

Adverse Event Reports Relating to Surgical Mesh Implants

Summary of data received by Medsafe

August 2018

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	Sept-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

9	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>
10	June 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>

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.

Table of Contents

About Medsafe	5
Introduction	5
Report Period	5
Report data comment.....	5
Summary of data supplied to Medsafe.....	7
Summary of Reports	7
Denominator Data	7
Summary table of devices supplied in New Zealand.	9
General comments on Data	10
Summary of Data	11
Reporting a Medical Device Adverse Event.....	15
Who can report an adverse event?	16
Investigation of reports.....	16

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 2018.

Report data comment

Previous versions of this report have included tables containing limited information about adverse events reported to Medsafe. Since the last version of this document was published, Medsafe has received a large number of retrospective notifications from the Accident Compensation Corporation (ACC). These included treatment injury claims where the assessed level of seriousness did not meet the criteria for notification to the regulator, and where information about the injury that had previously been provided to Medsafe was minimal.

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, 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 data, 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 1070 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	187
Pelvic Organ Prolapse (POP) devices	254
SUI and/or POP	182
Hernia mesh	394
Not specified	53
	1070

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

Suppliers of devices (sponsors)	28
Manufacturer of device	2
Healthcare professionals	4
Accident Compensation Corporation (ACC)	992
Patients	44
	1070

Denominator Data

To better understand the rate of adverse events being reported, Medsafe requested information about the quantity of devices supplied in New Zealand between 2005 and December 2017. The information supplied by the importers of these devices in New Zealand is summarised in the table on the next page.

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

The volume of surgical mesh sold for stress urinary incontinence (SUI) and pelvic organ prolapse (POP) has been declining in the last three years. It is expected that as a result of the regulatory action by Medsafe in December 2017, where surgical mesh for POP using the transvaginal route is no longer able to be sold in New Zealand, the volume of surgical mesh sold for POP will show an even greater decline.

The data in relation to hernia mesh shows an increase in supply since 2015; the reason for this is not clear from Medsafe's information.

Summary table of devices supplied in New Zealand.

Table 1: Summary of devices supplied in New Zealand for the period 1 Jan 2005 to 31 December 2017

Product Grouping	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	Total Units
Urinary Incontinence Products (male)	0	0	0	24	37	40	40	56	60	2	29	39	7	334
Urinary Incontinence Products (female)	1314	1533	1721	1625	1844	1833	1761	1924	2131	1612	1291	1137	823	20549
Pelvic Organ Prolapse Products	557	591	568	842	1011	755	679	597	377	267	205	159	105	6713
Hernia products in relation to groin, ventral repairs	3756	4212	3460	2780	2661	2467	2805	3860	3911	4155	8494	8669	10380	61610
Total	5627	6336	5749	5271	5553	5095	5285	6437	6479	6036	10019	10004	11315	89206

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; the initial treatment claim may be for e.g. pain, and then later claims may be made for e.g. mesh erosion.

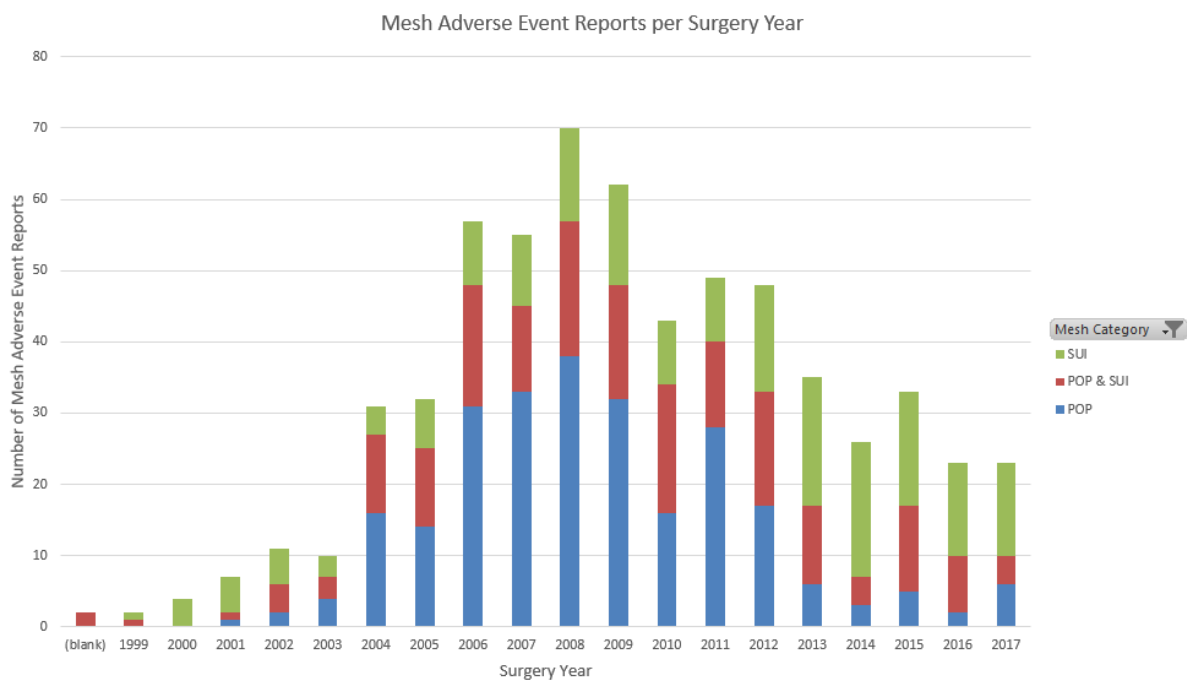
Claims made to ACC are in relation to a treatment injury. Some treatment injuries such as post-surgery pain, or infection consequent to surgery may not be 'adverse events' associated with mesh implantation, rather expected possible consequences of surgical procedures in general. As it is not possible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

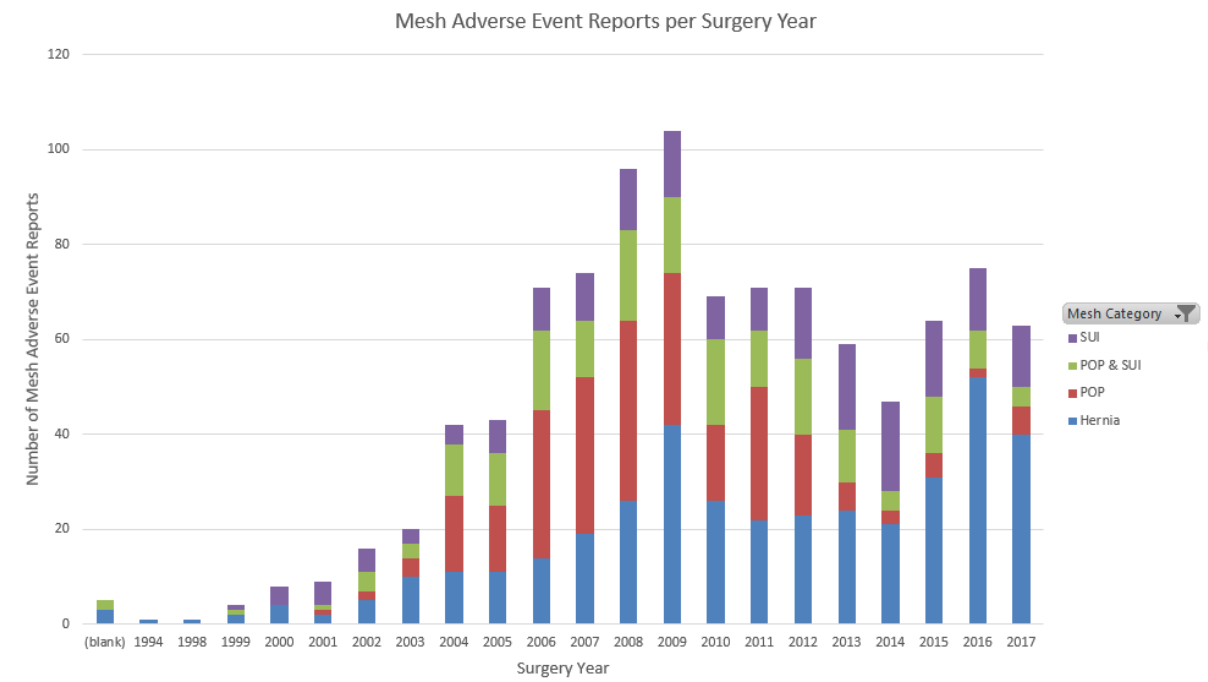
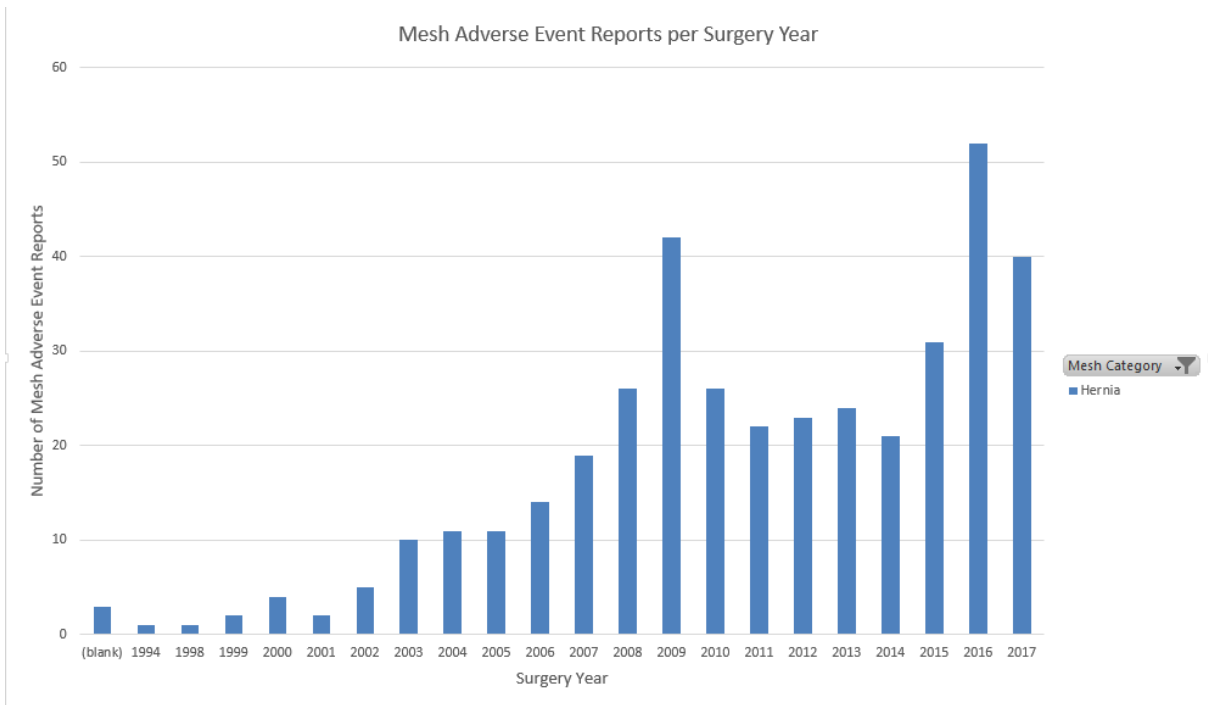
All graphs use the mesh implant date as the reference. In the past Medsafe has referred to 'report date'. This was the date the adverse event was reported to Medsafe, and is not reflective of the date the adverse event associated with the mesh implant was first identified and/or reported to a treatment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

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), 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.

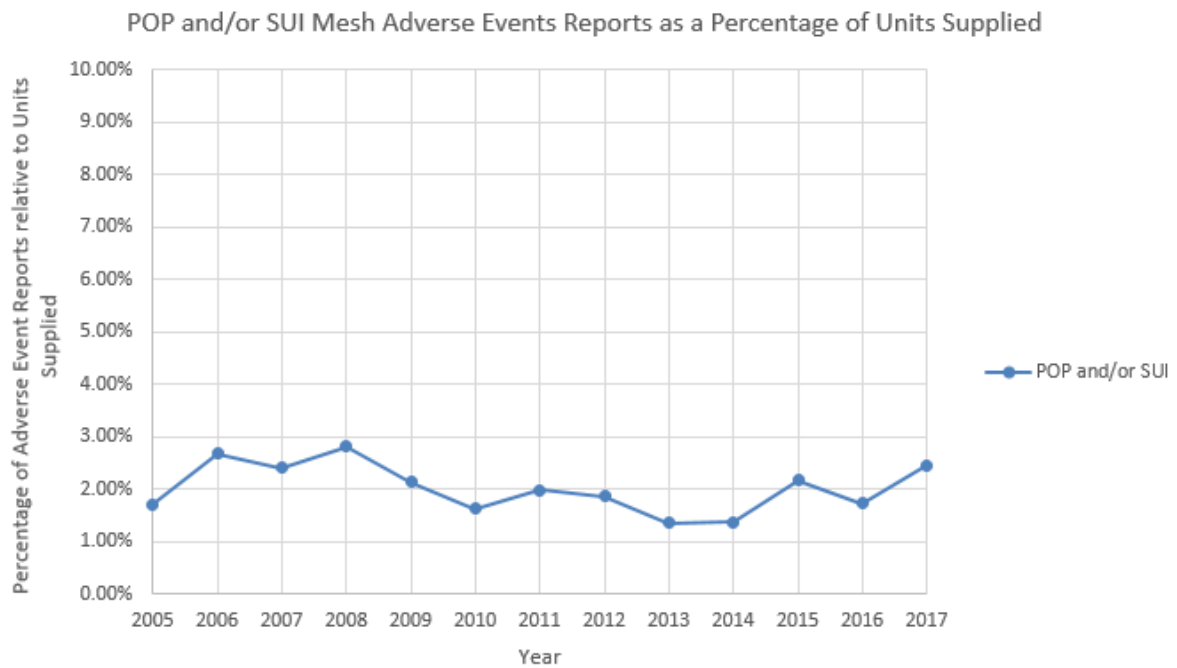




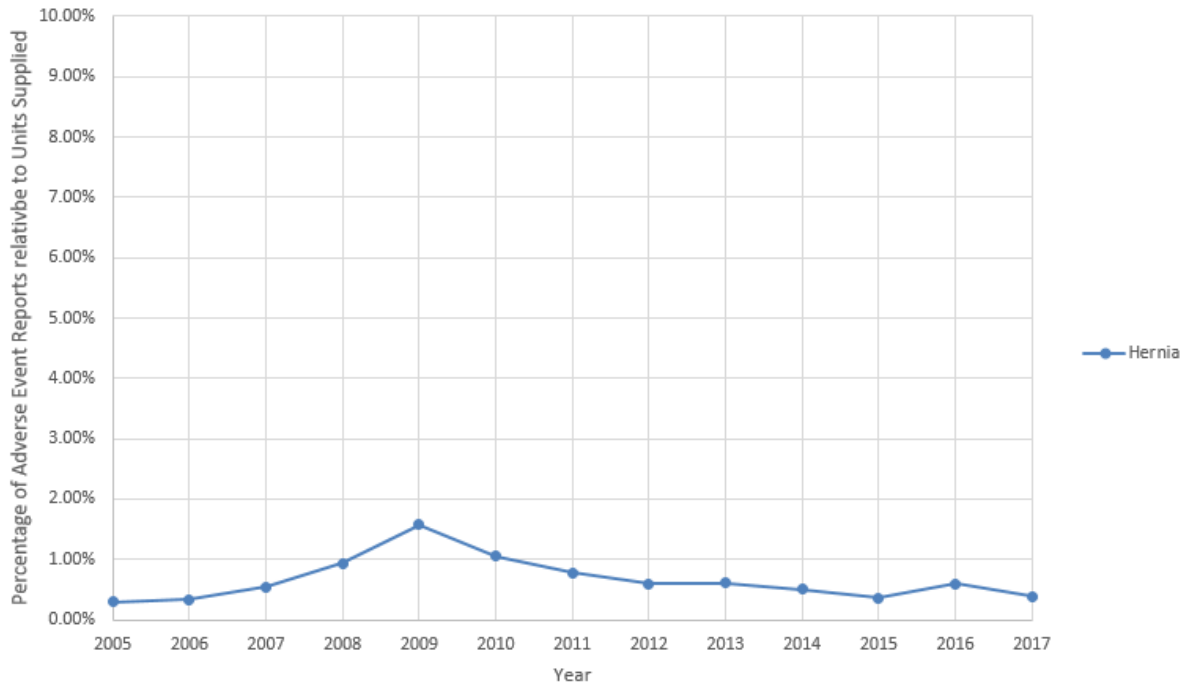
2. Adverse events against units supplied.

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.

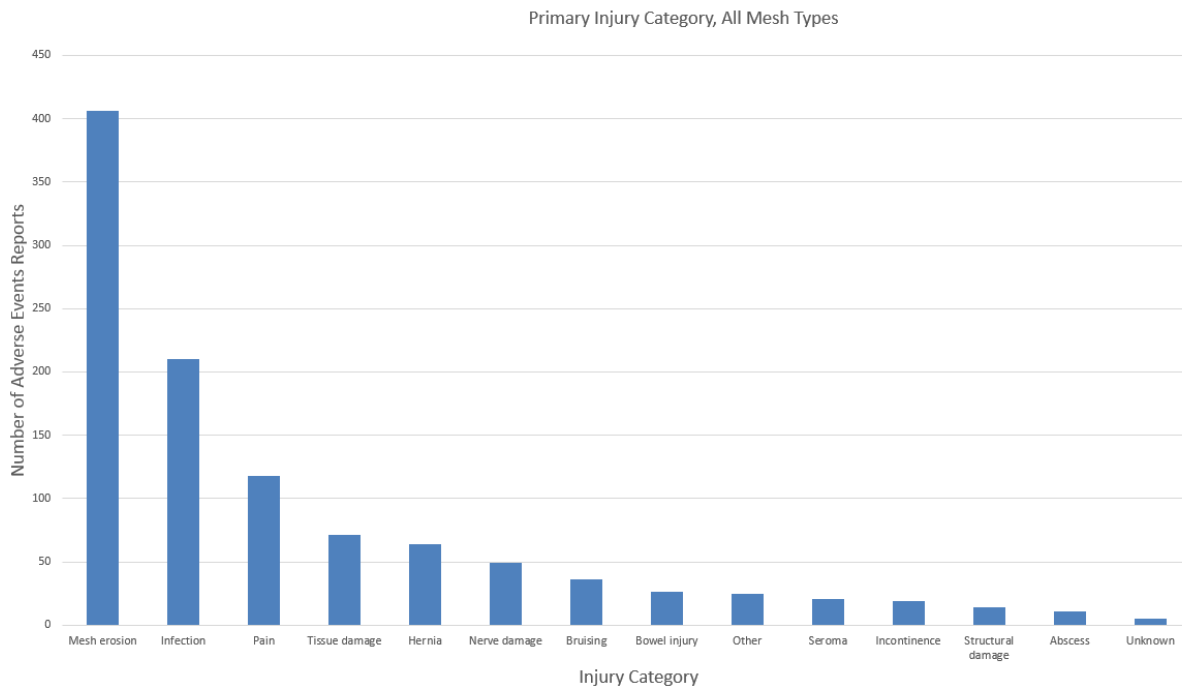


Hernia Mesh Adverse Events Reports as a Percentage of Units Supplied



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 the majority of cases, the first time an adverse event is reported to a treatment provider is usually within 3 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.