitals and clinicians undertaking these procedures are eligible to participate in the registry. The registry conforms to the national operating principles for CQRs, as set out by the ACSQHC and expects to continue to collect and report pelvic floor procedures and outcomes on an ongoing basis.

The registry uses an opt-out consent model to recruit women having surgery. Women are introduced to the registry by their clinician and are given an APFPR patient leaflet. Thereafter, the registry dispatches an invitation and explanatory statement to the patient clearly outlining the process for opting out of the registry. Once the opt-out period has elapsed, the patient is considered recruited into the registry, unless they have indicated otherwise. To date, the opt-out rate from the APFPR is approximately 2.4% 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.

Ethical review

The ethical requirements of the APFPR have been approved by the Human Research Ethics Committee of Monash Health under the National Mutual Acceptance Scheme (NMA) and Monash University Research Ethics Committee. Additional ethics approvals are sought from participating sites that do not operate under the NMA. This means that the registry is carried out in accordance with the National Statement on Ethical Conduct in Human Research (2018)[13]. This statement has been developed to protect the interests of people who agree to participate in human research studies. The APFPR seeks ethics approval and governance sign-off at participating hospitals prior to recruitment and data collection commencing.

Surgeon recruitment and training

Identification of eligible hospitals occurs via recommendation from the APFPR clinical craft group leads, as well as meetings and information provided by jurisdictions and the Commission. In addition, sites or surgeons may pro-actively contact the registry to express interest in participating. Pelvic floor procedures are undertaken by urologists, gynaecologists, urogynecologists and colorectal surgeons in metropolitan or regional settings, and through public or private hospitals.

Once hospital approvals are obtained, surgeons are trained on the purpose of the registry, data entry and the REDCap database. The APFPR coordinating centre provides digital and paper resources to support clinician participation, and continues to maintain contact with sites, including site visits where possible.

Patient eligibility

All patients undergoing a SUI and/or POP procedure and attending a participating site or having a procedure through a participating surgeon are eligible to participate.

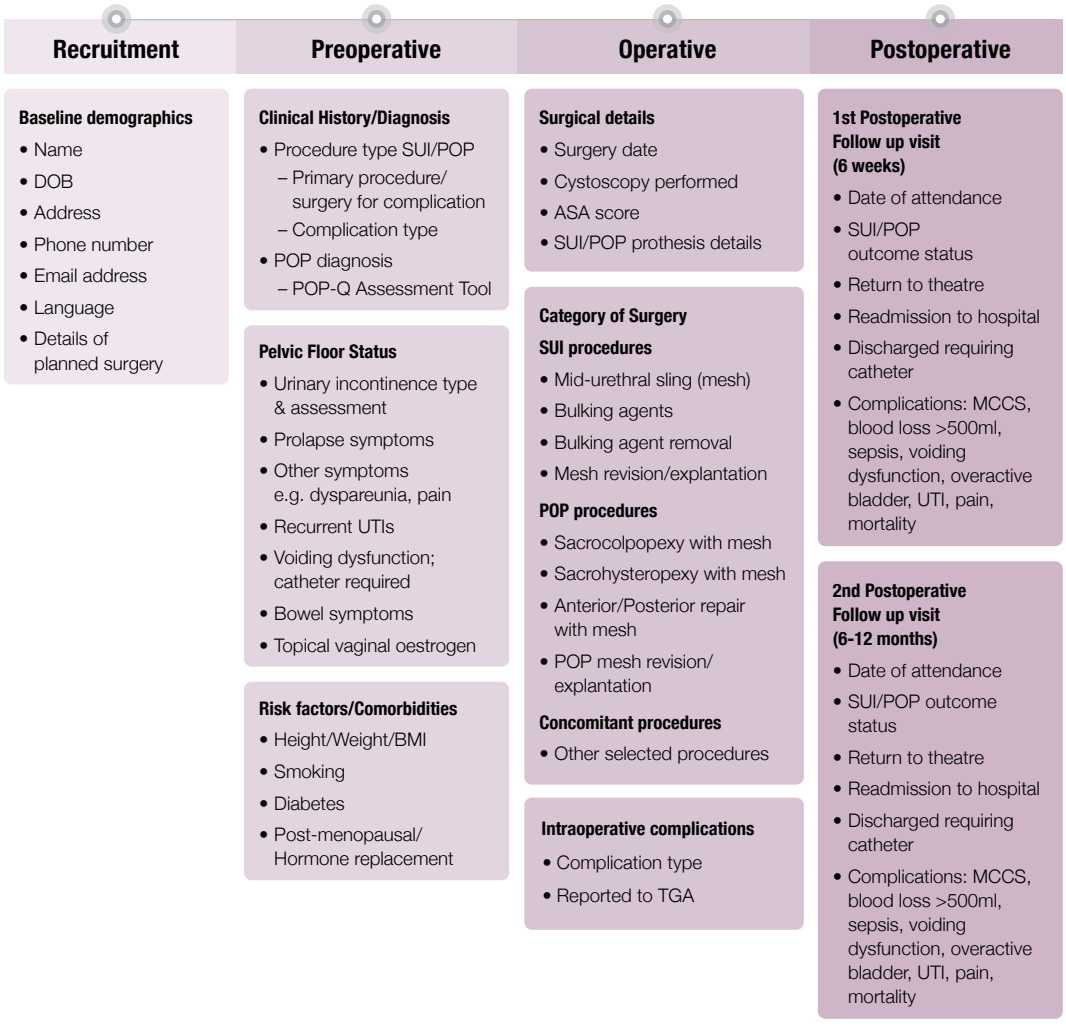
SUI and POP minimum data sets

The registry undertook a modular roll out, with the first module to be implemented being SUI, followed by the POP module one. The APFPR SUI and POP dataset development consisted of Steering Committee clinical leads and a selection of additional invited clinicians participating in an expert review panel that considered the importance, feasibility and accuracy of proposed data items. The APFPR dataset has also been designed to support clinicians meet any credentialing requirements of their institutions or professional training bodies, based on the ACSQHC's transvaginal mesh credentialing guidance, and to do this in a manner that reduces data collection burden. For more information visit: www.safetyandquality.gov.au

Data Collection

Data is uploaded into the APFPR REDCap database. The data elements are depicted below:

Figure 7 *Summary of data collected*



PATIENT REPORTED OUTCOME MEASURES (PROMs)

The collection of PROMs is a critical activity for the registry, providing additional information on outcomes of importance to women. As there are various PROMs surveys related to pelvic floor procedures, the registry tested those most commonly used with women who had previously undergone pelvic floor procedures, to determine the best surveys to meet the needs of the APFPR.

PROMs are currently being piloted in the APFPR with the aim to test the feasibility and practicality of various methods of administration and reporting to health services and clinicians. The Australian Pelvic Floor Questionnaire (APFQ) is being trialled via e-mail, mail, and telephone prior to surgery and 6 months post-surgery; options to use SMS reminders for patients are also being investigated. Some hospitals will administer the survey onsite (clinical rooms or hospitals), while patients from other sites will receive the PROMs directly by mail or email from the APFPR coordinating centre. At the end of the pilot, an evaluation will be conducted to understand optimal administration and reporting methods to maximise completeness and usefulness of data. Ongoing consumer involvement is key. Ideally PROMs would be collected over a longer timeframe post-surgery, but experience from other registries shows there is a tendency for response rates to dwindle significantly as time passes from the initial operation.

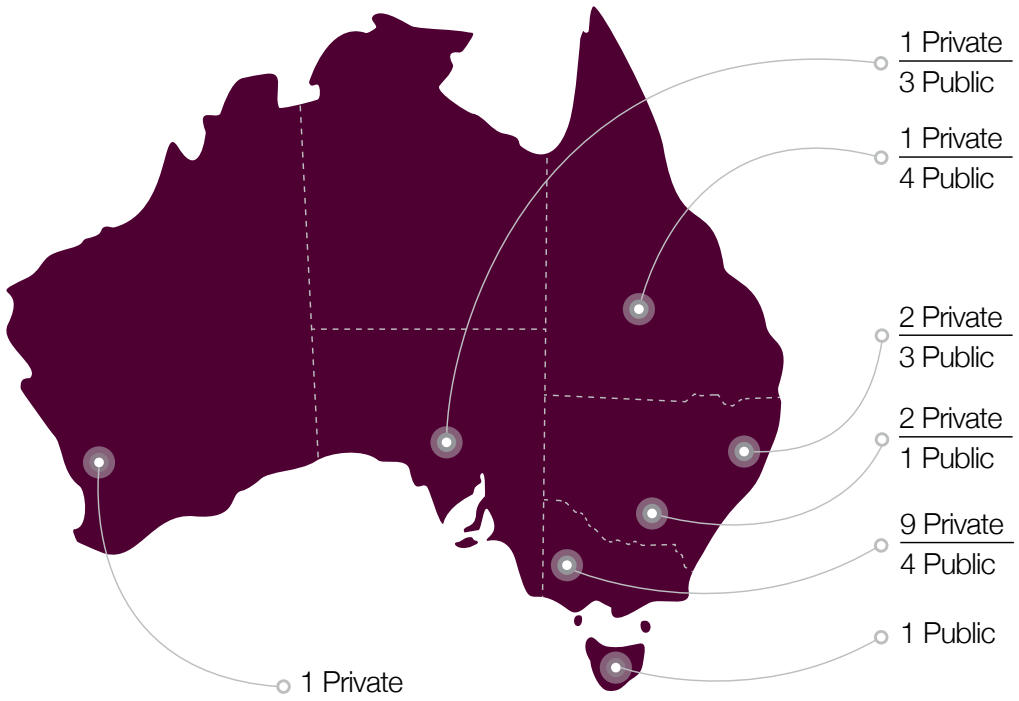
REGISTRY PARTICIPATION

THE FOLLOWING SECTION DESCRIBES THE INITIAL SITE AND PATIENT RECRUITMENT DURING THE ESTABLISHMENT PHASE OF THE APFPR.

Site recruitment

Figure 8 depicts the participating jurisdictions of the first **32 hospitals** that have obtained approval to participate as of 1 December 2022. This means that they are now set up to participate and contribute patient data. Overall, the APFPR has identified approximately 81 eligible sites across Australia.

Figure 8 *Site Recruitment Progress*



CLINICAL/DATA FINDINGS TO DATE

Patient cohort, age and residency

As at 15 November 2022, 167 women were registered in the APFPR database. Of these, 152 have been recruited so far (Table 2), with four patients opting out of the registry (2.4%), and the remainder still within the initial opt-out period. Of these, patients resided in Victoria (49%), South Australia (29%), New South Wales (13%), Queensland (8%), Tasmania and the ACT (<1% each). Western Australian public hospital groups are currently unable to participate in the APFPR due to jurisdictional legislation that prohibits an opt-out model of participation. Approximately two-thirds of the participants are from public hospitals, as a large public health service was the first to contribute patient data. However approximately 70% of pelvic floor surgery is undertaken in private hospitals; as the registry expands the public-private split will change.

Table 2 provides a summary of the characteristics of the recruited women. Patient numbers in this first report are low but are provided to highight the potential of the data as numbers increase. The median age was 59 years, with nearly 80% of women recruited having surgery for SUI procedures (note the APFPR commenced SUI procedures in 2021 and POP procedures in mid-2022); and the remainder having surgery for both SUI and POP or for POP only. Forty-three percent of participants (65 women) had their surgery performed at the time of this report (60 of these were women who had SUI procedures); 35% had attended their first post-operative visit; and 15% had attended their second post-operative visit.

The APFPR collects patient contact details in order to administer PROMs surveys: 100% of participants provided a phone number.

Table 2: *Summary of participant characteristics*

Variable	All, N (%)	Public, N (%)	Private, N (%)
N recruited patients	**152**	**103**	**49**
Age at registration (years), median (IQR)	59 (48, 73)	59 (51, 73)	61 (47, 74)
Planned surgery for SUI only*	119 (78.3)	73 (70.9)	46 (93.9)
Planned surgery for POP only, and SUI and POP	33 (21.7)	30 (29.1)	3 (6.1)
Surgery performed	65 (42.8)	36 (35.0)	29 (59.2)
Attended first post-operative visit	53 (34.9)	30 (29.1)	23 (46.9)
Attended second post-operative visit	22 (14.5)	12 (11.7)	10 (20.4)
Phone number provided	152 (100)	103 (100)	49 (100)
Email provided	93 (61.2)	46 (44.7)	47 (95.9)

*The following analyses are presented solely for the SUI only cohort, due to insufficient size of the POP only and SUI and POP procedure cohorts with surgery performed

Patient risk factors and comorbidities (SUI procedures only)

Table 3 reports a summary of clinical characteristics for women having SUI procedures with surgery performed. The majority (78%) of patients had a urodynamic study to objectively assess their SUI prior to surgery. Six patients (10%) reported dyspareunia pre-operation. Patients had a median BMI of 27 kg/m^2, and the majority (60%) of the women were post-menopausal.

Table 3: *Summary of clinical characteristics for SUI only patients with surgery performed*

Clinical characteristics	N (%)
N surgery performed	**60**
Method of objective SUI assessment*	
Cough stress test/pad test	12 (20.0)
Urodynamic studies	47 (78.3)
Pelvic floor status*	
Dyspareunia	6 (10.0)
Pelvic pain	4 (6.7)
Voiding dysfunction/recurrent UTIs	5 (8.3)
Patient risk factors	
BMI, median (IQR)	27 (23, 32)
Current smoker	6 (10.0)
Diabetes	9 (15.0)
Post-menopause	36 (60.0)

***Note:** Multiple responses allowed, the total might be greater than 100%.

Procedure Characteristics

Procedure characteristics relating to a total of 60 procedures for SUI were recorded by the APFPR. The majority of these procedures (77%) were for those having their first (primary) procedure for treatment of SUI, with 12% having procedures performed for a complication or revision surgery from a previous SUI procedure (legacy procedures), and another 12% were not stated (Table 4).

Table 4: Summary of procedure characteristics for SUI patients with surgery performed

Procedure characteristics	N (%)
N surgery performed	**60**
Surgery indication	
Primary (implantation)	46 (76.7)
Legacy (revision) Procedure#	7 (11.7)
Not stated*	7 (11.7)

legacy procedure numbers are insufficient for reporting at this stage
* currently following up with sites

Postoperative outcomes

Fifty of the 60 women who had procedures for SUI (83%) attended their first postoperative follow up (Table 5), of which 39 underwent a primary procedure for SU. The median time to the first postoperative visit was 42 days. Thirty-nine of the 46 women who had primary procedures for SUI attended their first postoperative visit (Table 5). The median time to the first postoperative visit was 42 days. The majority (85%) of women with a primary procedure reported an imporvement in their SUI symptoms at thsi visit. Three patients were discharged requiring catherisation.

Table 5: *Summary of postoperative outcomes for primary SUI patients who attended the first follow-up visit*

Outcomes at first postoperative visit	Primary Procedure, N (%)
N postoperative visit attended	**39**
Time to postoperative visit (days), median (IQR)	42 (38, 46)
SUI outcome status	
Improved	33 (84.6)
Same	6 (15.4)
Worse	0 (0)
Complications	
Patient discharged requiring catheterisation	3 (7.7)

Thirteen patients attended their second postoperative visit with a median of 180 days; their SUI outcome status remained improved for 77% of these patients (Table 6).

Table 6: *Summary of postoperative outcomes for SUI patients who attended the second follow-up visit*

Outcomes at second postoperative visit	Primary Procedure, N (%)
N second postoperative visit attended	**13**
Time to postoperative visit (days), median (IQR)	180 (147, 208)
SUI outcome status	
Improved	10 (76.9)
Same	3 (23.1)
Worse	0 (0)

The data presented here is indicative of what the APFPR is collecting. We look forward to presenting more comprehensive data from over 1,000 procedures in our next Report.

ACADEMIC OUTPUTS

Publications

1. Ralphsmith M., Ahern S., Dean J., Ruseckaite R., Patient-reported outcome measures for pain in women with pelvic floor disorders: a systematic review. International Urogynecology Journal, 2022, https://doi.org/10.1007/s00192-022-05126-4

2. Ruseckaite R., Bavor C., Marsh L., Dean J., Daly JO., Vasiliadis D., Ahern S. Evaluation of the acceptability of patient-reported outcome measures in women following pelvic floor procedures. Qual of Life Res, 2022, https://doi.org/10.1007/s11136-022-03099-x

3. Ruseckaite, R., Daly, J.O., Dean, J. and Ahern, S. (2021), Outcomes collected in female pelvic floor surgical procedure registries and databases: a scoping review. Int Urogynecol J (2021). https://doi.org/10.1007/s00192-021-04839-2

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ACKNOWLEDGEMENTS

Steering Committee

Professor Susannah Ahern: Chair and Registry Custodian
Pip Brennan: Systemic improvement consumer representative (from June 2021)
Amanda Craig: Therapeutic Goods Administration representative
Professor Anne Duggan (former representative: **Dr Robert Herkes**): ACSQHC representative
Dr Elizabeth Gallagher: General gynaecology craft group representative
Professor Stephen Graves: External device registry representative
Gwili Holme: The Australian Government Department of Health and Aged Care representative
Associate Professor Emmanuel Karantanis: Urogynaecology craft group representative
Mr James Keck: Colorectal craft group representative
Dr Jennifer King: Urogynaecology craft group representative
Professor Helen O'Connell: Urology craft group representative
Dr Oliver Daly: Clinical Data Lead and Urogynaecologist
Sally Rayner: The Australian Government Department of Health and Aged Care representative
Mr John Short: New Zealand General gynaecology craft group representative
Kirstine Sketcher-Baker: Queensland Jurisdictional representative
Jarrod Williams (former representative: **Anne Stewart**): New Zealand Government representative
Dora Vasiliadis: Lived experience consumer representative (up until April 2022)
Associate Professor Jessica Yin: Urology craft group and Private Hospital representative

Registry personnel

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
Dr Rasa Ruseckaite - Senior Research Fellow
Kelly Tapley - Project Manager
Claudia Lassetter - Communications Manager
Aruna Kartik - Registry Coordinator
Randi Jayasinghe - Research Assistant
Anagi Wickremasinghe - Database Coordinator (Up until October 2022)
Jessy Hansen - Data Analyst
John Liman - Senior Software engineer
Michelle Merenda - Research Assistant
Marisa Caruso - Senior Coordinator (From September 2022)

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ABBREVIATIONS

Abbreviation	Description
ACHI	Australian Classification of Health Interventions
ACSQHC	Australian Commission on Safety and Quality in Health Care
AFS	Autologous Fascial sling
AIHW	Australian Institute of Health and Welfare
APFPR	Australasian Pelvic Floor Procedure Registry
APFQ	Australian Pelvic Floor Questionnaire
ARHA	Australian Research Healthcare Alliance
AUGS	American Urogynaecologic Society
BMI	Body Mass Index
BNI	Bladder Neck Injections
BSUG	British Society of Urogynaecology
CHF	Consumer Health Forum (Australia)
CORRP	Clinical Outcomes data Reporting and Research Program
CPD	Continuing Professional Development
CSSANZ	Colorectal Surgery Society of Australia and New Zealand
CQR	Clinical Quality Registry
DugaBase	Danish Urogynaecological Database
FDA	Food and Drug Administration (US)
HREC	Human Research Ethics Committee
ICD	The International Classification of Diseases (ICD) is a globally used diagnostic tool for epidemiology, health management and clinical purposes
IQR	Inter-quartile range (Statistical measure)
IUGA	International Urogynaecology Association
Lap Colpo	Laparascopic Colposuspension
MBS	Medicare Benefits Schedule
MC	Management Committee
MCCS	Mesh Complication Classification Scale
MDS	Minimum dataset
NFIR	Norwegian Female Incontinence Register
NMA	National Mutual Acceptance Scheme
Open Colpo	Open Colposuspension
OPS4 Code	OPCS Classification of Interventions and Procedures (Clinical Classification Code) (UK)
PI	Principal Investigator
PFD	Pelvic Floor Disorder
PFDR	Pelvic Floor Disorder Registry (US)
POP	Pelvic Organ Prolapse
PROMs	Patient reported Outcome Measures
PREMs	Patient Reported Experience Measures
RANZCOG	Royal Australian and New Zealand College of Obstetrics and Gynaecology
Rectopexy	An operation to repair rectal prolapse by attaching/fixing the rectum to the pelvis
REDCap	Research Electronic Data Capture
RP MUT	Retropubic Mid-urethral sling
SD	Standard Deviation (Statistical measure)
SUI	Stress Urinary Incontinence
TGA	Therapeutic Goods Administration
TO MUT	Transobturator Mid-urethral sling
TOT	Transobturator tape (relating to Mid-urethral sling)
TV Mesh	Transvaginal mesh
UGSA	Urogynaecological Society of Australia
USANZ	Urological Society of Australia and New Zealand
UTI	Urinary Tract Infection

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Figure 9: Number of hospital sites per state/territory with ethics and governance approvals

State/Territory	Site Name
NSW	St George Hospital
NSW	Westmead Hospital
NSW	Nepean Hospital
NSW	St George Private
NSW	Westmead Private Hospital
QLD	Buderim Private Hospital
QLD	Gold Coast University Hospital
QLD	Robina Hospital
QLD	Varsity Lakes Day Hospital
QLD	Sunshine Coast University Hospital
SA	The Royal Adelaide Hospital
SA	The Queen Elizabeth Hospital
SA	Calvary North Adelaide
SA	Flinders Medical Centre
TAS	Royal Hobart Hospital
WA	Hollywood Private Hospital
VIC	Monash Health
VIC	Cabrini Health
VIC	Western Health
VIC	Mercy Hospital for Women
VIC	St Vincent's Private Hospital
VIC	Bendigo Health
VIC	St John of God Bendigo Hospital
VIC	St John of God Geelong Hospital
VIC	Epworth HealthCare Richmond
VIC	Epworth HealthCare Freemasons
VIC	Epworth HealthCare Geelong
VIC	Epworth HealthCare Eastern
VIC	Waverley Private Hospital
ACT	Calvary John James Hospital
ACT	Canberra Private Hospital
ACT	Canberra Public Hospital

As at 1 December 2022

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