

Adverse Event Reports Relating to Surgical Mesh Implants

Summary of data received by Medsafe

October 2019

Document History

Version Number	Revision Date	Summary of Changes
0	Dec-2013	Reports received to Dec-2013.
1	Mar-2014	Addition of reports received to Mar-2014.
2	Sep-2014	Addition of reports received to Jun-2014.
3	Apr-2015	Document history information added. Addition of reports received to Dec-2014. Gynaecological mesh reports divided into separate tables for Stress Urinary Incontinence (SUI) and Pelvic Organ Prolapse (POP) devices. Summary of reports received added. Summary of devices supplied in New Zealand added.
4	Jul-2015	Addition of reports received to Jun-2015. Removal of duplicate reports POP report (ref #14978, original report #14217). Following an audit of all reports, Event Dates corrected to reflect the implant date of the device (where this information has been provided). Summary of reports received updated.
5	May-2016	Addition of reports received to Mar-2016. Summary of reports received updated. Removal of a duplicate report (#18962).
6	Sep-2016	Addition of reports received to Sept-2016. Summary of reports received updated. Event Dates corrected to reflect the implant date of the device (where this information has been provided).
7	Dec-2016	Addition of reports received to Nov-2016.

		Summary of reports received updated.
8	Aug-2017	<p>Addition of reports received up to 21 July-2017.</p> <p>Corrections and additions to reported adverse events as a result of data verification.</p> <p>Reformatted tables to better identify date of implant, and date of report received at Medsafe.</p> <p>Summary of devices supplied in New Zealand for the period 1 Jan 2005 to 31 March 2017.</p>
9	Jun-2018	<p>Reformatted data presentation that includes all data supplied to Medsafe by ACC and all reports to Medsafe up to 30 June 2018.</p> <p>Update to, and correction of, denominator data.</p>
10	Oct-2019	<p>Update to and correction of, denominator data and inclusion of all adverse event reports received up to 30 June 2019.</p> <p>Correct version numbers in document history.</p>

Medsafe uses adverse event reports to monitor the safety of medical devices. This is part of the on-going monitoring and compliance activities undertaken by Medsafe. An adverse event report does not mean that the medical device is the cause of the adverse event. If you are experiencing an adverse event, or think you may be experiencing one, please seek advice from a health professional as soon as possible.

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About Medsafe

- ☞ Medsafe is the New Zealand Medicines and Medical Devices Safety Authority and is responsible for the regulation of therapeutic products in New Zealand through administration of the *Medicines Act 1981*.
- ☞ Medsafe is a business unit of the New Zealand Ministry of Health.
- ☞ Medsafe's Mission is: 'To enhance the health of New Zealanders by regulating medicines and medical devices to maximise safety and benefit.'
- ☞ In working to achieve the stated mission Medsafe:
 - applies accepted international practice to the regulation of therapeutic products
 - provides efficient services measured against agreed stated performance indicators
 - prepares and maintains regulatory guidelines reflecting sound science and promoting evidence-based decisions
 - applies processes that are consistent, transparent and minimise the costs of regulatory action
 - provides timely and unbiased information to health professionals and consumers about the safe use of therapeutic products.

Introduction

Concerns have been raised about the implantation of surgical mesh devices for the treatment of pelvic organ prolapse, stress incontinence, and hernia repair. Medsafe has been monitoring adverse events relating to surgical mesh devices since the first adverse event reports were received in 2006.

Medsafe acknowledges the significant impact the adverse effects of mesh implantation have had on the lives of a number of New Zealanders.

Report Period

This report covers adverse event reports received by Medsafe from 2005 until 30 June 2019.

Report data comment

Earlier versions of this report have included tables containing limited information about adverse events reported to Medsafe.

This comprehensive body of information now provides a more complete picture of the adverse events experienced following surgical mesh implantation in New Zealand. However, some caution should be exercised as there are important caveats that apply to some of the data.

As reports to Medsafe may be submitted by patients, healthcare professionals, and the medical device industry; in addition to information supplied by ACC, it is possible that Medsafe has received the same adverse event report from more than one source. Medsafe has endeavoured to identify multiple reports of the same adverse events affecting the same patient following the same surgery, but elimination of duplicate reports has not always been possible.

In some, very few, instances, reports have been received from a medical device supplier following court action overseas that references a New Zealand patient. These reports have been included but, as only very minimal information is available, it is not possible to identify if the event has already been reported to Medsafe.

Some patients have more than one treatment injury claim that has been submitted to ACC for a variety of reasons. In these instances, each claim is included as a separate 'adverse event report' even though it may relate to the same patient and the same mesh surgery. All claims made to ACC have been included in the dataset, regardless of whether ACC accepted or declined the claim.

It is important to note that there has been no attempt to determine whether an adverse event was directly related to the implantation of surgical mesh, or whether it was related to the general risks of surgery (such as post-operative infection).

Internationally there is concern that adverse events are underreported. The legislative provision to submit a treatment injury claim to ACC in New Zealand where injury or harm is experienced following surgery, and the provision for information relating to these claims to be supplied to Medsafe, is seen as having a positive effect on the number of reports received by Medsafe.

While there is no way to ensure that all adverse events associated with mesh implantation are reported, it would seem reasonable to expect that the numbers of reports received by Medsafe are indicative. This is on the basis that:

- not all treatment injury claims following surgery where mesh was implanted may be adverse events associated with the mesh,
- there may be more than one ACC treatment injury claim relating to a single mesh implantation surgery,
- some adverse events may be reported more than once from different sources and it is not possible to identify all duplicates.

Summary of data supplied to Medsafe

Summary of Reports

Since 2005 Medsafe has received a total of 1325 adverse event reports relating to surgical mesh and stress urinary incontinence devices. By product types the numbers of reports received are:

Stress Urinary Incontinence (SUI) devices	262
Pelvic Organ Prolapse (POP) devices	288
SUI and/or POP	221
Hernia mesh	473
Other, or not specified	81
	1325

These reports have been received from a range of reporters as summarised below:

Suppliers of devices (sponsors)	29
Manufacturers of device	2
Healthcare professionals	4
Accident Compensation Corporation (ACC)	1232
Patients	58
	1325

Denominator Data

Identification of the incident rate of adverse events associated with a particular surgery is something Regulators internationally have difficulty with, particularly in regard to how to obtain reliable denominator data. The Australian Senate Inquiry Community Affairs References Committee report on the 'Number of women in Australia who have had transvaginal mesh implants and related matters' includes a discussion in Chapter 3 on the most effective way to obtain accurate denominator data in relation to patients that have had mesh implanted. The most reliable indicator of the extent of use was considered to be sales data from sponsors/suppliers of the mesh devices.

www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/MeshImplants/Report

Medsafe has requested information from the suppliers of surgical mesh devices for stress urinary incontinence, pelvic organ prolapse, or hernia, in regard to the quantity of devices supplied in New Zealand between 2005 and June 2019. The information supplied by the importers of these devices in New Zealand is summarised in the following table.

Note that these figures relate to the number of devices supplied in New Zealand and may not be the number of devices actually implanted.

The volume of surgical mesh sold for stress urinary incontinence (SUI) and pelvic organ prolapse (POP) has been declining in the last three years. As a result of the regulatory action by Medsafe in December 2017, surgical mesh for POP using the transvaginal route is no longer able to be sold in New Zealand. Consequently the volume of surgical mesh sold for POP has shown a decline since 2017. This is expected to continue, though it is important to note that surgeons may choose to import this mesh themselves for clinical use.

The data in relation to hernia mesh shows an increase in supply from 2014; the reason for this is not clear from Medsafe's information.

Note that it is possible for a sheet of hernia mesh to be used in multiple procedures and so the figures used as denominator data represent the worst-case scenario.

In September 2019, suppliers of surgical mesh devices were requested to confirm data for the period 2005 to 30 June 2019. Where a discrepancy between data previously reported by Medsafe and the most recent data supplied has been identified, this has been queried with the supplier. As a result there have been some changes in the denominator data from that published previously.

Summary table of devices supplied in New Zealand.

Table 1: Summary of devices supplied in New Zealand for the period 1 Jan 2005 to 30 June 2019

Product Grouping	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019 (to June 30)	Total Units
Urinary Incontinence Products (male)	0	0	0	24	37	40	40	56	60	63	115	82	69	101	35	722
Urinary Incontinence Products (female)	1292	1528	1723	1614	1848	1833	1761	1914	2131	1597	1431	1382	1117	764	260	22,195
Pelvic Organ Prolapse Products	1104	593	570	848	1018	759	681	596	464	363	330	266	154	100	36	7,882
Hernia products in relation to groin, ventral repairs	5025	5636	4966	4086	3823	3436	3963	4594	4532	12471	11502	11212	9276	8194	5999	98,715
Total	7421	7757	7259	6572	6726	6068	6445	7160	7187	14494	13378	12942	10616	9159	6330	129,514

General comments on Data

In some instances, from the information supplied, it is not possible to identify whether the mesh implanted was for the treatment of stress urinary incontinence (SUI) or pelvic organ prolapse (POP) or both. In such instances these reports are referred to as SUI/POP.

Every ACC report is entered as a separate adverse event report. It is possible that more than one report may relate to the same surgery, e.g. initial treatment claim is declined and then this decision is appealed resulting in a new record. For example an initial treatment claim may be for pain, and then a later claim may be made for mesh erosion.

Claims made to ACC are in relation to a treatment injury. Some treatment injuries such as post-surgery pain, or infection consequent to surgery may not be 'adverse events' associated with mesh implantation, rather expected possible consequences of surgical procedures in general. As it is not possible to identify whether the treatment injury claims can be directly attributed to the use of surgical mesh, these claims have been included.

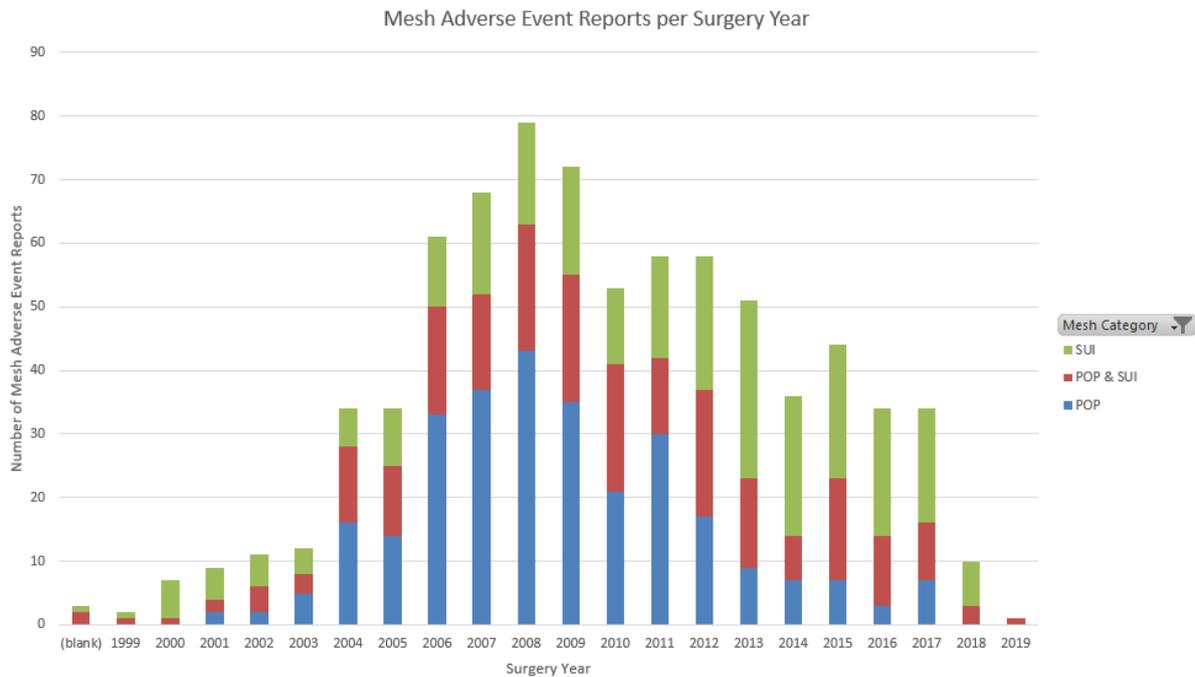
All graphs use the mesh implant date as the reference. In the past Medsafe has referred to 'report date'. This was the date the adverse event was reported to Medsafe, and is not reflective of the date the adverse event associated with the mesh implant was first identified and/or reported to a treatment provider.

For graphs including a 2019 time points, data is for the period of 1 Jan 2019 – 30 Jun 2019. These data points on the graphs will therefore change at future publications of this document, where full year data will be reported.

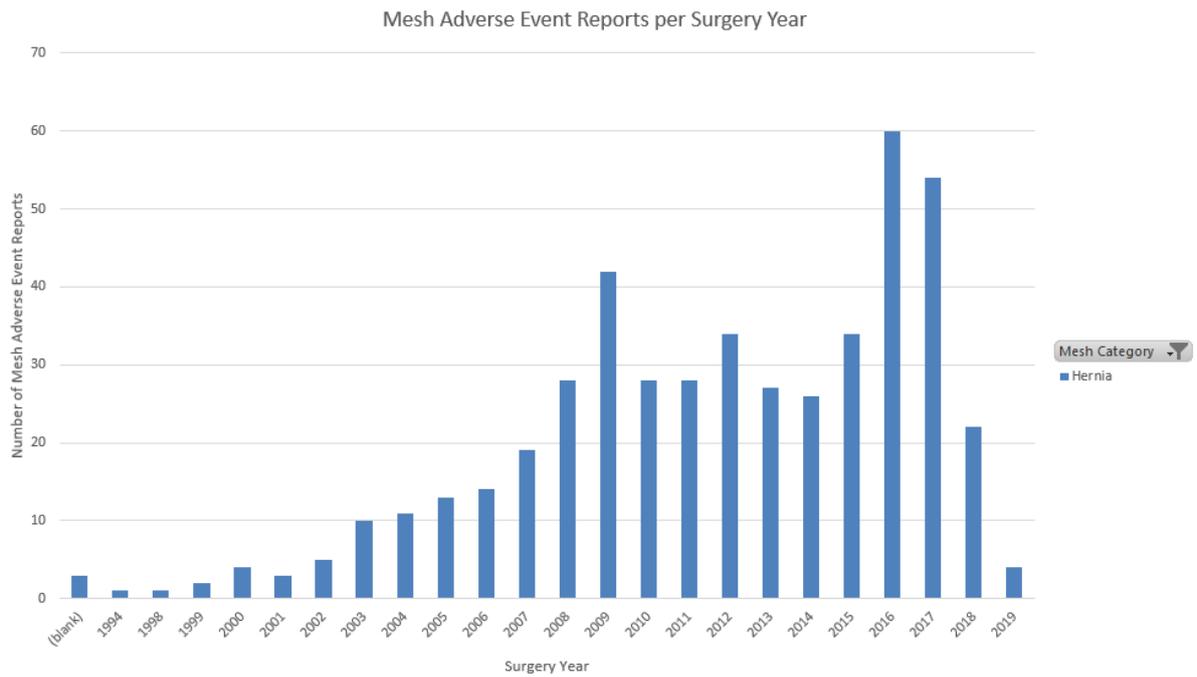
Summary of Data

1. Mesh Adverse Event Reports per surgery year per mesh type.

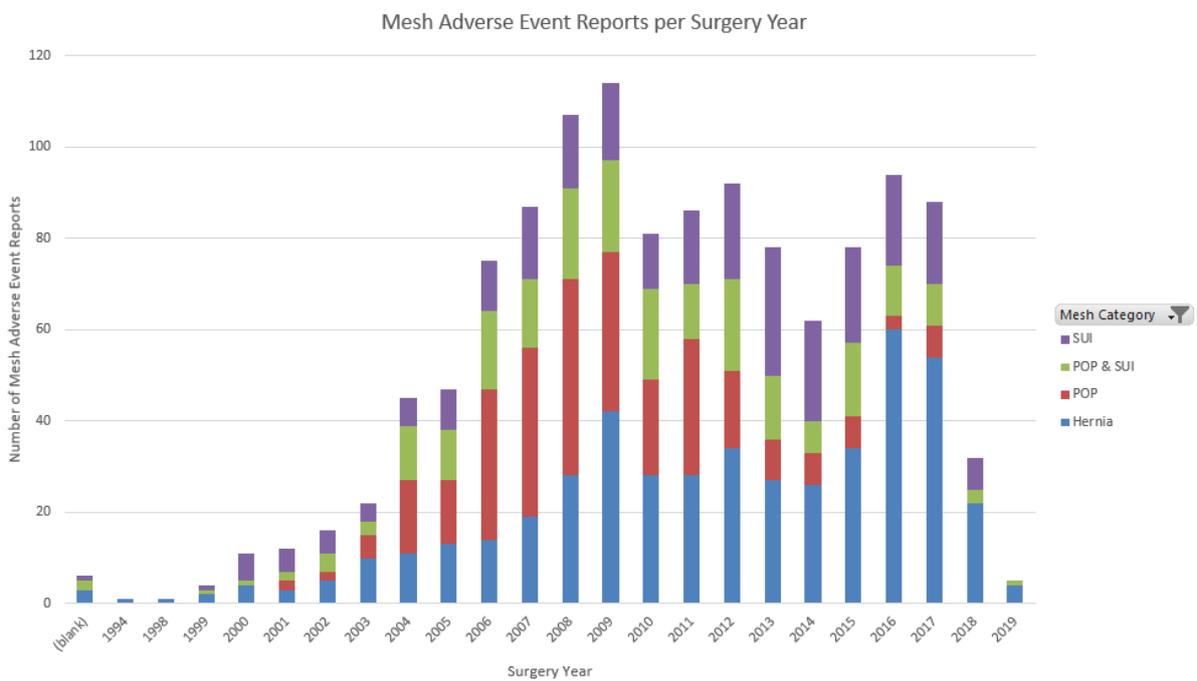
The following three charts provide information on the number of adverse event reports received associated with surgery in a year as numerical values. The first chart relates to adverse events reported following surgery for stress urinary incontinence (SUI) or pelvic organ prolapse (POP). The second chart is specific to adverse events reported following hernia surgery, and the third chart is cumulative for all mesh types.



*2019 data is from 1 Jan 2019 – 30 June 2019



*2019 data is from 1 Jan 2019 – 30 June 2019



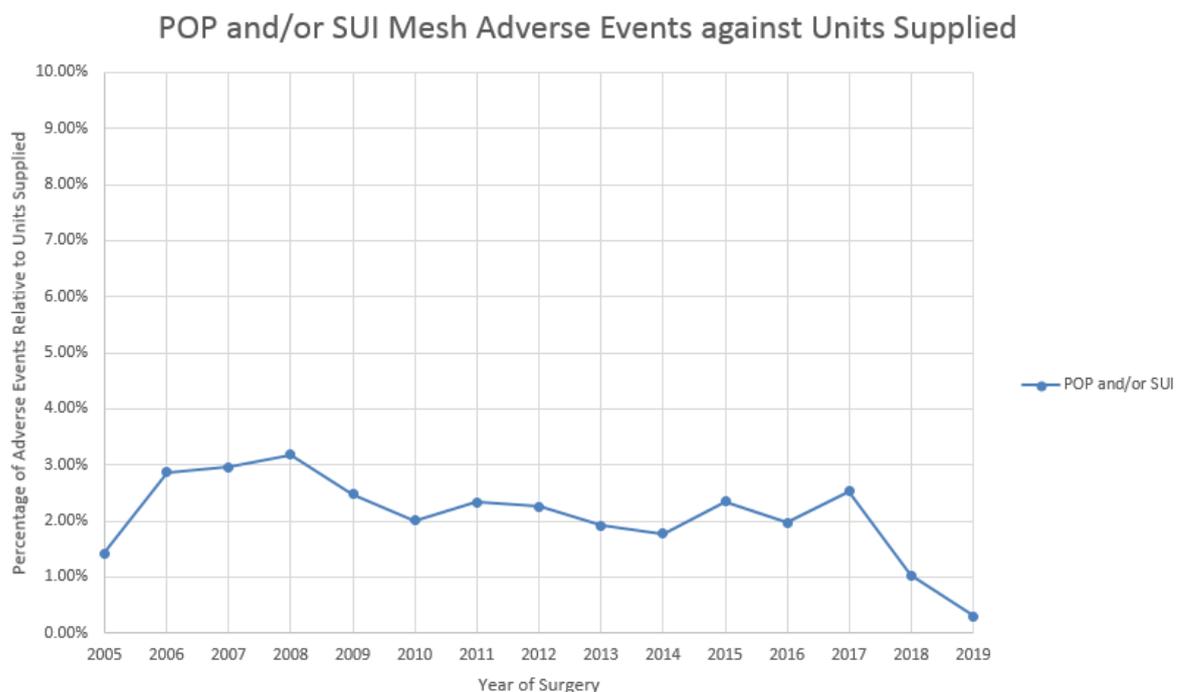
*2019 data is from 1 Jan 2019 – 30 June 2019

2. Adverse events against units supplied.

The following charts compare the number of adverse event reports received associated with surgery in a year, with the number of units of surgical mesh supplied in that year.

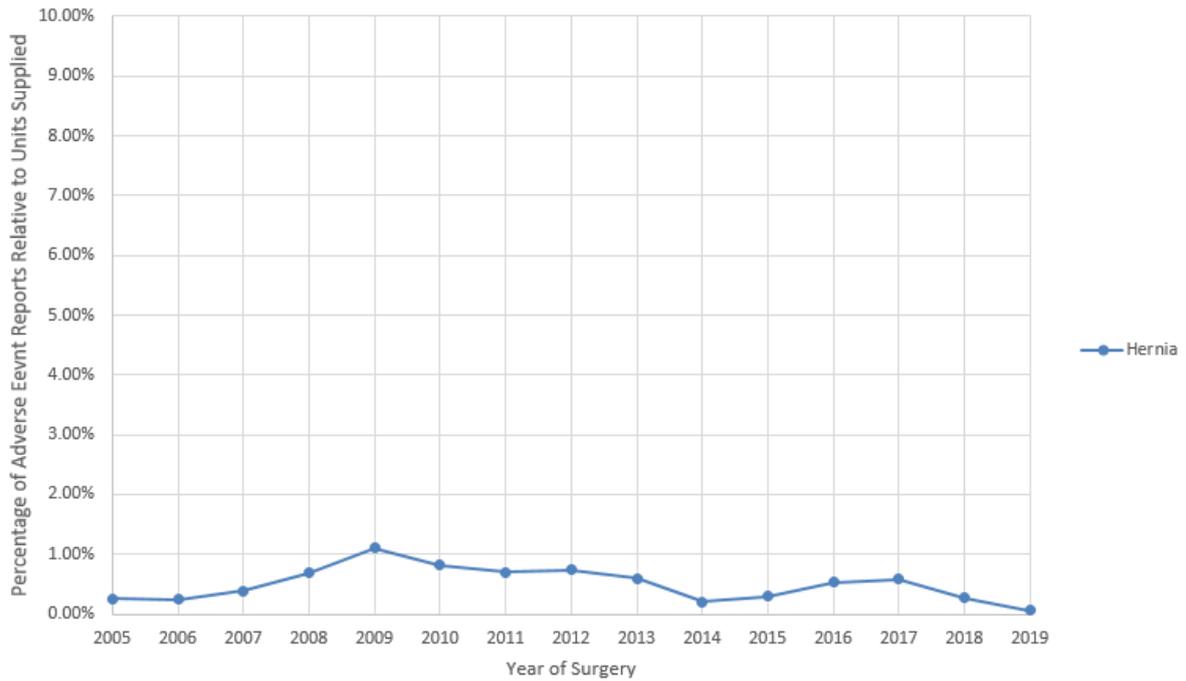
There are assumptions around the denominator data, which are based on units of surgical mesh supplied as a surrogate for units of mesh implanted. The adverse event is linked to the year of mesh implantation, and the number of surgeries in a year for which an adverse event report was received was compared with the number of surgical mesh devices of that type sold in that year.

Note that because this refers to year of surgery, recent information received which relates to an earlier surgery will change the data points of this graph from that previously published.



*2019 data is from 1 Jan 2019 – 30 June 2019

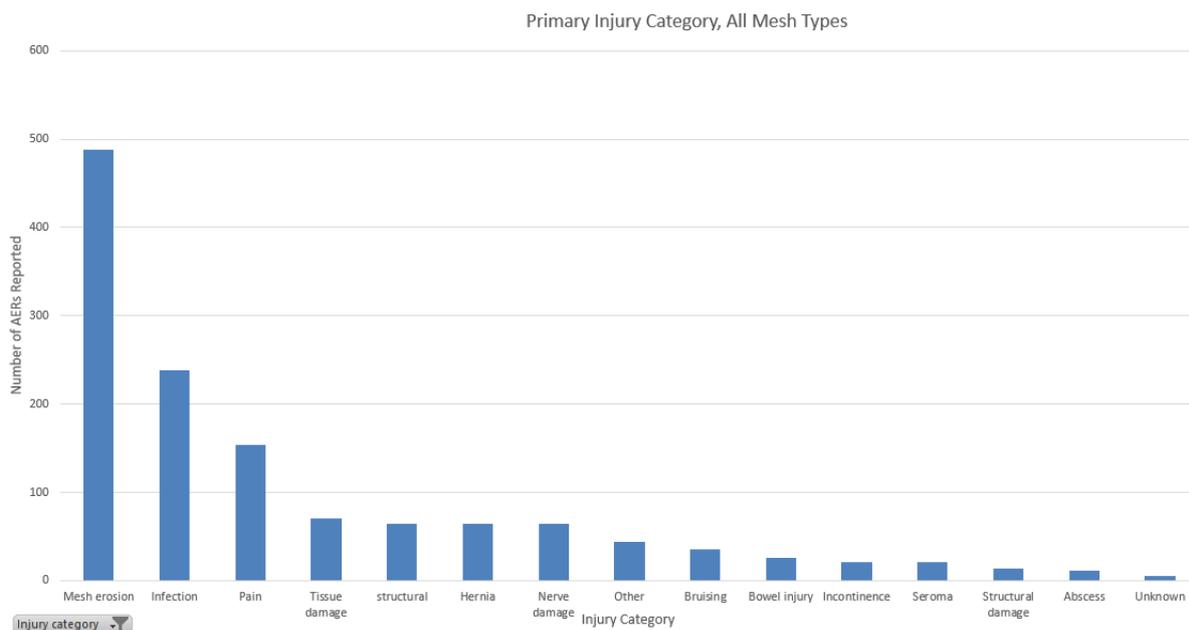
Hernia Mesh Adverse Events against Units Supplied



*2019 data is from 1 Jan 2019 – 30 June 2019

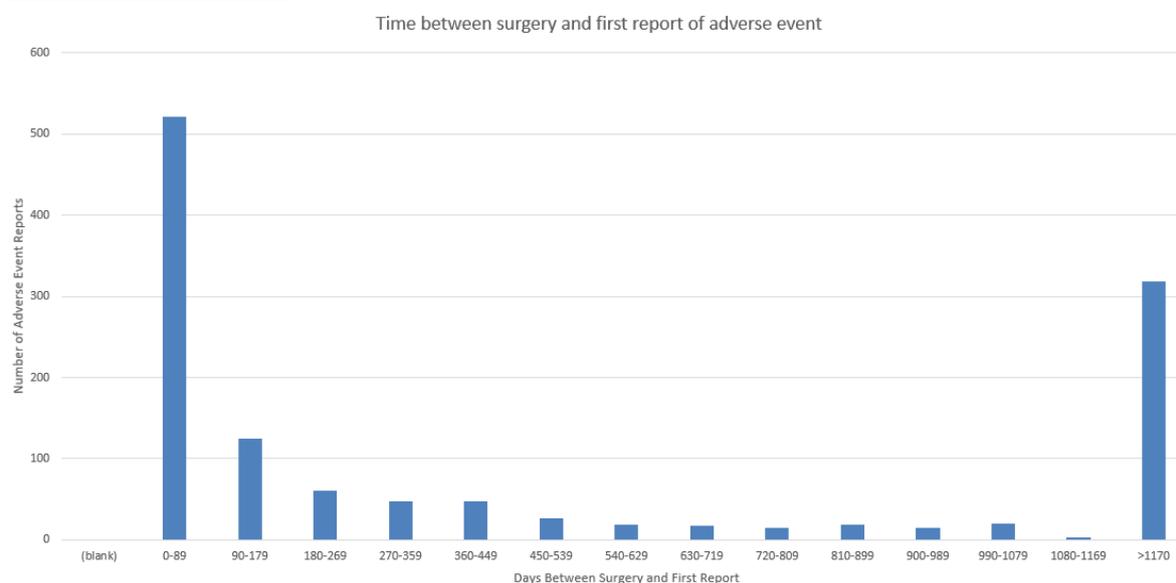
3. Primary injury category

This chart has been included to provide an indication of the frequency with which any particular adverse event is reported as the primary event. Note that many reports received by Medsafe include more than one adverse event. The chart below only includes the adverse event first specified, or specified as the primary event reported where this information is identifiable.



4. Time between surgery and first report of adverse event

This chart has been included to help identify that, in many cases, the first time an adverse event is reported to a treatment provider is usually within three months (90 days) of surgery. Where a treatment provider was contacted after three years this is represented by the right hand bar on the graph.



Reporting a Medical Device Adverse Event

Adverse events that cause injury and that are associated with medical devices should be reported to Medsafe. Such events may be indicative of a quality or safety issue that needs to be addressed in some form. By reporting these to Medsafe, seemingly isolated incidents may be collated and responded to.

Who can report an adverse event?

Anyone can submit an adverse event report. Patients, caregivers, healthcare professionals and suppliers are all encouraged to lodge an adverse event report if an incident has occurred and there is a concern about the safety of the device or its use. See information on the link below:

www.medsafe.govt.nz/regulatory/devicesnew/9AdverseEvent.asp

Investigation of reports

All adverse events are reviewed by Medsafe with both safety and quality issues being considered. As part of these reviews further information may be requested from the reporter and/or the device supplier. If necessary, Medsafe may also contact overseas regulatory agencies to ascertain whether they have received similar reports about the device.

All reports received are retained by Medsafe.