

Dear clinician,

Trends in Pelvic Floor Procedures in Australia – A Survey

You are invited to take part in this survey that is being administered by the Australasian pelvic floor procedure registry (APFPR). The APFPR monitors safety and quality of pelvic floor procedures undertaken in Australian hospitals. This survey is designed to understand current pelvic floor procedures (PFPs) undertaken by Australian gynaecologists, urogynaecologists and urologists.

The aim of the survey is to document current surgical practice in PFPs, existing variation in PFPs across jurisdictions and sectors, factors relating to clinician selection of PFPs, potential clinician consequences of changing practice and the impact of changing practice on patient care and outcomes.

The results of this survey will be used to inform the future procedure scope of the APFPR. It may also be used to inform regulators such as the TGA of current practice. All the information obtained from the survey will remain confidential.

Participation is voluntary and the survey will be open for two weeks for you to complete.

We thank you for your contribution.

Prof Susannah Ahern
MBBS (Hons), MBA, PhD

APFPR Coordinating Principal Investigator
Head, Clinical Outcomes data Reporting and Research Program (CORRP)
Department of Epidemiology and Preventive Medicine
Monash University

Explanatory Statement

Project ID: 34517

Project Title: Trends in pelvic floor procedures in Australia – A Survey

Chief Investigator:

Professor Susannah Ahern MBBS (Hons),
MBA, PhD
Chair and Academic Lead Head
Australasian and Pelvic Floor Procedure
Registry
Phone: +61 3 9903 0139
Email: susannah.ahern@monash.edu

Co-investigator:

Randi Thisakya Jayasinghe BBioMed Sci
(Hons)
Dept of Epidemiology & Preventive
Medicine
Phone: +61 3 9903 0701
Email : randi.jayasinghe@monash.edu

You are invited to take part in this survey. Please read this Explanatory Statement in full before deciding whether or not to participate in this research. If you would like further information regarding any aspect of this project, you are encouraged to contact the researchers via the phone numbers or email addresses listed above.

Participation in this survey is voluntary. This Explanatory Statement explains the purpose of this survey and describes what will be involved should you decide to participate.

All the information obtained from the survey will remain confidential. No information that could lead to the identification of any individuals will be disclosed in any medical articles or to any party.

Background

Given the significant adverse events resulting from transvaginal mesh implants, the Senate Community Affairs References Committee made 13 recommendations, six of which related to the establishment of a system for monitoring and reporting the number of devices implanted and patient outcomes including complications and adverse events.

The Australasian Pelvic Floor Procedures Registry (APFPR) was established by the Registry Science and Research Unit, Department of Epidemiology and Preventive Medicine (DEPM), Monash University following successful acquisition of a Department of Health, Government grant. The registry is 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 collected will assist with benchmarking and other safety and quality activities.

As a clinical quality registry, it is imperative that the scope of the registry remains relevant in the current environment. The Therapeutic Goods Administration (TGA) banned a number of mesh devices and transvaginal procedures for POP which resulted in marked decline in the availability of mesh products for PFPs. This has meant a reduction in the number of PFPs being undertaken in Australia that has impacted registry recruitment.

To ensure that the registry remains relevant, the APFPR has decided to conduct this survey to evaluate the trends in PFPs that are being performed in Australia to better inform the scope of the registry. As a major stakeholder, your input will assist in ensuring the registry is relevant and meaningful.

Aim of the survey

The **aim** of this project is to gain an understanding of the current trends in PFPs undertaken by gynaecologists, urogynaecologists and urologists in Australia.

The survey is also to document current surgical practice in PFPs including procedures undertaken and whether their nature and volume has changed over time, observe variation in PFPs across jurisdictions and public and private sector, factors that relate to clinician selection of PFPs, other consequences of mesh restrictions and the potential significance of the impact on mesh restriction on patient care and outcomes. Findings of this survey will support ongoing development of a pelvic floor procedure clinical quality registry so that its scope will remain relevant to current clinical practice.

How to complete this survey?

The short online survey comprises of 17 questions (predominantly multiple choice). It should be completed by surgeons who undertaken pelvic floor procedures that include SUI and POP.

The survey is expected to take approximately **5** minutes to complete.

The survey will be open for you to complete for two weeks. Please note that a reminder email will be sent to you again by your college or society in one week's time. This is regardless of the completeness status of this survey due to responses being anonymous.

Data storage and access

All data collected through the survey will be stored electronically; initially via the Monash-licensed Qualtrics platform, which is accessible only via a Monash log in and password. Following export on a database for analysis the data will be stored on the secure Monash University server which will be accessible only to the research team. Data collected will be collated and published as summary data for public access.

In accordance with Monash University requirements and policy, data will be stored for at least five years post completion of this project. It will be deleted after this time, if it is no longer required.

Further information

If you have any questions about this study or wish to obtain a paper copy of the survey, please contact Randi Jayasinghe, Research Assistant (T +61 3 9903 0701), E Randi.Jayasinghe@monash.edu

Complaints

Should you have any concerns or complaints about the conduct of the project, you are welcome to contact the Executive Officer, Monash University Human Research Ethics (MUHREC):

Executive Officer

Monash University Human Research Ethics Committee (MUHREC)

Room 111, Chancellery Building D,

26 Sports Walk, Clayton Campus

Research Office

Monash University VIC 3800

Tel : +61 3 9905 2052 Email : muhrec@monash.edu Fax : +61 3 905 3831

Thank you,



Professor Susannah Ahern MBBS (Hons), MBA, PhD

Chair and Academic Lead Head

Australasian and Pelvic Floor Procedure Registry

Please note, by completing the survey you consent to take part in this research and agree to the information provided in the Explanatory Statement.