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On the 5th of April, this year, the federal health minister announced the Australian Government would invest $2.3 million over three years to establish the Australasian Pelvic Floor Procedure Registry (APFPR).[1] The objective of the registry is to improve the health outcomes of the tens of thousands of women who undergo pelvic floor reconstructive procedures annually. In 2018, the Australian Senate Community Affairs Reference Committee investigating the number of women in Australia who have had transvaginal mesh implants and related matters [2] reported that for many Australian women, there has been significant suffering including life changing adverse effects due to the complications and long-term effects of pelvic floor mesh. To date there has been no systematic tracking mechanism for the outcome of these procedures in the short or long term with respect to quality, safety and relative effectiveness. The APFPR will address these systemic deficits in the collection, analysis and reporting of pelvic floor procedures, to establish early warning systems, provide feedback to clinicians, hospital and ultimately the public regarding the

status of pelvic floor interventions which have the potential to provide significant improvements in quality of life.

Rationale for the establishment for the Clinical Quality Registry

Pelvic floor disorders are a common problem with up to 50% of Australian women affected by stress urinary incontinence (SUI); 9% symptomatic of pelvic organ prolapse (POP);[3] with a 20% lifetime risk for a pelvic floor reconstructive procedure.[4] By 2030 a 34% increase is expected in the number of women affected by pelvic floor disorders.[5] Approximately 25% of these procedures involve the use of a mesh product, with an estimated 150,000 mesh devices being implanted since 1998.

When conservative treatment such as pelvic floor rehabilitation has been unsuccessful, the impact of these disorders is sufficient for many patients to consider surgical intervention, and this will remain the case. However, the lack of satisfaction with the outcomes of native tissue procedures and promise of mesh in early studies has driven the development and uptake of mesh techniques to augment deficient tissue and suspend the pelvic floor.[6] Historically these new products were introduced into clinical practice with Federal Drug Administration (FDA) approval through the 510(k) process clearing a product for use if it was deemed to have substantial equivalence to a predicate device[5]. While the approval process differs in Australia, the approval of specific devices by the Therapeutic Goods Administration (TGA) has not substantially differed from those cleared for use in the USA. As a result, most mesh procedures and products have been deemed to be substantially comparable without requiring new evidence of safety or effectiveness, with high level evidence reporting the outcomes for some products published a median of 5 years after their introduction.[7]

In 2008, the FDA issued a public health notification regarding adverse events associated with urogynaecological mesh procedures[8] based on 2800 case reports of serious complications in SUI and POP surgery, subsequently updated in 2011. From 2013-2019, 109 post-market surveillance “522” studies were ordered for SUI mini-slings and transvaginal POP products. In response, many manufacturers withdrew their products. In 2017 the Therapeutic Goods Administration (TGA) cancelled registration for the remaining products in Australia[9]. As of December 2018, the TGA reclassified all surgical mesh product as class III device, requiring assessment of safety and efficacy, with existing products needing to

comply by December 2020. In 2019, the FDA ordered all transvaginal POP mesh products to be withdrawn, due to a lack of evidence that the probable benefits outweighed their probable risks with no reasonable assurance of safety and effectiveness. Currently, mid-urethral SUI slings can still be used in Australia, as can mesh used in abdominal sacrocolpopexy and rectopoexy. The message for clinicians is that just because a specific product has regulatory approval does not necessarily mean it is effective, or that the benefits outweigh the risks when compared with native tissue procedures. This emphasizes the importance of the ongoing monitoring of outcomes for the individual clinician and health system, such that patients can provide informed consent and the system ensures the safety and efficacy of approved products.

The disconnect between regulatory approval and clinical evidence supporting use, has had far reaching consequences for affected women and society at large. These consequences have led to enquiries in Australia, Canada, the European Union, New Zealand, the United Kingdom and United States; and medicolegal class actions involving thousands of women costing nearly 8 Billion US dollars[11], with a pending class action in Australia. Another potential cost of actions like the NHS pause on virtually all pelvic mesh procedures[12], is a significant reduction in access to procedures with high-level evidence of effectiveness. With the withdrawal of many of the mesh products, there has been a loss of techniques and accumulated evidence that may improve patient care. This demonstrates the need to invest in infrastructure to support continued improvement in the safety, performance and quality of medical devices, such as the TGA's action plan for medical devices[13], and the APFPR.

While the growing mesh 'crisis' was recognised by senior clinicians across several craft groups, a call to act has been long in coming. By late 2016, state Health Ministers were receiving complaints from increasing numbers of women with complications of mesh surgery regarding their inability to receive what they believed was adequate treatment. Several women had travelled to the US for mesh removal and were lobbying for a ban on the future use of transvaginal mesh, and expanded mesh removal services in Australia. The Australian Commission on Safety and Quality in Health Care (ACSQHC) was asked to review women's concerns, and in 2017, held consumer forums in most states. These forums led to the convening of a Pelvic Mesh Advisory Group which reviewed the published clinical data on mesh and concluded that there were significant complications associated with the use of

transvaginal mesh for POP and that it should only be used in a clinical trial setting. The working group published guidelines for the treatment of POP and SUI for clinicians, and consumer fact sheets to inform the public[14]. To ensure the highest standard of care for women with SUI and POP, the ACSQHC also published Hospital Credentialing Guidelines for senior medical practitioners performing mesh insertion and/or removal procedures, incorporating training requirements, sufficient surgical volumes and patient outcome review.[14]

In March 2018, the Senate Inquiry recommended implementation of the ACSQHC guidelines and the establishment of a mesh registry with the finding that there is no single source of information defining the number women who have had mesh implants, the rate and severity of complications[2]. This recommendation acknowledges that current sources of routinely collected administrative data and clinical records, do not provide reliable denominators or information about outcomes of mesh or non-mesh procedures. For example, Medicare Benefits Schedule (MBS) item numbers have not differentiated mesh from non-mesh procedures, nor do MBS statistics include inpatient medical and surgical procedures in the public sector.

In October 2018, the Australian Government response supported the Senate inquiry's recommendation[15] paving the way for the development of a clinical quality registry proposal and business case by gynaecology, urology and colorectal clinical leads, consumers, the ACSHQC and registry experts in collaboration with the Commonwealth and in-principle support from colleges and professional societies (RANZCOG, RACS, UGSA, USANZ, CSSANZ), culminating in the funding announcement.

Date	Event
1998	First urogynaecological mesh approved for use
2006	First mesh-related adverse event reported to TGA
2006-12	TGA receives 63 adverse event reports involving urogynaecological mesh
2010	TGA review of urogynaecological meshes reporting low complication rates
2012-2014	TGA receives 32 adverse event reports involving urogynaecological mesh
2014	TGA repeated review of urogynaecological meshes concluding little evidence for transvaginal POP mesh and low but likely under-reported complications.

Jan 2016	FDA reclassifies transvaginal POP mesh products from class II to III
Jan-Sept 2017	ACSHQC convenes consumer consultations
Aug 2017 – Mar 2018	Australian Senate Community Affairs Reference Committee investigates the number of women in Australia who have had transvaginal mesh implants and related matters
Nov 2017	TGA cancels registration of transvaginal POP mesh devices and SUI mini-slings
Jul 2018	ACSHQC Clinical care pathways and credentialing guidelines published
Oct 2018	Australian Government supports recommendations of Senate inquiry report
Dec 2018	TGA reclassifies all surgical mesh products as Class III devices
Apr 2019	Australian Government funding announcement
Jul 2019-20	Design and development APFPR governance structure
Jul 2020-22	Recruitment and implementation at pilot sites
Jul 2022	Evaluation report and national roll-out

Table 1: Timeline of events leading to establishment of Australasian Pelvic Floor Procedure Registry

Clinical Quality Registries

Clinical Quality Registries (CQRs) systematically monitor the quality of health care, within specific clinical domains, by routinely collecting, analysing and reporting health-related information.[16] The Commonwealth Government has supported and continues to support the national development of procedural CQRs, including the Australian Breast Device Registry (ABDR)[17] and Bariatric Surgery (BSR) Registry[18]. Following the development of pilot registries in 2012, the ABDR and BSR currently record more than 13,000 and 50,000 procedures per year, respectively, that represent 65-80% of related procedures, with increasing ascertainment rates each year. Both these registries have provided public annual reports and are in various stages of implementing site-based or clinician-level reporting. Data access procedures have enabled the provision of data and reports to jurisdictions, clinicians, researchers and industry for the purposes of quality improvement or research, and data from the ABDR has been used to inform TGA regulatory decisions, particularly in relation to the emergence and further investigation of a rare breast-implant associated lymphoma monitored by this registry[17].

In accordance with the ACSQHC's Framework for Australian clinical quality registries,[16] the APFPR will be designed to collect prospective, uniform longitudinal health outcome data for

all women undergoing pelvic floor reconstructive procedures for SUI, POP and any repeat surgery to manage complications. Data governance, including data validation, and reporting process will be developed to produce a range of periodic risk-adjusted reports providing appropriate feedback to clinicians, the public, health regulators and researchers. This information will be used to establish benchmarks, identify significant outcome variance related to products or practices, and inform improvements related to mesh and non-mesh pelvic floor procedures in the Australian population.

By collecting provider and patient data, the APFPR will also support the Senate report's recommendations[15] related to the adoption of the ACSQHC's SUI and POP care pathways and credentialing.[14] The APFPR will provide the necessary infrastructure and a minimum dataset for clinicians to inform their patients about outcomes, and meet continuing professional development and credentialing requirements. The APFPR dataset will enable device tracking and monitoring to support the TGA's role as a medical device regulator.

Development and Implementation of the APFPR

The APFPR will be established under the auspices of a Steering Committee (SC) representing key stakeholders including clinicians, consumers, colleges/professional societies (RANZCOG, RACS, UGSA, USANZ, CSSANZ), the ACSHQC, NHMRC-recognised Academic Health Research and Translation Centres (AHRTCs), the Therapeutic Goods Administration (TGA), state and federal jurisdictions, private health organisations and registry experts. Development of the registry structure will be informed by a review of the literature and existing pelvic surgery databases. Considerations include the governance and management processes; determination by consensus of a minimum dataset and clinical quality indicators; data collection, management, analysis and reporting processes; technical requirements to house and organise data; and a communication and engagement plan. Subsequently the APFPR will be piloted in public and private hospitals with a track record of contributing to registries or quality improvement activities, and then rolled out nationally, potentially utilising existing infrastructure such as the AHRTCs to facilitate engagement across these institutions.

To inform the governance structure, the APFPR will assess innovative registry methodologies that operationalise the Commonwealth draft National Clinical Quality Registry Strategy[19]. These will include investigation of opportunities to streamline ethics

approval and site governance processes to support collection of CQR data for quality improvement purposes, while adhering to privacy and confidentiality principles[19]. Additionally, the Commonwealth has signalled its intent to incorporate new clinical registry datasets into the Australian Institute of Health and Welfare's (AIHW) data hub, to support data sharing and linkage more readily[20]. Such initiatives, if successful, will support the efficiency, effectiveness and sustainability of the APFPR, as well as provide a model for future national registries.

Of greatest interest to clinicians will be what data is to be collected, how it will be collected, and how it will be used. The minimum data set and clinical quality indicators will be informed by the importance, feasibility and reliability of existing measures of SUI and POP procedures outcomes, safety and variation in care. To account for procedure type, outcomes and risk factor adjustment, the following domains will be considered:

- Patient identifiers and demographic data
- Surgical and perioperative data including
    - Indication for surgery including mesh insertion and removal
    - Procedure details (clinical site, surgeon, procedure date and type/s, MBS item number)
    - Device details (brand, device type, relevant serial numbers), if used.
- Complications and adverse event information
- Validated Patient Reported Outcome Measures (PROMs) for a specified period, and if complications occur or retreatment is required.

While the main impetus for the development of the APFPR is the concern over transvaginal mesh outcomes, it will be important to include SUI and POP procedures both with and without mesh, to calculate denominators and compare outcomes for procedures, existing and new.

The development and establishment of the APFPR will no doubt face challenges that include the recruitment of sites and clinicians, and building a consensus for a suitable minimum dataset that is feasible for routine collection. It will be foremost in the minds of the SC that the dataset achieves a balance between providing meaningful outcomes allowing risk-adjustment and benchmarking, while minimising the clinician burden of data collection.

However, as has been shown with the ABDR and BSR, a well-designed APFPR has the potential to support high levels of practitioner engagement and foster a practice of routine audit and clinical review. For patients who have suffered complications, and those undergoing pelvic floor procedures in the future, the APFPR will be designed to redress past system failures and inform evidence-based care driving improvement in patient safety and clinical outcomes.

References

1. $2.3 million to improve safety of pelvic floor surgery [Internet]. 2019. Available from: https://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2019-hunt115.htm

2. Australia, Parliament, Senate, Community Affairs References Committee, Siewert R. Number of women in Australia who have had transvaginal mesh implants and related matters. 2018.

3. 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: An International Journal of Obstetrics & Gynaecology. 2000;107(12):1460–1470.

4. Smith FJ, Holman CJ, Moorin RE, Tsokos N. Lifetime risk of undergoing surgery for pelvic organ prolapse. Obstetrics & Gynecology. 2010;116(5):1096–1100.

5. Economics DA. The economic impact of incontinence in Australia. Continence Foundation of Australia. 2011;

6. Weber AM, Walters MD, Piedmonte MR, Ballard LA. Anterior colporrhaphy: A randomized trial of three surgical techniques. American Journal of Obstetrics and Gynecology. 2001 Dec;185(6):1299–306.

7. Heneghan CJ, Goldacre B, Onakpoya I, Aronson JK, Jefferson T, Pluddemann A, et al. Trials of transvaginal mesh devices for pelvic organ prolapse: a systematic database review of the US FDA approval process. BMJ Open. 2017 Dec;7(12):e017125.

8. FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary

Incontinence [Internet]. 2008 [cited 2019 May 24]. Available from: http://wayback.archive-it.org/7993/20170111190506/http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm061976.htm

9. Transvaginal (urogynaecological) surgical mesh hub [Internet]. 2017. Available from: https://www.tga.gov.au/hubs/transvaginal-mesh

10. Urogynecologic Surgical Mesh Implants [Internet]. 2019. Available from: https://www.fda.gov/medical-devices/implants-and-prosthetics/urogynecologic-surgical-mesh-implants

11. Goldstein M. As Pelvic Mesh Settlements Near $8 Billion, Women Question Lawyers' Fees. The New York Times [Internet]. 2019 Jan 2; Available from: https://www.nytimes.com/2019/02/01/business/pelvic-mesh-settlements-lawyers.html

12. High vigilance restrictions on use of vaginal mesh [Internet]. Royal College of Obstetricians and Gynaecologists; 2019 [cited 2019 May 18]. Available from: https://www.rcog.org.uk/en/guidelines-research-services/patient-safety/mesh/

13. Action Plan for Medical Devices: Improving Australia's medical device regulatory framework [Internet]. Therapeutic Goods Administration. Australian Department of Health; 2019. Available from: https://www.tga.gov.au/publication/action-plan-medical-devices

14. Resources for consumers, clinicians and health service organisations – transvaginal mesh [Internet]. Australian Commission on Safety and Quality in Health Care; 2018. Available from: https://www.safetyandquality.gov.au/our-work/transvaginal-mesh/resources/

15. Australian Government response to the Senate Community Affairs References Committee report: The number of women in Australia who have had transvaginal mesh implants and related matters. 2018 Oct 18;15.

16. Framework for Australian clinical quality registries. Sydney: Australian Commission on Safety and Quality in Health Care; 2014.

17. Hopper IK, Parker EJ, Pellegrini B, Mulvany CM, Pase M, Ahern S, et al. Australian Breast Device Registry: 2017 Annual Report. 2019;

18. Bariatric Surgery Registry 2017/18 Report [Internet]. Monash University; 2018 Aug. Report No.: 6th. Available from: https://www.monash.edu/__data/assets/pdf_file/0003/1481943/Bariatric-Surgery-Registry-2018_FINAL.pdf

19. Draft National CQR Strategy May 2019 - Consultation.pdf [Internet]. Department of Health, Australian Government; 2019. Available from: https://www.health.gov.au/internet/main/publishing.nsf/Content/Draft_National_%20CQR_Strategy

20. Data availability and use [Internet]. Australian Government; 2018. Available from: https://dataavailability.pmc.gov.au/overview.html