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Surgical Mesh Registry: Cost Benefit Analysis

Ministry of Health

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Stewart Jessamine
Director Protection, Regulation and Assurance
Ministry of Health
PO Box 5013
Wellington 6140

Dear Stewart

Surgical Mesh Registry: Cost Benefit Analysis

Please find attached our report on "Surgical Mesh Registry: Cost Benefit Analysis".

It has been a pleasure working with the Ministry of Health on this important project. We look forward to working with you again in the near future.

Yours sincerely

Linda Meade
Partner

for Deloitte Limited (as trustee for the Deloitte Trading Trust)

Contents

Glossary

Acronym	Full name
ACC	Accident Compensation Corporation
ACSQHC	Australian Commission on Safety and Quality in Health Care
AIHW	Australian Institute of Health and Welfare
ANZDATA	Australia and New Zealand Dialysis and Transplantation Database
ANZICS APD	Australia and New Zealand Intensive Care Society Adult Patient Database
AOANJRR	Australian Orthopaedic Association National Joint Replacement Registry
AUD	Australian dollar
ARTG	Australian Register of Therapeutic Goods
CQR	clinical quality registry
CRM	customer relationship management
DALY	disability-adjusted life year
DHB	District Health Board
FDA	Food and Drug Administration (US)
HREC	Human Research Ethics Committee
ICD10	International Classification of Diseases, 10th edition
IT	information technology
LOS	length of stay
MoH	Ministry of Health
MUS	mid-urethral sling
NPV	net present value
PCR	Prostate Cancer Registry
PFMT	pelvic floor muscle training
POP	pelvic organ prolapse
PPP	purchasing power parity
PSM	positive surgical margin
QALY	quality adjusted life year
SUI	stress urinary incontinence
TGA	Therapeutic Goods Administration
TOT	trans obturator tape
TVT	tension-free vaginal tape
US	United States
VSL(Y)	value of a statistical life (year)
VSTR	Victorian State Trauma Registry
WHO	World Health Organization
YLD	Years of life (lost to) disability
YLL	Years of life lost

Executive summary

The Ministry of Health (MoH) asked Deloitte Access Economics to estimate the costs and benefits of setting up a register for surgical mesh. As well as patient follow up, registries can reduce the costs and adverse consequences of surgery. The main uses of surgical mesh are for hernia repair (mostly males) and pelvic organ prolapse (POP) and stress urinary incontinence (SUI). POP is by definition a female-only condition, and the use of mesh for SUI repair relates almost exclusively to females.

There are a number of types of medical registries. Some mainly keep track of patients so they can provide early warning of unsafe devices identified through other sources and/or monitor patient outcomes. Some very large long-running registers in populous countries are designed to detect unsafe devices. A third type, a clinical quality registry (CQR) is designed to continually monitor and improve surgical outcomes, resulting in lower treatment cost, mortality and morbidity. After consultations with relevant parties (see Appendix A) a QCR had strong support. Further, the benefits of such registries are both predictable and quantifiable, unlike either of the other two options. Accordingly, the registry has been modelled as a QCR.

Number and cost of mesh surgery in New Zealand

Estimating the number of mesh surgeries in New Zealand is a difficult exercise. Unlike under Australia's Medical Benefits System (MBS) there are no separate codes for surgeries that contain mesh and for those that do not. Further, the majority of mesh surgery in New Zealand is conducted in private hospitals, which do not have to report their data to the Government.

However, Deloitte Access Economics has been able to estimate the prevalence of hernias, SUI and POP, from a mixture of New Zealand and international sources. This was used to forecast the total number of people expected to have these conditions over the next decade (section 3.1). The proportion of these conditions severe enough to require surgery was estimated by comparing current surgery rates in public hospitals from data supplied by MoH and weighted estimates for private hospital surgeries from those that do report to MoH. This ratio was then used to estimate the total numbers of hernia, SUI and POP surgeries between 2018 and 2027 (section 3.2

Finally, the proportion of surgeries for each condition that entail mesh implants was largely estimated from peer-reviewed journal articles, and consultations with general, urological and gynaecological surgeons in New Zealand.

As transvaginal mesh products for POP are no longer supplied in New Zealand, POP will remain limited to a small number of abdominal mesh operations. While the New Zealand population is forecast to grow by half a million people over the decade, it is expected that POP and SUI surgery numbers will only grow by 300 between them. Conversely, the peak age for hernia is 65, and as the population ages there will be over 1,500 more such surgeries in 2027 than currently.

Table 1.1: Estimated numbers of mesh surgeries, by type, 2018 to 2027

Category	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027
Hernia	9,064	9,259	9,445	9,627	9,799	9,969	10,139	10,305	10,470	10,633
SUI	1,448	1,469	1,488	1,506	1,522	1,539	1,557	1,576	1,595	1,612
POP	761	779	795	812	827	843	858	873	887	900
Total	**11,273**	**11,506**	**11,729**	**11,945**	**12,148**	**12,352**	**12,555**	**12,754**	**12,952**	**13,145**

Source: Table 3.4

Chapter 5 considered two types of costs from mesh surgeries: health system costs, and burden of disease costs. The costs of surgery for hernia, SUI and POP in public hospitals and such private hospitals as supply data were provided by MoH. While these costs did not differentiate between mesh and non-mesh surgeries,

for hernia and SUI, mesh is the 'gold standard', so the average cost for all forms of surgery was assumed to be the same as for mesh surgery. Even though mesh is definitely not the gold standard for POP, in the absence of other data, the average costs was assumed to apply to mesh surgery too. However, this errs on the side of caution, as the mesh itself can cost several hundred dollars.

- Costs were assumed to be the same for both initial and revision surgeries, on the basis that a recurrence of a condition will require similar treatment to its original instance.
- Other health system expenditure, such as GP visits or pain medication were not included due to lack of data.

The other cost included is burden of disease. The World Health Organization (WHO) measures the impact of conditions in terms of disability adjusted life years (DALYs). The New Zealand Government has an official parameter estimate for the value of healthy life lost when a person experiences reduced wellbeing or dies prematurely due to a disease or injury. This is known as the 'value of a statistical life year' (VSLY), which is $172,684 in 2018 (section 5.1). This enables DALYs to be converted to monetary values, on the basis that the VSLY is the value of one DALY.

Morbidity costs are modelled for all three conditions, but mortality is only modelled for hernia. While mortality rates for elective hernia surgery are no higher than for the general population, mortality rates for emergency hernia surgery are seven times higher (Nilsson et al, 2007). Given that there are several thousand hernia surgeries in New Zealand every year, some emergency mortality is to be expected. Conversely, however, mortality from POP or SUI mesh surgery in New Zealand, appears to be too low to be modelled. The US FDA (2011) reports only around one fatality per year on average from POP surgery in the US. Similarly, rates from the literature would suggest that no fatalities from SUI surgery would be expected in New Zealand over the decade being modelled. Accordingly, potential benefits from any averted POP or SUI mortality from a mesh registry have not been incorporated in the model.

The financial and burden of disease costs of mesh surgery for each type of condition were between $13,000 and $14,000.[1]

Table i: Summary of costs by category and type of surgery

Cost type	Hernia	SUI	POP
Mortality	$2,244		
Morbidity	$5,356	$7,292	$6,809
Treatment costs	$5,653	$6,621	$7,019
Total	**$13,253**	**$13,913**	**$13,828**

Source: Table 5.1, Table 5.2 and Table 5.3

Multiplying the costs per surgery for each type of surgery by the estimated future surgeries of that type, yields over $1.6 billion in expected total future costs of mesh surgeries in New Zealand over the next decade. All future financial costs are converted to net present values using the New Zealand Treasury's required real 6% discount rate, and thus reported in real 2018 dollars.

Table ii: Estimated costs of mesh surgery, by type, 2018 to 2027 ($m, NPV)

Category	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	Total
Hernia	$120.1	$122.7	$125.2	$127.6	$129.9	$132.1	$134.4	$136.6	$138.8	$140.9	$1,308.2
SUI	$20.1	$20.4	$20.7	$21.0	$21.2	$21.4	$21.7	$21.9	$22.2	$22.4	$213.1
POP	$10.5	$10.8	$11.0	$11.2	$11.4	$11.7	$11.9	$12.1	$12.3	$12.4	$115.2
Total	**$150.8**	**$153.9**	**$156.9**	**$159.8**	**$162.5**	**$165.2**	**$167.9**	**$170.6**	**$173.2**	**$175.8**	**$1,636.5**

Source: Table 7.4

[1] All costs in this report are in New Zealand dollars, unless specified otherwise.

Costs and benefits of clinical registries

The Australian Commission on Safety and Quality in Health Care (ACSCHC, 2016) conducted a landmark study on the benefits of Australian QCRs. While the absolute impact of the conditions they dealt with varied considerably, the relative benefits of continuous quality improvements were similar across the registries studied.

Table iii: Attributable impacts of clinical quality improvements

Type of impact	Mean reduction attributable to CQRs
Treatment costs	8.2%
Morbidity	9.8%
Mortality	3.4%

Source: Table 6.5

Based on the analysis of Australian CQRs in section 4.3, fixed costs for a New Zealand mesh registry would be expected to be around a half a million (2018) dollars per year. In Australia, the average variable cost per patient was $61. However, as Australian health record systems are nearly all electronic, whereas New Zealand's District Health Boards (DHBs) still mostly use paper-based records, per patient variable costs were doubled to reflect the double handling entailed in recording patient details firstly on paper and then again electronically. That is, if a mesh register were operating in New Zealand now, it would be expected to cost around $1.95 million per year to operate.

Table 1.2: Estimated operating costs for a New Zealand mesh registry, 2018

Type of cost	Sub component	Total $'000
Total fixed		576
Variable per person	$122.24	
Patients	11,273	
Total variable costs		1,378
Total costs		**1,954**

Source: Table 4.5

Assuming that the (fixed and per patient variable) costs of operating a registry do not vary in real terms going forward, then the costs of a hypothetical registry set up now would total $14.8 million by 2027.

Assuming that a New Zealand mesh CQR would confer the same average percentage reductions in treatment costs and morbidity and mortality as its Australian counterparts, then it could be expected to confer $45.6 million in benefits between years six and ten of its operations. Benefits are not counted before year six, as the average Australian CQR took five years before it had collected enough longitudinal data to be able isolate modifiable risk factors and enhance overall clinical quality outcomes This leads to benefit to cost ratio of 3.1 to 1. Despite the higher variable costs, this still falls within the BCR ranges identified by the ACSQHC for Australian CQRs.

Table 1.3: Estimated potential benefits for a new mesh registry, 2018 to 2027 ($m)

Category	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	Total
Costs	$0.90	$1.86	$1.78	$1.69	$1.61	$1.53	$1.56	$1.38	$1.32	$1.25	**$14.78**
Benefits						$9.97	$9.52	$9.09	$8.68	$8.28	**$45.55**
BCR											**3.08:1**

Source: Table 7.4 and Table 7.1

2 Background

Surgical mesh is a loosely woven sheet used as a permanent or temporary support for organs and other tissues during surgery. Surgical mesh is created from both inorganic and biological materials and is used in a variety of surgeries. Though hernia repair surgery is the most common application, it can also be used for reconstructive work, such as in pelvic organ prolapse.

In January 2018 Medsafe used the provisions in the Medicines Act 1981 to request safety information from four suppliers of surgical mesh products in New Zealand. The results of the review meant all surgical mesh products whose sole use is the treatment of pelvic organ prolapse via transvaginal implantation will no longer be supplied. One product, a single incision mini-sling for the treatment of stress urinary incontinence, is also now no longer supplied in New Zealand

The Parliamentary Health Committee's report on Petition 2011/102 of Carmel Berry and Charlotte Korte recommended investigating options for establishing and maintaining a surgical mesh registry in New Zealand.

2.1 Conditions that mesh is used for

2.1.1 Pelvic organ prolapse

POP is a condition of weakness of the supporting tissues of the vagina and uterus. Women experience a sensation of a lump in the vagina, discomfort, and a 'dragging' sensation in the pelvis. This can result in functional changes affecting the bladder and bowel, as well as impact sexual function. There are three main types of POP and it is possible for a patient to have one or more types of prolapse at the same time. These include:

- Anterior vaginal wall prolapse
- Posterior vaginal wall prolapse
- Apical vaginal prolapse (which abdominal mesh is still permitted for).

2.1.2 Stress Urinary Incontinence

SUI is the condition of involuntary urinary leakage, which occurs with events such as coughing, sneezing, and exercise. It is common, with one in three women experiencing urinary incontinence after childbirth.[2] When conservative (non-surgical) treatments are unsuccessful, there are a number of surgical treatments available.[3]

2.1.3 Hernia

A hernia is the abnormal exit of tissue or an organ, such as the bowel, through the wall of the cavity in which it normally resides. Hernias come in a number of different types but, most commonly, they involve the abdomen. Symptoms may include pain or discomfort especially with coughing, exercise, or going to the bathroom.

2.1.4 Other conditions

Mesh is also used in range of less common surgeries, for example, breast reconstruction. These procedures are out of scope for our analysis.

2.2 Surgical mesh

Surgical mesh is a medical device implanted in the human body to repair damaged or weakened body tissue. This can be in the form of synthetic material, biologic material or a combination of both.[4] Between 2005 and October 31 2014, 56,508 mesh devices were sold domestically.[5]

[2] https://www.continence.org.au/pages/pregnancy.html
[3] Medsafe (2017) reports very small numbers of mesh devices for male urinary incontinence (less than 30 a year on average). Such devices are not covered in this report.
[4] https://www.acc.co.nz/assets/provider/surgical-mesh-report.pdf
[5] https://www.acc.co.nz/assets/provider/surgical-mesh-report.pdf

Various types of mesh are available; synthetic mesh differs in porosity and filament combinations, and biologic mesh differs in donor species.[6] Synthetic mesh is a non-absorbable material commonly comprising macroporous monofilament polypropylene, also referred to as type 1-mesh.

According to Accident Compensation Corporation (ACC) surgical mesh reports, type 1-mesh is the recommended and most widely used synthetic material in continence surgery. It is the synthetic mesh most compatible for implantation and has the lowest tendency to cause infections due to its admission of macrophages and the consequent fibroplasia and angiogenesis. [7]

According to the Medicines (Database of Medical Devices) Regulations 2003, surgical mesh has a risk classification of Class IIb. The classification scheme is used internationally and, for schemes where pre-market approval is required, is used to determine the level of scrutiny required before a device is approved for supply. In New Zealand, medical devices require no pre-market approval, and market entry just requires listing the product on Medsafe's Web Assisted Notification of Devices (WAND) database within 30 days of marketing. There is no requirement for approval by an overseas medical device regulator before a device is listed and supplied. There is no specific requirement for suppliers to hold documentation of the device's safety and effectiveness, however, this can be requested should a concern arise in regard to the safety of a device.[8]

During December 2017, Medsafe requested safety information from surgical mesh suppliers in New Zealand in accordance with section 38 of the Medicines Act 1981. This request led to the removal of products from supply whose sole purpose was treatment of pelvic organ prolapse via transvaginal implantation, and the removal of one product, a single incision mini-sling, for the treatment of stress urinary incontinence. Information in relation to use and indications was required to be changed for certain other products.[9]

2.3 Traditional treatment for these conditions and role of mesh

2.3.1 Stress Urinary Incontinence

Traditional treatments of SUI can involve lifestyle interventions such as pelvic floor muscle training (PFMT), physiotherapy and drug therapy. However if these do not to provide satisfactory outcomes, doctors may consider surgery.[10]

Procedures carried out prior to the introduction of surgical mesh include open retropubic and laparoscopic colposuspension, which was commonly practiced during the late 1990s and early 2000s, and had been a widely evaluated surgical technique for SUI. However, colposuspension surgery has significant incidence of secondary POP.

In the late 1990s, a new treatment for stress incontinence was introduced. This involved a permanent synthetic sling, called a mid-urethral sling (MUS) placed under the urethra to give it support. By 2002, the mid-urethral sling became one of the most frequently performed incontinence surgeries in Australasia, because it was equivalent to, or better than, alternative procedures. The blood loss and operating time were less and recovery times were shorter than older procedures. High-quality clinical studies demonstrated their effectiveness in in the long term.[11]

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[6] Haines, M., Kobashi, K., & Rashid, P. (2017). The mid-urethral sling: current issues. Australian & New Zealand Continence Journal, 23(4), 92-96.
[7] https://www.acc.co.nz/assets/provider/surgical-mesh-report.pdf
[8] MedSafe Medical Device Registration in New Zealand. https://www.emergobyul.com/services/new-zealand/medsafe-medical-device-registration-new-zealand
[9] https://www.health.govt.nz/news-media/media-releases/regulatory-action-surgical-mesh-products
[10] Chapple, C. R., Cruz, F., Deffieux, X., Milani, A. L., Arlandis, S., Artibani, W., & ... Abdel-Fattah, M. (2017). Consensus Statement of the European Urology Association and the European Urogynaecological Association on the Use of Implanted Materials for Treating Pelvic Organ Prolapse and Stress Urinary Incontinence. *European Urology*, 72(3), 424-431.
[11] Royal Australian and New Zealand College of Obstetrics and Gynaecology (RANZCOG) Submission to the Inquiry into the number of women in Australia who have had transvaginal mesh implants and related matters.

Three most common vaginal mesh implants used are:

- TVT (tension free vaginal tape) – the operation involves inserting the tape from an incision on the front wall of the vagina (retropubic) and then up to two small incisions on the lower abdomen. The tape supports the urethra, lying between the vaginal wall and the urethra.
- TOT (trans obturator tape) – similar to TVT but involves a different insertion technique, involving a small cut at the top of each thigh where the tape is brought out and cut off level with the skin.
- Mini-slings – these were designed to minimize the operative procedure as much as possible to reduce complications of thigh pain and bladder outlet obstruction. Unlike the above two implants, mini-slings only have a single incision, and so in principle should be safer. In 2005 the Australian Therapeutic Goods Administration (TGA) approved new mini-slings. However, as Christopher Maher, Professor of Urogynaecology at the University of Queensland states, there was no robust evidence at the time confirming whether they were safer or more effective than the traditional mid-urethral sling.[12]

2.3.2 Pelvic Organ Prolapse

Traditional surgery for pelvic organ prolapse involved repairing the torn connective tissue with sutures. This was called vaginal repair, and was associated with a high rate of the prolapse recurring. Following the success of the sling tape in stress incontinence and of mesh use for hernias, doctors and manufacturers looked to introduce a mesh product to treat vaginal prolapse. This involved sheets of mesh placed under the bladder, or in front of the bowel, to stop prolapse and prevent recurrence.[13]

2.3.3 Hernia

Surgery is recommended for some types of hernias, although others may just be watched, or treated with medication. Most abdominal hernias can be surgically repaired, although surgery can have complications. When mesh is used, it is placed either over the defect (anterior repair) or under the defect (posterior repair).[14]

2.4 Issues with mesh

The non-absorbable monofilament of mesh is generally considered inert and safe. Despite this, mesh can be associated with infection, seroma formation, extrusion and shrinkage. Nevertheless, surgeons use this across specialities for augmentation of tissue in reconstructive techniques.

2.4.1 International issues

In 2014, the Scottish Government suspended mesh use pending safety investigations.[15]

The Scottish independent review of mesh procedures identified that research studies on safety had not provided sufficient evidence on long-term impacts of mesh surgery. This is due to a lack of long-term follow up and corresponding outcome data, such as quality of life and activities of daily living.[16]

In early 2018 the British Government launched a retrospective audit of women who have undergone vaginal mesh surgery to understand how many have experienced complications following the procedure. The Health and Social Care Secretary has also launched a review into how the National Health Service addresses concerns about medical treatments, including vaginal mesh devices.[17]

In Australia, the Community Affairs Reference Committee released its report, *Number of women in Australia who have had transvaginal mesh implants and related matters*, in March 2018. The report made 13 recommendations, including considering establishing a registry for all high-risk implantable devices.

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[12] Explaining the vaginal mesh controversy: https://medicine.uq.edu.au/article/2017/06/explaining-vaginal-mesh-controversy

[13] https://www.womenshealth.gov/a-z-topics/pelvic-organ-prolapse

[14] http://www.nhs.uk/conditions/hernia/Pages/Introduction.aspx

[15] http://www.bbc.com/news/uk-scotland-27887766

[16] The Scottish Independent Review of the Use, Safety and Efficacy of Transvaginal Mesh implants in the treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse in Women: Report (2017), http://www.gov.scot/Resource/0051/00515856.pdf

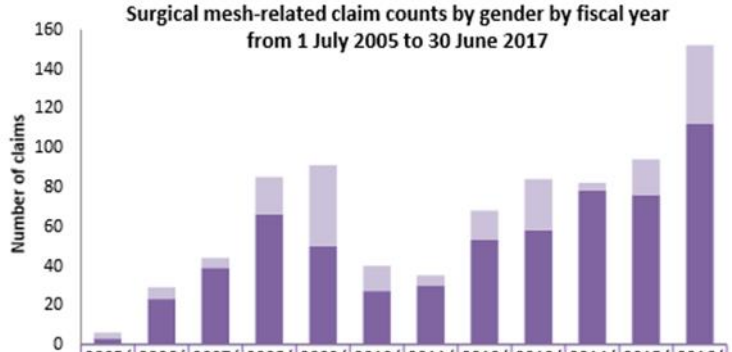
[17] https://www.theguardian.com/society/2018/feb/21/jeremy-hunt-launches-review-into-handling-of-surgical-mesh-scandal

The Therapeutic Goods Administration (TGA) decided in November 2017 to remove transvaginal mesh products whose sole use is the treatment of pelvic organ prolapse via transvaginal implantation from the Australian Register of Therapeutic Goods (ARTG). The TGA also decided to remove single incision mini-slings for the treatment of stress urinary incontinence from the ARTG. Mini-slings are different devices to mid-urethral slings, which are not being removed from the ARTG.[18]

2.4.1.1 New Zealand context

In New Zealand, there has been a small, but steadily rising number of claims for treatment-injury compensation presented to ACC.

Figure 1.1: ACC mesh treatment injury claims by year and gender



	2005/06	2006/07	2007/08	2008/09	2009/10	2010/11	2011/12	2012/13	2013/14	2014/15	2015/16	2016/17
Total decision	6	29	44	85	91	40	35	68	84	82	94	152
Male	<4	6	5	19	41	13	5	15	26	4	18	40
Female	<4	23	39	66	50	27	30	53	58	78	76	112

Note: Claim counts fewer than four (n=1, 2 or 3) are presented as "<4"

Source: ACC (2017)

Following the review of the information supplied as a result of the of the regulatory action taken by Medsafe under section 38 of the Medicines Act 1981, Medsafe announced in January 2018 that all surgical mesh products used solely for the treatment of pelvic organ prolapse via transvaginal implantation will no longer be supplied. Single incision mini-slings for the treatment of stress urinary incontinence are also no longer supplied in New Zealand.

2.4.2 Parliamentary report and Government response

In March 2014, a private petition was presented to the Health Committee requesting an independent inquiry of safety regarding surgical mesh use as medical treatment in New Zealand.[19] The Health Committee's June 2016 report on the petition made seven recommendations to the Government, including working with relevant medical colleges to investigate options for establishing and maintaining a centralised surgical mesh registry. The Government's response, tabled on 24 August 2016, supported all of the Committee's recommendations.

2.5 Clinical registries

Clinical registries are databases that collect health-related information on patients who are:

- Treated with a particular surgical procedure, device or drug
- Diagnosed with a particular illness
- Managed via specific healthcare resource[20]

[18] https://www.tga.gov.au/alert/tga-actions-after-review-urogynaecological-surgical-mesh-implants
[19] https://www.acc.co.nz/assets/provider/surgical-mesh-report.pdf
[20] Monash Clinical Registries: https://www.monash.edu/medicine/sphpm/registries

2.5.1 New Zealand registries[21]

There are a number of registries already in use in New Zealand. Some collect information pertinent to New Zealand only, while others maintain trans-Tasman data sets.

- Prostate Cancer Outcome Registry (Australia and New Zealand)
- Australians and New Zealand Hip Fracture Registry
- Australian and New Zealand Massive Transfusion Registry
- Australian and New Zealand Society of Cardiac and Thoracic Surgeons
- Australian and New Zealand Thyroid Cancer Registry
- Burns Registry of Australia and New Zealand
- Bariatric Surgery Registry. This is a bi-national initiative from the Obesity Surgery Society of Australia and New Zealand. The registry tracks patients for 10 years following bariatric surgery, recording any need for re-operation, and any changes in weight and diabetes status.[22][23]
- New Zealand Cancer Registry - a population-based register of all primary malignant diseases diagnosed in New Zealand, excluding squamous and basal cell skin cancers.
- New Zealand Joint Registry, established by the New Zealand Orthopaedic Association to collect data on implants and outcomes.[24] In 2000 data collection was expanded to include total hip replacements for fractured neck of femur, unicompartmental replacements for knees, and total joint replacements for ankles, elbows and shoulders.

2.5.2 Australian and international registries

There are a large number of clinical registries around the world. Australia – which like New Zealand is a small population country by world standards – has over 40 clinical registries. Sweden has over 100 registries. Across the world, there are registries specifically devoted to mesh implants, as well as for pelvic floor disorders and hernias.

2.6 Types of registries

This report provides estimates of possible costs and benefits for a prospective surgical mesh registry in New Zealand.[25] In order to do so, some high-level assumptions regarding the nature of the registry have had to be made. Essentially, there were three broad types to choose from.

- 1) A simple customer relationship management (CRM) system. This would essentially be a kind of advanced address list that could warn patients if their devices were found unsafe from other contexts. While it would be a cheaper option, it would also have relatively low benefits. Such a registry would not be able to identify unsafe products. When such products were identified from other sources, the CRM system could alert patients. However, most such cases are likely to be identified by the ACC and improved adverse event reporting under proposed Medsafe regulations. Further, as mesh explant is often a more complicated operation than mesh implant, earlier warning may not lead to alleviated symptoms.
- 2) A clinical quality registry. This registry would include the CRM components of the first option, but its aim would be more to prevent problems than to provide early warning after problems have occurred. Clinical quality registries have been shown to yield substantial improvements in surgical morbidity and mortality, and to reduce treatment costs.[26] There was strong support for a QCR in consultations – most of the ones in Australia were established by and for the benefit of surgeons.

[21] https://www.health.govt.nz/nz-health-statistics/national-collections-and-surveys/collections

[22] https://clinicaltrials.gov/ct2/show/NCT03441451

[23] http://www.scoop.co.nz/stories/GE1707/S00050/bariatric-surgery-registry-launches-in-new-zealand.htm

[24] https://nzoa.org.nz/nz-joint-registry

[25] Deloitte has been asked to model a registry which only includes new mesh implants, rather than retrospective cases.

[26] Australian Commission on Safety and Quality in Health Care (ACSQHC, 2016)

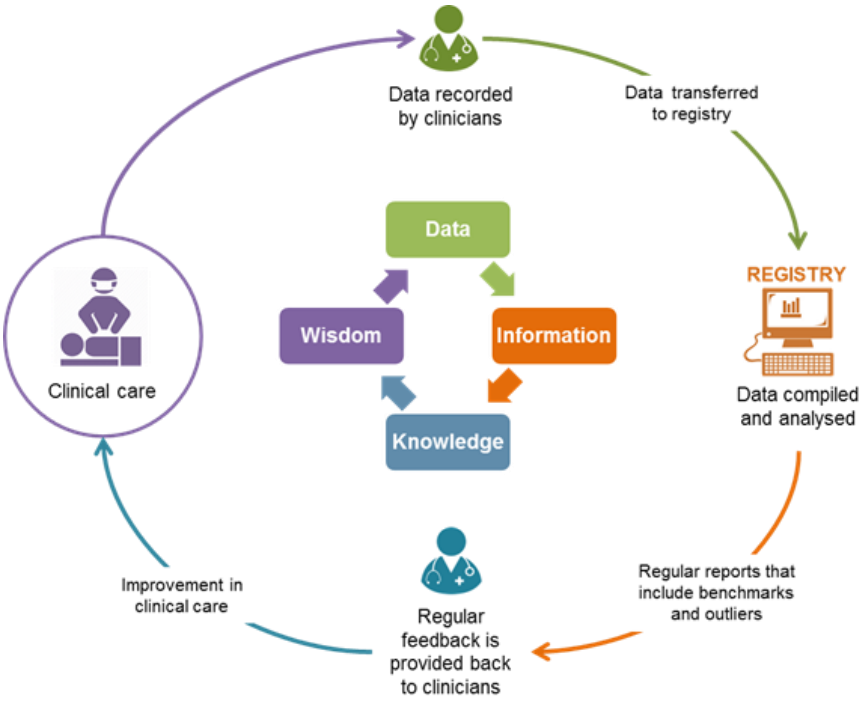
- 3) A safety registry. Some registries have the statistical power to identify device safety against the large range of confounding factors (for example, patient age and gender, other health conditions, surgical technique, surgeon experience). However, registries which can do this are very large and long running. The most frequently cited example in the literature is the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR), which has over a million surgeries in its database and has been running for almost 20 years. It is unlikely that any clinical registry for a single device in New Zealand would be large enough to function as a safety registry

As well as being the most feasible option, a clinical quality registry (Option 2) has predictable and quantifiable benefits, unlike the other two. Accordingly that is the option modelled in this report.[27]

2.6.1 Clinical quality registries

Clinical quality registries systematically monitor the quality (appropriateness and effectiveness) of health care, within specific clinical domains, by routinely collecting, analysing and reporting health-related information. They use the data they collect to identify benchmarks and variation in clinical outcomes. They then feed this information back to clinicians to inform clinical practice and decision-making. This clinical outcome feedback loop is the defining feature of clinical quality registries.

Figure 2.1: Illustrative example of a clinical registry



Source: Australian Commission on Safety and Quality in Health Care

[27] However, it is entirely possible that the Government may choose to implement another form of registry.

3 Patient and surgery numbers

An important component of research into establishing a surgical mesh registry is an understanding of how many people would be likely to be included in such a registry. In this vein, this report provides estimated values for total prevalence, total operations, and mesh operations for each of the three conditions (hernia, SUI, and POP) in New Zealand. This chapter sets out the approach taken in calculating prevalence figures, as well as providing a summary of the prevalence estimates used in this report.

3.1 Prevalence of each condition in New Zealand

In order to estimate the prevalence of each condition in New Zealand, a targeted review of publicly available literature was conducted. Where studies could not be located for New Zealand, studies from countries with demographically and epidemiologically similar characteristics were chosen. The following sub-sections set out the overall estimated prevalence of each condition in 2018, stratified by 5-year age and gender.

These estimates were then used to forecast the number of prevalent cases for each condition for the 10-year period from 2018 to 2027 by multiplying against New Zealand population forecasts provided by Statistics New Zealand (2018). Implicitly, growing prevalence in line with age- and gender-specific population growth rates accounts for a change resulting from both a) an increased number of people within the New Zealand population, and b) a changing age distribution of the New Zealand population.

3.1.1 Prevalence of hernia

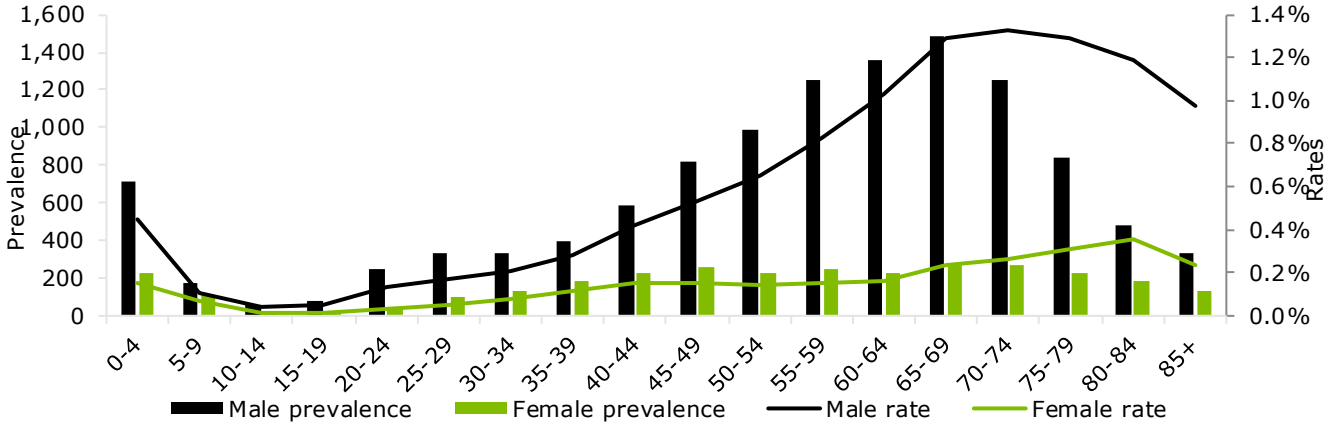
The prevalence of hernias reported by academic studies was found to vary widely, and thus it was difficult to obtain a reliable estimate.

Given this inconsistency among the academic literature, it was assumed that initial and revision surgeries are treated as separate cases, even though they may be for the same person. Thus, hernia prevalence was defined as a lockstep function of total hernia operations. This approach is consistent with a number of other academic papers, including Burcharth et al (2013, 2015) which estimated the nationwide prevalence of hernia cases in Denmark based on a surgery register.

Data from the Ministry of Health (MoH) (2015) was used to estimate the number of hernia operations across both public and private hospitals – and thus prevalence, by age and gender for New Zealand for 2014. Reporting is not always mandatory for private hospitals, and private hospitalisation data was adjusted for under-reporting on the basis of further information provided by the MoH. The number of total operations was divided by 2014 population data to obtain estimated prevalence rates of hernia by age and gender. These rates were then multiplied out by 2018 population forecasts provided by Statistics New Zealand (2018) to arrive at an estimated number of prevalent cases of hernia for New Zealand for 2018.

The estimated rates and number of prevalent hernia cases, by age and gender, is shown in Chart 3.1. Total prevalence was estimated to be 14,777 with men accounting for 79.2% (11,705) of cases and women accounting for 20.8% (3,073) of cases. Specific estimates of the number of prevalent cases by age and gender are provided in Appendix C.

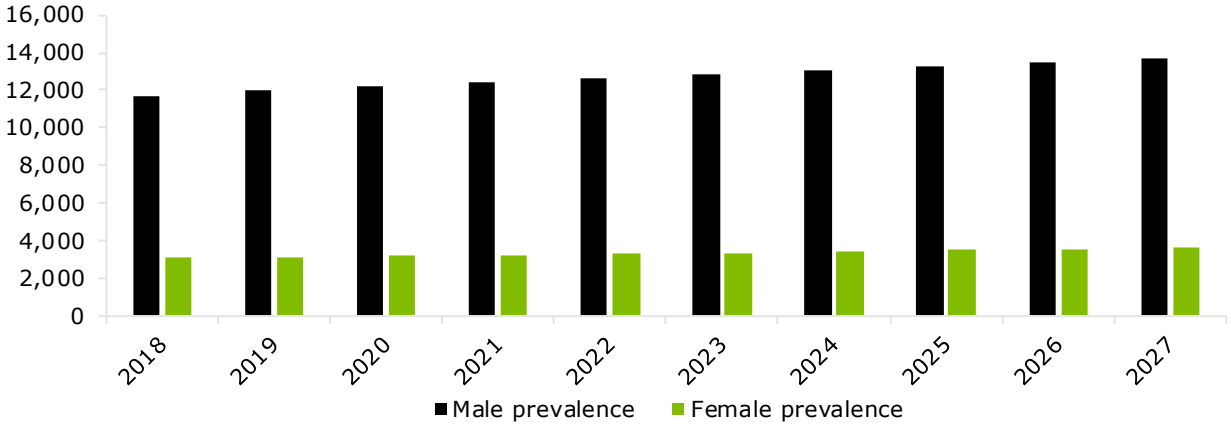
Chart 3.1 Prevalence of hernia, New Zealand, 2018



Source: Deloitte Access Economics (2018) modelling based on publicly available information.

The prevalence of hernia cases was forecast for the period 2018 to 2027, using age- and gender-specific prevalence rates estimated for 2018 and New Zealand population forecasts provided by Statistics New Zealand. The forecast of prevalent hernia cases is summarised in Appendix A, and shown below.

Chart 3.2 Forecast hernia prevalence for New Zealand, 2018-2027



Source: Deloitte Access Economics (2018) modelling based on publicly available information.

3.1.2 Prevalence of SUI

The prevalence estimates of SUI contained in the New Zealand Burden of Disease (2006) study are inconsistent with the magnitude of prevalence reported by academic studies, and are likely to be outdated with underlying source data being from the late 1980s and early 1990s (Holst & Wilson, 1988; Lara & Nacy, 1994).

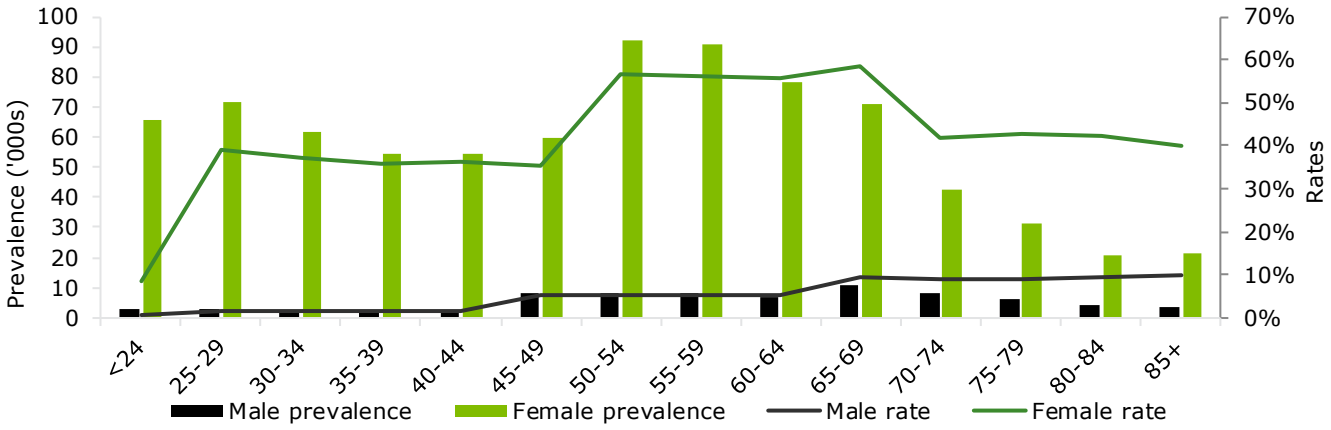
As such, the estimated prevalence of SUI for women was based on estimates calculated by Deloitte Access Economics (2011). This was determined to be a reliable proxy for the New Zealand population cohort due to: a paucity of other recent studies; the qualitative similarity between the Australian and New Zealand epidemiological profile; and the rigour of systematic review taken across the Australian evidence base by the Deloitte Access Economics (2011) report.

In order to estimate the prevalence of SUI among New Zealand males, prevalence rates were taken by age and gender from Shamilyan et al's (2009) United States study. The authors conduct a meta-analysis of observational studies and randomised control trials from 1990 to 2007 of studies published in English, from which a pooled prevalence estimate is calculated. The results from their study also compare similarly to other prevalence estimates provided in the academic literature.

The prevalence rates of SUI, respectively taken from Shamilyan et al (2009) and Deloitte Access Economics (2011) for males and females, were then multiplied against population forecasts (Statistics New Zealand, 2018) in order to estimate the number of prevalent cases in New Zealand in 2018.

Chart 3.3graphs the estimated prevalence rate and number of SUI cases in New Zealand for 2018, by age and gender. Prevalence is highest among middle-aged women, peaking for those aged 50-54 at 92,032.

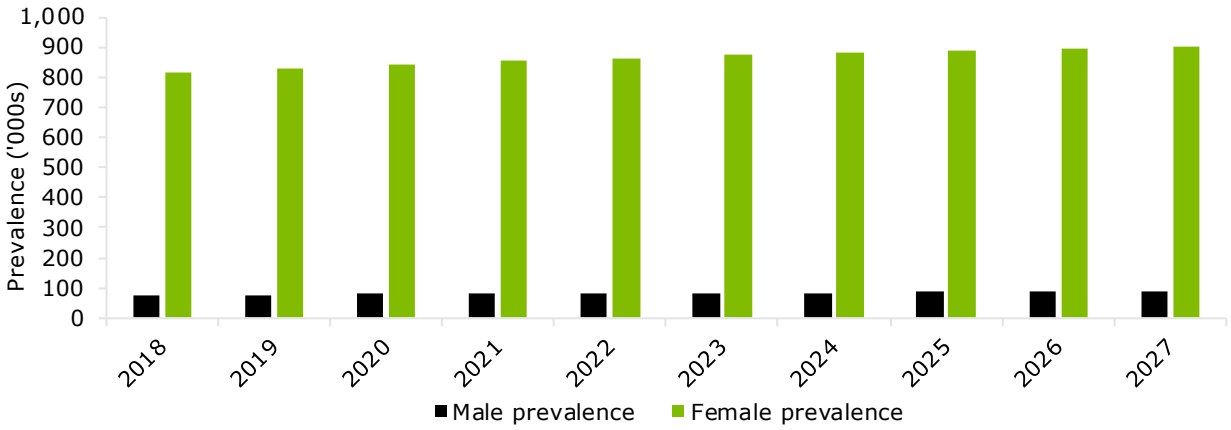
Chart 3.3 Prevalence of SUI, New Zealand, 2018



Source: Deloitte Access Economics (2018) modelling based on publicly available information.

The prevalence of SUI cases was forecast for the period 2018 to 2027, using age- and gender-specific prevalence rates estimated for 2018 and New Zealand population forecasts provided by Statistics New Zealand. The forecast of prevalent SUI cases is summarised in Appendix C, and shown below.

Chart 3.4 Forecast SUI prevalence for New Zealand, 2018-2027



Source: Deloitte Access Economics (2018) modelling based on publicly available information.

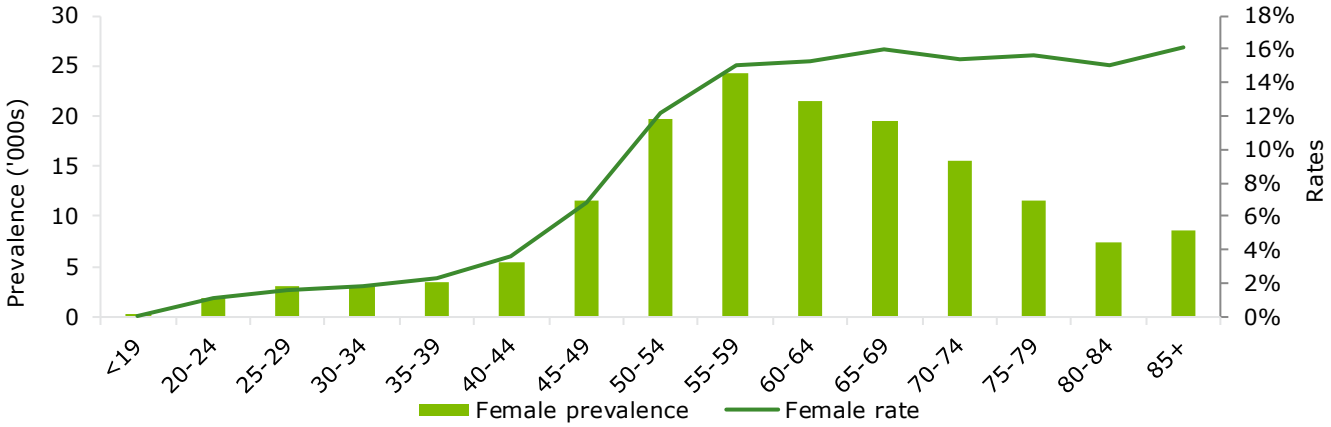
3.1.3 Prevalence of POP

Based on a review of academic literature, and hospitalisation data (MoH, 2015), it was assumed that men do not experience prevalent cases of POP.

The estimated prevalence rate for women was based on estimates provided by the New Zealand MoH, based on the 2016 Global Burden of Disease study. These rates were triangulated against those provided by a range of academic studies, and found to provide a reasonable estimate.

In order to estimate the number of prevalent POP cases for New Zealand in 2018, the prevalence rates were multiplied by Statistics New Zealand (2018) population forecasts. Total prevalence in 2018 was estimated to be 156,395, which represents 6.4% of women (Appendix C).

Chart 3.5 Prevalence of POP, New Zealand, 2018



Source: Deloitte Access Economics (2018) modelling based on publicly available information.

3.2 Prevalence of operations in New Zealand

In order to estimate the number of mesh operations, it was first necessary to estimate both the overall prevalence as well as the prevalence of operations – this section deals with the latter.

Hospitalisation data were collected by 5-year age and gender groups, with the most recent year of data availability being 2014. Specifically, for each of the conditions, the prevalence of operations was defined to be a function of the following hospital procedures delivered (across both private and public hospitals):

- hernias, including: inguinal hernia; femoral hernia; umbilical, epigastric or linea alba hernia; incisional hernia; parastomal hernia; other abdominal wall hernia; incarcerated, obstructed or strangulated hernia; and diaphragmatic hernia;
- stress incontinence, including: male stress incontinence; and female stress incontinence; and
- prolapse or uterus, pelvic floor or enterocele.

Based on information provided by the MoH, under-reporting by private hospitals was identified and adjusted for. Adjustment to correct under-reporting was made by comparing the relative number of private hospitals which data reported in 2014, and the proportion of total private hospital beds which these hospitals represented. The ratio of operations to beds was assumed to loosely remain constant, and thus published private hospital operations were inflated by the magnitude of under-reporting in order to obtain a more accurate estimation of total operations delivered for each condition.

Since hospitalisation data are only available until 2014, the total number of operations is grown in line with population forecasts (Statistics New Zealand, 2018). This approach is consistent with the forecasting method used for prevalence.

3.2.1 Number of hernia operations

The total number of hernia operations estimated for 2018 is equal to the number of hernia operations delivered, at 14,777 – with males and females respectively accounting for 11,705 operations and 3,073 operations. This represents a rate of 4.87 operations per 1,000 men; 1.25 operations per 1,000 women; or 3.04 operations per total persons. The forecast number of mesh operations is summarised in Table 3.1.

Table 3.1 Number of hernia operations, New Zealand, 2018 - 2027

	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027
Male	11,705	11,953	12,190	12,419	12,634	12,846	13,057	13,262	13,466	13,665
Female	3,015	3,073	3,131	3,189	3,246	3,302	3,357	3,413	3,470	3,526
Total	**14,720**	**15,026**	**15,321**	**15,608**	**15,880**	**16,148**	**16,414**	**16,675**	**16,935**	**17,192**

Source: Deloitte Access Economics (2018) calculations based on publicly available information.

3.2.2 Number of SUI operations

Total SUI operations in 2018 were estimated to be 1,558 and considerably higher for women (1,485, 95.4%) than for men (72, 4.6%). Chart 3.6graphs the number of SUI operations and the rate of SUI operations per prevalent cases. It can be seen that the operation rate is highest among women aged 45-49. Table 3.2 summarises the forecast number of mesh operations by gender.

Chart 3.6 SUI Operations, New Zealand, 2018

Source: Deloitte Access Economics (2018) modelling based on publicly available information.

Table 3.2: Number of SUI operations, New Zealand, 2018 – 2027

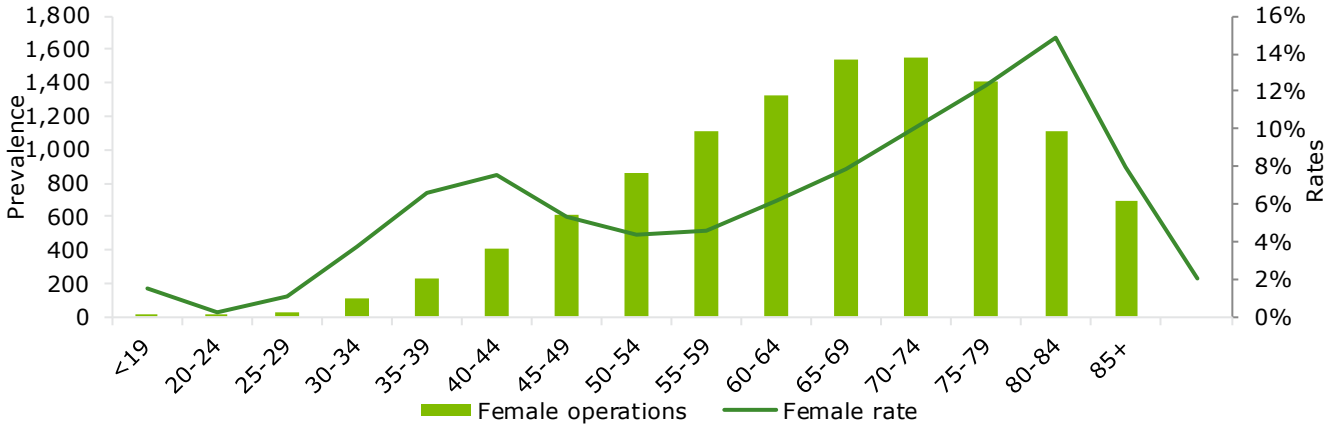
	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027
Male	72	74	76	78	80	82	83	85	87	88
Female	1,485	1,505	1,524	1,541	1,556	1,572	1,589	1,607	1,625	1,643
Total	**1,558**	**1,579**	**1,600**	**1,618**	**1,635**	**1,654**	**1,672**	**1,692**	**1,712**	**1,731**

Source: Deloitte Access Economics (2018) calculations based on publicly available information

3.2.3 Number of POP operations

The total number of POP operations for New Zealand in 2018 were estimated to be 3,219 and to increase with age. The highest rate of operations per prevalent case is reported for women aged 80-84 at 14.9%. The number of POP operations and the rate of POP operations per prevalent cases is graphed in Chart 3.7 and Appendix C summarises the forecast number of mesh operations by gender.

Chart 3.7 POP Operations, New Zealand, 2018



Source: Deloitte Access Economics (2018) modelling based on publicly available information.

Table 3.3: Number of POP operations, New Zealand, 2018-2027

	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027
Female	2,872	2,934	2,992	3,049	3,103	3,158	3,211	3,261	3,308	3,352
Total	**2,872**	**2,934**	**2,992**	**3,049**	**3,103**	**3,158**	**3,211**	**3,261**	**3,308**	**3,352**

Source: Deloitte Access Economics (2018) modelling based on publicly available information.

3.3 Mesh utilisation for operations

New Zealand hospitalisation does not distinguish between traditional and mesh surgeries, hence mesh utilisation has been estimated by age and gender for each of the conditions from a range of sources. This section outlines the methods adopted to estimate the mesh utilisation rates for each condition, which is then used to derive an estimate for the total number of mesh surgeries for 2018 to 2027.

The rate of mesh utilisation is assumed to have stabilised in 2014 and beyond, after a few years of volatility. For example, whilst the mesh share of total POP and SUI surgeries have risen and fell over the last 10 to 15 years, it is now assumed to be in a steady state.

Where possible, the estimated rate of mesh utilisation as a proportion of operations has been stratified by age and gender groups. However, desktop research conducted revealed a paucity of relevant studies, and as such where it has not been possible to locate a reliable age and gender breakdown, the rate of mesh utilisation is assumed to be held constant over these groups for a given condition type.

Based on the available evidence, and Deloitte Access Economics' modelling conducted as part of this report, there does not appear to be a long-term trend in any of the following:

- prevalence of conditions as a function of the future size and age-gender distribution of the New Zealand population;
- the number of surgeries as a function of prevalent cases; or
- the number of mesh surgeries as a function of the number of total surgeries.

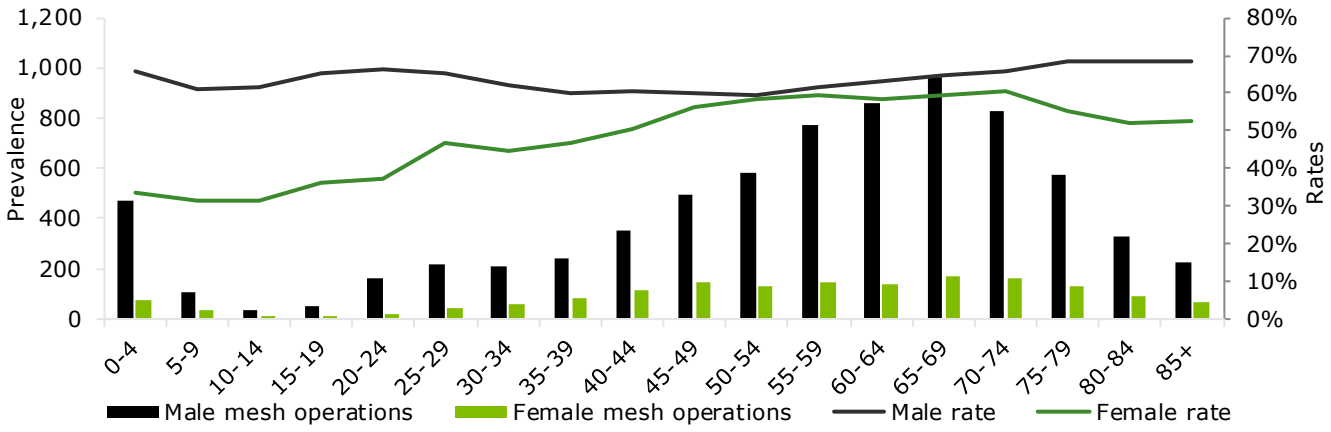
As such, it is assumed that the current ratios will remain approximately constant over the next 10 years. This means that population remains an appropriate factor to grow mesh surgeries in line with, consistent with the approach used for both overall prevalence and the prevalence of total operations in New Zealand.

3.3.1 Mesh utilisation rates for hernia

A targeted review of the literature was conducted into the frequency of surgery types used to treat hernia conditions. Based on this research, surgery types which use mesh and those which do not use mesh were identified by hernia type. The estimated rates of mesh utilisation by type of hernia were then weighted by the relative number of surgeries reported by MoH hospitalisation data for that hernia type compared to total surgeries. For types of hernia where several academic papers were used to estimate a rate of mesh utilisation, an average was calculated and weighted by the sample size used by the following studies Burcharth et al (2011) Burcharth et al (2015) Funk et al (2013) and Kohler et al (2015).

These rates were applied to the MoH data using a weighted average to calculate an estimate of the overall mesh utilisation for hernias. The utilisation was estimated to be slightly higher for males than for females, respectively amounting to 63.8% and 52.1% of operations. Chart 3.8 provides a breakdown by age and gender of mesh operations, along with corresponding utilisation rates, for hernias in New Zealand in 2018 (Appendix C).

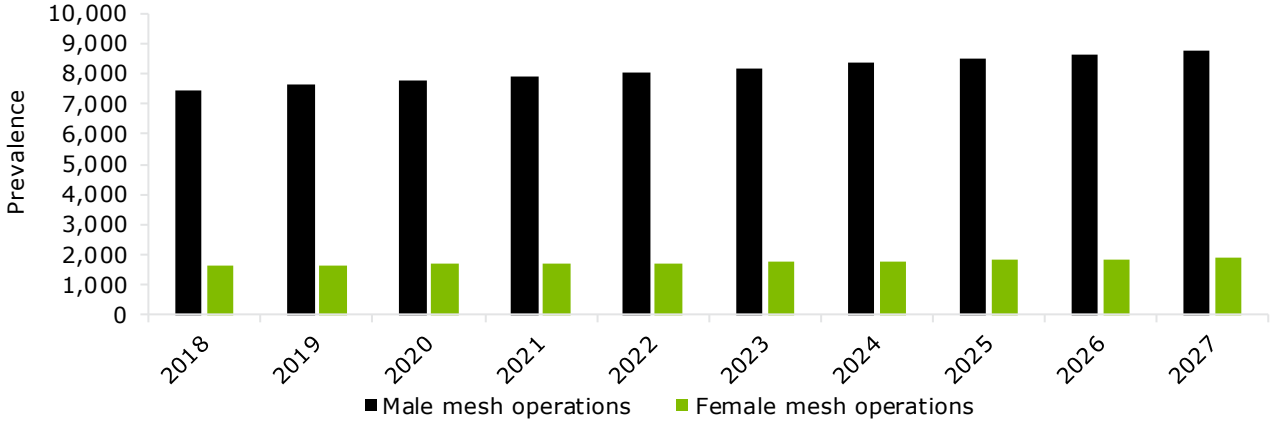
Chart 3.8 Mesh operations for hernia, New Zealand, 2018



Source: Deloitte Access Economics (2018) modelling based on publicly available information.

In order to forecast mesh operations for the period from 2018 to 2027, mesh operations in 2018 are grown in line with New Zealand population forecasts, as shown below.

Chart 3.9 Forecast hernia mesh operations for New Zealand, 2018-2027



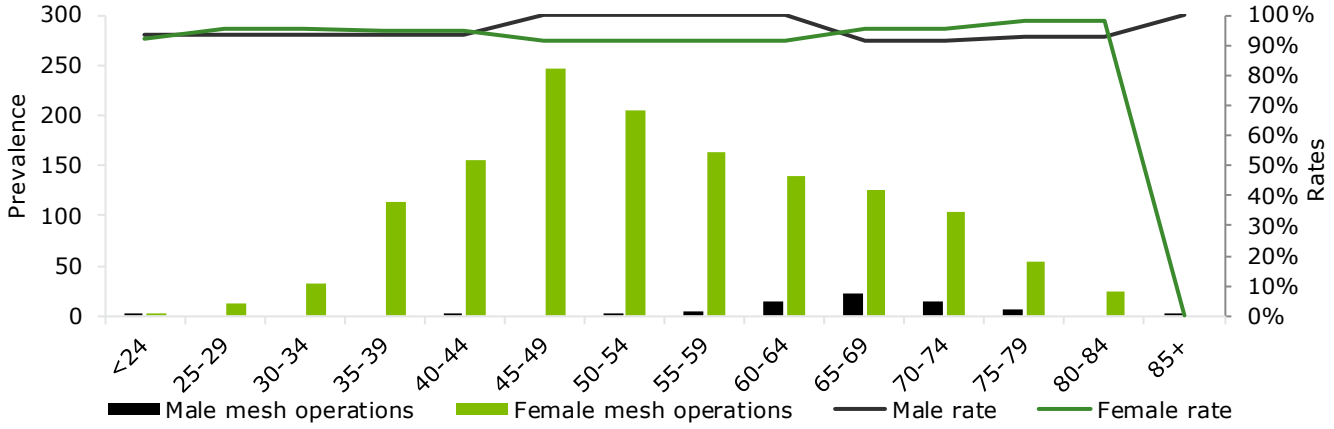
Source: Deloitte Access Economics (2018) modelling based on publicly available information.

3.3.2 Mesh utilisation rates for SUI

For SUI, the rate of mesh utilisation of operations was estimated using Australian Medicare Benefits Scheme claims data from June 2016 to June 2017 (the latest period for which data is available). This assumption was driven by a lack of a reliable estimate of mesh utilisation for SUI from the literature, as well as the similarity of profile of mesh usage between Australia and New Zealand. Specifically, items relating to mesh were defined to include 35599 and 37042, whilst non-mesh codes were defined as 37043 and 37044. This determination of item codes corresponding to mesh versus non-mesh, was made on the basis of a Deloitte Access Economics assumption. The rate of mesh utilisation, stratified by age and gender breakdowns provided in the MBS data, was estimated by dividing the items which related to mesh by total SUI claims.

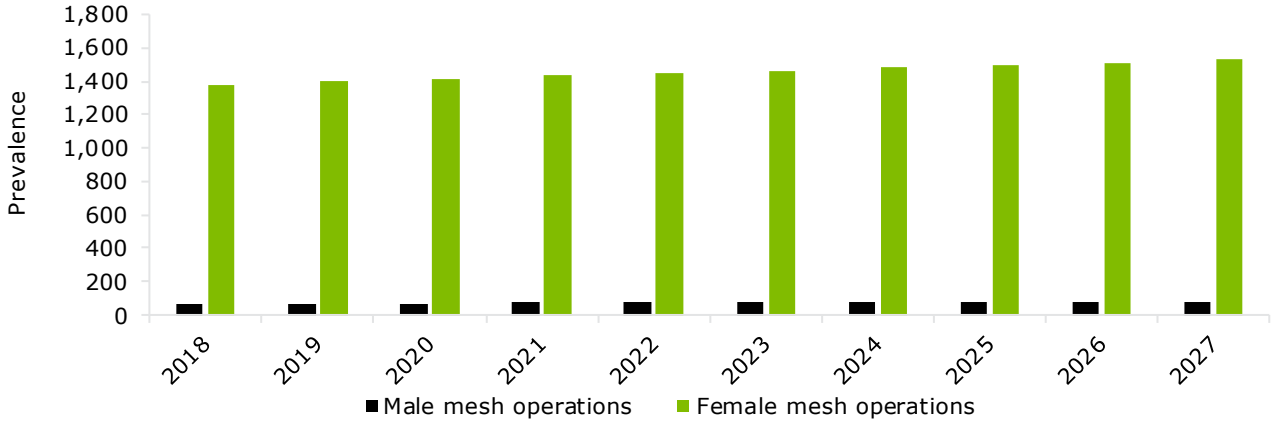
In order to estimate the number of mesh operations in New Zealand, this rate of mesh utilisation was multiplied against estimated operations for SUI in 2018, and for each year to 2027. The breakdown by age and gender for mesh operations in 2018 is shown in Chart 3.10, whilst the forecast number of mesh operations to 2027 is provided in (Appendix C).

Chart 3.10 Mesh operations for SUI, New Zealand, 2018



Source: Deloitte Access Economics (2018) modelling based on publicly available information.

Chart 3.11 Forecast SUI mesh operations for New Zealand, 2018-2027



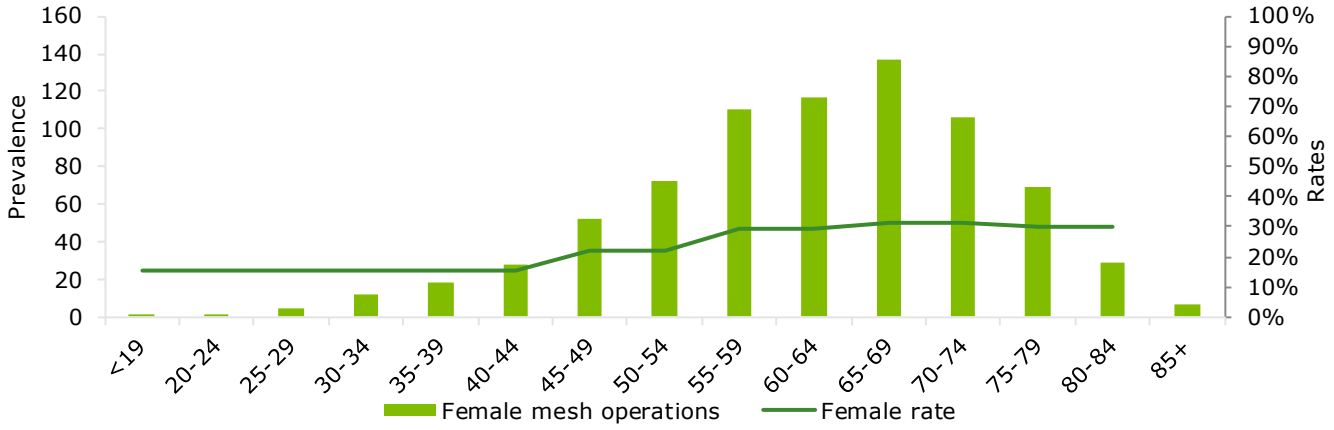
Source: Deloitte Access Economics (2018) modelling based on publicly available information.

3.3.3 Mesh utilisation rates for POP

For POP, age-specific rates of mesh utilisation were obtained from Chugtai et al (2015) who conducted a study of POP treatment based on the US general population. The sample used in the paper was based on a cohort of 27,991 women reported in the New York State Department of Health Statewide Planning and Research Cooperative System who underwent prolapse repair procedures from 2008 to 2011. From these records the rate of mesh utilisation versus non-mesh utilisation was estimated, stratified by age and gender.

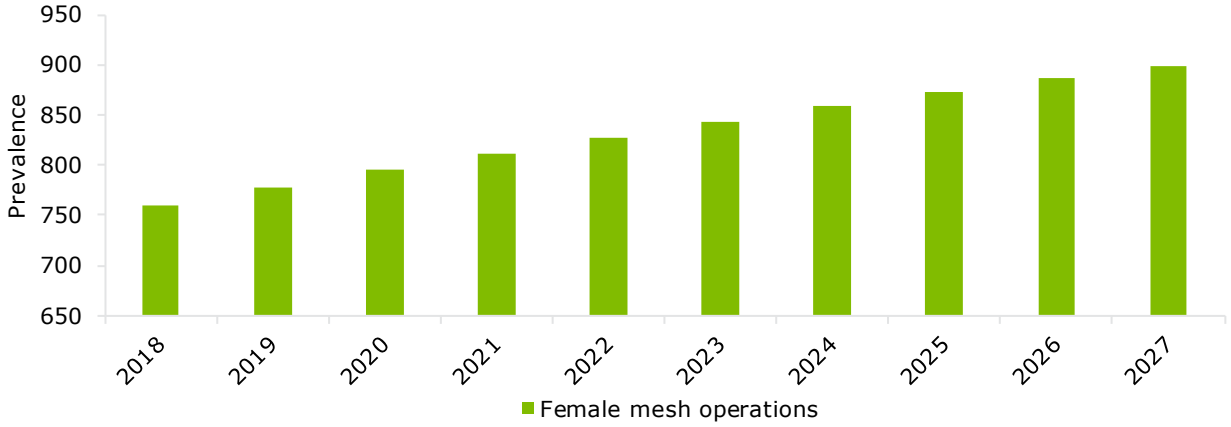
In order to estimate the number of mesh operations in New Zealand, this rate of mesh utilisation was multiplied against estimated operations for POP in 2018, and for each year to 2027. The breakdown by age and gender for mesh operations in 2018 is shown in Chart 3.12 whilst the forecast number of mesh operations to 2027 is provided in Chart 3.13.

Chart 3.12 Mesh operations for POP, New Zealand, 2018



Source: Deloitte Access Economics (2018) modelling based on publicly available information.

Chart 3.13 Forecast POP mesh operations for New Zealand, 2018-2027



Source: Deloitte Access Economics (2018) modelling based on publicly available information.

3.4 Trends in recorded mesh sales

Medsafe has some records of device sales in New Zealand. As with many aspects of mesh-related conditions and treatment, these numbers may not represent the full picture.

- For example, records for hernia only include mesh used for groin and ventral hernia repair (excluding umbilical, epigastric, linea alba, incisional, parastomal and "other").
- Conversely, for some years and mesh types, sales figures exceed total operations (that is mesh and non-mesh).

If these records were complete, it would imply that New Zealand surgeons have substantially different practices from their colleagues in the rest of the developed world. For example, while mesh has been the gold standard for hernia operations internationally for many decades (Köckerling et al, 2014), Medsafe figures imply that mesh is still only used for a minority of mesh repairs in New Zealand.

- It is possible that surgeons import mesh privately.[28] Another explanation may be that one length of mesh can be cut up and used for multiple operations, or that types of surgical mesh may be classified differently by Customs at the border – the US FDA has codes for over 500 different types of surgical mesh[29].
- Sensitivity tests were run using the lower mesh utilisation rates inferred by recorded device sales (7.5.3).

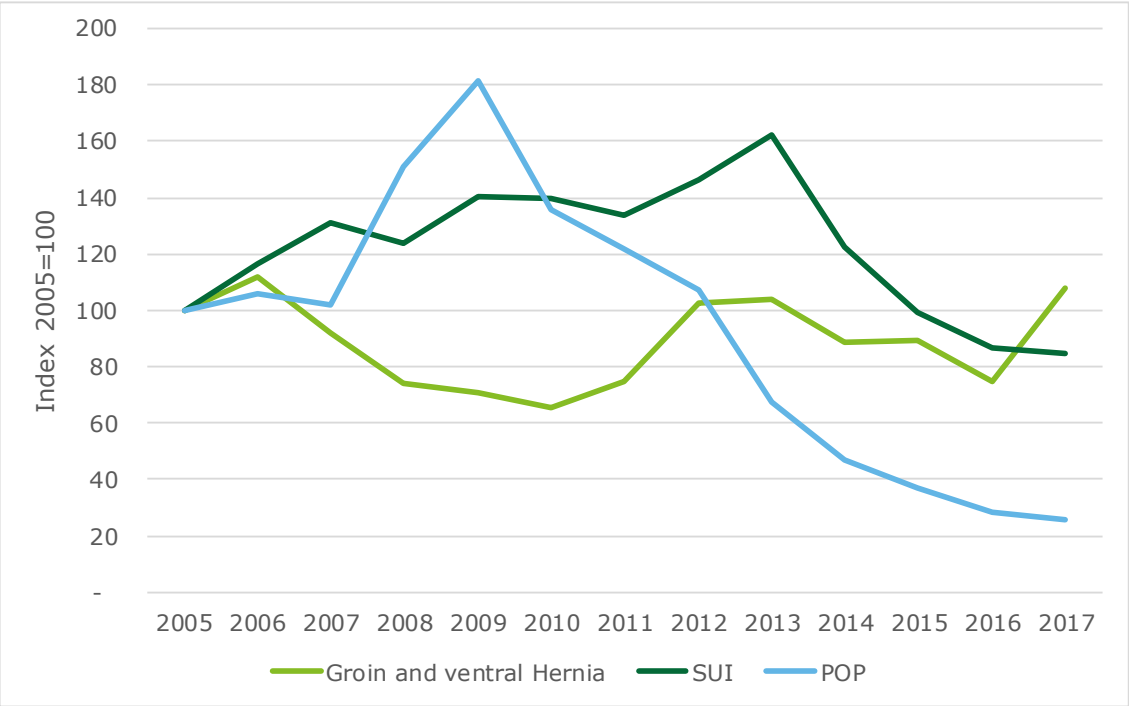
However, if it is assumed that the above factors do not vary substantially from year to year, then recorded mesh sales can provide a good picture of trends (Chart 3.14).

- Compared to the base year (2005) mesh for groin and ventral hernia repair has fallen, risen, fallen and then risen to just slightly more than it was initially, so the assumption appears reasonable that the average ratio of mesh to non-mesh surgery will remain similar over the next 10 years.
- Similarly, while mesh sales for SUI repair have risen and fallen, they appear to be levelling off, and are also not dissimilar to base-year figures. It is possible that the recent decline below baseline figures has been due to discontinuation of mini-slings. While Medsafe's restriction on the use of mini slings only came into effect after the last data release, it is plausible that Medsafe's decision followed surgeons' preference not to use those products.
- On the other hand, mesh sales for POP repair have plummeted. The decline from sales in 2009 to sales in recent years is of a similar magnitude to the share of transvaginal products during those years (US FDA, 2011). Again, it is possible that Medsafe's decision to restrict supply lagged behind falling demand by surgeons due to widespread adverse incident reporting. This decline also appears to have been tapering off in recent years. Accordingly, it is reasonable to assume that what is left is (still permitted) abdominal mesh, and that future utilisation rates will remain similar to current ones.

[28] During consultations, anecdotes were shared about surgeons holidaying abroad and returning with suitcases full of mesh.

[29] https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/Gastroenterology-UrologyDevicesPanel/UCM490205.pdf

Chart 3.14: Trends in recorded mesh sales



Note: 2017 figures partial year, extrapolated to full year

Source: Medsafe

3.5 Estimated number of mesh surgeries

In section 3.1, this chapter forecast the prevalence, by age and gender, for hernia, SUI and POP in New Zealand over the coming decade. Then the proportion of each condition that would be severe enough to require surgery was estimated in section 3.2. Of those patients undergoing surgery, the share who would receive mesh implants was calculated in section 3.3. As transvaginal mesh products for POP have recently been removed from the market in New Zealand, POP will remain limited to a small number of abdominal mesh operations. While the New Zealand population is forecast to grow by half a million people over the decade[30], it is expected that POP and SUI surgery numbers will only grow by 300 between them. Conversely, the peak age for hernia is 65 (Chart 3.1), and as the population ages there will be over 1,500 more such surgeries in 2027 than currently.

Table 3.4: Estimated numbers of mesh surgeries, by type, 2018 to 2027

Category	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027
Hernia	9,064	9,259	9,445	9,627	9,799	9,969	10,139	10,305	10,470	10,633
SUI	1,448	1,469	1,488	1,506	1,522	1,539	1,557	1,576	1,595	1,612
POP	761	779	795	812	827	843	858	873	887	900
Total	**11,273**	**11,506**	**11,729**	**11,945**	**12,148**	**12,352**	**12,555**	**12,754**	**12,952**	**13,145**

Source: Deloitte Access Economics (2018) modelling based on publicly available information.

[30] http://nzdotstat.stats.govt.nz/OECDStat_Metadata/ShowMetadata.ashx?Dataset=TABLECODE7542&ShowOnWeb=true&Lang=en

4 Costs of a registry

From the literature, clinical registers are not expensive operations. For example, Thor (2016) reports that Swedish registries cost between $50,000 and $800,000 per year to run.[31] While there generally are economies of scale, small size does appear to be a barrier to cost-effectiveness. There are nonetheless single-state registries in Australia - dealing with smaller populations than in New Zealand, and dealing with smaller numbers of procedures than mesh surgeries in New Zealand – that have performed well in evaluations.

A range of costs are involved with the establishment and maintenance of a registry. Establishment costs may involve capital costs, purchasing information technology (IT) equipment, labour costs involved in training of clinicians and the design of the register. After a register has been established, ongoing costs may include labour of inputting and cleaning the data by medical professional and other staff, costs of renting the location of office space where the registry is based, and labour costs involved with analysis and reporting of the data collected. Funders of registries may range from a single source, or a range of contributors including the government, medical colleges, and advocacy or peak bodies.

The Monash University (2017) Registry Science Handbook lists the following typical cost categories in establishing a clinical quality register:

- developing and testing the minimum data-set;
- building and maintaining the web-based data acquisition and reporting system;
- development and support of the governance committees;
- establishing a liaison with clinicians and agreements with institutions;
- gaining ethics approval at each institution;
- data-collection and reporting costs;
- outcome determination via a call centre and/or data-linkage;
- statistical analysis costs; and
- implementing quality control procedures.

The Handbook states that while some costs, like building the registry, are relatively fixed, other costs are variable and depend significantly on the number of sites, patients and clinicians contributing to the registry.

Ballpark costs listed in the Monash University Registry Science Handbook for a large national Australian registry with 50,000 cases reported annually, is around 250,000 AUD for the establishment of the IT systems and an additional 500,000-800,000 AUD for other set up costs.

The maintenance of a major national Australian registry is estimated in the Handbook to be in the order of 1-1.5 million AUD per year. It is noted that these costs are impacted by both population size and number of procedures targeted by the registry occurring in the population.

As a result, a national registry in New Zealand for surgical mesh may not require the same magnitude of funding. An example of costs scaling with case load can be seen in Table 4.1, which shows the total costs, caseload and cost per case of the Victorian PCR. In this scenario, the only reported variable costs according to case load were the data collection costs, with the other costs remaining constant.

[31] Thor et al (2016) 'Swedish National Quality Registries and Their Contribution to the Best Possible Care for Patients', The Jönköping Academy for Improvement of Health and Welfare.

Table 4.1: Victorian PCR, costs by type, 2013

	2013
Total cost	553,643
Data collection cost	134,339
Number of cases	2,198
Total cost per case	252
Data collection cost per case	61

Source: ACSQHC (2016). *Note: the total costs in 2009 include initial build costs of 200,000 AUD.

The Australian Commission on Safety and Quality in Health Care (ACSQHC) undertook an economic evaluation of clinical quality registries in 2016 (ACSQHC, 2016). While the amount of detail of the cost breakdowns varied, the economic evaluation includes the costs of the following five registries:

- the Victorian Prostate Cancer Clinical Registry (Victorian PCR);
- Victorian State Trauma Registry (VSTR);
- the Australian and New Zealand Intensive Care Society Adult Patient Database (ANZICS APD);
- Australia and New Zealand Dialysis and Transplantation Registry (ANZDATA); and
- Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR)

Section 4.2 provide additional detail on establishment and ongoing costs of setting up a registry, including examples of known costs of registries currently in existence from the ACSQHC report (ACSHC, 2016) and consultations. However, costs vary depending on registry purpose, caseload, activities undertaken in the register, and register structure. Further context on the registries from which costings are based is available in Appendix B.

4.1.2 Capital costs

A registry requires a base location, with land and infrastructure costs associated with it. This may involve renting or purchasing office space, and purchasing computers and other hardware to house and back up the register data system and/or renting cloud storage space.

4.1.3 Labour costs

The initial start-up of a register involves labour costs over the annual labour involved in the maintenance of the register. This includes analysis involved with the design and testing of the register, recruitment of registry staff, as well as training for clinicians, hospital management and registry operators.

Finally, most registries require approval from a Human Research Ethics Committee (HREC). Typically, registries may be required to undergo an overarching ethics approval process, as well as ethics approval processes from specific or nominated HRECs at all participating sites. Based on the consultation with the Bariatric Surgery Registry (BSR), separate ethics approval was required for each DHB.

The **Vic PCR** required 200,000 AUD for initial build costs in 2009 (ACSQHC, 2016).

4.2 Ongoing costs

4.2.1 Labour

A range of ongoing labour costs are involved in maintenance and use of registries, including data collection, research and administration, and analysis and reporting.

4.2.1.1 Data collection costs

Consultations undertaken for this analysis suggest that for medical practitioners (i.e. surgeons undertaking the mesh procedure), the recording of data related to the registry inputs would largely be absorbed into the pre- and post-operative paperwork carried out already. The data would then be recorded into the registry by nurses, clinical coders and/or staff at district health boards. In addition to procedural data being collected, the database may collect separate outcomes data, for example through several phone interviews or surveys a set time after the diagnosis or procedure.

In the **Vic PCR**, it takes five minutes on average to record a patient case in the registry. Staff also phone patients at 12 and 24 months' post diagnosis for a follow up questionnaire. This questionnaire takes approximately 10 minutes to complete and includes a general health Quality of Life questionnaire (SF-12) and six disease-specific complications questions. The cost of principle data collection was 75,815 and the cost of outcomes data collection at the Vic PCR was 58,524 AUD in 2013 (Sampurno & Evans, 2015). Data collection (both principal and outcomes data) in the **VSTR** was 438,943 AUD in 2013 (Sampurno & Evans, 2015).

In the **BSR**, follow up forms are completed by treating surgeons or BSR call centre staff contact participants for a 5-minute phone call, however the BSR is in the process of developing an SMS, email or web-based platform allowing patients to submit information themselves (Monash, 2017).

4.2.1.2 Liaison, data validation, and administration

In addition to primary data collection, a clinical registry may involve additional data cleaning, verification, and collection of missing information. If something is missing or outside of the expected range, registry staff may be required to contract the submitting health care professional asking them to review or verify the data.

Registries may require a secondary verification or audit process to improve accuracy of information. The ACSQHC Operating Principles for Australian Clinical Quality Registries state that data should be checked in a sample of cases, usually involving an audit against source records with a sample size sufficient to produce reliable measures of data completeness and accuracy (ACSQHC, 2010). Data may be further verified through manufacturer sales or import data (e.g. number of product sales per healthcare facility), as well as through the patient follow-up via interviews or questionnaires.

It was also noted in consultations undertaken for this project that a full time registry staff member would likely be required for liaison of the registry with all relevant stake holders.

In the **Vic PCR**, follow up interviews are also used to check information accuracy and completeness in addition to collecting follow up information. Where possible, missing information is also collected from the patient's GP (Sampurno & Evans, 2015).

4.2.1.3 Data analysis, linkage, and reporting

Labour is required for the statistical analysis of collected findings. There may be a range of analysis and reporting waves, ranging from automated data output reports which are shared automatically with relevant stakeholders and regular analysis provided to medical practitioners and medical colleges, to more detailed annual public reports with analysis and outcomes from the register, as well as other ad hoc reports which may be requested by medical professionals, industry, academic institutions or government bodies. Finally, the respective HREC processes are also likely to require regular reporting in order to maintain ethics approval.

If registries are used as an assessment of clinical quality, analysis needs to be undertaken in order to correct for higher risk patients or outliers. A risk stratification and outlier management program would assist in producing reliable quality data and gain buy in from medical practitioners and colleges. The ACSQHC Operating Principles for Australian Clinical Quality Registries state that clinical quality registries 'should collect objective, reliable co-variates for risk adjustment to enable factors outside the control of clinicians to be taken into account by using appropriate statistical adjustments' (ACSQHC, 2010). The document also notes that registries must have formal plans in place which are ratified by a steering committee on addressing outliers or unexplained variance, and ensure that quality of care issues are effectively addressed and escalated appropriately.

Researchers may request permission to use (de-identified) data in a registry for additional analysis. Similarly, additional information may be sought from a registry to answer specific questions that cannot be addressed by the minimum data-set, data may be collected from a random sample of the clinical providers or for a short period from all participating units. This work would typically get funded through specific grants, however in order to ensure existing data and additional research is managed appropriately, requests for use of participants and data from the registry may need to pass through a managing board or steering committee.

In the **Vic PCR** the annual cost of biostatistics and analysis is 38,074 AUD, and the annual cost of data analysis and report writing in the **VSTR** is 40,000 AUD. The **ANZICS** outlier management program has an incremental cost of 40,000 AUD per year. In the **AOANJRR** the costs of data analysis, entry and reporting by the registry staff was 5,219,340 from 1999-2015 (approximately 300,000 per year) (ACSQHC, 2016).

4.2.2 Information Technology (IT)

Registries require a secure and user friendly information technology system for inputting, storing, exporting and analysing data. Depending on the system design of the register, data management systems may also be bought on an annual basis.

The **Vic PCR** required 36,050 AUD per year for ongoing IT and infrastructure costs from 2009 to 2013. The **VSTR** costs include between 52,000 and 40,000 AUD in costs for IT (amortised) (ACSQHC, 2016).

4.2.3 Overheads and other costs

Registries may have other ongoing overhead and one-off costs. This may include accounting fees, rent, utilities, repairs, supplies, telephone and internet bills, or travel expenditure.

The **Vic PCR** costs include an additional 112,717 AUD per year for overhead costs, 68,538 AUD in casual staff costs and 34,561 AUD in 'lead' cots. The **VSTR** costs include around 100,000 to 120,000 AUD in overhead costs (ACSQHC, 2016).

Appendix B gives more detail into the complex set up procedures and numerous decisions that would be entailed in any decision to establish a mesh registry in New Zealand.

4.3 Estimated costs for a New Zealand mesh registry

4.3.1 Fixed costs

The overall costs of running an Australian CQR do not vary greatly. For example, the most expensive registry – the ANZICS APD - has almost 50 times as many patients as the cheapest – the Victorian PCR - but only costs twice as much to run. This implies that the substantial fixed cost component does not vary greatly across registries.

Table 4.2: Annual operating costs and number of patients of Australian CQRs in 2013-14

Registry	Patients	Costs
Victorian PCR	2,198	$553,643
VSTR	2,899	$964,989
ANZDATA	11,983	$1,000,000
AOANJRR	95,515	$1,023,400
ANZICS APD	107,923	$1,134,534
Average		**$935,313**

Source: ACSQHC (2016)

Triangulating across the various sources discussed in this chapter, Deloitte Access Economics estimates that fixed costs for a New Zealand mesh registry would be around $500,000 to $600,000 a year (Table 4.3)[32]

Table 4.3: Estimated fixed costs for a New Zealand mesh registry

Component	Patients	Costs
Fixed capital	Registry Development	$50,000
	Maintenance	$56,000
Fixed labour	Overheads	$88,000
	Casual staff	$54,000
	Lead staff	$27,000
	Research & admin	292,000
Other	Consumables	$9,000
Total fixed costs		**$576,000**

Source: Sampurno & Evans (2015), Monash University (2017), ACSQHC (2016)

4.3.2 Variable costs

Unlike fixed costs, there was considerable variation in patient data collection costs across Australian QCRs. The estimate for the AOANJRR was only $3.72 per patient, that for the Victorian PCR $61.12, and for the VSTR, $131.56. Mean costs of $65.47 were almost the same as median costs of $61.12. Median costs have been used here, as the Victorian PCR gave the most detailed breakdown of its variable costs.

Table 4.4: Estimated variable costs per patient for Australian CQRs

Registry	Average patients	Average variable costs	Variable cost per patient
AOANJRR	87,690	326,209	$3.72
Victorian PCR	1,953	$119,340	$61.12
VSTR	2,826	$371,760	$131.56
Average			**$65.47**

Source: Sampurno & Evans (2015), Monash University (2017), ACSQHC (2016)

However, the vast majority of health records in Australia are electronic, while most records in New Zealand DHBs are still paper based. Accordingly, to allow for double handling, variable costs of $122.24 per patient are assumed for a New Zealand mesh registry.

- [32] Costs have been converted to New Zealand dollars using purchasing power parity (http://stats.oecd.org/Index.aspx?DataSetCode=PPPGDP) and then inflated to 2018 values (https://www.stats.govt.nz/information-releases/consumers-price-index-march-2018-quarter).

4.3.3 Total costs

Thus, were there already such a registry in New Zealand, for the estimated 11,273 mesh surgeries in 2018 Table 3.4, the total annual operating cost would be $1.96 million. This is considerably higher than for much larger Australian QCRs, such as the AOANJRR or the ANZDATA, both of which have around 10 times as many patients. However, the New Zealand mesh registry would have three to four times as many patients as the small Australian QCRs that conduct similar levels of patient follow up - and thus are not much cheaper than the largest Australian QCRs.

Table 4.5: Estimated operating costs for a New Zealand mesh registry, 2018

Type of cost	Sub component	Total $'000
Total fixed		576
Variable per person	$122.24	
Patients	11,273	
Total variable costs		1,378
Totals		**1,954**

Source: Table 4.3 and Table 3.4

5 Costs of mesh surgery and its consequences

5.1 Impacts of mesh surgery

Following a similar methodology to that employed by the ACSQHC (2016) this section examines the treatment costs and morbidity and mortality impacts of POP, SUI and hernia mesh surgery. As this is a cost benefit analysis, only those costs that can a) be quantified and then b) converted to monetary values are included.

While there is a very large number of journal articles on mesh surgery and its consequences, only a few of them include both cost data and quantifiable health impacts (QALYs / DALYs).[33] For internal consistency purposes, only articles that employed both of these metrics were used.

This report does not compare surgical and non-surgical treatment for POP, SUI and hernia. Nor does it compare mesh surgery against traditional suture surgery for these conditions. Neither does it assess the impacts of those forms of mesh products no longer supplied to the market in New Zealand (transvaginal mesh for POP, and mini-slings for SUI).[34]

- Registries can lower treatment costs by reducing the number of revision surgeries, or the LOS for first surgeries. They cannot, however, reduce the number of first surgeries.
- Equally, the benefits of successful surgery in stopping the pain and suffering is not considered attributable to the registry in this study. That is what surgery should already do. Rather, the benefit of the registry is how much it reduces cases of surgical failure – as measured by reduced numbers of subsequent revision surgery and/or adverse consequences.

The studies used to here to estimate event probabilities were usually meta-analysis or systematic reviews of clinical trials. Follow up times for individual studies varied greatly – and sometimes was not even recorded – but the most common period was 12 months. As a simplifying assumption, where not clearly indicated otherwise, morbidity measures are assumed to be at 12 months follow up. Under the DALY system, morbidity is a combination of how severe a condition is, as measured by its disability weight (DW), and how many years it lasts for. Where studies only include a DW (or a "utility state" for Markov models), the condition / consequence is assumed to last for one year, where otherwise not specified.

- Similarly, due to lack of data, increases in morbidity costs over longer periods are not accounted for. For example, hernia recurrence has only been included for the first year - whereas, Köckerling et al (2015) report that the majority of hernia recurrences do not occur until 5 years after the initial surgery. This understates the true costs of surgeries as only that fraction of recurrences that have been reported at one year follow up are included as costs in the model.

A further simplifying assumption for modelling is made in that, it is assumed that if surgery is unsuccessful, patients will live with the symptoms for a year, whereupon there will be follow up surgery, and that that will be successful. Both of these assumptions are conservative. The patients in the NICE study may live with persistent long-term pain for many years without follow up surgery. But the available data do not tell us how many will do so, or for how long. Similarly, future surgery would have the same chance of failure as first round surgery, but these impacts would be very small. In case of hernia, if 2% of patients have first round failure, then there would be only 2% of 2% who would have second round failures – that is, 4 out of 10,000.

[33] For example, entering the term "surgical mesh" into Google Scholar yields over 800,000 articles.
[34] The number of articles with dollars and DALYs and that permitted the impacts of those forms of POP and SUI mesh surgery still suppliable in New Zealand to be separately identified was very small.

DALYs are converted into monetary values by multiplying them by the value of a statistical year (VSLY). The latest VSL published by the New Zealand Government is $4.21 million for 2017 (Department of Transport, 2017). The formula for converting VSL to VSLY is:

$$VSLY = VSL / \Sigma_{i=0,\ldots,n-1}(1+r)^n$$

Where: n = years of remaining life, and
r = discount rate

As the average New Zealander has a life expectancy of 45.5 years[35] using a discount of 3%, the VSLY for 2017 was $170,805. Updating that for inflation to 2018 gives a **VSLY of $172,684**.[36]

5.1.1 Mesh for hernia surgery

5.1.1.1 Treatment costs

Data supplied by MoH showed that the average hernia procedure cost $5,448 in 2016-17, with an average LOS of 1.4 days. This has been updated to $5,538 in 2018 using Statistics New Zealand health inflation.[37] While the classification system used (ICD-10 codes k40-K46) does not differentiate as to whether mesh was used or not, mesh is the "gold standard" for hernia operations (Köckerling et al, 2014).[38] It is assumed that this cost is the same for revision surgery.

5.1.1.2 Morbidity costs

Out of the 1062 patients in the studies included in the National Institute for Clinical Excellence hernia study (NICE, 2003) 22 had recurrence of hernia after surgery (2.1%).

The average disability weight (DW) for hernia from the studies cited in Table 5.1 was 0.32 (range 0.21 to 0.46). NICE (2003) reported that the average time spent under recurrence for those receiving revision surgery was 0.72 years. Added to this are 0.134 DALYs from the revision surgery itself, for a total of 0.37 DALYs.

NICE (2003) measured both the number of cases of persistent long-term pain, and the DALYs inflicted by that pain at 12 months follow up.

5.1.1.3 Mortality costs

Nilsson et al (2007) studied almost a quarter of a million (234,066) cases of groin hernia surgery from the Swedish Hernia Registry. The authors noted that "mortality risk was not raised above that of the background population for elective groin hernia repair" but equally that for emergency surgery was seven times higher. Out of these operations, 646 patients died within 30 days of surgery – mostly men over the age of 80 who had had emergency surgery. Swedish life expectancy tables indicate that men aged 85 (proxy for over 80) had a life expectancy of 5 years. For monetisation purposes, this has been discounted by 3% to 4.71 DALYs.

[35] https://www.stats.govt.nz/information-releases/new-zealand-period-life-tables-201214
[36] https://www.stats.govt.nz/information-releases/consumers-price-index-march-2018-quarter
[37] https://www.stats.govt.nz/information-releases/consumers-price-index-march-2018-quarter
[38] International Classification of Diseases, 10th edition.

Table 5.1: Hernia mesh surgery treatment costs and DALYs

Event	DALYs of condition	Cost	Probability	Expected value	Sources
Revision surgery		$5,538	1.021	$5,653	Probability: NICE (2003) Cost: MoH
Recurrence	0.37	$63,382	0.021	$1,313	DALYs: Shilcutt et al(2013), Naghavi et al (2009), Ock et al (2106)
Persisting long-term pain	0.12	$20,031	0.202	$4,043	NICE (2003)
Mortality	4.71	$813,144	0.0028	$2,244	Nilsson et al (2007)
Total				**$13,253**	

Note: cost of condition is DALY*VSLY. Probability of surgery includes original and revisions

Sources: As given in table

5.1.2 Mesh for SUI surgery

5.1.2.1 Treatment costs

Data supplied by MoH showed that the average hernia procedure cost $6,486 in 2016-17, with an average LOS of 2.0 days. Updated to $6,531 for 2018 to account for health inflation. While the classification system used (ICD-10 code N39) does not differentiate as to whether mesh was used or not, however mesh is the gold standard for treatment of SUI (Nambiar et al, 2014). It is assumed that this cost is the same for both original and revision surgery.

5.1.2.2 Morbidity costs

Laudano et al (2013) reviewed 7 RCTs with a median follow up of 12 months and observed revision surgery in 1.38% of patients. Conversely, Wu et al (2007) estimated that mesh SUI surgery had an 80% success rate – that is, the chance of recurrence is 20%

Laudano et al, 2013 estimated a "utility state" (equivalent to a DW) for SUI from 7 RCTs with median 12 months follow up. Ohno et al, 2016; and Seklehner et al 2014 both estimated utility states of 0.22. The Australian Institute of Health and Welfare (AIHW, 2016) also reports a DW for SUI of 0.14. However, Montesino-Sempler et al (2013) estimated that surgical cure of SUI only yielded 0.05 QALYs. A simple average across these studies has been utilised here to estimate DALYs incurred from having SUI for a year between first unsuccessful and second successful surgeries.

The probability of mesh exposure from Richardson and Sokol (2014) is at 12 months after first surgery. In the absence of any data specific to SUI, DALYs for mesh exposure are assumed to be the same as for mesh exposure in POP as reported by Culligan et al (2013) for mesh exposure after POP surgery, which was 0.12 QALYs lost at 12 months follow up.

5.1.2.3 Mortality costs for urogynaecological procedures

The question of how to address mortality in mesh surgery for urogynaecological procedures is problematic. On the one hand, the risk of death is not zero for any form of surgery. On the other hand, the numbers of confirmed deaths are very low.

The US Food and Drug Administration (FDA) receives notifications of medical device adverse events in that country, and reported in 2011 that between 2008 and 2010, there were seven reported deaths associated with POP repairs. Follow up investigation on the death reports revealed that three of the deaths associated with POP repair were related to the mesh placement procedure (two bowel perforations, one haemorrhage). The other four deaths were due to post-operative medical complications that were not directly related to the mesh placement procedure.[39] Three deaths in 3 years in the US translates on a per capita basis to around 1.4 deaths per century in New Zealand from POP repair.

[39]https://www.fda.gov/downloads/medicaldevices/safety/alertsandnotices/ucm262760.pdf

Fairfax's Stuff.co.nz claims that an investigation it conducted into ACC data reveals that four people have died as a result of mesh complications (for all forms, including hernia) in New Zealand[40]. If so, while this is tragic, it is still too small a number to be robustly modelled, given there have been perhaps 100,000 mesh surgeries in New Zealand since 2000.

Laudano et al (2013) and Seklehner et al (2014) both use a parameter of 0.0005 for SUI mortality in their Markov modelling. However, neither attribute a source for this parameter nor explain how it was calculated. This may be a default figure used for death from surgery in general in Markov modelling.

Culligan et al (2103) have a more precise figure of 0.0096 for mortality from POP surgery. However, none of the sources they cited contained that number.[41]

Further – and perhaps as a consequence of the tiny numbers involved - there are no data available on average age of death following SUI surgery. In order to estimate the monetary value of a life lost, it is necessary to know how many years the patient might otherwise have expected to live. Such deaths as occur in hernia surgery are nearly all in people who are emergency cases over the age of 80 (see section 5.1.1.3), but there are almost no women that age receiving POP or SUI surgery.

Accordingly, this model does not include a value for the benefit of deaths from POP or SUI surgery averted by a registry.

- Conversely, Device Events, a US firm that mines public FDA data for healthcare providers argues that there is little consistency in the way that operations, devices or adverse events are reported to the FDA. Device Events estimates that there have been 430 deaths from polymeric slings in the US over the last ten years.[42] However, as this data is neither official nor peer-reviewed, it is not included in this report. Similarly, the US Department of Health and Human Services (2012) in audit found that hospitals only report 14% of adverse events to the FDA. As this included only one source (hospitals) and drug and procedural adverse events as well as device ones, no adjustments are made to US FDA SUI fatality figures. However, it does imply that assuming no urogynaecological mesh deaths in New Zealand may be a conservative assumption.

Table 5.2: SUI mesh surgery treatment costs and DALYs

Event	DALYs of condition	Cost of condition	Probability of condition	Expected cost	Sources
Revision surgery		$6,531	1.0138	$6,621	Laudano et al (2013)
Recurrence	0.16	$28,248	0.20	$6,943	Probability: Wu et al (2007) DALYs: Shilcutt et al(2013), Naghavi et al (2009), Ock et al (2106) AIHW (2016)
Mesh exposure	0.15	$25,903	0.013	$336.73	Probability: Richardson & Sokol (2014). DALYs: Culligan et al (2103)
Mortality	-	-	0.0005	-	Nilsson et al (2007)
Total				**$13,913**	**MoH**

Note: cost of condition is DALY*VSLY. Probability of surgery includes original and revisions Sources: As given in table

[40] https://www.stuff.co.nz/national/health/93268557/four-mesh-deaths-but-government-drags-heels-on-inquiry-mum-always-put-on-a-brave-face-for-us
[41] One of the sources was in French, so it is possible that number appeared in written form.
[42] https://www.meshmedicaldevicenewsdesk.com/fda-pelvic-mesh-data-thousands-deaths-not-reported/

5.1.3 Mesh for abdominal POP surgery

As noted above, the likelihoods and severity of consequences from transvaginal mesh for POP is not considered here. All the following references pertain solely to use the use of abdominal mesh for POP repair (sacrocolpopexy).

5.1.3.1 Treatment costs

Data supplied by MoH showed that the average POP repair procedure cost $6,527 in 2016-17, with an average LOS of 3.1 days. Updated to $6,591 for 2018 using Statistics New Zealand health inflation. The classification system used (ICD-10 code N81) does not differentiate as to whether mesh was used or not, and unlike hernia and SUI, mesh is not the gold standard for POP surgery. However, in the absence of other data, this figure has still been taken for the cost of mesh POP surgery.

- The actual figure is likely to be higher, as the mesh itself can be expensive. For example, Carracedo et al (2015) report that the average cost of the transvaginal mesh used for POP repair was €1196 (over $2,000 in current New Zealand dollars). Hence, this is a conservative assumption, as it will under-estimate the savings from fewer revision surgeries under a registry.

5.1.3.2 Morbidity costs

Disability weights for POP varied considerably across sources, depending on exactly what was measured. Ohno et al (2016) estimated 0.18 for vaginal apex prolapse, while Jacklin et al (2012) estimated 0.05 for vaginal wall prolapse. Ock et al (2106) estimated 0.46 for "genital prolapse" while Montesino-Semper et al (2013) estimated 0.02 gain in QALYs following POP surgery. A simple average of 0.18 is used here. This is the same as Ohno et al's estimate, which is the only one specifically for apex prolapse (the only form of POP treated by abdominal mesh).

The probability of revision surgery for POP was estimated at 0.06 by Culligan et al (2103) and 0.07 by Ohno et al (2016).

The probability of surgical complications was 0.102 at one year from Jacklin & Duckett (2013).

All the impacts from Culligan et al (2103) are explicitly QALYs lost at one year follow up.

Mortality impacts from POP repair surgery are not included, as discussed in section 5.1.2.3 above.

Table 5.3: POP mesh surgery treatment costs and DALYs

Event	DALYs of condition	Cost of condition	Probability of condition	Expected cost	Sources
Revision surgery		$6,591	1.065	$7,019	Probability: Culligan et al (2013) Ohno et al (2106)
Recurrence	0.18	$30,362	0.012	$364	Probability: Jacklin & Duckett (2013) DALYs: Jacklin & Duckett (2013), Montesino-Semper et al (2103) Ohno et al (2106), Ock et al (2016)
Surgical complications	0.04	$6,907	0.102	$705	Jacklin & Duckett (2013)
Dyspareunia	0.03	$5,181	0.016	$83	Ohno et al (2106)
Bleeding requiring transfusion	0.01	$1,727	0.005	$9	Culligan et al (2013)
Mesh exposure	0.15	$25,903	0.001	$26	Culligan et al (2013)
Infection	0.14	$24,176	0.005	$121	Culligan et al (2013)
Lower urinary tract symptoms*	0.34	$58,712	0.051	$2,977	Culligan et al (2013)
Chronic pain	0.34	$58,712	0.043	$2,525	Culligan et al (2013)
Mortality	-	-	0.0096		Culligan et al (2013)
Total				**$13,828**	

Notes: * Lower urinary tract symptoms is a technical term for the inability to retain or to empty urine. Cost of condition is DALY*VSLY. Probability of surgery includes original and revisions. Sources: As given in table

5.1.3.3 Summary of economic impacts of mesh surgery

The overall economic impact of an average hernia surgery is $13,253 (Table 5.1). This is composed of $5,653 in treatment costs, $5,356 in morbidity costs and $2,244 in mortality costs. The overall expected average cost of a case of SUI mesh surgery is $13,913 (Table 5.2). This is composed of $6,621 in treatment costs, and $7,280 in morbidity costs. Overall, the expected economic costs from a case of (abdominal) POP surgery are $13,828 (Table 5.3). This is composed of $7,019 in treatment costs, and $6,809 in morbidity costs.

Table 5.4: Summary of economic cost by category and type of surgery

Cost type	Hernia	SUI	POP
Mortality	$2,244		
Morbidity	$5,356	$7,292	$6,809
Treatment costs	$5,653	$6,621	$7,019
Total	**$13,253**	**$13,913**	**$13,828**

Source: Table 5.1, Table 5.2 and Table 5.3

6 Potential benefits of a registry

6.1 Benefits of clinical quality registries

As established from the literature, the potential benefits of having a clinical quality registry (CQR) for mesh surgeries can include both improved health outcomes and reduced costs from unnecessary or ineffective procedures:

- *Reduced treatment costs*. McNeil et al (2010) reported that since the introduction of the AOANJRR there has been a decline in the rate of hip and knee revision surgery over a 4-year period from 14.8% to 11.1% and from 10.4% to 7.9%, respectively, with an associated annual cost saving of $44.6 million. Further, other results from the Registry have led to certain devices being voluntarily withdrawn from the Australian market.
- *Reduced morbidity*. Hannan et al (2012) show that when results from individual hospitals are made publicly available, outliers rapidly improve.
- *Reduced mortality*. Hannan et al (2012) report how the New York cardiac registry lead to reforms in identified high-mortality sites (such as introducing multidisciplinary reviews and dedicated nurse) that resulted in mortality rates being more than halved in some participating hospitals.

The benefits of clinical quality registries have been well established through a number of high quality studies such as:

- Van Den Veer et al (2010) conducted a systematic review on how medical registries provide information feedback to health care providers. Of the 43 process of care measures evaluated in the analytic studies, 26 were positively affected by the feedback initiative.
- Krysinska et al (2017) conducted a systematic review of dementia registries around the globe. The study found registries provide a positive return on investment.
- Hoque et al (2017) conducted a systematic review of clinical care registries on quality of patient care and clinical outcomes. Of 17 studies, 16 demonstrated positive findings in their outcomes after implementation of the registry.

6.2 Impact parameters from Australian CQRs

The parameters used in this report to model the potential clinical impacts of a mesh CQR are based on a recent study by the Australian Commission for Safety and Quality in Health Care (ACSQHC, 2016). The study estimated the mortality, morbidity and treatment cost impacts of five CQRs:

- Victorian Prostate Cancer Registry (Victorian PCR)
- Victorian State Trauma Registry (VSTR)
- Australia and New Zealand Intensive Care Society Adult Patient Database (ANZICS APD)
- Australia and New Zealand Dialysis and Transplantation Database (ANZDATA)
- Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR)

This study's aims were to provide an objective economic basis to support future registry investment, and to "develop and articulate a methodology for other registries to assess their impact and cost-effectiveness".

The study only focussed on health system expenditure and burden of disease and found significant net positive returns on investment for each of the registries under "very conservative" assumptions. Burden of disease impacts were monetised by multiplying disability-adjusted life years (DALYs) by the value of a statistical life year (VSLY).

Substantial benefits were measured reflecting improvements to clinical practice and outcomes over time. These included enhanced survival, improvements in quality of life and avoided costs of treatment or hospital stay. The study presented only incremental benefits that could be directly attributed independently to each registry, rather than other influences on practice, such as guidelines, novel therapies or newly published trials.

- The authors noted that there were likely to have been considerable other clinical, societal and economic benefits not captured by the study, such as increased workplace productivity of patients.

Each of the five clinical quality registries improved clinical practice at a relatively low cost, by Australian standards, of around $1 million a year. The return on investment varied between clinical quality registries, with benefit-to-cost ratios ranging from 2:1 to 7:1. Costs were included from the establishment of the registry, while benefits were only included for those years where they were clearly measurable. On average registries took around 5 years to collect sufficient longitudinal data to quantify benefits.

Table 6.1: BCRs of Australian QCRs

Registry	Years analysed	Costs ($m)	Benefit ($m)	Benefit to cost ratio
Victorian PCR	2009-13	2.7	5.2	2:1
VSTR	2005-13	6.5	36	6:1
ANZICS APD	2000-13	9.8	36	4:1
ANZDATA	2004-13	8.8	58	7:1
AOANJRR	2002-14	13	65	5:1
Average				**4.5:1**

Source: ACSQHC (2016)

6.2.2 Lower treatment costs

The CQRs in the ACSQHC's study were often able to avoid unnecessary surgery, or reduce length of stay (LOS).

The Victorian PCR achieved a 3% reduction in surgery due to less revision surgery from better positive surgical margin (PSM) outcomes. (PSM is a technical term describing whether or not all of the cancer is successfully removed from the prostate during surgery.) It also saw an 8.5% reduction in unnecessary surgery as a result of better adherence to the guidelines that direct surveillance for low risk cases.

The ACSQHC study estimated that the ANZICS APD registry had resulted in 19,566 fewer intensive care bed days nationally between 2009 and 2013, a 5% saving.

Over the period where benefits could be quantified (2011 to 2013) under the ANZDATA registry, kidney transplant failures were 32% lower than they were at the start of the registry in 2004. ACSQHC data showed that 77% of this reduction was due the registry's feedback access groups. That is, a 24% reduction in kidney graft losses can be attributable to the registry. Each transplant that works saves an estimated $80,000 a year in dialysis costs.

Over the same period, there was a reduction of 39% in cases of peritonitis (an infection that is frequently associated with dialysis). ACSQHC data showed that 40% of this reduction was due the registry's feedback access groups. That is, a 16% reduction in kidney graft losses can be attributable to the registry. Every avoided case of peritonitis saved $5,074 in treatment costs.

Over the existence of the AOANJRR the hip revision rate fell from 13.21% in 2002 to 10.21% in 2014 – equivalent to almost 6,500 fewer hip replacement procedures. The ACSQHC attributed around one fifth (17%) of this reduction to the registry. The average avoided hip replacement saved $44,396 in treatment costs.

Similarly, the knee revision rate fell from 8.96% to 7.70%, equivalent to almost 3,900 fewer knee replacements. The ACSQHC attributed around a quarter of this revision (24%) to the registry. The average avoided knee replacement saved $36,642 in treatment costs.

Table 6.2: Impact of CQRs on treatment costs

Registry	Benefit	Attributable reduction in treatment costs
Victorian PCR	Reduction in PSM	3.2%
	Avoided unnecessary surgery	8.5%
ANZICS APD	Reduced LOS	5.0%
ANZDATA	Reduced graft loss	24.4%
	Reduced peritonitis	15.5%
AOANJRR	Reduced hip revision	0.4%
	Reduced knee revision	0.2%
Mean		**8.2%**
Median		**5.0%**

Source: ACSQHC (2016)

6.2.3 Lower morbidity

By encouraging adherence to the Prostate Research International Active Surveillance (PRIAS) guidelines, the Victorian PCR saved patients a lot of bother. Each case of unnecessary therapy (surgery, chemotherapy and other) prevented was estimated to save that patient 0.14 quality adjusted life years (QALYs) of urinary bother, bowel bother, and sexual bother over the following year.[43] Converting this to monetary values using the value of a statistical life year (VSLY) required for use by Australian government agencies ($182,000 AUD) yielded a value for healthy life saved of $25,000 per avoided unnecessary treatment.

Similarly, each case of peritonitis prevented by the ANZDATA was estimated to save 0.05 QALYs, representing a saving of healthy life worth $9,646. Each avoided graft loss was estimated to save 0.55 QALYs per year from not having to be on dialysis. As the average period on dialysis was 4.5 years, this translated to $425,000 worth of healthy life saved.

Like all forms of surgery, hip replacement causes pain directly, and caries subsequent risks such as dislocation, embolism, thrombosis and pneumonia. The ACSQHC estimated that the average loss of QALYs from hip revision surgery was 0.12. Thus each avoided revision that could be attributable to the AOANJRR represented a gain in healthy life worth $25,969. On the same basis, each attributable knee revision avoided conferred a benefit of 0.15 QALYs worth $44,671.

[43] A QALY and a DALY are more or less interchangeable. They both measure the value of healthy life lost or gained using the same scale. The main difference is that QALYs are subjectively reported by individual patients, where DALYs are objectively assessed by teams of medical experts. DALYs are thus preferred for economic modelling, but like most intervention studies, the ACSQHC used QALYs here.

Table 6.3: CQR impact on morbidity

Registry	Impact type	QALYs per case	Attributable reduction
Victorian PCR	Avoided unnecessary therapy	$25,000	8.5%
ANZDATA	Reduced graft loss		24.0%
	Reduced peritonitis	$9.646	15.5%
AOANJRR	Reduced hip revision	$25,969	0.4%
	Reduced knee revision	$44,671	0.2%
Mean			**9.8%**
Median			**8.5%**

Source: ACSQHC (2016)

6.2.4 Less mortality

The Victorian PCR resulted in a 3.2% reduction in deaths due to fewer tumours being missed as a result of better PSM outcomes.

The VSTR resulted in a 3.1% reduction in trauma deaths.

Over the period where benefits could be quantified (2011 to 2013) under the ANZDATA registry, there were 770 fewer deaths during dialysis than there would have been if mortality rates at the start of the registry in 2004 had continued unabated, or a 14% reduction. A quarter of these lives saved (196) were directly attributable to the registry, thus the registry was responsible for a 3.7% reduction in deaths.

The mean attributable reduction in mortality from these three QCRs was 3.4%. [44]

Table 6.4: Impact of CQRs on mortality

Registry	Attributable reduction in mortality
Victorian PCR	3.2%
VSTR	3.1%
ANZDATA	3.7%
Mean	**3.4%**
Median	**3.2%**

Source: ACSQHC (2016)

Thus, overall, Australian CQRs were found to reduce treatment costs by 8%, morbidity by 10% and mortality by 3%. While there were not a lot of observations, the fact that there was little variation across registries (as evidenced by the closeness of means and medians in the above tables) confers a degree of confidence in the results. That is, while the impacts of the diseases addressed varies greatly, the percentage improvement afforded by similar quality control mechanisms is reasonably similar.

[44] The ANZICS APD also saw a reduction in intensive care mortality, but the figures were only presented in absolute, rather than relative terms.

Table 6.5: Attributable impacts of clinical quality improvements

Type of impact	Mean reduction attributable to CQRs	Median reduction attributable to CQRs
Treatment costs	8.2%	5.0%
Morbidity	9.8%	8.5%
Mortality	3.4%	3.2%

Sources: Table 6.2, Table 6.3, Table 6.4

6.3 Safety / device recall benefits

In the absence of detailed epidemiological data for mesh surgeries in New Zealand it is not possible to calculate how large a registry would need to be in order to be used principally to detect unsafe devices. We don't even know how many surgeries there are, let alone the risk profiles of patients. However, observations of international safety registries would indicate that a New Zealand mesh registry is unlikely to be large enough to do so.

For a clinical trial that is only testing one thing against another (an intervention against treatment as usual) it is a relatively straightforward matter to determine minimum sample sizes required.[45] Most of the clinical trials registered in ClinicalTrials.gov (mandatory for any drug sold in the United States) have fewer than 100 participants.[46]

However, clinical registries are not designed to test an intervention against a counterfactual. With mesh, not only are there different types of mesh (synthetic, biological, mixed) for different purposes (permanent, temporary) and many different types of surgery for POP / SUI (transoburator, retropubic sacrocolpopexy) and hernia (multiple) – each with many individual mesh products, which can all be open or laparoscopic. But there are also a range of confounding factors, age, weight, diabetic status, smoking status, previous operations. And the skill of the surgeon has to be considered.

Accordingly, estimating the minimum enrolment for a mesh registry to be an effective safety assessment mechanism would require a substantial epidemiological study that is beyond the scope of this exercise.

However, it can be observed that in practice clinical registries designed for safety monitoring (rather than clinical quality) generally have annual enrolments in the tens of thousands to hundreds of thousands. The most widely cited example in the literature is Australia's AOANJRR, which has over a million surgeries in its database, and has over decades identified a handful of unsafe devices. Thus, a POP/SUI mesh registry for New Zealand alone is highly unlikely to be large enough to be used principally as a safety register.

- Were MoH to engage in full business case study for a mesh registry at some point in the future, with a long enough lead time, the necessary epidemiological data to estimate mean and variance of mesh risk factors could possibly be obtained from international registries.
- Moreover, even for databases the size of the US FDA, the probability of any given product a) actually being dangerous, and b) being found to be so by registry is, a priori, unknown. Accordingly, the potential benefits of even such a registry cannot be estimated in advance.

[45] See, for example, Chow, S. C., Shao, J., Wang, H., & Lokhnygina, Y. (2017). *Sample size calculations in clinical research*. Chapman and Hall/CRC.
[46] Califf, R. M., Zarin, D. A., Kramer, J. M., Sherman, R. E., Aberle, L. H., & Tasneem, A. (2012). 'Characteristics of clinical trials registered in ClinicalTrials. gov, 2007-2010'. *JAMA* 307(17), 1838-1847.

7 Cost benefit analysis

7.1 Parameters

Following standard practice, the time frame for this benefit cost analysis is 10 years. So as to use current costs, 2018 is chosen as the base year, leading to 2027 being the out year. Year one is assumed to be spent on setup, with no data collected.

Following Treasury's requirement for public cost benefit analysis, a real discount rate of 6% p.a. is used to convert all future financial quantities into net present values (NPV).[47]

- This reflects the time value of money – which is why people are willing to pay interest to borrow and consume now, rather than save and consume later.
- Deloitte Access Economics usually discounts health states by 3% as there is not the uncertainty associated with financial markets. However, following Treasury guidelines, all future values are discounted by 6%.
- All costs and benefits are measured in real, rather than nominal terms. That is future figures are net of inflation.

7.2 Costs

As noted in section 4.3, establishment costs for a registry are estimated to be around $900,000. Ongoing fixed costs are estimated at around $576,000 a year and ongoing variable costs for Australian QCRs were estimated at around $630,000 a year.

In Australia, average variable costs for registries that followed up patients were estimated at $66 per patient per year. As health records in Australia are now nearly all electronic, whereas most DHBs still use paper records, to allow for double-handling, variable costs are assumed to be $122 per patient for the mesh registry. Given the forecast number of annual mesh surgeries of between 11,000 to 13,000 over the next decade Table 3.4 this yields annual variable costs of between $1.4 to $1.6 million a year, or between $1.3 and $0.9 million in NPV terms[48]. **Total (NPV) costs for the registry over the decade of $14.8 million** (Table 7.3)

7.3 Benefits

The treatment costs, and monetised values for morbidity and mortality per case of hernia, SUI and POP mesh surgery were established in section 5.1. These are repeated in the top three lines of Table 7.1 below. The average impacts of Australian CQRs on treatment costs, morbidity and mortality were established in section 6.2. These are repeated as line four ("Registry savings %") of Table 6.1. The last three lines of Table 6.1 simply multiplies these percentage savings (for treatment costs, morbidity and mortality) by the relevant cost types for each of hernia, SUI and POP surgery. By comparing the value of these savings against the original cost for each type of surgery (bottom three lines of the "Total" column against the top three lines), this analysis shows that a mesh register should be able to reduce overall costs of hernia surgery by 8%, and POP and SUI surgery by 9%. On a weighted average against 2018 surgeries, the potential savings if New Zealand already had a mesh registry in place would be 8.2%.

[47] https://treasury.govt.nz/information-and-services/state-sector-leadership/investment-management/plan-investment-choices/cost-benefit-analysis-including-public-sector-discount-rates/current-discount-rates

[48] Unless noted otherwise, all future financial values in this chapter are in NPV terms.

Table 7.1: CQR benefits per case, by condition and type of cost

	Mortality	Morbidity	Treatment costs	Total	Registry savings %
Hernia costs, no registry	$2,244	$5,356	$5,653	$13,253	
SUI costs, no registry		$7,292	$6,621	$13,913	
POP costs, no registry		$6,809	$7,019	$13,828	
Registry savings %	**3.4%**	**9.8%**	**8.2%**		
Hernia, registry savings	$75	$526	$462	$1,063	8.0%
SUI, registry savings		$716	$542	$1,257	9.0%
POP, registry savings		$668	$574	$1,243	9.0%

Source: Table 5.4, Table 6.5

The estimated financial and burden of disease costs for all mesh surgeries to be conducted in New Zealand over the next 10 years is over a billion dollars (Table 7.4). Thus the benefits of an average 8.2% reduction from a mesh QCR could appear to be very large compared to annual running costs. However, such registries take on average five years of accumulating data before they start to reap clinical benefits. So, over the 10-year horizon of this exercise, there are twice as many more years of costs than there are of benefits. Further, the 6% real discount rate required by the Treasury tends to reduce the NPV of benefits accruing down five years or more down the track quite substantially.[49]

If, hypothetically, New Zealand already had a mesh register that had already been running long enough to be yielding measurable benefits, then its potential benefits over the next 10 years would be around $100 million (Table 7.5).

However, the ACSQHC (2016) shows that on average, there is around five years between when a registry is established, and when it has amassed enough longitudinal data to clearly distinguish improvements in quality from confounding data.

Table 7.2: Duration of CQR establishment before measurable benefits

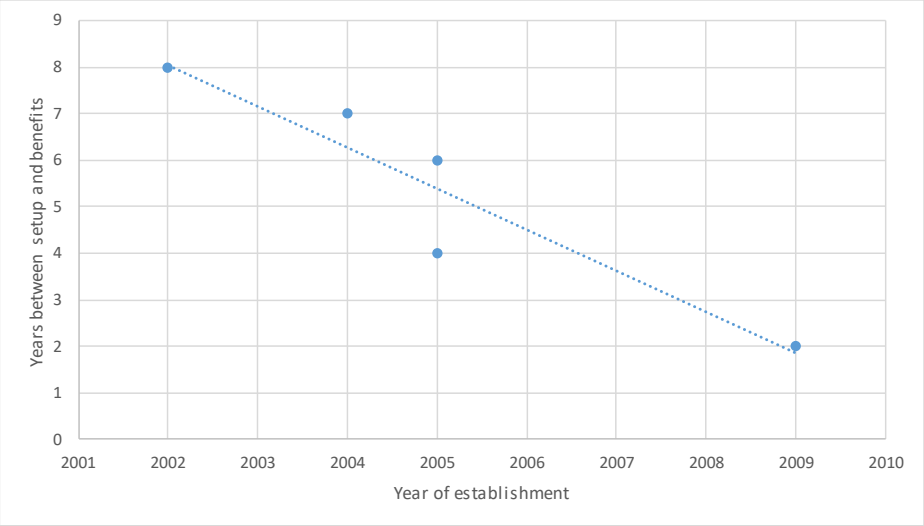
	Year established	Year benefit first measurable	Gap years
Vic PCR	2009	2011	2
VSTR	2005	2011	6
ANZICS APD	2005	2009	4
ANZDATA	2004	2011	7
AOANJRR	2002	2010	8
Average			**5**

Source: ACSQHC (2016)

[49] By way of comparison, the official interest rate in New Zealand is currently 1.75%. And that is a nominal rate – to convert to a real rate requires it to be net of inflation (currently 1.1%). https://www.rbnz.govt.nz/monetary-policy/official-cash-rate-decisions

However, it also clear that newer CQRs have shorter lead times to their predecessors (Chart 7.1)[50]. The oldest registry in the ACSQHC study was established for eight years before it yielded measurable benefits, whereas the newest one was only established for two years. Accordingly, adopting a five-year time frame before benefits are measurable for the New Zealand mesh registry may be a conservative assumption.

Chart 7.1: Newer QCRs have shorter lead times



Source: ACSQHC (2016)

7.4 Benefit to cost ratio

Ten years' worth of costs (including setup costs) gives total costs in NPV terms of $14.8 million. Assuming that benefits only accrue from year 6, then the mesh registry would confer $45.6 million in benefits. **This yields an overall BCR of 3.1 to 1.**

This is below the average benefit for Australian QCRs of 4.5:1 (Table 6.1). This is to be expected, as the proposed mesh registry also has considerably higher total operating costs than any of the Australian QCRs because patient records will be paper-based. However, the BCR does still fit within the range of 2:1 to 7:1 observed by the ACSQHC (2016).

[50] Trend analysis indicates a 90% correlation between year of establishment and benefit lead duration.

Table 7.3: Estimated costs for a mesh registry, 2018 to 2027 ($m, NPV)

Category	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	Total
Setup costs	$0.90										0.90
Fixed costs		$0.54	$0.51	$0.48	$0.45	$0.42	$0.40	$0.37	$0.35	$0.33	$3.86
patients		10,528	10,771	11,035	11,273	11,506	11,729	11,945	12,148	12,352	103,287
Variable costs		$1.32	$1.27	$1.21	$1.16	$1.11	$1.06	$1.01	$0.97	$0.92	$10.02
Total costs	**$0.90**	**$1.86**	**$1.78**	**$1.69**	**$1.61**	**$1.53**	**$1.46**	**$1.38**	**$1.32**	**$1.25**	**$14.78**

Source: Table 4.5

Table 7.4: Estimated costs of mesh surgery, by type, 2018 to 2027 ($m, NPV)

Category	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	Total
Hernia	$120.1	$122.7	$125.2	$127.6	$129.9	$132.1	$134.4	$136.6	$138.8	$140.9	$1,308.2
SUI	$20.1	$20.4	$20.7	$21.0	$21.2	$21.4	$21.7	$21.9	$22.2	$22.4	$213.1
POP	$10.5	$10.8	$11.0	$11.2	$11.4	$11.7	$11.9	$12.1	$12.3	$12.4	$115.2
Total	$150.8	$153.9	$156.9	$159.8	$162.5	$165.2	$167.9	$170.6	$173.2	$175.8	$1,636.5

Source: Table 5.4 and Table 3.4

Table 7.5: Estimated potential benefits for a hypothetical established mesh registry, 2018 to 2027 ($m)

Category	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	Total
Hernia	$9.6	$9.3	$8.9	$8.5	$8.1	$7.8	$7.4	$7.1	$6.8	$6.5	$80.0
SUI	$1.8	$1.7	$1.7	$1.6	$1.5	$1.4	$1.4	$1.3	$1.2	$1.2	$14.7
POP	$0.9	$0.9	$0.9	$0.8	$0.8	$0.8	$0.7	$0.7	$0.7	$0.6	$7.9
Total	**$12.4**	**$11.9**	**$11.4**	**$10.9**	**$10.4**	**$10.0**	**$9.5**	**$9.1**	**$8.7**	**$8.3**	**$102.6**

Source: Table 7.4 and Table 7.1

Table 7.6: Estimated potential benefits for a new mesh registry, 2018 to 2027 ($m)

Category	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	Total
Costs	$0.90	$1.86	$1.78	$1.69	$1.61	$1.53	$1.46	$1.38	$1.32	$1.25	**$14.78**
Benefits						$9.97	$9.52	$9.09	$8.68	$8.28	**$45.55**
BCR											**$3.08:1**

Source: Table 7.4 and Table 7.1

Table 7.7: Estimated potential benefits for a POP and SUI only mesh registry, 2018 to 2027 ($m)

Category	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	Total
Fixed costs	$0.90	$0.54	$0.51	$0.48	$0.45	$0.42	$0.40	$0.37	$0.35	$0.33	$4.76
Patients		2,247	2,284	2,318	2,349	2,382	2,416	2,448	2,481	2,512	
Variable costs		$0.26	$0.25	$0.24	$0.22	$0.21	$0.20	$0.19	$0.18	$0.18	$1.94
Total costs	**$0.90**	**$0.80**	**$0.76**	**$0.71**	**$0.67**	**$0.64**	**$0.60**	**$0.57**	**$0.54**	**$0.51**	**$6.69**
Benefits						**$2.19**	**$2.09**	**$1.99**	**$1.89**	**$1.80**	**$9.96**

Source: Table 7.4 and Table 7.1

7.5 Sensitivity testing

7.5.1 Registry solely for POP and SUI mesh

If the registry were only set up to contain SUI and POP patients, it would still have a positive BCR, albeit much smaller. Fixed costs would not change, despite around an 80% reduction in the number of patients covered. Variable costs per patient would not change either, but total variable costs would be far lower. Total costs for the registry over 2018 to 2027 would be $6.69 million, while total benefits would be $9.96 million, yielding a BCR of 1.5 to 1 (Table 7.7). While this is still squarely positive (a 50% return on investment), as it is not multiples of 1, such a BCR could become negative, for example if further adverse publicity on mesh impacts meant more women demand suture rather than mesh surgery

7.5.2 Higher or lower CQR efficacy

As Australia's health system is more high-tech than New Zealand's in some respects - for example, not using paper records - it is possible a New Zealand-only registry may be less able to bring about improvements in mortality, morbidity and treatment costs than the ones used in this study. Conversely, a new registry may be more efficacious than the older CQRs utilised, as the more recent ones tended to have better results. Accordingly, sensitivity testing was conducted where CQR impact parameters were 50% higher and 50% lower than the baseline. If the proposed registry managed to underperform its Australian counterparts by 50% in all three impact domains, the BCR would fall to 1.54.

Table 7.8: BCR under higher or lower CQR efficacy

Impact	50% below baseline efficacy	50% above baseline efficacy
Mortality	3.00	3.17
Morbidity	2.30	3.87
Treatment costs	2.41	3.75
All	1.54	4.62

Source: Deloitte Access Economics calculations

7.5.3 Lower mesh utilisation rates inferred by recorded device sales

In order to conduct a lower bound sensitivity analysis using Medsafe sales data, the total number of sales between 2014-17 (by condition) was divided by the total estimated number of operations for each condition. Medsafe data only reports hernia mesh sales for groin and ventral hernias; however, in the interests of conservatism, the same ratio of reported sales to total operations was assumed to apply to the other forms of hernia repair too. The prevalence of mesh surgeries for the purpose of this sensitivity analysis was then projected using the forecast number of operations for each condition by age and gender.

Based on Medsafe sales data, the following rates of mesh versus non-mesh utilisation were estimated for each condition – as outlined in Table 7.9.

Table 7.9: Overall utilisation rates by condition, estimated using Medsafe sales data

Condition	Mesh utilisation (%)	Non-mesh utilisation (%)
Hernia	24.27	75.73
SUI (female)	90.44	9.56
POP	7.09	92.91

Source: Deloitte Access Economics (2018) modelling based on publicly available information.

Table 7.10 : Estimated numbers of mesh surgeries, based on Medsafe device sales, 2018 to 2027

Category	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027
Hernia	6,432	6,554	6,672	6,785	6,890	6,995	7,099	7,202	7,304	7,403
SUI	1,288	1,307	1,327	1,350	1,370	1,388	1,406	1,422	1,436	1,452
POP	186	190	195	199	204	208	212	216	220	224
Total	**7,906**	**8,051**	**8,193**	**8,334**	**8,463**	**8,591**	**8,717**	**8,839**	**8,960**	**9,079**

Source: Deloitte Access Economics (2018) modelling based on publicly available information.

Overall, using mesh to total surgery ratios from Medsafe sales data, instead of deriving these from the literature, does not greatly change the BCR, albeit it does fall from 3.1 to 2.7. As the model estimates a net benefit per patient at the margin, the BCR will only become negative if there are so few patients that these benefits do not offset the fixed costs of the registry – which are only a minority of costs.

Table 7.11: Estimated BCR for a new mesh registry, based on Medsafe device sales,2018 to 2027 ($m)

Category	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	Total
Costs	$0.90	$1.47	$1.39	$1.32	$1.26	$1.19	$1.13	$1.07	$1.02	$0.97	$11.73
Benefits						$6.93	$6.61	$6.30	$6.00	$5.72	$31.56
BCR											**$2.69:1**

Source: Deloitte Access Economics calculations

The model is more sensitive to changes in the efficacy of CQRs than to patient numbers. However, given there is little difference between means and medians for CQR impact parameters, there may be less uncertainty there than there is with numbers of mesh operations.

8 Conclusions

This report has estimated that a CQR for mesh in New Zealand would cost around $15 million (NPV) over the next decade, including set up costs. The benefits, in terms of reduced treatment costs, and mortality and morbidity avoided, would be worth around $45 million. Thus the benefit to cost ratio is around 3:1.

Table 8.1: Estimated potential benefits for a new mesh registry, 2018 to 2027 ($m)

Category	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	Total
Costs	$0.90	$1.86	$1.78	$1.69	$1.61	$1.53	$1.56	$1.38	$1.32	$1.25	**$14.78**
Benefits						$9.97	$9.52	$9.09	$8.68	$8.28	**$45.55**
BCR											**3.08:1**

Source: Table 7.6

8.2 Summary of assumptions employed in modelling

Due to a paucity of relevant data, a number of assumptions have had to be employed in this modelling. These assumptions nearly all err on the side of caution – that is, they are likely to overstate registry costs and understate the benefits. (Understating the benefits of a registry include understating the costs of the conditions it is designed to alleviate.)

There are several assumptions in section 5.1 that do, or may, under-estimate the costs of mesh surgery and its consequences.

- In the absence of data, costs of initial mesh surgeries and revision surgeries are assumed to be the same. This may be conservative as, anecdotally, explant may be a more complicated operation than implant if body tissue has grown into the mesh.[51]
- The average cost of POP surgery provided by MoH was assumed to apply to mesh POP surgery, even though most such surgery does not involve mesh (section 5.1). This may be conservative, as the mesh itself can cost several hundred dollars.
- Health system expenditure other than hospitals - such as GP visits or pain medication - were not included for lack of data. This understates total costs.
- Impacts on patient's workplace productivity were not in scope. This understates the economic consequences of mesh surgery.
- Most of the studies sourced for consequences of mesh surgery only reported such consequences as had occurred at 12 months follow up. This understates total costs, as the many consequences which take far longer to appear are not included in the modelling.
- Fatalities from urogynaecological surgery are not included, as US FDA data indicates there is only around one death a year from SUI mesh in that country. However, to the extent that adverse events are under reported or incorrectly reported, that may be a conservative assumption.

On the other side of the equation, the model assumes that the per-patient variable costs of running a registry in New Zealand will be twice as high as in Australia, due to relative lack of electronic record keeping in this country (section 4.3). This makes the total running costs of a mesh registry in New Zealand higher than running a registry in Australia with several times as many patients. Further, at least one of the Australian registries used for cost benchmarking also still uses paper for initial record keeping (ACSQHC, 2016). So this is most likely a conservative assumption.

[51] https://meshmenot.wordpress.com/2014/11/23/partial-vs-full-mesh-removal-surgery/

8.3 Further considerations

While it is beyond the scope of this report, given Australia and New Zealand are the only two countries (so far) to no longer supply surgical mesh products whose sole use is the treatment of POP via transvaginal implantation or single incision mini-slings for the treatment of SUI, it may be worth considering a joint register to capture scale economies. This option was widely supported during consultations.

- There are successful precedents for this, such as the Australia and New Zealand Intensive Care Society Adult Patient Database and the Australia and New Zealand Dialysis and Transplantation Registry.

Although also beyond scope, many participants stated that they thought a register for all medical devices would be a better idea than a collection of isolated single-issue registries, such as the one proposed for mesh. In Australia a registry for all implantable devices was recommended by the recent *Expert Review of Medicines and Medical Devices Regulation*.[52]

Any decision to establish a mesh registry in New Zealand should be based on a fully detailed bottom-up costing exercise conducted by technical experts, and not rely on the simple averages of Australian registry costs, which was employed here for the purpose of an indicative cost benefit analysis.

[52] http://www.health.gov.au/internet/main/publishing.nsf/content/expert-review-of-medicines-and-medical-devices-regulation

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Appendix A: Consultations

Consultations were held with the following organisations

- Nick Kendall, from the Accident Compensation Corporation, 1 May 2018
- Chris James from Medsafe on 2 May
- Richard Lander, Royal Australasian College of Surgery, 4 May
- John Tait from the Royal Australian and New Zealand College of Obstetrics and Gynaecology, 7 May
- Patricia Sullivan and Charlotte Korte, Mesh Down Under, 8 May
- Andrew MacCormick from the Bariatric Surgery Registry, 14 May
- Sharon English, Urology Society of Australia and New Zealand, 14 May.

Appendix B: Registry establishment

B.1. Types of registry

This section provides an overview of three types of medical registry: (1) clinical registries; (2) condition (disease) registries; and (3) drug, device or product registries. The main differences between each of these registries is the key objectives targeted in their design. These registries are outlined as follows:

- **Clinical registries** – the primary purpose of a clinical quality registry is to monitor outcomes and report on quality of care. Quality indicators are collected by clinical registries to assess if care is safe, effective, and delivered in a timely and appropriate manner; this information is reported back to the institutions and/or clinicians. This type of registry can monitor quality of care within specific areas of health service or can target monitoring defined diseases or conditions.[22]
- **Condition (disease) registries** – the objective of a condition (disease) registry is to gather diagnostic details on patients with specific diseases or conditions. However, if this registry were to also collect outcome data and report quality indicators back to institutions or clinicians, then it would be considered a clinical registry.[22]
- **Drug, device or product registries** – the purpose of a drug, device or product registry is to monitor the medium to long-term safety of devices, drugs or products. As with condition registries, drug, device or product registries would instead be considered clinical registries if they collect and disseminate quality indicators back to institutions and clinicians.

B.2. Clinical trials versus registries

Clinical trials are another important contributor to evidence-based medicine, as they inform medical decision-making through trial outcomes.[53] The use of clinical trials in medical research involves the observation of a human or animal during the use of a treatment.[54] Trials conducted are of limited duration and size and generally focus on a narrowly defined population that represents only a small segment of the population with the disease or product use of interest.[55]

Whilst registries are established without a specific medical question in mind and without dividing patients into sub-groups, clinical trials are set up expressly to answer a specific question and the assignment of patients to treatment or comparator groups is stringently controlled. However, clinical trials *can use* registry patients. The following pull-out box provides some examples, which highlight the usefulness of registries in facilitating clinical trials and safety and monitoring functions to be performed.

[53] Mahmud, A., Zalay, O., Springerq, A., Arts, K., & Eisenhauer, E. (2018). Barriers to participation in clinical trials: a physician survey. *Current Oncology*, *25*(2), 119-125. doi:10.3747/co.25.3857
[54] Meinert, C. L. (2012). *Clinical trials : design, conduct, and analysis*. New York: Oxford University Press, [2012].
[55] Leavy, M. B. (2014). *Registries for evaluating patient outcomes. a user's guide*. Rockville, Maryland : U.S. Department of Health and Human Services, 2014.

*The **Bosentan Patient Registry*** was established as part of a risk-sharing arrangement for the release of the drug on the Pharmaceutical Benefits Scheme (PBS). The PBS Advisory Committee requested for the database to be established with the purpose of determining whether there was equivalence between patients in Australia receiving Bosentan and the results suggested by small clinical trials conducted overseas. The Australian registry provided real-world information on the efficacy, characteristics and management of pulmonary arterial hypertension in clinical practice, and showed that treatment with Bosentan improved survival outcomes compared with historical controls (Reid, 2015).

*The **Australian Rheumatology Association Database (ARAD)*** was established through a NHMRC grant with the aims of determining the short- and long-term efficacy and safety of the biologic Disease Modifying Anti-Rheumatic Drug (bDMARDs) therapies for inflammatory arthritis. Key outcomes examined included mortality/survival, function and disability, quality of life, incidence of adverse events, treatment side effects, and reasons for stopping or changing therapy. The ARAD continues to function, and as at 2015 reported outcomes on over 3000 patients taking a variety of bDMARDs in Australia (Reid, 2015).

B.3. How registries work

Planning, operating, and managing a patient registry is a complex, multi-stage process. The key steps involved in planning a patient registry include articulating its purpose, determining whether it is an appropriate means of addressing the research question, identifying stakeholders, defining the scope and target population, assessing feasibility, and lastly securing funding. The US Agency for Healthcare Registry and Quality outlines these in its *Registries for Evaluating Patient Outcomes: A users' guide*.[56] Each of the key stages involved in the operation and function of a patient registry is discussed as follows.

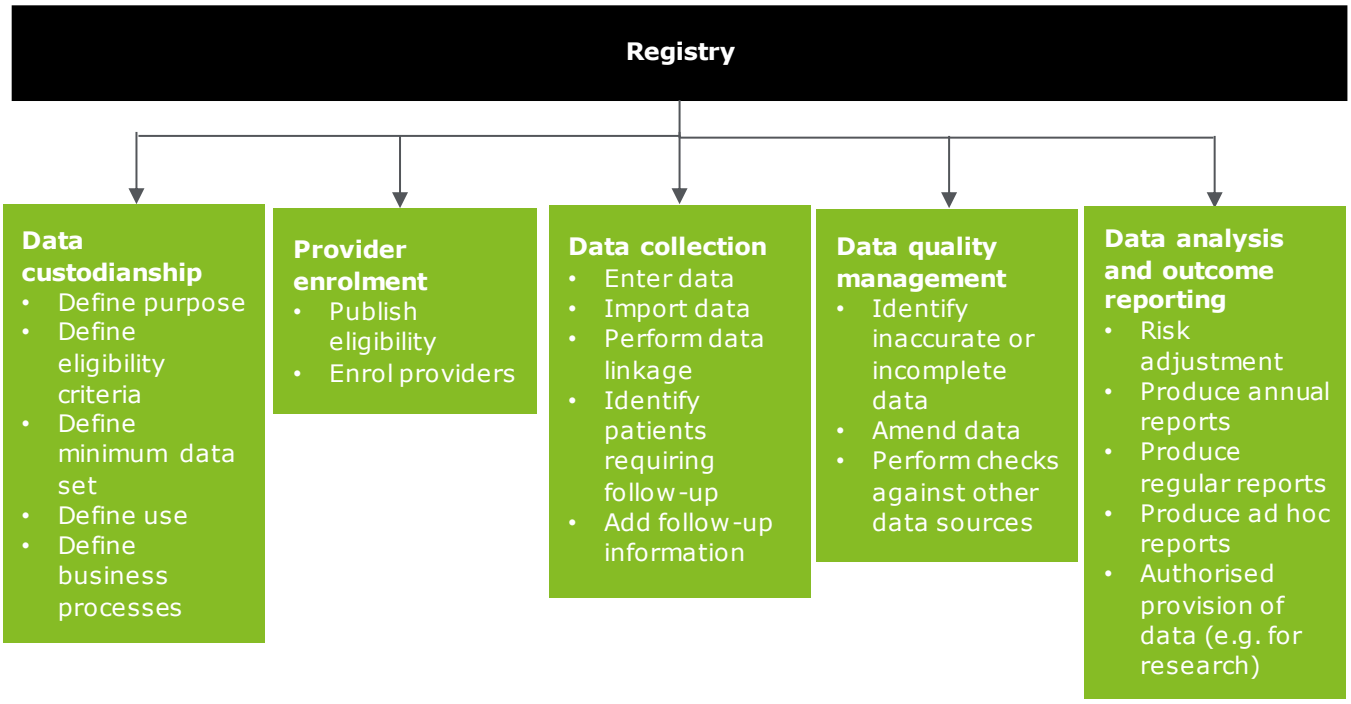
- **Registry Design**. A patient registry should be designed with respect to its major purpose, with the understanding that different levels of rigor may be required for registries designed to address focused analytical questions to support decision making, in contrast to registries intended primarily for descriptive purposes.
- **Data Elements**. The selection of data elements requires balancing such factors as their importance for the integrity of the registry and for the analysis of primary outcomes, their reliability, their contribution to the overall burden for respondents, and the incremental costs associated with their collection.
- **Data Sources**. A single registry may integrate data from various sources. The form, structure, availability, and timeliness of the required data are important considerations. Sufficient identifiers are necessary to guarantee an accurate match between data from secondary sources and registry patients.
- **Ethics, Data Ownership, and Privacy**. Critical ethical and legal considerations should guide the development and use of patient registries. The purpose of a registry, the type of entity that creates or maintains the registry, the types of entities that contribute data to the registry, and the extent to which registry data are individually identifiable affect how the regulatory requirements apply.
- **Informed Consent**. The requirement of informed consent often raises different issues for patient registries versus clinical trials. For example, registries may be used for public health or quality improvement activities, which may not constitute "human subjects research.".
- **Confidentiality and Legal Concerns**. As patient registries are increasingly recognized as a valuable data source, questions about privacy and the confidentiality of the data arise, particularly when data are desired for litigation or other judicial or administrative proceedings.
- **Patient and Provider Recruitment and Management**. Recruitment and retention of patients as registry participants, and of providers as registry sites, are essential to the success of a registry. Factors that motivate participation include the perceived relevance, importance, or scientific credibility of the registry, as well as a favourable balance of any incentives for participation versus the risks and burdens thereof.
- **Data Collection and Quality Assurance**. The integrated system for collecting, cleaning, storing, monitoring, reviewing, and reporting on registry data determines the utility of those data for meeting the registry's goals. Critical factors in the ultimate quality of the data include how data elements are structured and defined, how personnel are trained, and how data problems (e.g., missing, out of range, or logically inconsistent values) are handled.

[56] https://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0077814/

- **Adverse Events**. It is important for any registry that has direct patient interaction to develop a plan for detecting, processing, and reporting adverse events.
- **Analysis, Interpretation, and Reporting of Registry Data**. Analysis and interpretation of registry data begin with answering a series of core questions: Who was studied, and how were they chosen for study? How was data collected, edited, and verified, and how was missing data handled? How was the analyses performed?
- **Managing Patient Identity Across Data Sources**. As new technologies emerge to manage electronic health care data and create new opportunities for data linkage, patient identity management (PIM) strategies and standards grow increasingly important. If shared patient identifiers exist between two data sources, data can be linked using a unique patient identifier (UPI), such as a medical record number.

The Australian Commission on Safety and Quality in Health Care (ACSQHC, 2014) *Framework for Australian clinical quality registries* provides a comprehensive guide to all the functions that a clinical registry needs to perform. This is outlined in Figure B.1, and functions include data custodianship, provider enrolment, data collection, data quality management, and data analysis and outcome reporting.

Figure B.1: Functional overview of clinical quality registries



Source: ACQSHC, 2014

The ACQSHC also provides full manuals on the technical infrastructure required to enable clinical registries to operate safely and efficiently. Should the Minister decide that a full business case is required to be developed for the registry, further analysis will need to be undertaken.

B.4. Australasian clinical quality registries

Details of the size, focus, age and funding sources for the CQRs used as costing benchmarks in this report are reported in Table B.1.

Table B.1Characteristics of Australasian clinical quality registries

Vic PCR	*Prostate cancer clinical quality registry with approximately 75% of incident cases covered. Principle metrics include mortality, morbidity, surgical outcomes, patterns of care (and variations thereof), patient recorded outcome measures related to quality of life and disease impact.*
Total costs:	$2,857,000 AUD from 2009 to 2013
Average yearly cost:	$571,440 AUD between 2009 and 2013
Number of cases:	2,198 entries in 2013 (total of 9,763 from 2009 to 2013)
Funding:	Cancer Australia, the Victorian Department of Health, Movember foundation. Registry funds include data collection costs.
VSTR	*Collects data on all major trauma cases in Victoria across all phases of trauma care from 138 health services comprising; two adult and one paediatric major trauma services and staged care through regional and metropolitan health services. Principle metrics include system processes such as triage and transfer, discharge destination, mortality, length of stay, long term functional outcomes.*
Total costs:	$4,354,408 AUD from 2009 to 2013
Average yearly cost:	$870,882 AUD between 2009 and 2013
Number of cases:	3,000 eligible cases were covered by the registry in 2013/14.
Funding:	Victorian Department of Health and Human Services, and Transport Accident Commission. Data collection costs are included and met by a mixture of registry and health services.
ANZICS APD	*Part of a broader set of 4 linked clinical quality registries that benchmark performance and analyse outcomes at ICUs across Australia and New Zealand. Principal metrics include standardised mortality, ICU length of stay, central line infection rates.*
Total costs:	$5,186,792 AUD from 2009 to 2013
Average yearly cost:	$1,037,358 between 2009 and 2013
Number of cases:	100,000+ admissions in Australia in 2013/14
Funding:	Federal Government. Data collection costs are met by participating ICUs.
ANZDATA	*Registers all patients receiving renal replacement therapy, where the intention is to treat long term (renal function is not expected to recover). Principal metrics include mortality specific to modality of treatment, complications (peritonitis, dialysis technique failure) and comorbidities.*
Total costs:	10,000,000 AUD from 2004 to 2013
Average yearly cost:	1,000,000 AUD between 2009 and 2013
Number of cases:	2,654 Australian and 527 NZ new patients in 2015 (total of 21,000 patients recorded at the end of 2013).
Funding:	Australian Organ and Tissue Donation and Transplantation Authority (AOTDTA), NZ MoH, Kidney Health Australia and the Australia & New Zealand Society of Nephrology. Data collection costs are met by individual renal units.
AOANJRR	*Collects data on hip and knee replacement surgery that enables outcomes to be determined based on patient characteristics, prosthesis type and features, method of prosthesis fixation and surgical technique used. Principle metrics include revision rate, identification of prostheses with outlying rates, linked mortality data.*
Total costs:	$15,351,000 AUD from 1999 to 2015
Average yearly cost:	$959,438 AUD between 1999 and 2015
Number of cases:	~96,000 entries per year (8000 joint replacements per month)
Funding:	Registry costs met by the DoH, data collection costs met by individual hospitals. Cost recovery through manufacturer levy since 2009.

Source: ACSQHC (2016). Note: Vic PCR costs includes $200,000 AUD initial build costs. AOANJRR likely also includes development costs however the value is unknown. Set up costs were not included in ANZICS and ANZDATA costs. Costs do not include any discounting.

B.5. International Registries

The following list of international registries in the United States illustrates the diverse range of conditions that have their own registries:

- Cancer - Breast and Colon Cancer Family Registries; Breast Cancer Surveillance Consortium; Breast Cancer Family Registry; Cancer Genetics Network; Colon Cancer Family Registry; SEER registries
- Cerebral palsy - The Cerebral Palsy Research Network); Cerebral Palsy Research Registry (CPRR);
- Alzheimer's disease - Alzheimer's Prevention Registry; Dominantly Inherited Alzheimer Network (DIAN) — Expanded Registry;
- Liver - Drug Inducted Liver Injury Network (DILIN)
- Congenital muscle disease - Congenital Muscle Disease International Registry (CMDIR)
- Transplant and donors - Development of a National Incompatible Kidney Transplant Registry; National Marrow Donor Program (NMDP); Collaborative Islet Transplant Registry; Fecal Microbiota Transplant National Registry
- Arthritis - Consortium for the Longitudinal Evaluation of African-Americans with Early Rheumatoid Arthritis
- Myeolodysplastic Syndrome - Development of a Pediatric Myelodysplastic Syndrome Patient Registry
- Infertility and sexual health - Development of an Infertility Family Registry (IFRR); Disorders of Sex Development Network Patient Registry; PregSource®: Crowdsourcing to Understand Pregnancy
- Genomic - eyeGENE®: The National Ophthalmic Disease Genotyping and Phenotyping Network; GenomeConnect; The Environmental Polymorphisms Registry (EPR) — Using DNA to Study Disease; NIDA Center for Genetics Research; NIH Human Embryonic Stem Cell Registry
- Rare diseases - Global Rare Diseases (Patient) Registry and Data Repository (GRDR); Rare Diseases Clinical Research Network Consortium of Eosinophilic Gastrointestinal Disease Researchers Contact Registry; PKU Patient Registry
- Down Syndrome - DS-Connect™: The Down Syndrome Registry
- Dyskeratosis congenita and telomere biology disorders - Dyskeratosis Congenita and Telomere Biology Disorders
- Sarcoidosis - Foundation for Sarcoidosis Patient Registry
- Family and natural history - ITP Natural History Study Registry
- Dystrophy - NIH National Registry of U.S. Myotonic Dystrophy and U.S. Facioscapulohumeral Muscular Dystrophy (FSHD)
- Other - Clinical Trials Public Data Share Website; Sample Collection Registry
- Bone - Inherited bone marrow failure syndrome; National and State Cancer Registries; NIDCD National Temporal Bone, Hearing & Balance Pathology Resource Registry
- Circulatory - Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS)
- Werner Syndrome - International Registry of Werner Syndrome
- ALS - National ALS Registry
- Pediatric - Pediatric Imaging, Neurocognition, and Genetics (PING)
- Siogren's syndrome - International Sjogren's Syndrome Registry, or SICCA (closed to new participants)
- Lupus - Lupus Family Registry and Repository; Research Registry for Neonatal Lupus
- Myasthenia gravis - Myasthenia Gravis Patient Registry
- Alopecia Areata - National Alopecia Areata Registry
- Thoracic Aortic Aneurysms and Cardiovascular - National Registry of Genetically Triggered Thoracic Aortic Aneurysms and Cardiovascular Conditions (GenTAC)
- Addiction and HIV - National Addiction & HIV Data Archive Program
- Preeclampsia - The Preeclampsia Registry
- Neutropenia - Severe Chronic Neutropenia International Registry; Shwachman-Diamond Syndrome International Registry and Repository
- Deafness or blindness - Usher Syndrome Registry
- Immune - USIDNET Registry for Patients with Primary Immunodeficiency Diseases

In the United Kingdom, registries have also been established for breast and cosmetic implants (Breast and Cosmetic Implant Registry); renal conditions (UK Renal Registry, Scottish Renal Registry); cancer (Scottish Cancer Registry); ISRCTN; adult ITP (REVISED UK Adult ITP Registry); lung disease; and severe asthma (UK Severe Asthma Registry).

Appendix C: Prevalence

Table C.1 Prevalence of hernia by age and gender, New Zealand, 2018

	Male	Female	Total persons
0-4	711	228	947
5-9	177	110	268
10-14	57	16	71
15-19	76	15	90
20-24	246	49	258
25-29	327	95	315
30-34	330	128	387
35-39	399	178	538
40-44	582	227	864
45-49	820	255	1,051
50-54	984	227	1,218
55-59	1,249	243	1,345
60-64	1,357	229	1,450
65-69	1,484	280	1,580
70-74	1,257	264	1,258
75-79	842	226	879
80-84	479	177	600
85+	326	126	382
Total	**11,705**	**3,073**	**14,777**

Source: Deloitte Access Economics (2018) modelling based on publicly available information.

Table C.2 Prevalence of SUI by age and gender, New Zealand, 2018

	Male	Female	Total persons
<24	2,825	65,630	68,455
25-29	2,897	71,806	74,703
30-34	2,327	61,837	64,164
35-39	2,016	54,578	56,595
40-44	1,995	54,701	56,696
45-49	8,145	59,611	67,755
50-54	8,118	92,032	100,149
55-59	8,102	91,048	99,151
60-64	7,004	78,445	85,449
65-69	10,628	71,325	81,953
70-74	8,329	42,447	50,776
75-79	5,827	31,586	37,413
80-84	3,804	20,853	24,657
85+	3,230	21,512	24,742
Total	**75,246**	**817,412**	**892,658**

Source: Deloitte Access Economics (2018) modelling based on publicly available information.

Table C.3 Prevalence of POP by age and gender, New Zealand, 2018

	Female	Total persons
<19	209	209
20-24	1,763	1,763
25-29	2,986	2,986
30-34	2,931	2,931
35-39	3,441	3,441
40-44	5,414	5,414
45-49	11,520	11,520
50-54	19,732	19,732
55-59	24,313	24,313
60-64	21,534	21,534
65-69	19,457	19,457
70-74	15,502	15,502
75-79	11,502	11,502
80-84	7,438	7,438
85+	8,653	8,653
Total	**156,395**	**156,395**

Source: Deloitte Access Economics (2018) modelling based on publicly available information.

Table C.4 Mesh operations for hernia by age and gender, New Zealand, 2018

	Male			Female		
	Mesh utilisation	**Total operations**	**Mesh operations**	**Mesh utilisation**	**Total operations**	**Mesh operations**
0-4	65.68%	711	467	33.29%	228	76
5-9	60.99%	177	108	31.27%	110	34
10-14	61.59%	57	35	31.52%	16	5
15-19	65.45%	76	50	36.08%	15	5
20-24	66.38%	246	163	37.31%	49	18
25-29	65.40%	327	214	46.82%	95	44
30-34	62.20%	330	206	44.80%	128	57
35-39	60.03%	399	240	46.88%	178	83
40-44	60.50%	582	352	50.32%	227	114
45-49	60.15%	820	493	56.06%	255	143
50-54	59.53%	984	586	58.40%	227	133
55-59	61.83%	1,249	772	59.23%	243	144
60-64	63.27%	1,357	859	58.51%	229	134
65-69	64.66%	1,484	960	59.22%	280	166
70-74	65.99%	1,257	829	60.61%	264	160
75-79	68.54%	842	577	55.41%	226	125
80-84	68.58%	479	329	52.16%	177	93
85+	68.41%	326	223	52.63%	126	66
Total		**11,705**	**7,462**		**3,073**	**1,602**

Source: Deloitte Access Economics (2018) modelling based on publicly available information.

Table C.5 Mesh operations for SUI by age and gender, New Zealand, 2018

	Male			Female		
	Mesh utilisation	**Total operations**	**Mesh operations**	**Mesh utilisation**	**Total operations**	**Mesh operations**
<24	93.56%	2,825	2	91.95%	3	3
25-29	93.56%	2,897	0	95.56%	12	12
30-34	93.56%	2,327	0	95.56%	34	32
35-39	93.56%	2,016	0	94.64%	119	113
40-44	93.56%	1,995	1	94.64%	164	155
45-49	100.00%	8,145	0	91.53%	270	247
50-54	100.00%	8,118	1	91.53%	225	206
55-59	100.00%	8,102	5	91.86%	178	164
60-64	100.00%	7,004	14	91.86%	152	139
65-69	91.23%	10,628	23	95.27%	132	126
70-74	91.23%	8,329	14	95.27%	109	104
75-79	93.18%	5,827	6	98.15%	55	54
80-84	93.18%	3,804	0	98.15%	26	25
85+	100.00%	3,230	2	0.00%	6	0
Total		**75,246**	**68**		**1,485**	**1,380**

Source: Deloitte Access Economics (2018) modelling based on publicly available information.

Table C.6 Mesh operations for POP by age, New Zealand, 2018

	Female		
	Mesh utilisation	**Total operations**	**Mesh operations**
<19	15.11%	3	0
20-24	15.11%	5	0
25-29	15.11%	32	4
30-34	15.11%	110	12
35-39	15.11%	226	18
40-44	15.11%	408	28
45-49	22.32%	614	52
50-54	22.32%	859	72
55-59	29.25%	1,117	110
60-64	29.25%	1,330	116
65-69	31.04%	1,536	136
70-74	31.04%	1,556	107
75-79	30.22%	1,410	70
80-84	30.22%	1,109	29
85+	30.22%	690	6
Total		**11,004**	**760**

Source: Deloitte Access Economics (2018) modelling based on publicly available information.

Limitation of our work

General use restriction

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