Attachment 1

Chronology of regulatory, communication and other activities undertaken regarding PIP implants

Date	Event
13 September 1999	First application and approval for a PIP silicone gel implant for individual patient use under the Special Access Scheme (SAS).
22 September 1998	Precise Medical Supplies lodged application to register three types of breast implant manufactured by Poly Implant Prothèse (PIP): implants pre-filled with a polysaccharide solution; implants pre-filled with a silicone gel; and implants pre-filled with saline. Applications to register the polysaccharide-filled and silicone-filled implants were not pursued due to lack of data from PIP to support registration. The application for registration was supported by European Commission (EC) certification for each implant type issued by TÜV Rheinland in October 1997. Manufacturer was PIP at 337 Avenue de Bruxelles, La Seyne Cedex, France. EC certification was based on assessment for Class IIb products.
15 March 2000	PIP saline prefilled implants, sponsored by Precise Medical Supplies, registered on ARTG.
4 October 2002	New medical devices framework introduced in Australia - implantable mammary prostheses are classified as Class III medical devices.
16 October 2002	Transfer of sponsorship of all PIP-manufactured products from Precise Medical Products to Medical Vision Australia.
31 October 2002	First adverse event report for PIP silicone gel implant (arising from SAS use). Rupture of implant 2 years post-implantation.
14 November 2002	Medical Vision Australia applied to include PIP silicone gel implants on the ARTG. However, the application was not made under the provisions of the new regulatory framework and was not supported by the correct level of conformity assessment certification.
14 April 2003	Application for conformity assessment lodged by Medical Vision Australia for silicone gel breast implants manufactured by PIP.
28 May 2003	TGA accepted application for conformity assessment and notifies applicant.
28 May 2003	Evaluation of application for conformity assessment commences. Application referred within the TGA for the following evaluations of data provided in the dossier: a) microbiological assessment b) biocompatibility and biological safety assessment c) materials and manufacturing assessment d) clinical assessment.

Date	Event
May 2003	Arrangements for onsite audit of the PIP manufacturing facility commenced.
17-19 November 2003	TGA audit of PIP facilities at 337 Ave de Bruxelles, La Seyne Sur Mer, France.
15 December 2003	Manufacturer provided additional information relating to non-conformities identified during the audit.
March 2004	PIP obtained an EC Conformity Assessment Certificate (covering the necessary scope for PIP implants) from the European Notified Body, TÜV Rheinland.
23 August 2004	All non-conformities identified at the TGA onsite audit resolved and the TGA audit report closed out.
3 September 2004	Application considered by Medical Devices Evaluation Committee (MDEC) following referral by the TGA. The MDEC resolution was no objection to the inclusion of these implants on the ARTG subject to the provision of comprehensive annual post-market reports to the TGA for a period of 7 years from the date of inclusion.
18 October 2004	TGA issued Conformity Assessment Certificates (CAC) to PIP for the manufacture of a range of silicone gel-filled breast implants. CAC valid for five years.
3 November 2004	Application by the sponsor Medical Vision Australia for ARTG inclusion of the PIP implants covered by the TGA Conformity Assessment Certificate.
30 November 2004	PIP Implants included on ARTG (nine ARTG entries) for the sponsor Medical Vision Australia.
4 July 2006	First SAS approval for titanium dioxide coated silicone gel breast implants.
10 November 2006	First patient enrolled in a clinical trial sponsored by Medical Vision Australia using PIP titanium dioxide coated silicone gel breast implants.
4 June 2007	TGA acknowledged clinical trial notification for clinical trial using the PIP titanium dioxide coated implants.
31 August 2009	TGA contacted Medical Vision Australia regarding impending expiry of TGA CAC for PIP implants (expiry on 18 October 2009).
25 September 2009	Medical Vision Australia submitted an application to vary the manufacturer's evidence used to support their ARTG entries for PIP gel-filled implants. Variation was requested because the manufacturer was changing from TGA certification (due to expire on 18/10/2009) to European (CE) certification. CE certification was issued by EU Notified Body, TÜV Rheinland, and included Design Exam certification.
30 September 2009	TGA accepted the variation to the manufacturer's evidence with result that PIP implants were included in the ARTG on the basis of CE certification.
18 October 2009	PIP's TGA Conformity Assessment Certificate expired after 5 years.

Date	Event
31 March 2010	TGA notified by Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS) of its decision to recall and suspend the marketing of silicone breast implants manufactured by PIP because it had "registered" an increase in reports regarding implant rupture and local complications and had discovered that the company had used an unauthorised silicone gel in the products.
31 March 2010	TGA contacted by Medical Vision Australia regarding the French recall of PIP implants.
1 April 2010	TGA wrote to Medical Vision Australia requesting details of the distribution of PIP implants in Australia.
2 April 2010	AFSSAPS advised the TGA that further information would be very difficult to obtain because PIP officially went into receivership on 30 March 2010 and was "currently dissolved".
3 April 2010	Medical Vision Australia advises TGA that it had ceased importation and supply of PIP implants, and had contacted medical practitioners requesting that the stock be returned and not used.
3 April 2010	TGA request sent to UK Medicines and Healthcare products Regulatory Authority (MHRA) asking for any further information on the reasons for the PIP recall in France.
6 April 2010	Request for information from MHRA for implant rupture rates. Request information from AFSSAPS for implant rupture rates that led to recall action. Medical Vision Australia confirmed that all importation and distribution of PIP products had been halted. It also advised that it will advise all implanting surgeons to stop any further operations and return stock to the sponsor. Note: the 7 customers known to have stock were contacted by email and phone. All customers acknowledged the email.
6 April 2010	Notice posted on the TGA website advising that Medical Vision Australia was undertaking the recall of all non-implanted silicone gel breast implants manufactured by PIP. A copy of the recall notice to customers, the web statement and notification to colleges is attached
6 April 2010	TGA sent a copy of the recall notice to the Australasian College of Cosmetic Surgery (ACCS) and the Australian Society of Plastic Surgeons (ASPS).
6 April 2010	TGA requested information about implant ruptures from AFSSAPS.
7 April 2010	TGA requested Medical Vision Australia to send a "Product Notification" to all surgeons who may have purchased PIP implants.
7 April 2010	Medical Vision Australia advised all surgeons who have implanted PIP implants sourced from that company about the recall.
7 April 2010	Response from MHRA with general outline of the issues as understood. MHRA advice that rupture rate for PIP implants in UK was "not unusual".

Date	Event
8 April 2010	State and territory health departments notified of recall of PIP implants
8 April 2010	"Product Notification" sent to surgeons by Medical Vision Australia advising that all unused PIP implants were being recalled due to concerns about their failure rate and that at this time, no action is required other than the normal follow-up procedures for patients implanted with this product.
13 April 2010	TGA follow up with AFSSAPS regarding email request of 6 April 2010, concerning rate of breast implant rupture.
14 April 2010	PIP implants cancelled from ARTG.
29 April 2010	AFSSAPS advised the TGA that, while true rates of rupture were not available, it had observed a relative increase in the rate of rupture of PIP implants over the period 2007 to 2009 and it was this apparent increase that led to the discovery of gel substitution and subsequent recall.
April – May – June 2010	TGA performed laboratory testing of samples of PIP implants.
19 May 2010	TGA website updated with information for consumers stating it was continuing its investigation into issues relating to overseas reports of increased rupture rates of PIP implants and that the TGA was awaiting the results of tests being conducted internationally on the implants.
10 June 2010	TGA requested AFSSAPS to provide information on the unauthorised gel composition used by PIP and their test results.
11 June 2010	Outline of tests to be performed provided by AFSSAPS. No formulation details provided for unapproved gel other than "the silicone included in PIP implants are issued from known European industrial suppliers".
12 June 2010	TGA requested AFSSAPS to provide production records to match with lots supplied in Australia.
22 June 2010	AFSSAPS unable to provide information on production records but advised that they believed that implants of the types with "MX and Asymmetric references produced after 2006" would have had the approved gel.
29 June 2010	Email from AFSSAPS indicating that test results "have been delayed".
2 July 2010	TGA website updated with laboratory test results indicating that PIP implants supplied in Australia conform to the relevant international standards for gel cytotoxicity and shell strength.
28 July 2010	Email from AFSSAPS providing information when test results would be available, and seeking information about the laboratory testing performed by the TGA.
4 September 2010	AFSSAPS email advising that they had seized implants and raw materials from PIP.
20 September 2010	Request from MHRA to share the results of the TGA's laboratory testing.
28 September 2010	AFSSAPS provided advice about their test results and a copy of the accompanying press statement.

Date	Event
29 September 2010	TGA provided advice to MHRA regarding the TGA laboratory test results.
30 September 2010	TGA requested additional information from AFSSAPS regarding their test results.
30 September 2010	MHRA requested permission to use information provided by TGA.
1 October 2010	TGA received advice from MHRA about its web statement.
1 October 2010	TGA website updated to reference AFSSAPS and MHRA websites for additional information and confirming TGA test results. TGA sent notification of update to TGA's website to the Australian Society of Plastic Surgeons and the Australasian College of Cosmetic Surgeons.
5 October 2010	TGA requested information from MHRA about their awareness of any testing being undertaken in other countries.
12 October 2010	Medical Vision Australia advises the TGA that all recalled stock, which had not been provided to the TGA for testing, had been destroyed.
12 October 2010	Request from AFSSAPS for information regarding batches of breast implants tested by TGA.
22 October 2010	TGA responded to AFSSAPS with requested test information.
25 October 2010	Request from AFSSAPS for further clarification of TGA's test results.
25 November 2010	Recall was closed on TGA database following confirmation from Medical Vision Australia that all returned product had been destroyed.
27 January 2011	TGA coordinated simultaneous release of web statement with FDA in the USA regarding the issue of lymphoma associated with breast implants. TGA continued to consult the FDA on this issue.
7 February 2011	TGA held teleconference with Australian Society of Plastic Surgeons to discuss enhancing the breast implant registry and providing an update regarding PIP and also regarding ALCL.
7 December 2011	TGA received information from AFSSAPS about a case of ALCL associated with a PIP implant and confirming its previous advice to patients. AFSSAPS requested specific information about breast implants and cases of ALCL in Australia
21 December 2011	TGA provided advice to AFSSAPS in response to their questions about breast implants and reported cases of ALCL in Australia.
21 December 2011	AFSSAPS advised the TGA that in France, media coverage states health authorities were considering recommending removal of PIP implants from 30,000 women in France.
21 December 2011	TGA web statement posted regarding media coverage in France linking PIP with ALCL.

Date	Event
22 December 2011	Updated web statement from MHRA regarding consultations with other European agencies and TGA. MHRA stated that there is no evidence of any increase in incidence of cancer associated with PIP breast implants and no evidence of any disproportionate rupture rates other than in France.
23 December 2011	Announcement by the French Minister of Health recommending that women in France have their PIP implants removed although there is no urgency to do this. Recommendation was due to the increased rupture rate not to do with any association with cancer.
3 January 2012	TGA contacted ASPS, ACCS and RACS and members of TGA's statutory expert advisory committees regarding PIP breast implants and establishment of an expert advisory panel.
3 January 2012	TGA contacted all state and territory CHOs regarding PIP implants and requested data from their jurisdictions.
3 January 2012	TGA contacted regulatory authorities in Switzerland, Canada, Singapore, USA, Brazil, European Commission and Japan seeking further information on PIP available in their jurisdictions.
3 January 2012	TGA contacted Private Health Insurance Administration Council seeking information on private health insurance data on PIP implants.
4 January 2012	First meeting of TGA expert advisory panel.
4 January 2012	TGA website updated with media release and "PIP implants – the Australian perspective".
4 January 2012	TGA contacted NSW Clinical Excellence Commission requesting PIP implant information.
4 January 2012	TGA sent letter to all current sponsors of breast implants requesting information about ruptures, other complaints and number of implants supplied.
6 January 2012	TGA requested ASPS, ACCS and RACS to instruct their members to assemble lists of their patients who have received a PIP implant.
6 January 2012	Telephone discussion with the offices of state and territory CHOs regarding any use of PIP implants in their jurisdictions.
6 January 2012	TGA sent further requests for information to regulatory authorities in Switzerland, USA, Japan, France, Singapore, Canada and EC.
7 January 2012	Breast Implant Information Line established at 6am.
7 January 2012	Media release by the Gillard Government announcing new hotline for women concerned about their breast implants.
7 January 2012	Further request from TGA To AFSSAPS and MHRA regarding testing requirements/results.
7 January 2012	TGA web statements on PIP implant Questions and Answers.

Date	Event
7 January 2012	TGA began contacting surgeons who were supplied with PIP implants.
7 January 2012	TGA contacted sponsors who may have supplied PIP implants under SAS.
8 January 2012	TGA discussed with ASPS and ACCS the information being conveyed to their members by the TGA.
9 January 2012	DoHA Chief Medical Officer convened a Clinical Advisory Committee to provide him with regular and frequent advice related to PIP breast implants.
9 January 2012	TGA requested from European Commission copies of TÜV Rheinland audit reports. Referred to AFSSAPS.
9 January 2012	TGA requested information from AFSSAPS on audits of breast implant manufacturers.
9 January 2012	TGA received response from AFSSAPS to regarding audit reports.
9 January 2012	TGA received response from AFSSAPS in response to email of 7 January 2012 requesting information regarding testing.
9 January 2012	TGA contacted Australian Commission on Safety and Quality in Health Care requesting data on PIP implants.
9 January 2012	TGA contacted CHOs of each state and territory advising them of the surgeons in their state who had used PIP implants.
10 January 2012	TGA sent registered letters to surgeons who may have supplied PIP implants. Letters also sent to ASPS and ACCS as part of mail out.
10 January 2012	TGA contacted Chair of Advisory Committee on Safety of Medicines to request advice on possible study designs that could be used to detect rupture rate of PIP compared to other prostheses.
10 January 2012	Letter to ASPS, ACCS and RACS requesting further data on PIP implants for analysis by TGA and to also request data from the Breast Implant Registry.
10 January 2012	TGA convened teleconference with state and territory CHOs.
11 January 2012	Communication with French Government seeking clarification of allegations of fraudulent activity by manufacturers of PIP implants.
11 January 2012	TGA convened teleconference of overseas regulators.
12 January 2012	TGA website updated with information regarding the TGA's testing of PIP implants, and an update to Questions and Answers.
12 January 2012	TGA contacted Medical Vision Australia requesting additional information regarding supply of PIP implants under SAS.
12 January 2012	TGA website updated to reflect changes to Questions and Answers on DoHA website and provide the latest results of laboratory testing.

Date	Event
12 January 2012	Email to AFSSAPS requesting information about breast implant samples and the introduction of the gel.
13 January 2012	TGA requested advice from the MHRA and the European Commission on European wide plans to ensure the safety of breast implants currently on the market.
13 January 2012	A summary of TGA's Laboratory testing results circulated to overseas regulators.
13 January 2012	Communication from French Government noting advice from the French Authorities has not been received regarding allegations of fraudulent activities by manufacturers of PIP implants, and seeking information on Australian implant rupture rates.
13 January 2012	Email from AFSSAPS in response email 12 January 2012, regarding tests carried out on PIP implants.
13 January 2012	Email to AFSSAPS requesting sample of implant containing each type of gel.
16 January 2012	Teleconference with state and territory CHOs to discuss available prostheses implant and removal data that could potentially be used to assess rupture rates.
17 January 2012	TGA sent letter to ASPS, ACCS and RACS requesting they send further information to their members in case some PIP implanting surgeons could not be contacted from the TGA mail-out on 10 January 2012.
19 January 2012	TGA convened International Laboratory Testing Panel for PIP breast implants to confer about laboratory testing for the scientific analysis of the quality and safety of PIP implants: this panel includes Australia, Brazil, the Czech Republic, European Commission, Germany, Ireland, UK and the Netherlands.
20 January 2012	Second meeting (teleconference) of TGA's expert advisory panel on PIP implants.
20 January 2012	TGA website updated
20 January 2012	Response from AFSSAPS to email of 13 Jan 2012 re providing samples of gel for testing.
27 January 2012	TGA website updated.
30 January 2012	Communication from French Government regarding the use of a different silicone gel and the outcome of criminal proceedings against PIP founder.
1 February 2012	AFSSAPS advised TGA of detailed reports (in French) of work undertaken by AFSSAPS.
3 February 2012	Communication with French Government responding to request for information on the number of cases of implant rupture rates in Australia, and seeking advice from AFSSAPS to assist Australian testing program.

Date	Event
3 February 2012	TGA website updated.
7 February 2012	Intra-dermal irritation testing on PIP gel and shell commenced.
9 February 2012	TGA hosted second teleconference of International Laboratory Testing Panel for PIP breast implants.
10 February 2012	Communication with European governments (Czech Republic, French, German and Netherlands) regarding respective policy decisions on PIP implants.
10 February 2012	TGA website updated.
17 February 2012	TGA website updated.
20 February 2012	Communication from Czech Ministry of Health regarding policy decisions on PIP implants.
23 February 2012	Third teleconference of TGA's expert advisory panel on PIP implants.
24 February 2012	TGA website updated.
1 March 2012	Questionnaires sent to surgeons who have reported ruptures of PIP implants, with the aim of gathering detailed information about the rupture, the gel, the actual or potential issues of the rupture and the contra-lateral implant if there is one.
2 March 2012	TGA website updated.
7 March 2012	DoHA received detailed reports of the AFSSAPS chemical, mechanical and biological testing.
8 March 2012	TGA hosted 3rd meeting of the International Laboratory Testing Panel for PIP breast implants (ITPP).
9 March 2012	TGA website updated.
10 March 2012	Media release by the Minister for Health, the Hon Tanya Plibersek MP, announcing access to subsidised MRI scans for women with PIP breast implants from 12 March 2012.
10 March 2012	TGA website updated with advice on subsidised MRI scans.
12 March 2012	Breast Implant Information Line script updated with information regarding subsidised MRI scans for women with PIP breast implants.
13 March 2012	Fourth teleconference of TGA's expert advisory panel on PIP implants.
16 March 2012	TGA website updated.
23 March 2012	TGA website updated.
30 March 2012	TGA website updated.

Date	Event
2 April 2012	TGA website updated.
5 April 2012	TGA website updated.
13 April 2012	TGA website updated.

Key

- Unshaded rows indicate regulatory and communication activities undertaken by the TGA.
- Shaded rows indicate activity undertaken by DoHA and media releases from the Health Minister and Parliamentary Secretary for Health and Ageing.

Attachment 2

Media release: New hotline for women with breast implants

THE HON NICOLA ROXON MP
Attorney-General
Acting Minister for Health and Ageing

CATHERINE KING MP
Parliamentary Secretary for Health

7 January, 2012

NEW HOTLINE FOR WOMEN WITH BREAST IMPLANTS

The Gillard Government today announced a new hotline for women concerned about their breast implants.

The new service has been set up following concerns from France over PIP breast implants. While there is no evidence of increased rupture rates here in Australia, support is available for women who want more information.

Women who have had breast implants and are concerned should ring the Breast Implant Information Line on Ph: 1800 217 257 or contact their surgeon directly for clinical advice.

For women who require further follow up, clinical and radiological investigations will be covered under the usual Medicare arrangements.

"Australian women can be reassured that our experts advise that on the basis of current data available there is no evidence of increased rupture rates for PIP implants in Australia," Acting Minister for Health and Ageing Nicola Roxon said.

"The Breast Implant Information Line will operate 24 hours a day from today, to provide advice and support. This government service will also register women's contact details so follow up information can be provided if necessary."

Parliamentary Secretary for Health Catherine King said the TGA had only received 37 reports of ruptured PIP implants since 2000, representing 0.4% of PIP implants and was well within the international evidence of implant rupture rates.

"These figures remain within the expected risk of rupture but given concerns in Europe regarding this product, we recommend that women see their surgeons if they are concerned or require further advice."

"Obviously the TGA will continue to keep a close watch on this situation and further information will be provided if more information becomes available."

The TGA is contacting all Australian surgeons who have used the PIP implants to ask that they provide a clinical evaluation to their patients.

For all media enquiries please contact the Minister's Office on 0409 945 476

The 24 hours Breast Implant Information Line, Ph: 1800 217 257

For full TGA advice please visit http://www.tga.gov.au/safety/alerts-device-breast-implants-120104.htm

Attachment 3

Media release: Women with PIP breast implants to receive subsidised MRI scans

THE HON TANYA PLIBERSEK MP
Minister for Health

MEDIA RELEASE

10 March 2012

Women with PIP Breast Implants to Receive Subsidised MRI Scans

Women who know that they have PIP breast implants, or where clinical advice is that they might have, will from Monday be able to access Medicare rebates for MRI services to assess whether their implants are structurally sound, Minister for Health Tanya Plibersek said today.

"For 12 months, from Monday 12 March 2012, women with a PIP implant can access a Medicare rebate for an MRI to assess the state of their implant and whether it has ruptured or not," said Ms Plibersek. The listing of this Medicare item follows independent, expert advice from the Medical Services Advisory Committee.

"Medical advice from the Chief Medical Officer and expert committee is that removal of PIP breast implants in the absence of evidence of rupture is not routinely required.

"We want women to get the best clinical care including access to a subsidised MRI scan if they choose.

"MRI is a key tool for the diagnosis of problem implants at a time when many women with PIP implants maybe fearful about the condition of their breast implants," Ms Plibersek said.

"I know that women who received these implants were shocked when they heard that the manufacturers of the PIP implants had been using unauthorised silicone.

"We want to ensure that women have access to comprehensive and up to date information and the best diagnostic testing available.

"The patient's referring specialist or GP will need to identify in the referral that their patient is known or has a high probability of having a PIP-branded implant so they can be eligible for the Medicare rebate," she said.

Ms Plibersek said the Government would continue to investigate any potential legal liability of the manufacturer and distributor.

"The Therapeutic Goods Administration will continue to monitor and work with therapeutic goods regulators from around the world to identify the latest information and channels of investigation," she said.

For more information regarding the TGA's current advice, visit: http://www.tga.gov.au/safety/alerts-device-breast-implants-pip.htm or contact The Breast Implant Information Line which is available 24 hours a day to provide advice and support to people - 1800 217 257.

For media inquiries, please contact Minister Plibersek's office on 02 6277 7220

Attachment 4

TGA laboratory testing on PIP breast implants as at 29 March 2012

International Testing Panel

To date, the TGA has hosted three teleconferences (January 19th, February 9th and March 9th 2012).

Intra-dermal Irritation Study

The TGA commissioned intra-dermal irritation tests on PIP breast implants in laboratories both in Australia (Laboratory A) and France (Laboratory B). The purpose of this study was to assess the potential of polar (saline) and non-polar (oil) extracts of shell and gel components of PIP breast implants to produce irritation following intra-dermal injection into rabbits.

Laboratory A: All batches non-irritant
Laboratory B: All batches non-irritant

Table 1: Scores for the intra-dermal irritation study (N = not tested; ≤1.0 is non-irritant)

Batch	Expected Gel	Component	Extraction Conditions	Laboratory A		Laboratory B	
				Saline	Oil	Saline	Oil
40109	PIP2	Shell	37°C; 72hrs	0	0.1	N	N
		Gel	37°C; 72hrs	0	0	0	0
			50°C; 72hrs	N	N	0	0
16609	PIP2	Shell	37°C; 72hrs	0	0.1	N	N
		Gel	37°C; 72hrs	1.0	0.2	0	0
			50°C; 72hrs	N	N	0	0
37609	PIP2	Shell	37°C; 72hrs	N	N	N	N
		Gel	37°C; 72hrs	N	N	0	0
			50°C; 72hrs	N	N	0	0
22808	PIP2	Shell	37°C; 72hrs	0	0	N	N
		Gel	37°C; 72hrs	0	-0.1	N	N
30508	PIP2	Shell	37°C; 72hrs	N	N	N	N
		Gel	37°C; 72hrs	N	N	0	0
			50°C; 72hrs	N	N	Pending	Pending
03907	PIP1	Shell	37°C; 72hrs	0	0.3	N	N
		Gel	37°C; 72hrs	0	0.2	N	N
53407	PIP1	Shell	37°C; 72hrs	N	N	N	N
		Gel	37°C; 72hrs	N	N	0	0
			50°C; 72hrs	N	N	0	0
6009626	Brand M	Shell	37°C; 72hrs	0	0	N	N
		Gel	37°C; 72hrs	0	0.2	0	0
			50°C; 72hrs	N	N	0	0

Based on AFSSAPS reports, the 'expected gel type' has been included in table 1, above. Batch 30508 has been obtained from the Brazilian regulator and matches a batch that has been included in mechanical testing by AFSSAPS and been identified by AFSSAPS as containing PIP2 gel.

Cytotoxicity tests

Cytotoxicity tests measure whether there are chemical toxins in the material that are toxic to cells. To date, testing in France, UK and Australia has not shown that the gels contain such chemical toxins. Nevertheless, given that the manufacturer has used unauthorised gels and different formulations of those gels, the TGA is continuing to do cytotoxicity tests in order to increase the pool of results on PIP breast implants, as well as on the raw material silicone oil used to make the gels.

To date, none of the materials taken from any of the PIP shells or gels displayed a cytotoxic effect.

Chemical identification

Identification

The silicone gels are being chemically fingerprinted using Fourier transform infrared spectroscopy (FTIR) and chemically profiled using gas chromatography–mass spectrometry (GC-MS), thermogravimetric analysis (TGA) and gel permeation chromatography (GPC).

FTIR has not provided useful differences to distinguish gels. Tests for low molecular weight silicones using GC-MS show that those chemicals are not detectable in the authorised gel (NUSIL), but are detectable in both PIP1 and PIP2 unauthorised gels to varying levels. Assessment by TGA is showing different characteristics for the PIP1 and PIP2 breast implants, although the characteristics of PIP1 are similar to the NUSIL gel.

Presence of Metals

Samples of unused PIP breast implants were being screened for the presence of metals using inductively coupled plasma mass spectrometry (ICP-MS). No metals were identified at a level that was considered to be of concern.

Presence of D4, D5 and D6 siloxanes

The AFSSAPS reported that testing of raw materials and filling gels were carried out using GC-MS o determine their low molecular weight silicone content, in particular D4-D13 siloxanes. The AFSSAPS reported that this testing was justified as D4 siloxane has a toxic potential. The AFSSAPS concluded that the results of analyses and the observation of the texture of the gels extracted from the implants demonstrate that the formulations of the "PIP" gels are poor quality (particularly due to the presence of high levels of siloxanes D4 to D13). Since the initial reports did not quantify the level of these siloxanes, the TGA is measuring the quantities of D4, D5 and D6 in the PIP gels.

Test results from GC-MS analyses indicate D4 is present in the gels of PIP breast implants at between 0 and 261ppm, with a median of 136ppm. D5 is present between 0-710ppm, with a median of 434ppm. D5 is present between 0 and 1005, with a median of 470ppm. There does not seem to be any relationship between the year of manufacture of the gel and the presence of D4, D5 and D6 siloxanes. These values could change with the testing of further samples.

Information provided by the suppliers of the raw materials, which were used to produce the gel used in PIP breast implants, together with more recent detailed information provided to the TGA by AFSSAPS, does suggest that the TGA findings are a reasonable estimate of the content of these siloxanes. Expert toxicology advice confirms that the concentration of these siloxanes in the PIP gels tested does not constitute a health risk.

Physico-mechanical testing

The TGA has increased the number of samples of PIP breast implants tested for shell integrity by measuring the tensile elongation of a further 7 samples to the original 8 samples that were tested in 2010. All tensile elongation results for the 15 samples now tested meet the requirements of the standard (ISO 14607:2007 Annex B Section 1.2) - the elongation at break of the shell specimen must exceed 450% compared to the original length of the specimen.

Table 2: Median shell thickness, tensile properties and gel cohesion of PIP implants (NT = not tested)

Model	Lot No.	Expiry	Thickness (mm)	Force (N)	Elongation (%) Requirement is >450%	Gel Cohesion (mm) Requirement is <30mm
Textured Shell						
IMGHC-TX-S-205	25109	2014-05	0.81	19	581 *	2.0
IMGHC-TX-S-265	35008	2013-06	0.94	21	569 *	1.0
IMGHC-TX-H-430	16609	2014-03	0.98	20	578 *	0.5
IMGHC-TX-H-290	25009	2014-05	0.85	14	569	NT
IMGHC-TX-H-430	15809	2014-03	0.87	14	546	NT
IMGHC-TX-S-365	09709	2014-03	0.81	15	568	NT
IMGHC-TX-H-470	01809	2014-01	0.90	16.0	592	NT
IMGHC-TX-H-430	18809	2014-04	0.83	14	619	NT
Smooth Shell						
IMGHC-LS-S-205	56206	2011-10	0.50	13	513 *	NT
IMGHC-LS-S-305	54206	2011-10	0.47	15	567 *	3.0
IMGHC-LS-H-350	27909	2014-07	0.50	15	633 *	0.5
IMGHC-LS-H-350	36709	2014-09	0.63	20	666 *	0.0
IMGHC-LS-H-430	36709	2014-09	0.70	21	663 *	0.0
IMGHC-LS-H-430	36709	2014-09	0.89	17	661	NT
IMGHC-LS-H-350	35909	2014-09	0.68	17	661	NT

* These values were previously reported in January 2012. They have been adjusted to account for a testing instrument zeroing function, which was not included in the original calculation, and/or reporting as median values rather than average values.

Investigation of explanted breast implants

The TGA is investigating breast implants that have been *explanted* from patients to augment the information that has been provided to the TGA by surgeons. Surgeons who find features of an explant that cause them particular clinical concern are encouraged to report their findings to the TGA. The surgeon is asked to store the explant in a sterile container at 4 degrees until conveyed to the TGA under agreed biohazard control procedures. Generally, the gels from explants investigated to date have been firm and strongly cohesive, although the

TGA has observed gels that are less firm. To date, the ruptured explants received by the TGA are associated with a 'milky fluid'. An aliquot of the milky fluid was chemically fingerprinted using FTIR. This indicated that the milky fluid was predominantly water with polydimethylsiloxane (silicone).

Attachment 5

Scientific Committee on Emerging and Newly Identified Health Risks, *The Safety of PIP Silicone Breast Implants* (Version of 1st February 2012)

EXECUTIVE SUMMARY

2) The SCENIHR has been asked to address the potential risks from PIP breast implants because, according to the findings of the French Health Authorities, the French manufacturer (Poly Implant Prothèse; abbreviated as "PIP") made use of low-quality material (industrial silicone). In such an assessment, it is important to compare the available information with findings for breast implants from other manufacturers.
3) Important difficulties in making such an assessment are:
    a) The number of patients in the individual member states is unknown due to patient tourism and poor record keeping by the manufacturers of PIP silicone breast implants;
    b) Reporting of breast implant failure and of related adverse effects on health is not obligatory. Consequently, reported incident rates are unreliable. However, even for silicone implants of standard quality, reoperations are needed eventually for a high number of patients.
4) There is no indication from the available data that the group of women who have had PIP silicone breast implants differ significantly from the group having implants from other manufacturers. Overall around 80% of all breast implantations are performed for cosmetic reasons and about 20% for reconstructive purposes. A minor fraction of implantations involve women with congenital malformations.
5) There are various methods to identify implant failure. It is important to note that clinical breast examinations alone have little sensitivity for detecting implant rupture. If there are clinical signs of adverse effects, then a diagnostic work-up is mandatory. A clinical examination is therefore likely to miss implant rupture in the absence of positive signs. There is international agreement among professional radiologists and reconstructive and aesthetic surgeons that Magnetic Resonance Imaging (MRI) is the most accurate modality to detect ruptures. A meta-analysis has estimated the overall sensitivity to 78% (95% CI, 71%-83%) and the overall specificity was 91% (95% CI, 86%-94%). Ultrasonography is the second best imaging modality for detecting ruptures. However, ultrasonography is less precise and more dependent on the human operator than MRI. Mammography is even less useful.
6) Silicone breast implants can fail, regardless of manufacturer, and the probability of failure increases with time since implantation. This phenomenon is true for all the types of implants used in the human body. Most breast implants seem to be rather durable for the first 6-8 years, whereafter the risk of rupture increases. For third generation implants a general rupture risk 10%–15% within 10 years of implantation seems to be an appropriate estimate. Implants with more cohesive silicone seem to have lower risk of rupture.
7) The reported frequency of local complications among silicone breast implant recipients generally ranges between 17% and 36%. Additional surgery after primary implantation as a result of these complications has been reported to range from 10 to 30%. Capsular contracture is the most frequent reason for additional surgery in

women with breast implants with frequencies ranging from 2% to 23% in recent reports. Other complications include pain, haematoma and infection.

8) Other possible health effects of silicone breast implants that have been investigated in epidemiological studies include:
    a) Lymphoma: A causal link between breast implants and lymphoma has not been established.
    b) ALCL: A very rare type of lymphoma, the Anaplastic Large Cell Lymphoma (ALCL) has been found in the scar capsular tissue around breast implants in 60 patients globally. According to the US Food and Drug Administration (FDA), there might be a minimally increased risk to develop this tumour for patients with breast implants.
    c) Breast cancer and other cancers: Several high-quality studies have been conducted and they have provided clear evidence against an increased risk of breast cancer or any other type of cancer. An increased risk of lung cancer found in some studies appears to reflect a higher frequency of smoking among women with implants.
    d) Connective Tissue Diseases (CTDs): Although there were initial reports of associations with various forms of connective tissue disease, subsequent, largescale epidemiologic investigations provided consistent evidence against these claims.
    e) Effects on offspring: There were a few early case reports of children born to or breastfed by women with silicone breast implants who developed swallowing difficulties, irritability, nonspecific skin rashes, fatigue, and other symptoms. However, subsequent epidemiologic studies of these issues found no evidence of an association.
    f) Immunological effects: Occasionally foreign body reactions have been reported in a small number of women with breast implants.
    g) Suicide and psychological issues: It is a consistent observation that the population of women with cosmetic breast implants exhibits a two- to three-fold higher rate of suicide than similar-aged women in the general population.
9) The risk factors for breast implant failure may be identified as:
    a) Physical and chemical features of the implant;
    b) The implantation procedure;
    c) Time since the implantation;
    d) Patient specific factors, e.g., accidents.
10) This Opinion draws on three sources of data, namely,
    a) An extensive search of the published literature;
    b) Information provided by some Member States, in particular France, and other national authorities;
    c) Incident reports collected by the IPRAS (International Confederation for Plastic Reconstructive and Aesthetic Surgery) network.

    Because of the urgency of a Scientific Opinion from the SCENIHR, the Committee could only consider the readily available data. The SCENHIR is aware that PIP silicone breast implants have been found to vary considerably in composition and, as a result, are likely to vary substantially in performance characteristics. No clear temporal trend of implant problems has been identified for PIP silicone breast

implants. Consequently, it is very difficult to identify a truly representative PIP implant for risk assessment purposes.

11) The data available on PIP are inevitably limited at this stage. The focus of attention in this initial response is on the following aspects:
    a) Physical and chemical properties of the PIP silicone breast implants, where available;
    b) Findings of the effects of PIP implant contents in some required safety tests, where available;
    c) Reports of incidents of PIP implant failures, where available.

12) Physical and chemical properties: The more recent PIP silicone breast implants in common with those of other manufacturers comprise a single envelope/shell. The implants consist of an outer highly cross linked elastomer shell filled with a gel with more limited cross linking. In common with those of most other manufacturers, PIP silicone breast implants were manufactured using the polymer polydimethylsiloxane, also known as silicone. The chemical reaction resulting in gel formation must be controlled because it governs the degree of crosslinking. The more variable this reaction is the greater is the variation of the content of volatile and/or low molecular mass components in the implant (gel and shell). Use of industrial grade silicone, along with a lesser control of the cross linking process, appears to be associated with a higher content of low molecular weight components in PIP silicone breast implants. As a consequence of the migration of these components, it is reasonable to conclude that the shell might be weakened and that components could leak into the surrounding tissue. Tests conducted by the French Authorities on the physical integrity of a sample of PIP silicone breast implants indicated weaknesses in PIP shells not found in other commercially available implants.

13) Findings in Toxicity tests: A range of assays are available for toxicity testing. For implant devices with which there will be prolonged contact with the patient the most extensive toxicity testing is needed with end-points including cytotoxicity, sensitization, irritation, acute and subchronic systemic toxicity, genotoxicity, and implantation tests. Additional tests may be indicated by the risk assessment that is performed of a certain medical device/constituent and these may include biodegradation and toxicokinetic studies, chronic toxicity, carcinogenicity, immunotoxicity, neurotoxicity and reproductive/ developmental toxicity. To date few studies aimed at evaluating the toxicity of the contents of PIP silicone breast implants have been conducted using tests specified for assessing the safety of Class III medical devices. The tests that have been performed are designed to assess cytotoxicity, irritancy and genotoxicity. Medical grade silicone gels gave negative results in these tests. In the case of the contents of the PIP silicone breast implants, tests for cytotoxicity and genotoxicity were negative. However, an in vivo test for irritancy was positive. This indicates the potential for inducing local irritancy when the silicone gel is released from the implant. Any effects will depend on the amount released, the duration of exposure and other local conditions. The implications of this positive irritancy test result for women with PIP silicone breast implants are currently uncertain and further investigation is required.

14) Incident reports: There are cases reported suggesting that PIP silicone breast implants may have a higher failure rate in the first few years after implantation compared with those from other breast implant manufacturers. There are also case reports indicating that PIP silicone breast implants may be associated with a higher incidence of swollen

and painful lymph nodes not only in the axilla but also in the neck, the groin and the mediastinum, after rupture but sometimes even without rupture.

The limited and selective clinical data along with the absence of pidemiologic data specifically on the PIP silicone breast implants provide insufficient evidence to warrant a conclusion whether these implants pose hazards not identified among women with implants of standard quality. In particular, the data preclude a conclusion whether women with PIP silicone breast implants have greater risks to their health than women with breast implants from other manufacturers. However, when the limited available information is taken together with the findings from tests of the physical and chemical properties of the shell and silicone, and of the in vivo irritancy test, some concerns are raised about the safety of PIP silicone breast implants. The possibility for health effects cannot be ruled out.

15) The SCENIHR is asked to identify the generic risks and benefits of various actions that might be taken to address these concerns. As noted above there are obvious difficulties in providing scientifically based advice because:
    a) Regardless of the manufacturer, the failure rate of an implant increases over time;
    b) For many women, it is uncertain whether their breast implant is a PIP manufactured implant;
    c) Simple clinical examination alone is unlikely to identify those patients with a leaking/ruptured implant.
    d) Many PIP silicone breast implants have been inserted by surgeons who are not qualified in plastic surgery. This might be a source of higher failure rates among their patients.
16) It is important to identify, as far as possible, high-risk categories of patients based on the identified risk factors noted above. Key factors including manufacturer, duration of implant in the body of the patient, patient symptoms, and psychological state have been identified. However, these criteria are insufficiently established at present as regards PIP silicone breast implants and a patient-by-patient approach is therefore required. It is important that the potential risks identified in this opinion are considered in the light of the risks involved in prophylactic explantation.

    A controlled prophylactic explantation definitely carries less risk than an explantation after rupture or after the onset of symptoms of inflammation and/or lymphadenopathy. Considering the reduced stability of the shell of PIP silicone breast implants, it is possible that the implant will have to be exchanged for most of the women with such implants within the next 10–15 years.
17) The SCENIHR recommends that further work is undertaken as a priority to establish with greater certainty the type and magnitude of health risks, if they exist, associated with PIP silicone breast implants. In particular,
    a) A thorough assessment of the chemical composition of a range of PIP silicone breast implants/explants;
    b) Further assessment of biological effects of the silicone gel used in PIP silicone breast implants/explants;
    c) Further research on PIP explants to identify cause of failure;
    d) The development of simple tests that can be used for routine reliable low cost screening to identify ruptures in (PIP) implants;

e) The establishment of a reliable database on Silicone Breast Implant (SBI) and other implant failures and health effects of such failures.

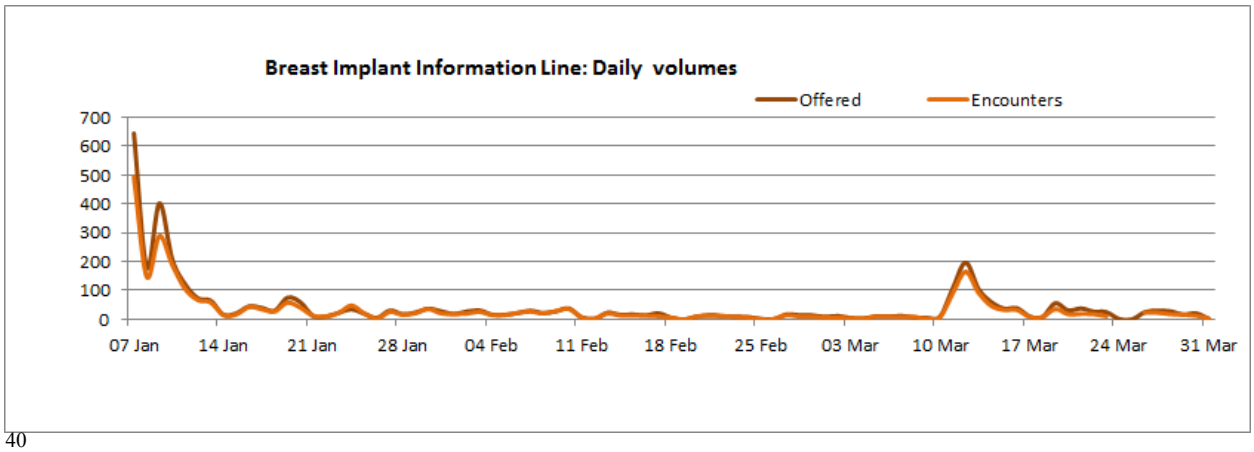
Attachment 6

Breast Implant Information Line **Report for the period 7 January – 31 March 2012**

Breast Implant Information Line

7 January - 31 March 2012

1. Telephony Summary



[40]

Date	Sat 07 Jan	Sun 08 Jan	Mon 09 Jan	Tue 10 Jan	Wed 11 Jan	Thu 12 Jan	Fri 13 Jan	Sat 14 Jan	Sun 15 Jan	Mon 16 Jan	Tue 17 Jan	Wed 18 Jan	Thu 19 Jan	Fri 20 Jan	Sat 21 Jan	Sun 22 Jan	Mon 23 Jan	Tue 24 Jan	Wed 25 Jan	Thu 26 Jan	Fri 27 Jan	Sat 28 Jan	Sun 29 Jan	Mon 30 Jan	Tue 31 Jan	Total
Offered	644	180	402	208	122	73	65	16	21	45	40	30	75	60	12	10	23	35	20	5	31	18	24	37	28	2,224
Encounters	493	148	289	189	106	67	59	15	17	43	35	27	58	41	13	10	22	48	21	3	26	16	21	36	21	1,824

Date	Wed 01 Feb	Thu 02 Feb	Fri 03 Feb	Sat 04 Feb	Sun 05 Feb	Mon 06 Feb	Tue 07 Feb	Wed 08 Feb	Thu 09 Feb	Fri 10 Feb	Sat 11 Feb	Sun 12 Feb	Mon 13 Feb	Tue 14 Feb	Wed 15 Feb	Thu 16 Feb	Fri 17 Feb	Sat 18 Feb	Sun 19 Feb	Mon 20 Feb	Tue 21 Feb	Wed 22 Feb	Thu 23 Feb	Fri 24 Feb	Sat 25 Feb	Sun 26 Feb	Mon 27 Feb	Tue 28 Feb	Wed 29 Feb	Total
Offered	19	27	31	16	16	22	30	22	28	38	7	2	23	16	17	14	21	6	0	10	15	12	9	8	2	1	17	15	14	458
Encounters	18	20	26	15	15	23	27	21	29	36	6	2	20	14	13	13	11	6	0	10	12	11	9	6	1	1	15	10	9	399

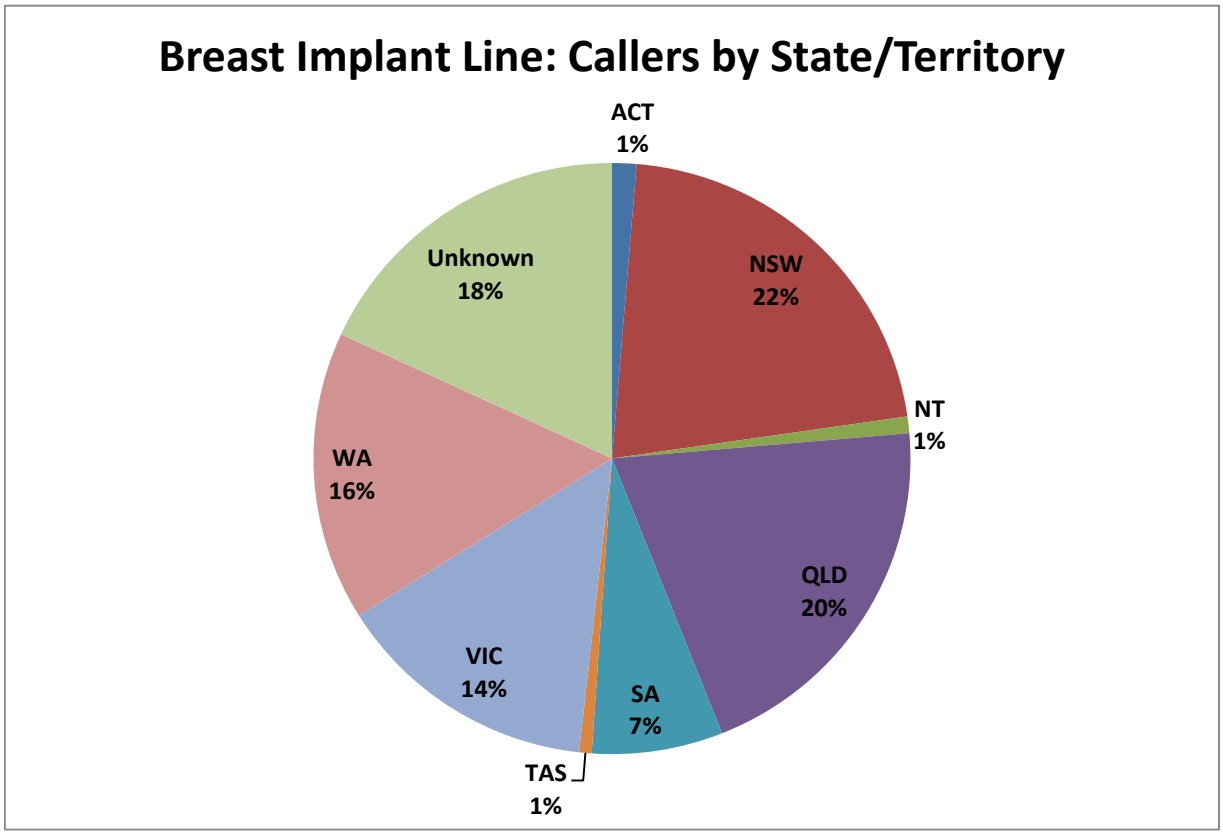
Date	Thu 01 Mar	Fri 02 Mar	Sat 03 Mar	Sun 04 Mar	Mon 05 Mar	Tue 06 Mar	Wed 07 Mar	Thu 08 Mar	Fri 09 Mar	Sat 10 Mar	Sun 11 Mar	Mon 12 Mar	Tue 13 Mar	Wed 14 Mar	Thu 15 Mar	Fri 16 Mar	Sat 17 Mar	Sun 18 Mar	Mon 19 Mar	Tue 20 Mar	Wed 21 Mar	Thu 22 Mar	Fri 23 Mar	Sat 24 Mar	Sun 25 Mar	Mon 26 Mar	Tue 27 Mar	Wed 28 Mar	Thu 29 Mar	Fri 30 Mar	Sat 31 Mar	Total
Offered	9	12	5	3	11	10	12	7	5	10	108	197	105	60	37	39	10	8	56	31	38	27	25	1	0	25	30	28	17	21	2	949
Encounters	6	6	4	3	9	9	8	8	3	8	91	165	92	47	33	33	8	8	36	18	19	18	11			23	23	18	16	13	3	739

[40] **Definitions**

Offered: This count is sourced at Telephony Carrier Level. This includes all attempted calls to the service and calls abandoned before being handled by a Nurse.

Encounters: Calls successfully handled by a Nurse.

2. Number of callers to Service by date, State/Territory



Date	ACT	NSW	NT	QLD	SA	TAS	VIC	WA	Unknown	Number of Encounters
7/01/2012	12	125	6	75	31	2	100	62	80	493
8/01/2012	4	24	1	23	6	2	32	28	28	148
9/01/2012	4	75	3	52	18	1	43	44	49	289
10/01/2012	2	39	1	33	16	2	30	33	33	189
11/01/2012	1	16	1	22	7	2	27	13	17	106
12/01/2012	0	16	0	12	6	0	15	6	12	67
13/01/2012	1	10	1	12	8	2	4	8	13	59
14/01/2012	0	0	0	5	1	0	1	4	4	15
15/01/2012	0	6	0	6	0	0	2	3	0	17
16/01/2012	1	8	1	8	4	2	7	5	7	43
17/01/2012	1	8	0	8	3	0	7	6	2	35
18/01/2012	0	4	0	4	0	1	8	6	4	27
19/01/2012	0	14	0	3	5	0	8	11	17	58
20/01/2012	0	3	0	6	4	0	4	13	11	41
21/01/2012	0	2	0	2	0	0	4	5	0	13
22/01/2012	2	0	0	4	0	0	0	3	1	10
23/01/2012	0	6	1	3	0	0	1	7	4	22
24/01/2012	1	11	1	11	4	0	8	10	2	48
25/01/2012	0	11	0	6	1	0	2	1	0	21
26/01/2012	0	0	0	1	0	0	0	1	1	3
27/01/2012	0	5	0	5	3	0	0	8	5	26
28/01/2012	0	3	0	6	2	0	0	2	3	16
29/01/2012	0	2	0	7	7	0	0	1	4	21
30/01/2012	1	12	0	7	2	0	4	4	6	36
31/01/2012	1	3	0	2	1	0	4	2	8	21
1/02/2012	0	6	0	2	0	0	4	5	1	18
2/02/2012	1	4	0	3	3	0	2	5	2	20
3/02/2012	0	6	0	7	5	0	2	2	4	26
4/02/2012	0	2	0	1	0	0	9	2	1	15
5/02/2012	0	2	0	1	0	0	5	7	0	15
6/02/2012	0	2	0	3	2	0	6	6	4	23
7/02/2012	1	3	0	3	1	0	3	7	9	27
8/02/2012	0	4	0	6	5	0	2	0	4	21
9/02/2012	1	8	1	1	3	1	3	4	7	29
10/02/2012	1	9	0	13	3	1	1	5	3	36
11/02/2012	0	1	0	3	0	0	0	1	1	6
12/02/2012	0	1	0	0	0	0	0	0	1	2
13/02/2012	0	3	0	7	1	0	1	3	5	20
14/02/2012	0	7	0	4	0	0	0	2	1	14
15/02/2012	0	2	1	2	0	0	2	4	2	13
16/02/2012	0	1	0	4	0	1	1	3	3	13
17/02/2012	0	1	0	4	3	0	2	0	1	11
18/02/2012	0	1	0	2	1	0	0	1	1	6
20/02/2012	0	3	0	3	1	0	1	1	1	10
21/02/2012	0	3	0	1	0	0	1	3	4	12
22/02/2012	0	2	0	1	0	0	0	5	3	11
23/02/2012	0	0	0	2	2	0	2	2	1	9
24/02/2012	0	0	0	1	0	0	2	2	1	6
25/02/2012	0	0	0	0	0	0	0	0	1	1
26/02/2012	0	0	0	0	0	0	1	0	0	1
27/02/2012	0	1	0	5	3	0	2	2	2	15
28/02/2012	0	3	0	2	0	0	0	2	3	10
29/02/2012	0	1	0	1	1	0	1	1	4	9

Date	ACT	NSW	NT	QLD	SA	TAS	VIC	WA	Unknown	Number of Encounters
1/03/2012	0	1	0	0	0	0	0	2	3	6
2/03/2012	0	2	0	0	0	0	3	0	1	6
3/03/2012	0	0	0	1	0	0	3	0	0	4
4/03/2012	0	0	0	0	1	0	1	1	0	3
5/03/2012	0	0	0	2	1	1	2	2	1	9
6/03/2012	0	1	0	1	0	0	0	5	2	9
7/03/2012	0	2	0	2	1	0	1	2	0	8
8/03/2012	0	2	0	1	0	0	1	3	1	8
9/03/2012	0	1	0	0	0	0	1	1	0	3
10/03/2012	0	2	0	2	1	0	1	0	2	8
11/03/2012	1	26	2	23	3	1	6	3	26	91
12/03/2012	0	42	2	68	4	0	3	19	27	165
13/03/2012	1	17	0	17	10	0	12	13	22	92
14/03/2012	0	7	0	12	6	0	4	7	11	47
15/03/2012	1	5	0	9	2	0	3	6	7	33
16/03/2012	0	10	1	5	1	0	6	4	6	33
17/03/2012	0	1	0	4	0	0	1	0	2	8
18/03/2012	0	1	0	4	2	0	0	1	0	8
19/03/2012	1	8	1	13	3	0	1	4	5	36
20/03/2012	0	3	0	4	2	0	2	4	3	18
21/03/2012	0	3	1	5	2	0	1	2	5	19
22/03/2012	0	4	0	4	1	0	1	3	5	18
23/03/2012	0	2	0	1	0	0	3	2	3	11
26/03/2012	0	2	0	8	2	0	3	3	5	23
27/03/2012	0	4	0	2	2	0	0	10	5	23
28/03/2012	0	4	1	2	1	1	0	4	5	18
29/03/2012	0	2	0	4	1	0	0	5	4	16
30/03/2012	0	3	1	3	1	0	2	0	3	13
31/03/2012	0	0	0	1	0	0	0	1	1	3
Total	**39**	**634**	**27**	**603**	**210**	**20**	**425**	**468**	**536**	**2962**

[41]

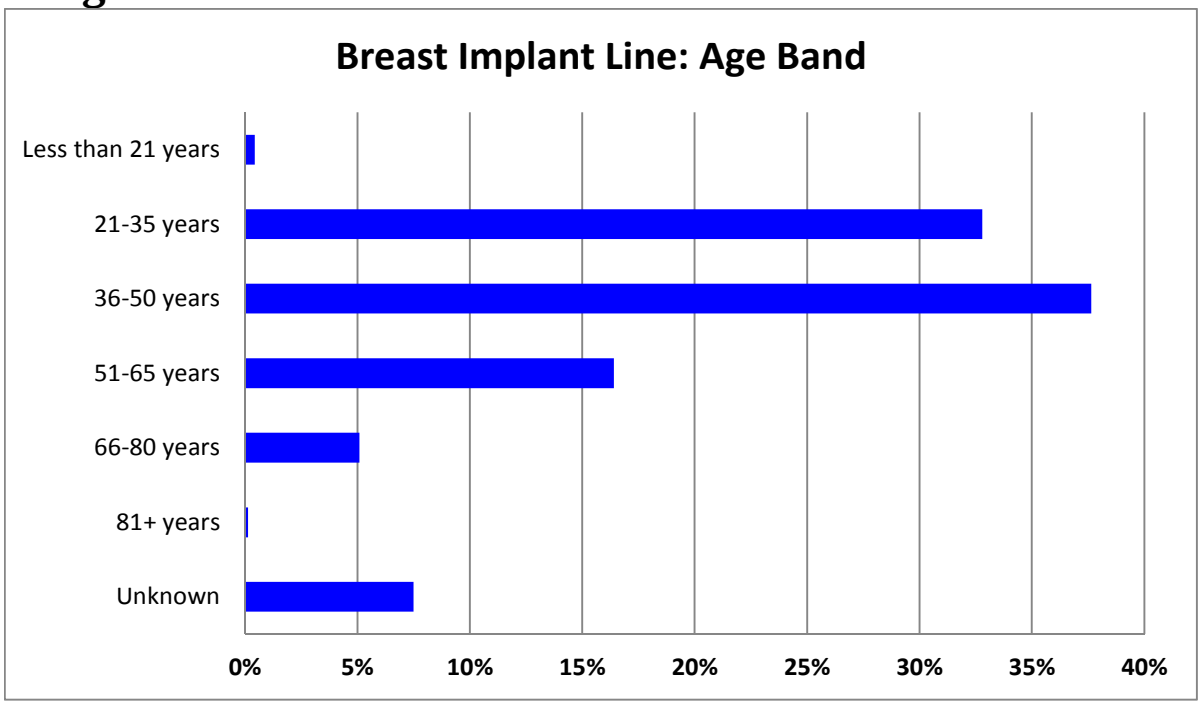
[41] Unknown reflects call encounters where the state/jurisdiction was not collected, this can be caused by callers that wished to be anonymous.

3. Top 10 postcodes of callers

Postcode	Region (to be defined)	Number of Encounters	% of Total Encounters
Unknown		536	18.1%
5108		17	0.6%
4217		16	0.5%
6065		16	0.5%
4870		16	0.5%
6164		16	0.5%
6069		15	0.5%
6019		15	0.5%
4551		14	0.5%
6210		13	0.4%

[42]

4. Age of caller



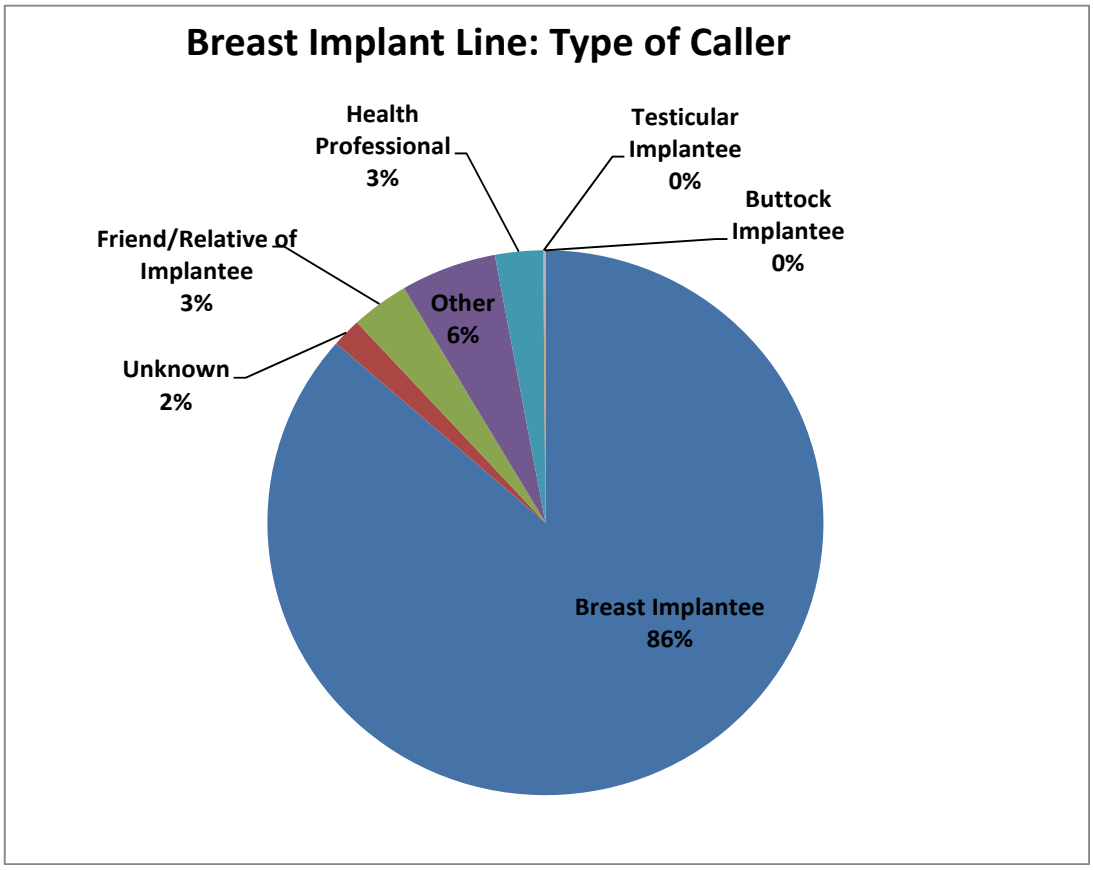
Age Band	Number of Encounters	% of Total Encounters
Less than 21 years	13	0.4%
21-35 years	971	32.8%
36-50 years	1115	37.6%
51-65 years	486	16.4%
66-80 years	151	5.1%
81+ years	4	0.1%
Unknown	222	7.5%
Total	**2962**	

[43]

[42] Unknown postcode reflects call encounters where the postcode was not collected, this can be caused by callers that wished to be anonymous. Data collected from 7 January 2012

[43] Unknown Age Band reflects call encounters where the date of birth was not collected, this can be caused by callers that wished to be anonymous. Data collected from 7 January 2012

5. Type of caller



	7Jan onwards		16Jan onwards		
Type of caller	Number of Encounters	% of Total Encounters	Number of Encounters	% of Total Encounters	Extrapolated Number of Encounters (based on 16Jan+ % and 7Jan+ volume)
Breast Implantee	2196	74.1%	1363	86.4%	2560.1
Unknown	544	18.4%	27	1.7%	50.7
Friend/Relative of Implantee	88	3.0%	53	3.4%	99.5
Other	88	3.0%	88	5.6%	165.3
Health Professional	44	1.5%	44	2.8%	82.6
Testicular Implantee	1	0.0%	1	0.1%	1.9
Buttock Implantee	1	0.0%	1	0.1%	1.9
Total	**2962**		**1577**		**2962**

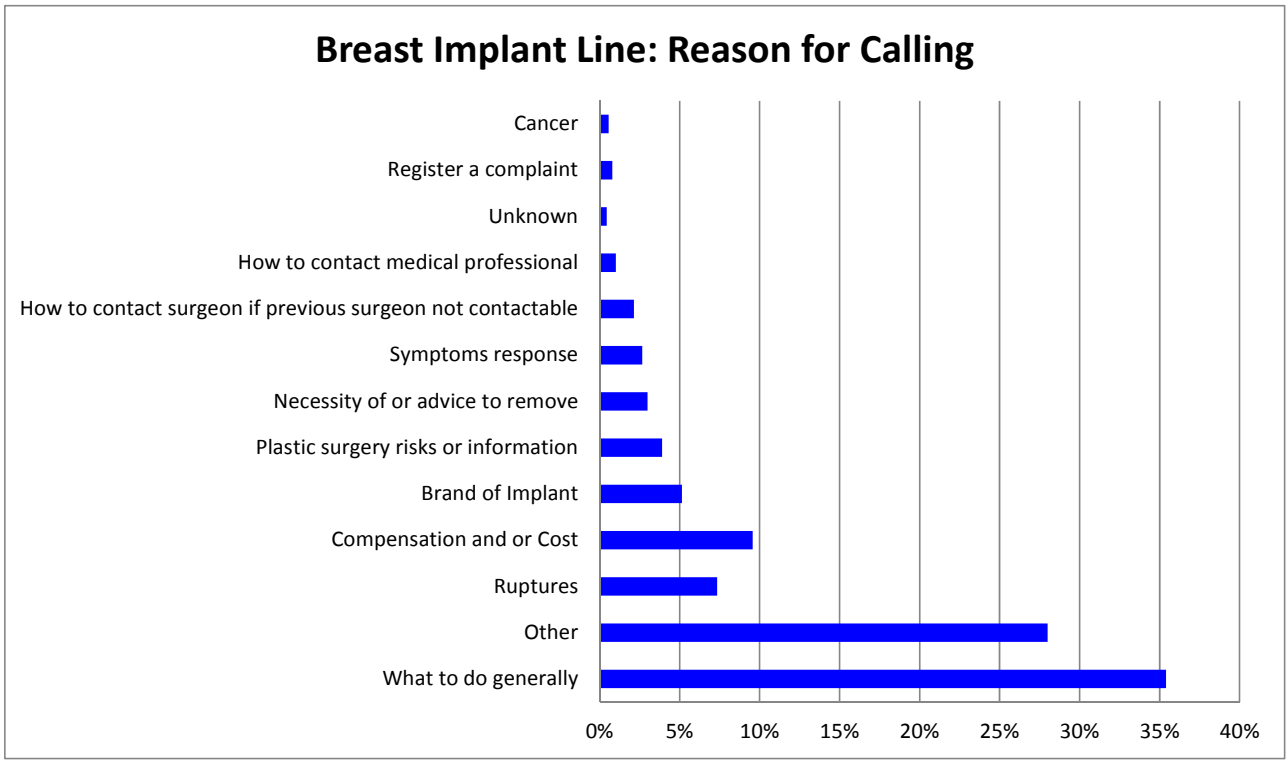
44

[44] Unknown Type of Caller reflects call encounters where the caller type data was not collected. This scenario predominantly occurred pre-16Jan where Nurses were not asked to collect the data. On 16Jan the Nurses were asked to start collecting this data. Post 16Jan Unknowns were due to the caller not wanting to reveal their caller type.

Data collected from 16 January 2012, minimal data was pulled from the free text fields (going back to 7 Jan). Therefore an extrapolation of the 16Jan onwards data was applied to the 7Jan onwards total volumes in order to get a sense of what the big picture could be (shown in the last column).

The pie chart above reflects the Post 16Jan caller type percentage.

6. Reason for calling

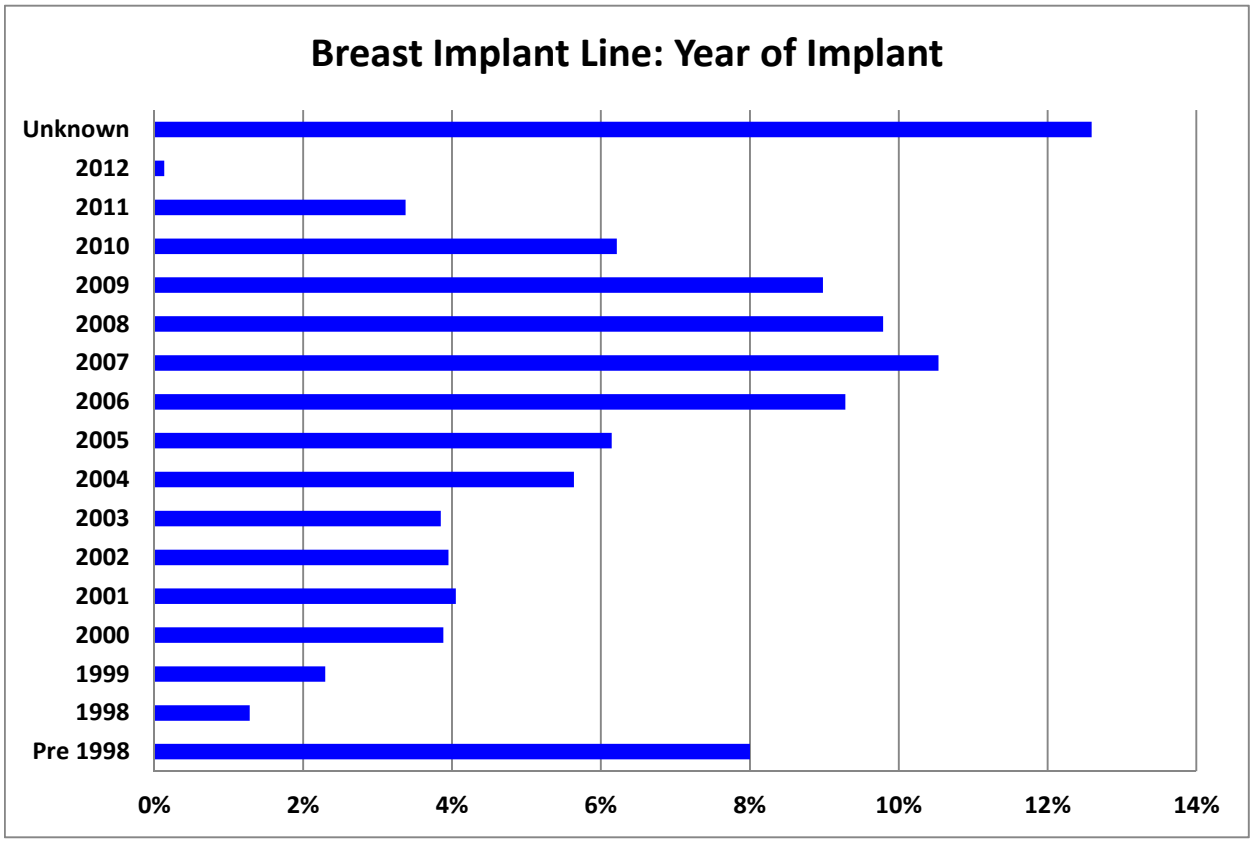


	7Jan onwards		11Jan onwards		
Reason for calling	**Number of Encounters**	**% of Total Encounters**	**Number of Encounters**	**% of Total Encounters**	**Extrapolated Number of Encounters (based on 11Jan+ % and 7Jan+ volume)**
Unknown	1187	40.1%	8	0.5%	13.4
What to do generally	626	21.1%	626	35.4%	1048.8
Other	497	16.8%	495	28.0%	829.3
Compensation and or Cost	170	5.7%	169	9.6%	283.1
Ruptures	133	4.5%	130	7.4%	217.8
Brand of Implant	92	3.1%	91	5.1%	152.5
Plastic surgery risks or information	69	2.3%	69	3.9%	115.6
Necessity of or advice to remove	57	1.9%	53	3.0%	88.8
Symptoms response	51	1.7%	47	2.7%	78.7
How to contact surgeon if previous surgeon not contactable	38	1.3%	38	2.1%	63.7
How to contact medical professional	18	0.6%	18	1.0%	30.2
Register a complaint	14	0.5%	14	0.8%	23.5
Cancer	10	0.3%	10	0.6%	16.8
Total	**2962**		**1768**		**2962**

45

[45] Unknown Reason of Calling reflects call encounters where the calling reason data was not collected. This scenario predominantly occurred pre-11Jan where Nurses were not asked to collect the data. On 11Jan the Nurses were asked to start collecting this data. Post 11Jan Unknown's were due to the caller not wanting to reveal their reason for calling. Data collected from 11 January 2012 (5:30pm onwards), minimal data was pulled from the free text fields (going back to 7 Jan). Therefore an extrapolation of the 11Jan onwards data was applied to the 7Jan onwards total volumes in order to get a sense of what the big picture could be (shown in the last column).

7. Year of implant

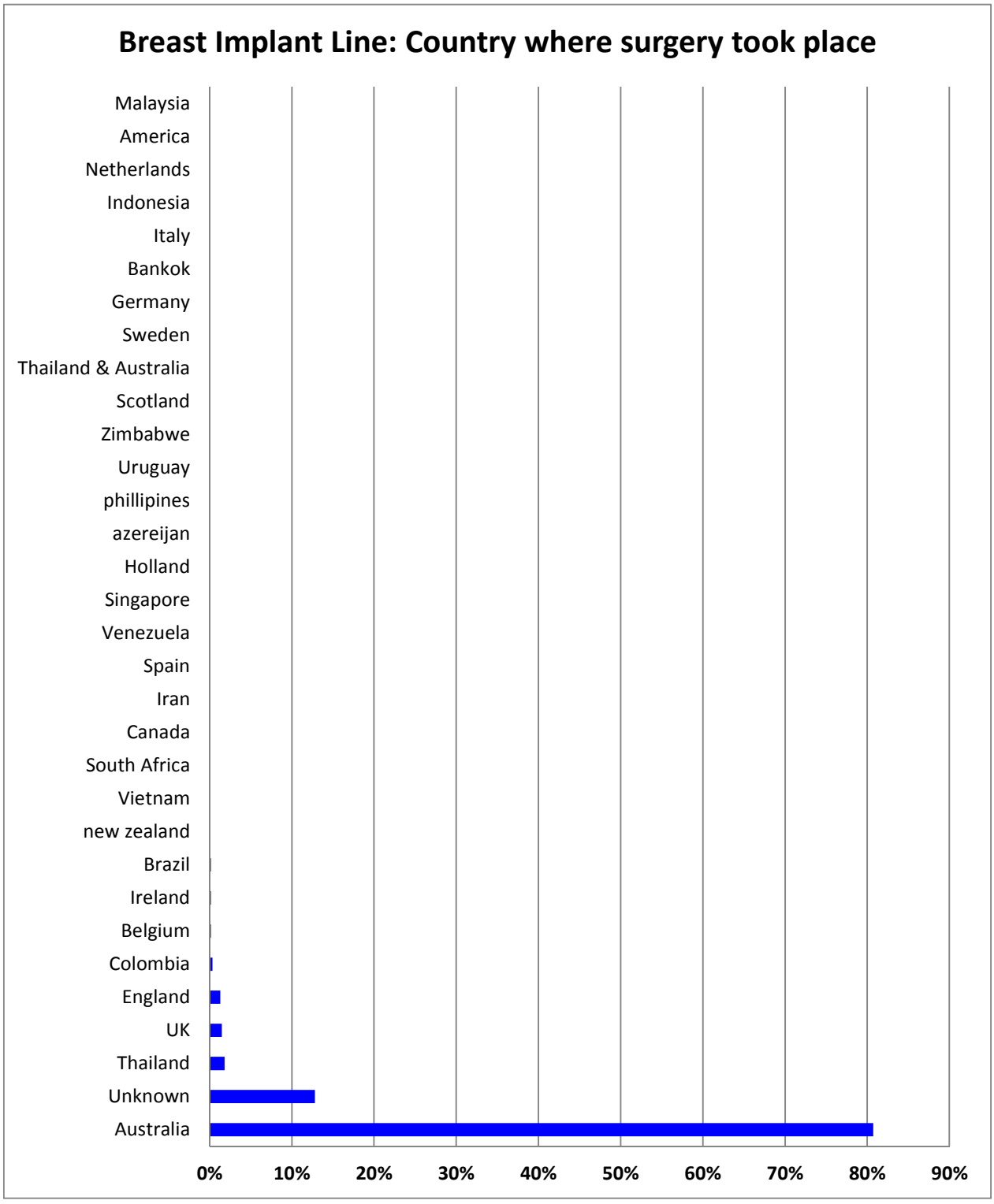


Year	Number of Encounters	% of Total Encounters
Pre 1998	237	8.0%
1998	38	1.3%
1999	68	2.3%
2000	115	3.9%
2001	120	4.1%
2002	117	4.0%
2003	114	3.8%
2004	167	5.6%
2005	182	6.1%
2006	275	9.3%
2007	312	10.5%
2008	290	9.8%
2009	266	9.0%
2010	184	6.2%
2011	100	3.4%
2012	4	0.1%
Unknown	373	12.6%
Total	**2962**	

[46]

[46] Unknown Year of implant reflects call encounters where the caller did not want to reveal or did not know when the breast implant was inserted.

8. Country where surgery took place

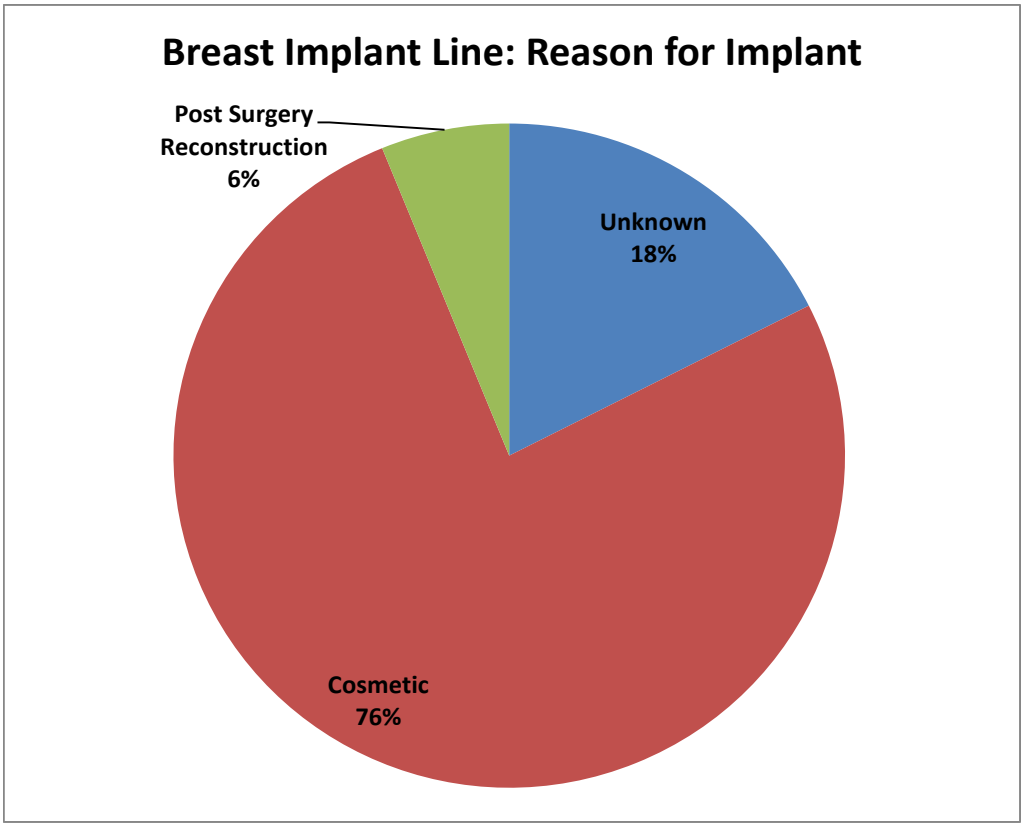


	7Jan onwards		11Jan onwards		
Country	Number of Encounters	% of Total Encounters	Number of Encounters	% of Total Encounters	Extrapolated Number of Encounters (based on 11Jan+ % and 7Jan+ volume)
Australia	1435	48.4%	1423	80.5%	2384.0
Unknown	1387	46.8%	226	12.8%	378.6
Thailand	39	1.3%	32	1.8%	53.6
UK	29	1.0%	26	1.5%	43.6
England	25	0.8%	23	1.3%	38.5
Colombia	12	0.4%	6	0.3%	10.1
Belgium	3	0.1%	3	0.2%	5.0
Ireland	3	0.1%	3	0.2%	5.0
Brazil	3	0.1%	3	0.2%	5.0
new zealand	2	0.1%	2	0.1%	3.4
Vietnam	2	0.1%	2	0.1%	3.4
South Africa	2	0.1%	2	0.1%	3.4
Canada	1	0.0%	1	0.1%	1.7
Iran	1	0.0%	1	0.1%	1.7
Spain	1	0.0%	1	0.1%	1.7
Venezuela	1	0.0%	1	0.1%	1.7
Singapore	1	0.0%	1	0.1%	1.7
Holland	1	0.0%	0	0.0%	0.0
azereijan	1	0.0%	1	0.1%	1.7
phillipines	1	0.0%	1	0.1%	1.7
Uruguay	1	0.0%	1	0.1%	1.7
Zimbabwe	1	0.0%	1	0.1%	1.7
Scotland	1	0.0%	1	0.1%	1.7
Thailand & Australia	1	0.0%	1	0.1%	1.7
Sweden	1	0.0%	1	0.1%	1.7
Germany	1	0.0%	1	0.1%	1.7
Bankok	1	0.0%	1	0.1%	1.7
Italy	1	0.0%	1	0.1%	1.7
Indonesia	1	0.0%	1	0.1%	1.7
Netherlands	1	0.0%	0	0.0%	0.0
America	1	0.0%	1	0.1%	1.7
Malaysia	1	0.0%	0	0.0%	0.0
Total	**2962**		**1768**		**2962**

[47]

[47] Unknown Country reflects call encounters where the country data was not collected. This scenario predominantly occurred pre-11Jan where Nurses were not asked to collect the data. On 11Jan the Nurses were asked to start collecting this data. Post 11Jan Unknown's were due to the caller not wanting to reveal which country the breast implant took place. Data collected from 11 January 2012 (5:30pm onwards). Therefore an extrapolation of the 11Jan onwards data was applied to the 7Jan onwards total volumes in order to get a sense of what the big picture could be (shown in the last column).

9. Reason for implant



	7Jan onwards		17Jan onwards		
Reason for implant	Number of Encounters	% of Total Encounters	Number of Encounters	% of Total Encounters	Extrapolated Number of Encounters (based on 17Jan+ % and 7Jan+ volume)
Unknown	1721	58.1%	264	17.5%	519.6
Cosmetic	1148	38.8%	1148	76.3%	2259.4
Post Surgery Reconstruction	93	3.1%	93	6.2%	183.0
Total	**2962**		**1505**		**2962**

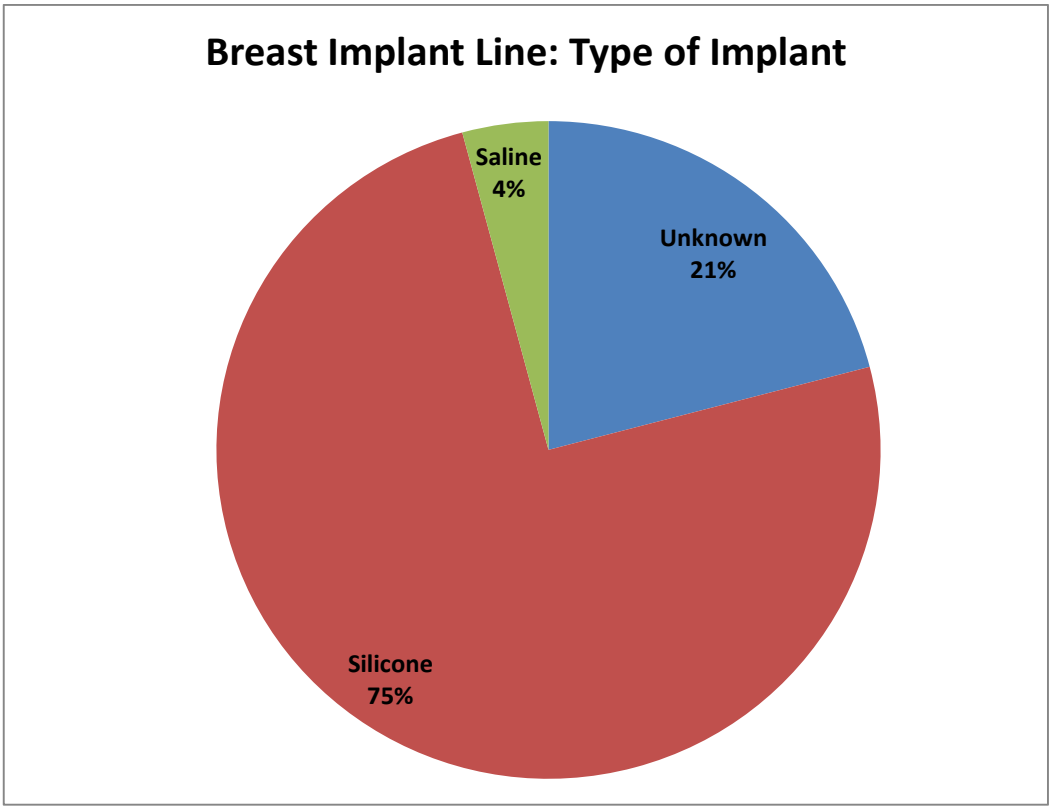
48

[48] Unknown Reason for implant reflects call encounters where the implant reason data was not collected. This scenario predominantly occurred pre-17Jan where Nurses were not asked to collect the data. On 17Jan the Nurses were asked to start collecting this data. Post 17Jan Unknown's were due to the caller not wanting to reveal the reason for the implant.

Data collected from 17 January 2012 (5:00pm onwards). Therefore an extrapolation of the 17Jan onwards data (5pm onwards) was applied to the 7Jan onwards total volumes in order to get a sense of what the big picture could be (shown in the last column).

The pie chart above reflects the Post 17Jan reason for implant percentage.

10. Type of implant



	7Jan onwards		17Jan onwards		
Type of implant	Number of Encounters	% of Total Encounters	Number of Encounters	% of Total Encounters	Extrapolated Number of Encounters (based on 17Jan+ % and 7Jan+ volume)
Unknown	1683	56.8%	315	20.9%	620.0
Silicone	1197	40.4%	1127	74.9%	2218.1
Saline	82	2.8%	63	4.2%	124.0
Total	**2962**		**1505**		**2962**

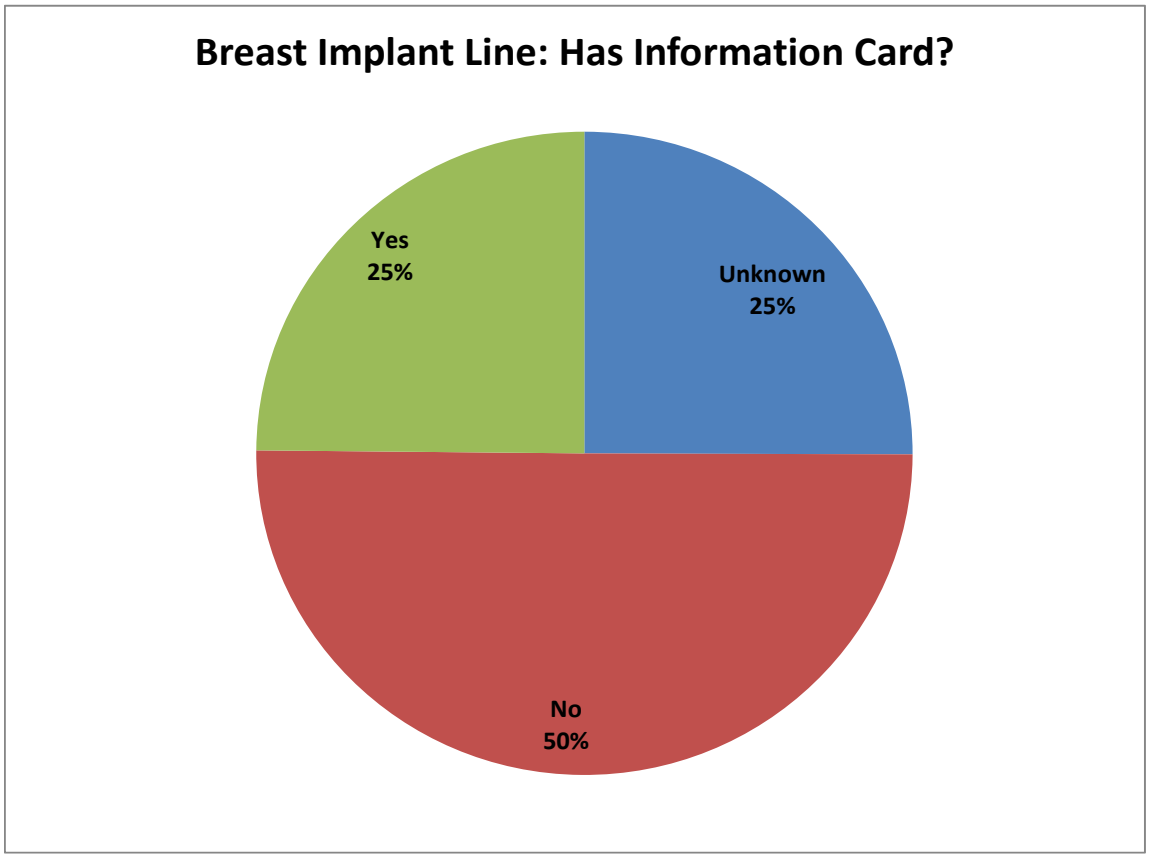
[49]

[49] Unknown Type for implant reflects call encounters where the implant type data was not collected. This scenario predominantly occurred pre-17Jan where Nurses were not asked to collect the data. On 17Jan the Nurses were asked to start collecting this data. Post 17Jan Unknown's were due to the caller not wanting to reveal or not knowing the type of implant.

Data collected as a mandatory field from 17Jan @ 5:00pm, minimal data was pulled from the free text fields (going back to 7 Jan). Therefore an extrapolation of the 17Jan onwards data (5pm onwards) was applied to the 7Jan onwards total volumes in order to get a sense of what the big picture could be (shown in the last column).

The pie chart above reflects the Post 17Jan type of implant percentage.

11. Implant Information Card

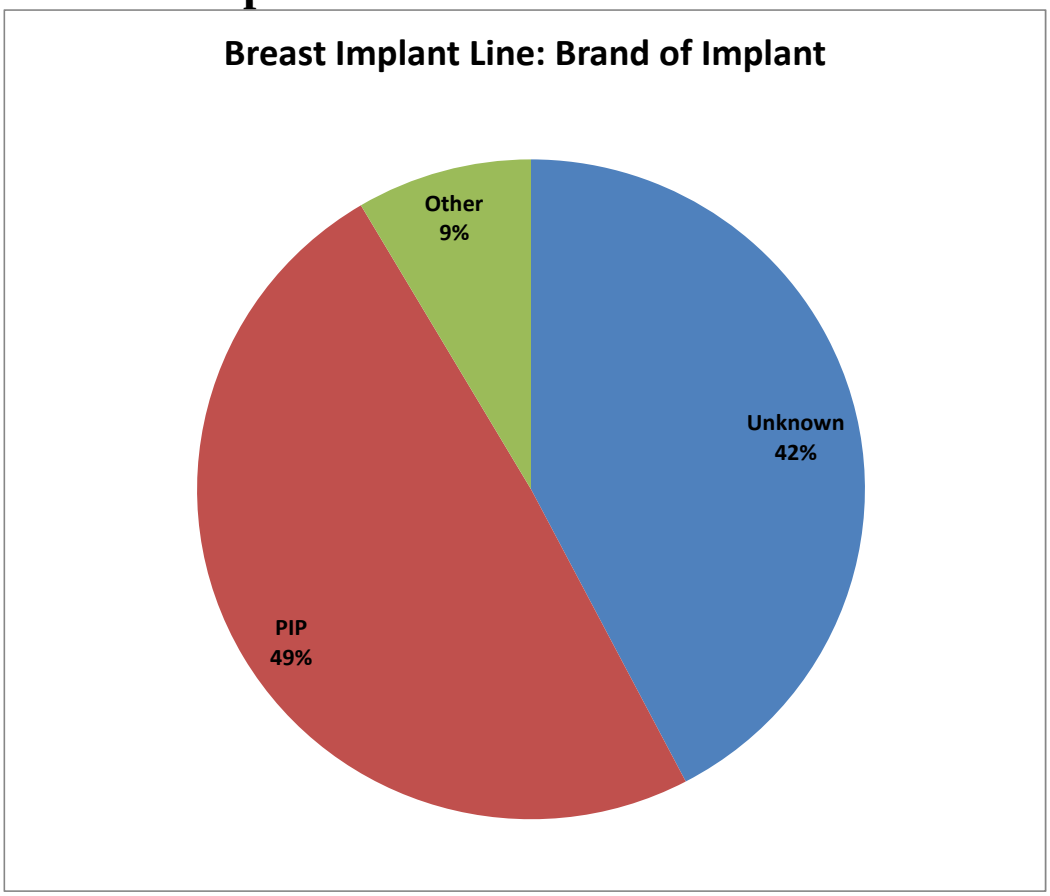


	7Jan onwards		17Jan onwards		
Has information card?	Number of Encounters	% of Total Encounters	Number of Encounters	% of Total Encounters	Extrapolated Number of Encounters (based on 17Jan+ % and 7Jan+ volume)
Unknown	1702	57.5%	377	25.0%	742.0
No	825	27.9%	754	50.1%	1484.0
Yes	435	14.7%	374	24.9%	736.1
Total	**2962**		**1505**		**2962**

[50]

[50] Unknown Has Information Card reflects call encounters where the information card data was not collected. This scenario predominantly occurred pre-17Jan where Nurses were not asked to collect the data. On 17Jan the Nurses were asked to start collecting this data. Post 17Jan Unknown's were due to the caller not wanting to reveal whether they had an information card.

12. Brand of implant



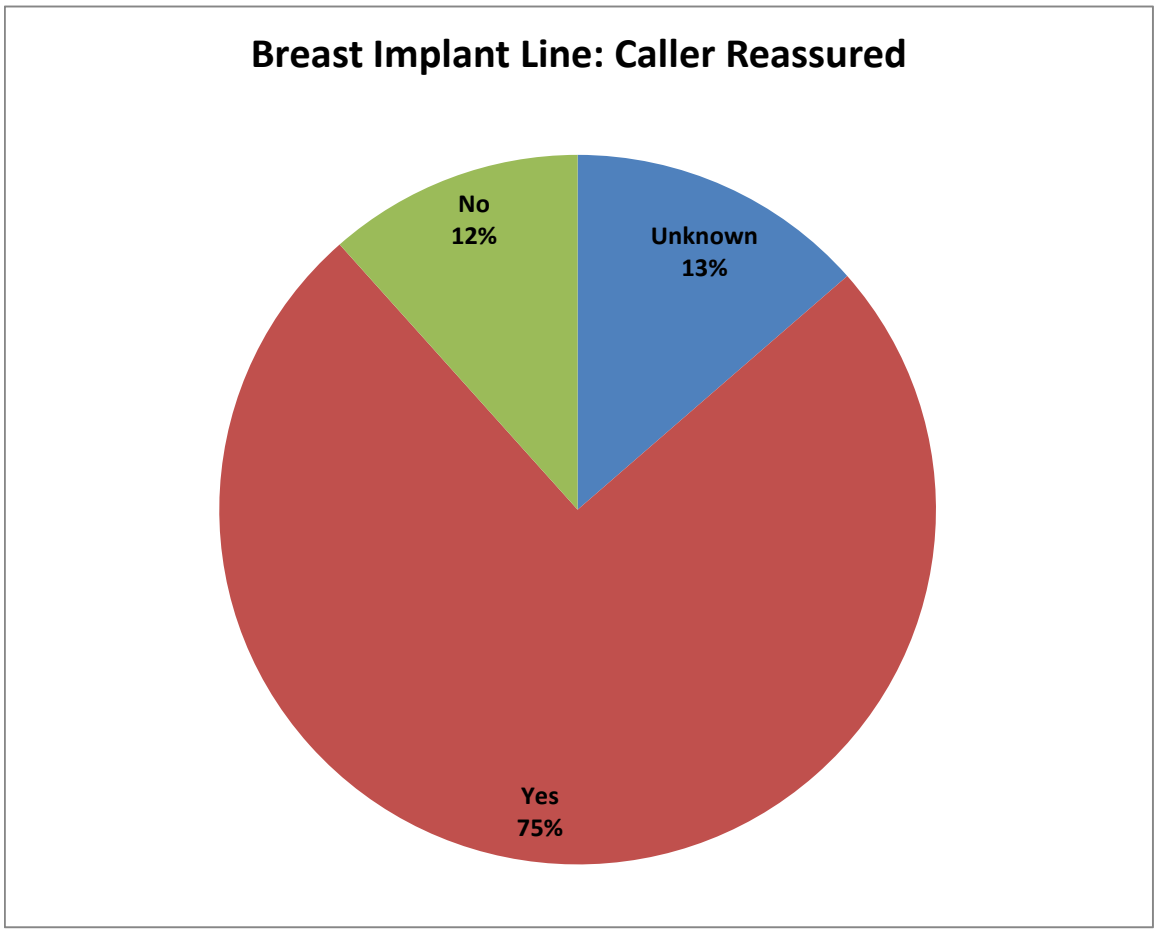
	7Jan onwards		17Jan onwards		
Brand of implant	Number of Encounters	% of Total Encounters	Number of Encounters	% of Total Encounters	Extrapolated Number of Encounters (based on 17Jan+ % and 7Jan+ volume)
Unknown	1838	62.1%	637	42.3%	1253.7
PIP	939	31.7%	740	49.2%	1456.4
Other	140	4.7%	128	8.5%	251.9
Mentor	14	0.5%	0	0.0%	0.0
Allergan	12	0.4%	0	0.0%	0.0
McGhan	5	0.2%	0	0.0%	0.0
Inamed	3	0.1%	0	0.0%	0.0
Eurosilicone	3	0.1%	0	0.0%	0.0
Siltex	3	0.1%	0	0.0%	0.0
Nagor	2	0.1%	0	0.0%	0.0
Device technologies	2	0.1%	0	0.0%	0.0
MLC	1	0.0%	0	0.0%	0.0
Total	**2962**		**1505**		**2962**

[51]

[51] Unknown Brand of implant reflects call encounters where the brand of implant data was not collected. This scenario predominantly occurred pre-17Jan where Nurses were not asked to collect the data. On 17Jan the Nurses were asked to start collecting this data. Post 17Jan Unknown's were due to the caller not wanting to reveal or did not know the brand of implant.

Data collected as a mandatory field from 17Jan @ 5:00pm, minimal data was pulled from the free text fields (going back to 7 Jan). Therefore an extrapolation of the 17Jan onwards data (5pm onwards) was applied to the 7Jan onwards total volumes in order to get a sense of what the big picture could be (shown in the last column).

13. Caller reassured (Nurse Assessment)



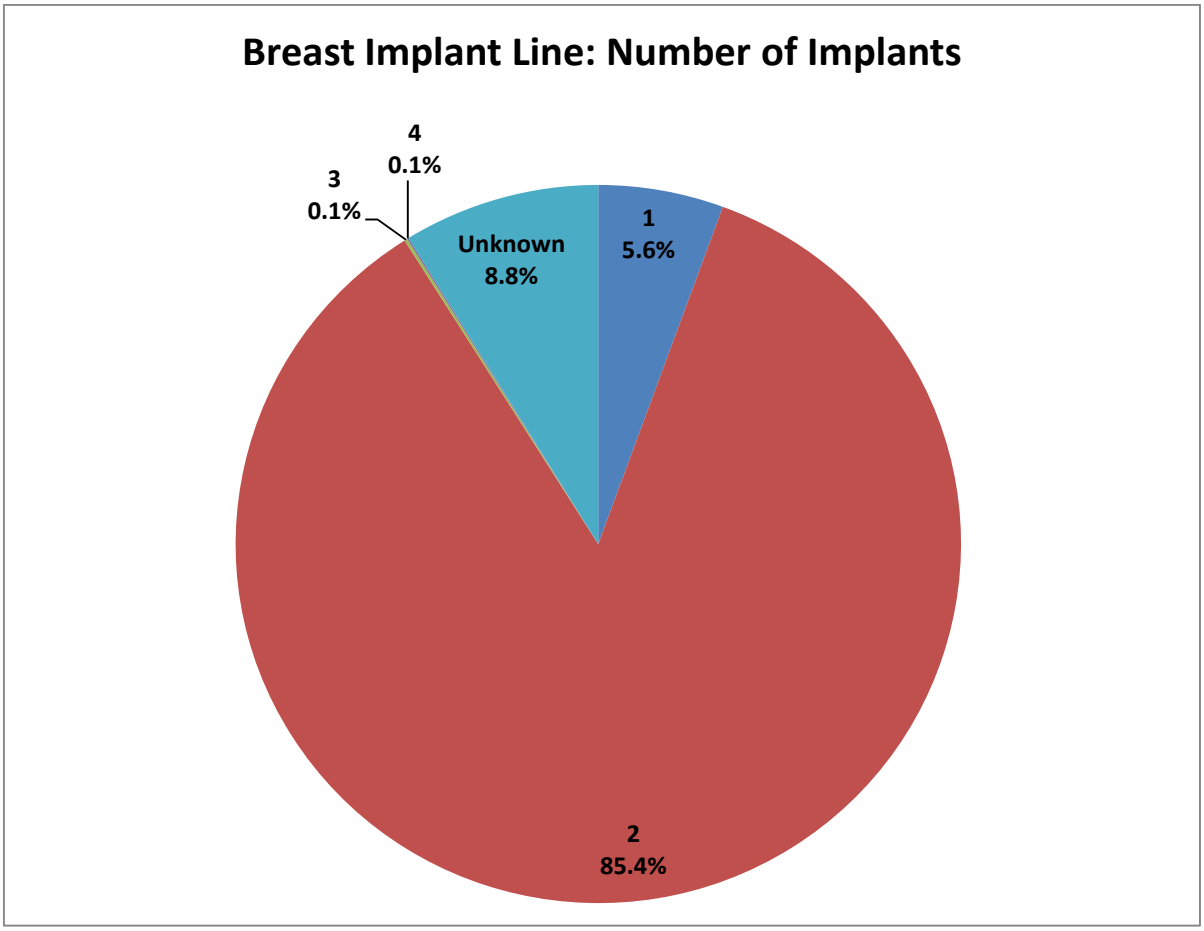
	7Jan onwards		17Jan onwards		
Caller reassured	Number of Encounters	% of Total Encounters	Number of Encounters	% of Total Encounters	Extrapolated Number of Encounters (based on 17Jan+ % and 7Jan+ volume)
Unknown	1661	56.1%	204	13.6%	401.5
Yes	1127	38.0%	1127	74.9%	2218.1
No	174	5.9%	174	11.6%	342.5
Total	**2962**		**1505**		**2962**

[52]

[52] Unknown Caller Reassured reflects call encounters where the caller reassured data was not collected. This scenario predominantly occurred pre-17Jan where Nurses were not asked to collect the data. On 17Jan the Nurses were asked to start collecting this data. Post 17Jan Unknown's were due to the reassurance of the caller not being assessed and captured by the Nurse.

Data collected as a mandatory field from 17Jan @ 5:00pm, minimal data was pulled from the free text fields (going back to 7 Jan). Therefore an extrapolation of the 17Jan onwards data (5pm onwards) was applied to the 7Jan onwards total volumes in order to get a sense of what the big picture could be (shown in the last column).

14. Number of implants



	7Jan onwards		17Jan onwards		
Number of implants	Number of Encounters	% of Total Encounters	Number of Encounters	% of Total Encounters	Extrapolated Number of Encounters (based on 17Jan+ % and 7Jan+ volume)
1	84	2.8%	84	5.6%	165.3
2	1286	43.4%	1286	85.4%	2531.0
3	2	0.1%	2	0.1%	3.9
4	1	0.0%	1	0.1%	2.0
Unknown	1589	53.6%	132	8.8%	259.8
Total	**2962**		**1505**		**2962**

[53]

[53] Unknown Number of Implants reflects call encounters where the data was not collected. This scenario predominantly occurred pre-17Jan where Nurses were not asked to collect the data. On 17Jan the Nurses were asked to start collecting this data. Post 17Jan Unknown's were due to the caller not wanting to reveal how many implants they have or had.

Data collected as a mandatory field from 17Jan @ 5:00pm. Therefore an extrapolation of the 17Jan onwards data (5pm onwards) was applied to the 7Jan onwards total volumes in order to get a sense of what the big picture could be (shown in the last column).

15. Top 8 Themes

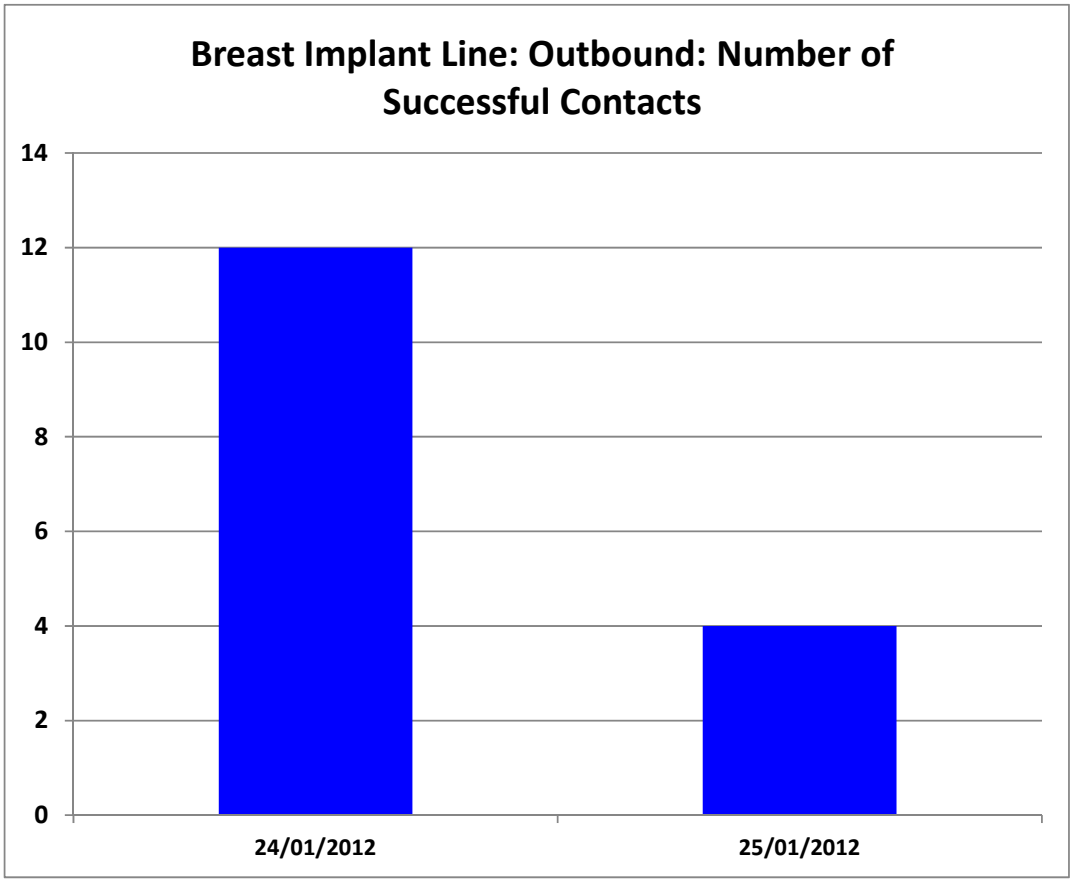
Here are the eight most common themes that the Breast Implant Information Line has been experiencing:

1. Many callers were calling as they were unsure of the brand of their implant.
2. Many callers were calling to register their details with us.
3. Many callers were calling to clarify conflicting information that they heard.
4. Many callers were asking if they need to have their implants removed.
5. Many callers were asking what they should do next.
6. Some callers were querying whether Medicare would cover any required treatment.
7. Some callers were querying compensation.
8. Some callers were querying what symptoms they should be looking out for.

16. Outbound Calls

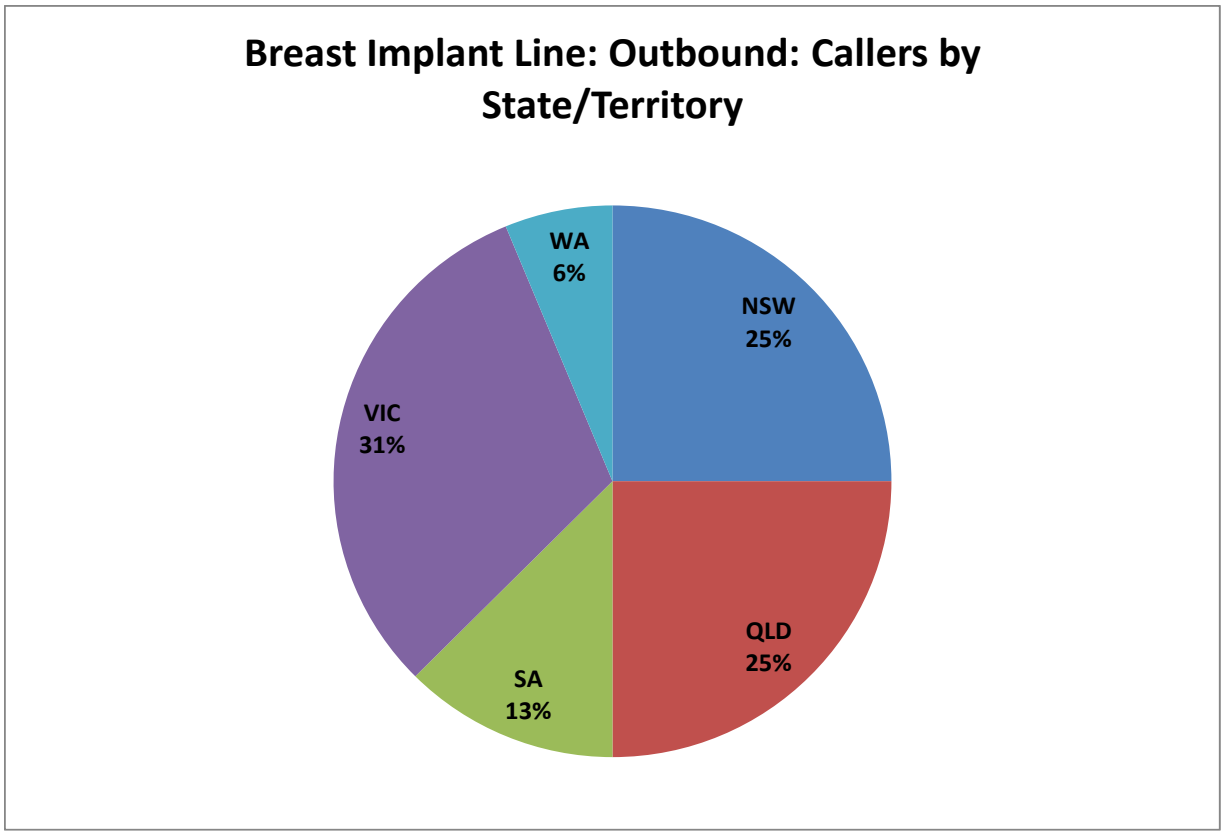
On 24 and 25 January 2012, an outbound component to the service was implemented. Attempts were made to contact 23 callers who had indicated that their implants had been inserted in pre-1999. Contacts to 16 callers were successful, while contacts to 7 callers were unsuccessful after a minimum of 3 attempts over the two days at different times. All but one of the successful call recipients were breast implantees.

16.1 Outbound Calls: Number of successful contacts



Date	Number of Encounters
24/01/2012	12
25/01/2012	4
Total	**16**

16.2 Outbound Calls: Number of Outbound calls by date, State/Territory

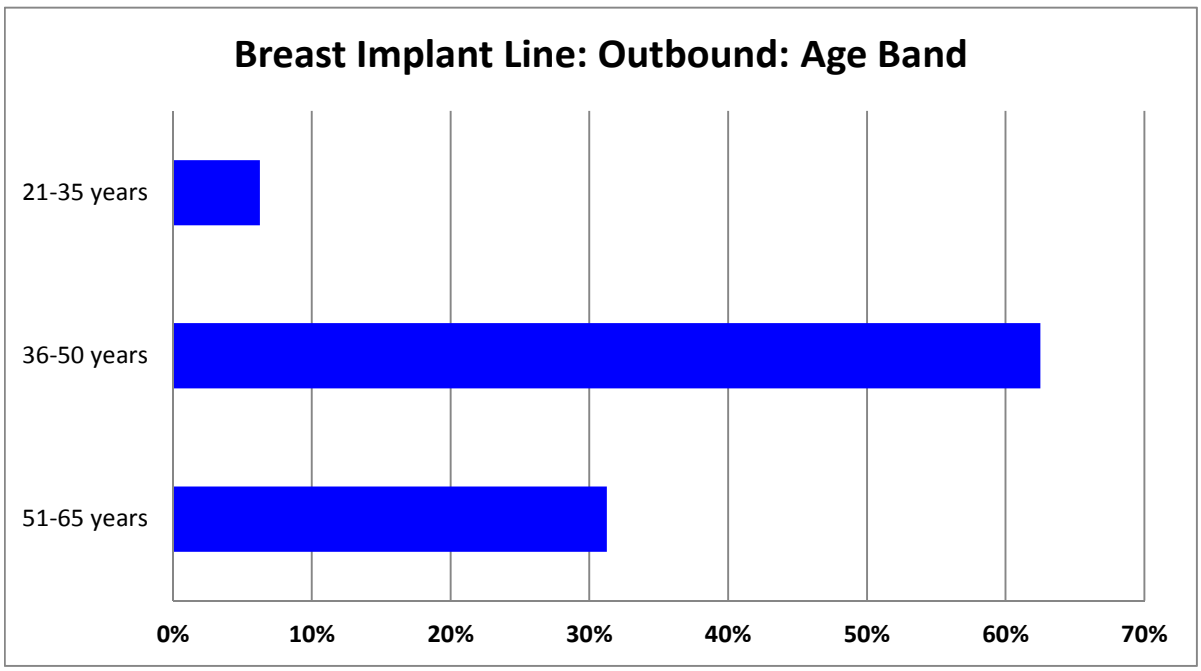


Date	NSW	QLD	SA	VIC	WA	Total
24/01/2012	2	4	2	3	1	12
25/01/2012	2	0	0	2	0	4
Total	**4**	**4**	**2**	**5**	**1**	**16**

16.3 Outbound Calls: Postcodes of call recipients

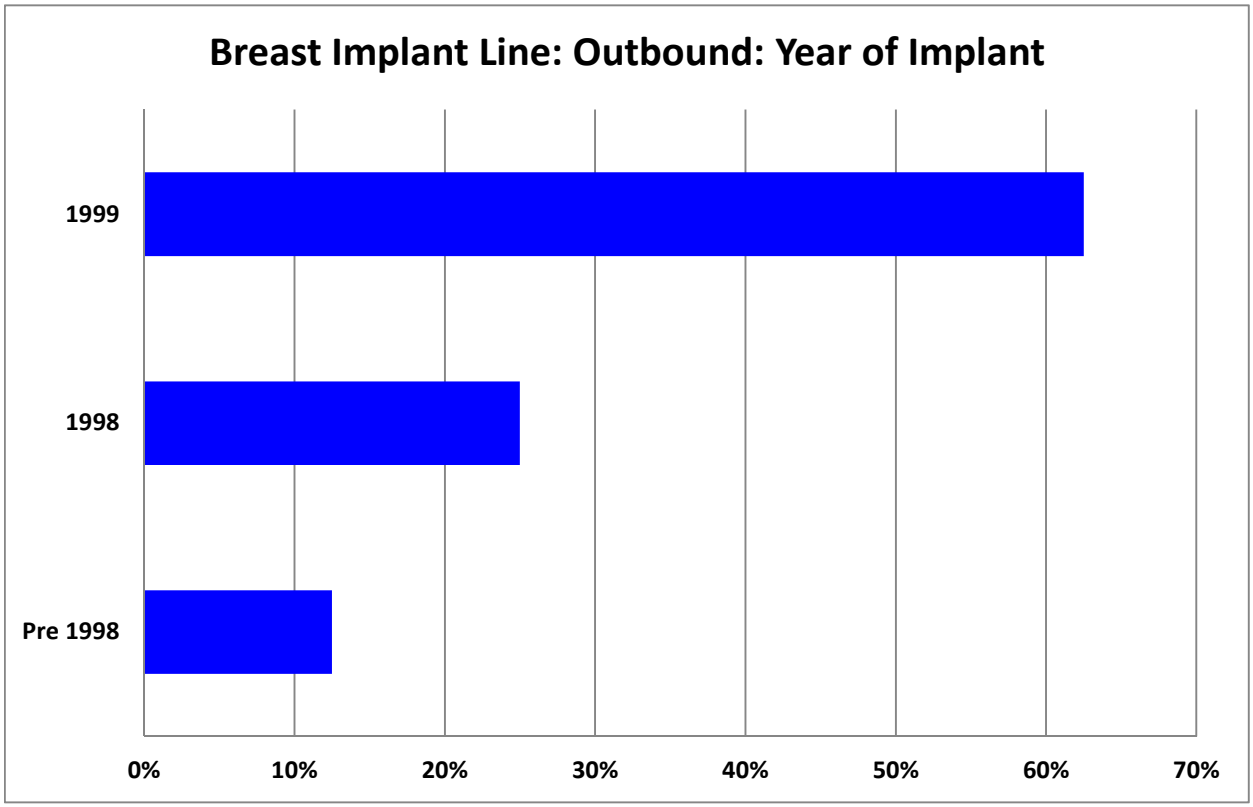
Postcode	Number of Encounters	% of Total Encounters
2115	1	6.3%
2230	1	6.3%
2250	1	6.3%
2428	1	6.3%
3141	1	6.3%
3142	1	6.3%
3165	1	6.3%
3187	1	6.3%
3201	1	6.3%
4074	1	6.3%
4216	1	6.3%
4570	1	6.3%
4876	1	6.3%
5023	1	6.3%
5244	1	6.3%
6112	1	6.3%
Total	**16**	

16.4 Outbound Calls: Age of call recipient



Age Band	Number of Encounters	% of Total Encounters
21-35 years	1	6.3%
36-50 years	10	62.5%
51-65 years	5	31.3%
Total	**16**	

16.5 Outbound Calls: Year of implant

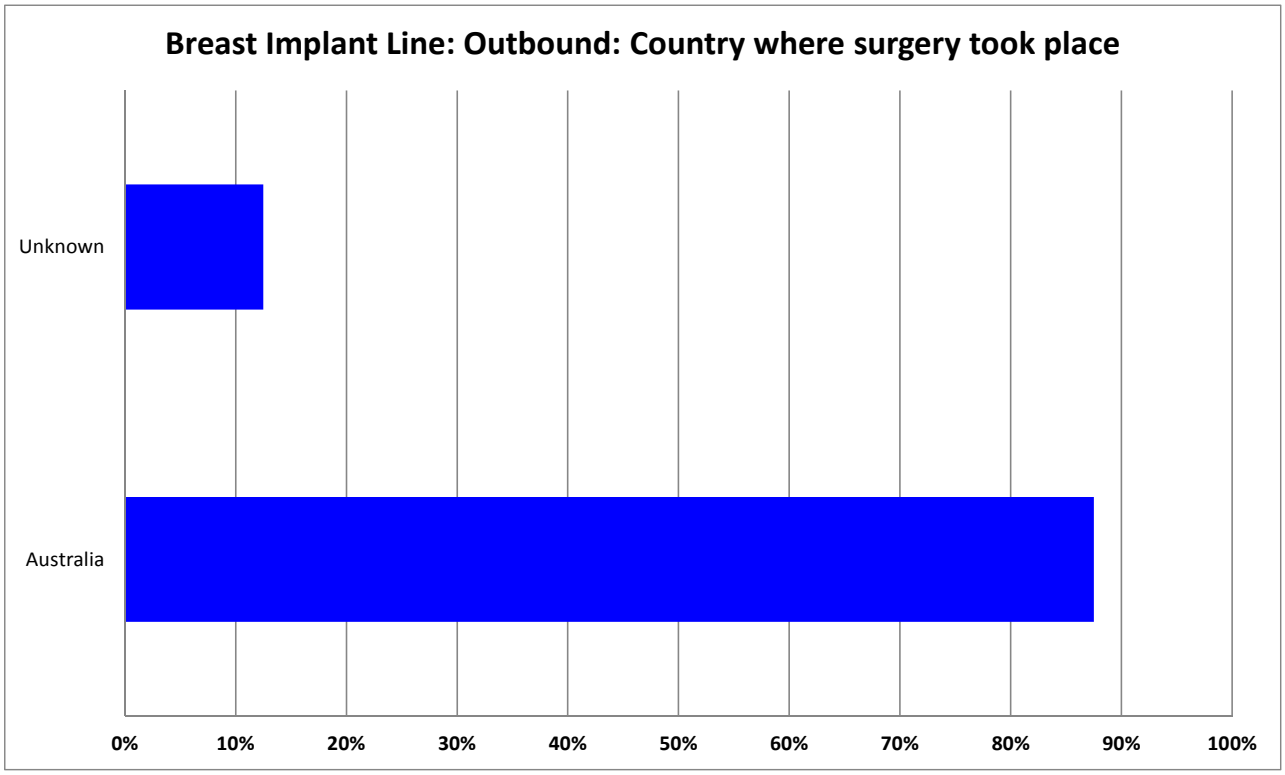


Year	Number of Encounters	% of Total Encounters
Pre 1998	2	12.5%
1998	4	25.0%
1999	10	62.5%
Total	**16**	

[54]

[54] Unknown Year of implant reflects call encounters where the caller did not want to reveal or did not know when the breast implant was inserted.

16.6 Outbound Calls: Country where surgery took place

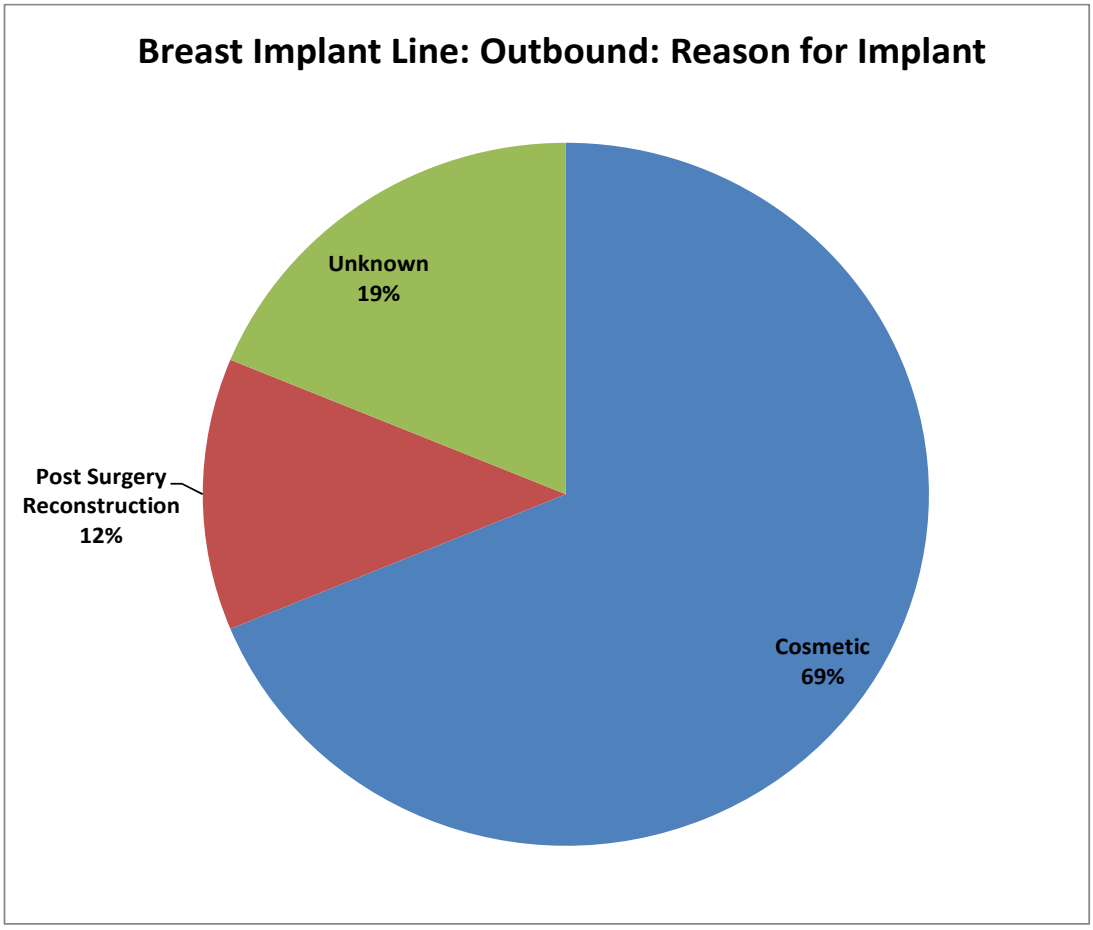


Country	Number of Encounters	% of Total Encounters
Australia	14	87.5%
Unknown	2	12.5%
Total	**16**	

[55]

[55] Unknown Country reflects call encounters where the country data was not collected.

16.7 Outbound Calls: Reason for implant

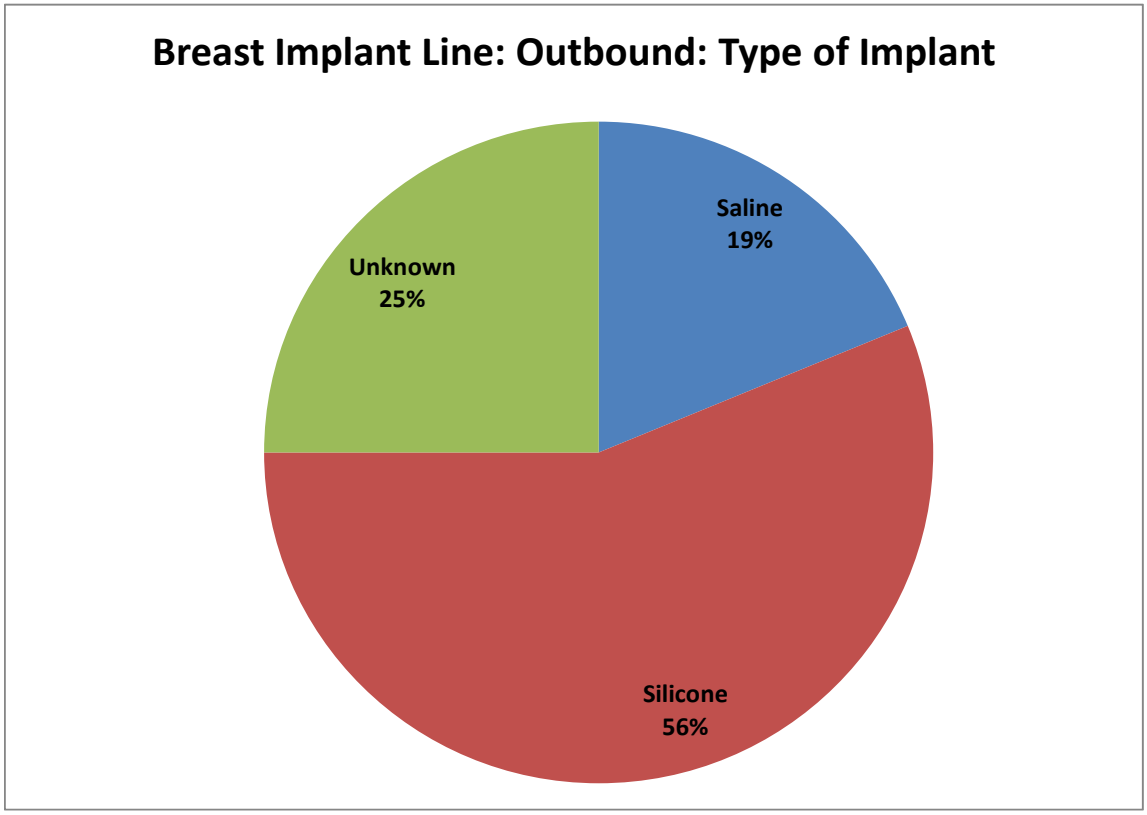


Reason for implant	Number of Encounters	% of Total Encounters
Cosmetic	11	68.8%
Post Surgery Reconstruction	2	12.5%
Unknown	3	18.8%
Total	**16**	

[56]

[56] Reason for implant reflects call encounters where the implant reason data was not collected.

16.8 Outbound Calls: Type of implant

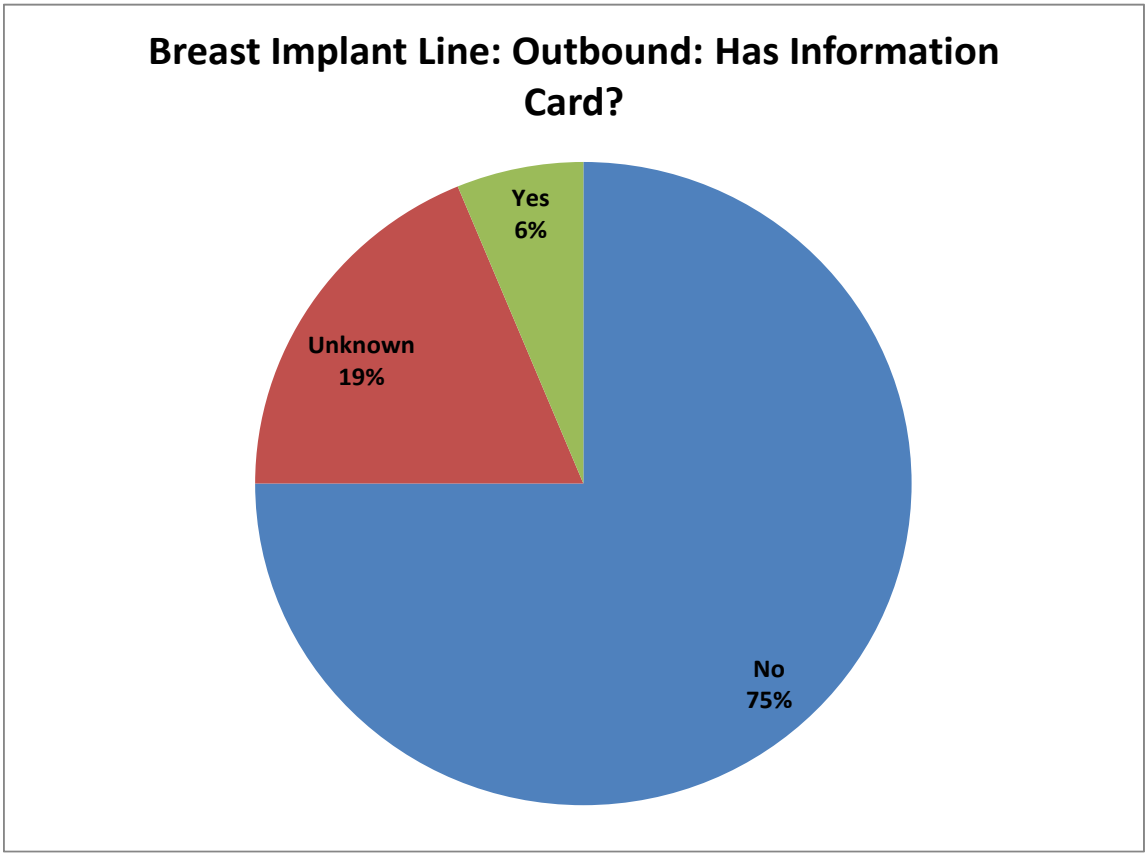


Type of implant	Number of Encounters	% of Total Encounters
Saline	3	18.8%
Silicone	9	56.3%
Unknown	4	25.0%
Total	**16**	

[57]

[57] Unknown Type for implant reflects call encounters where the implant type data was not collected or where the caller was not too sure.

16.9 Outbound Calls: Implant Information Card

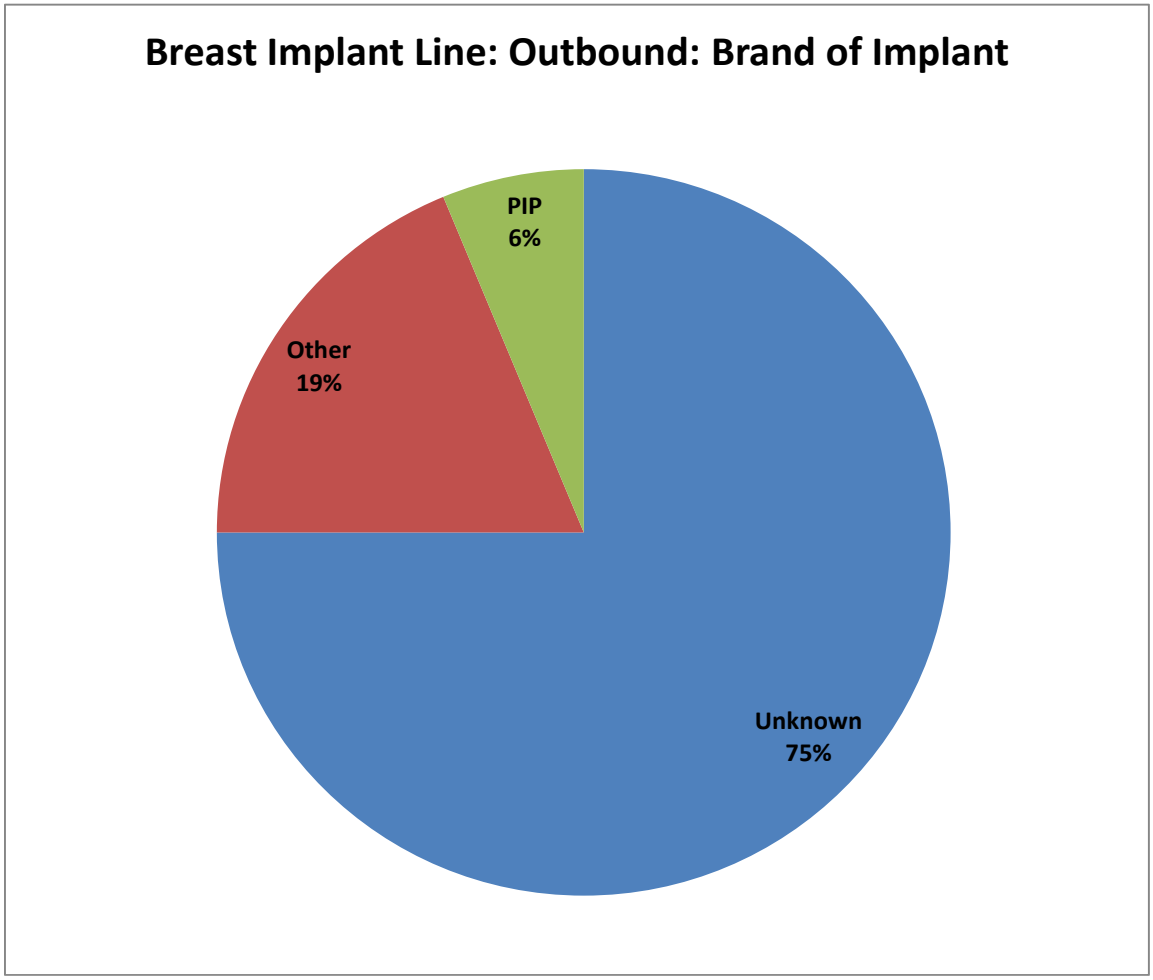


Has information card?	Number of Encounters	% of Total Encounters
No	12	75.0%
Unknown	3	18.8%
Yes	1	6.3%
Total	**16**	

[58]

[58] Unknown Has Information Card reflects call encounters where the information card data was not collected. This scenario occurs where the caller did not want to reveal whether they had an information card

16.10 Outbound Calls: Brand of implant

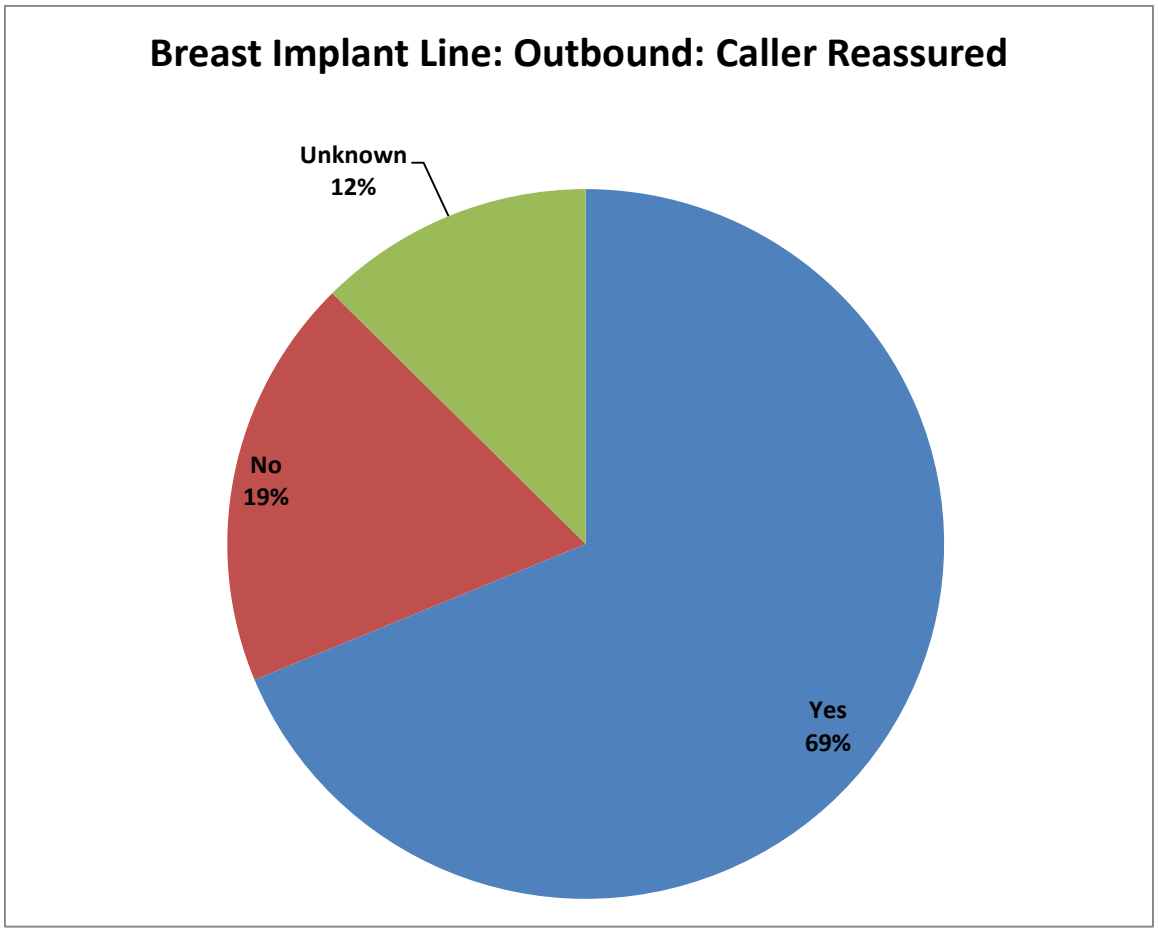


Brand of implant	Number of Encounters	% of Total Encounters
Unknown	12	75.0%
Other	3	18.8%
PIP	1	6.3%
Total	**16**	

[59]

[59] Unknown Brand of implant reflects call encounters where the brand of implant data was not collected. This scenario occurs where the caller did not want to reveal or did not know the brand of implant

16.11 Outbound Calls: Caller reassured (Nurse Assessment)

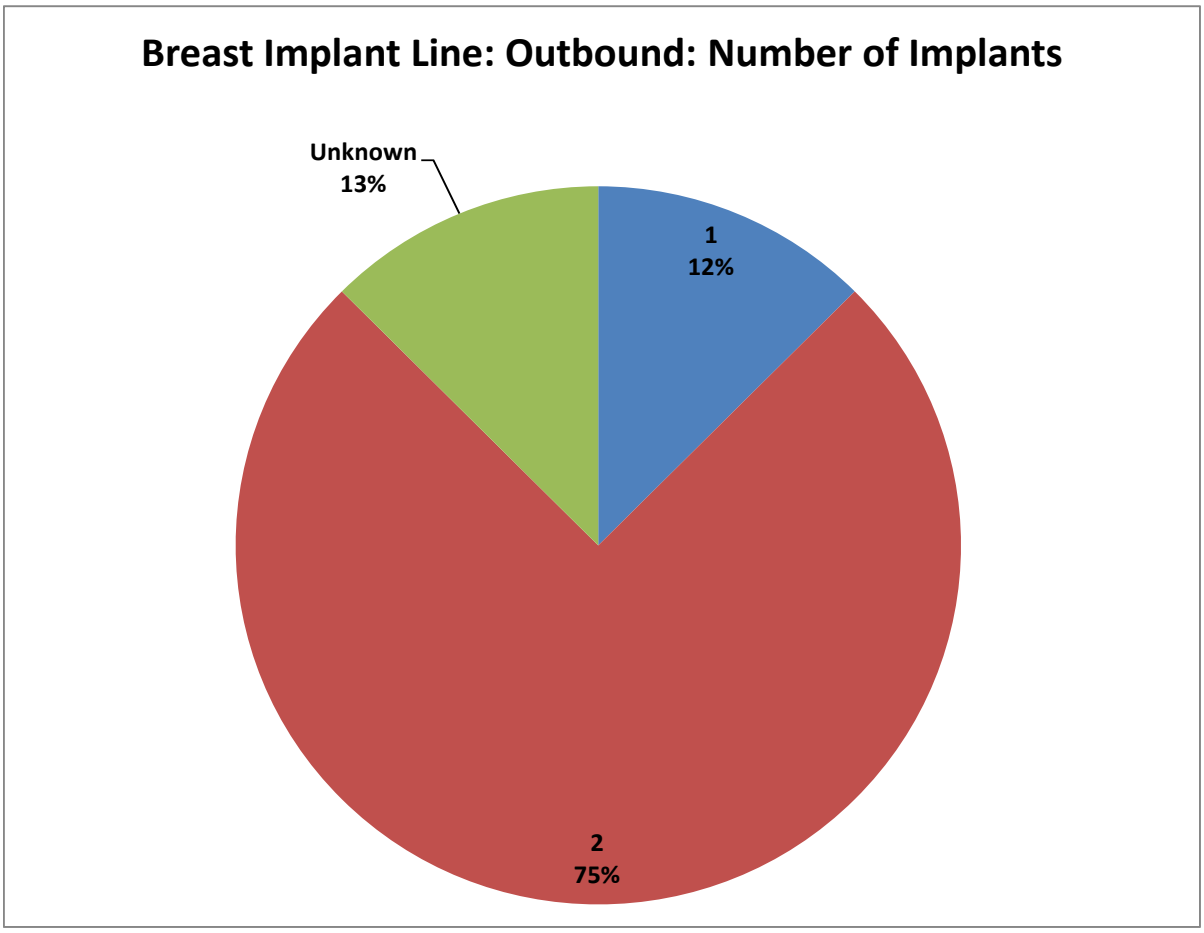


Caller reassured	Number of Encounters	% of Total Encounters
Yes	11	68.8%
No	3	18.8%
Unknown	2	12.5%
Total	**16**	

[60]

[60] Unknown Caller Reassured reflects call encounters where the caller reassured data was not collected. This scenario occurs where the reassurance of the caller was not assessed and captured by the Nurse.

16.12 Outbound Calls: Number of implants

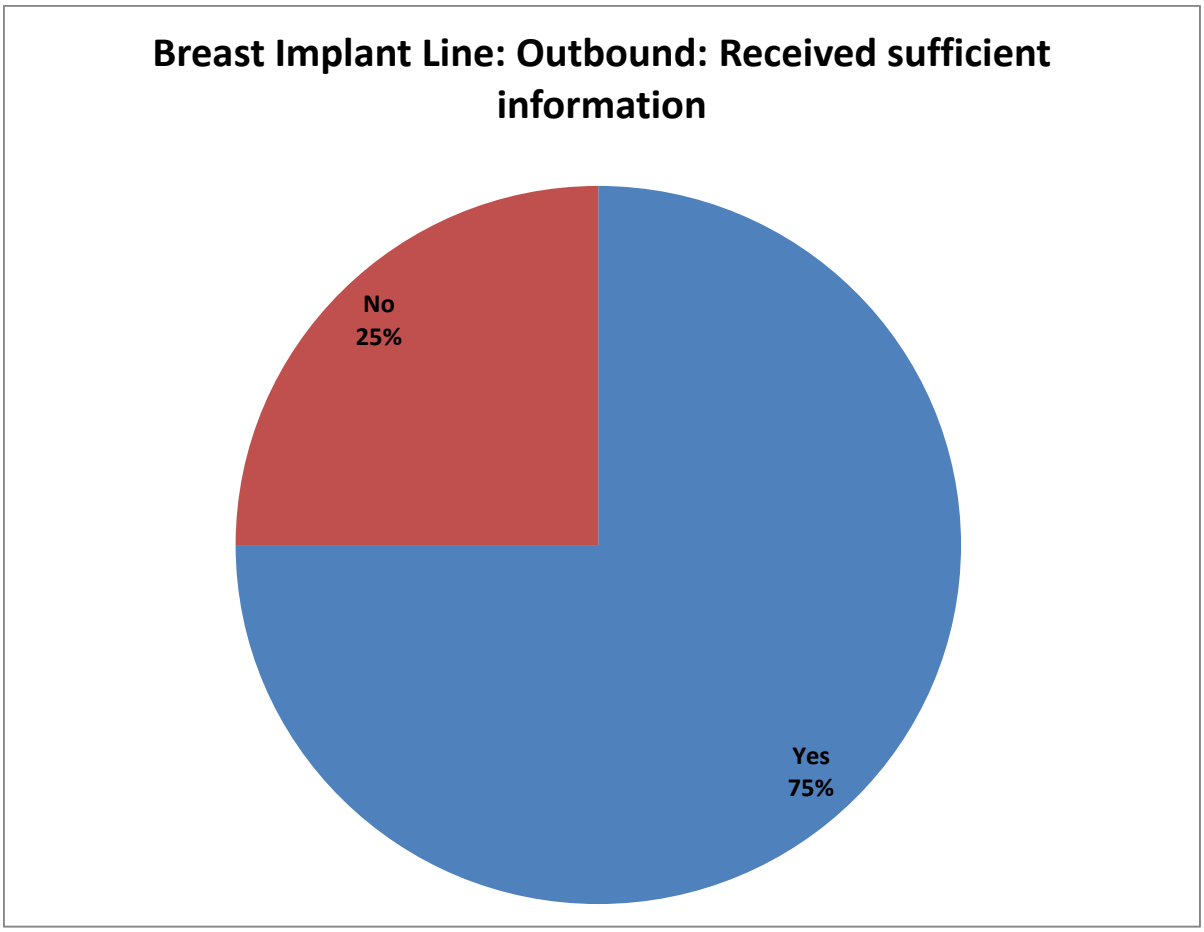


Number of implants	Number of Encounters	% of Total Encounters
1	2	12.5%
2	12	75.0%
Unknown	2	12.5%
Total	**16**	

[61]

[61] Unknown Number of Implants reflects call encounters where the caller did not want to reveal how many implants they had.

16.13 Outbound Calls: Caller received sufficient information



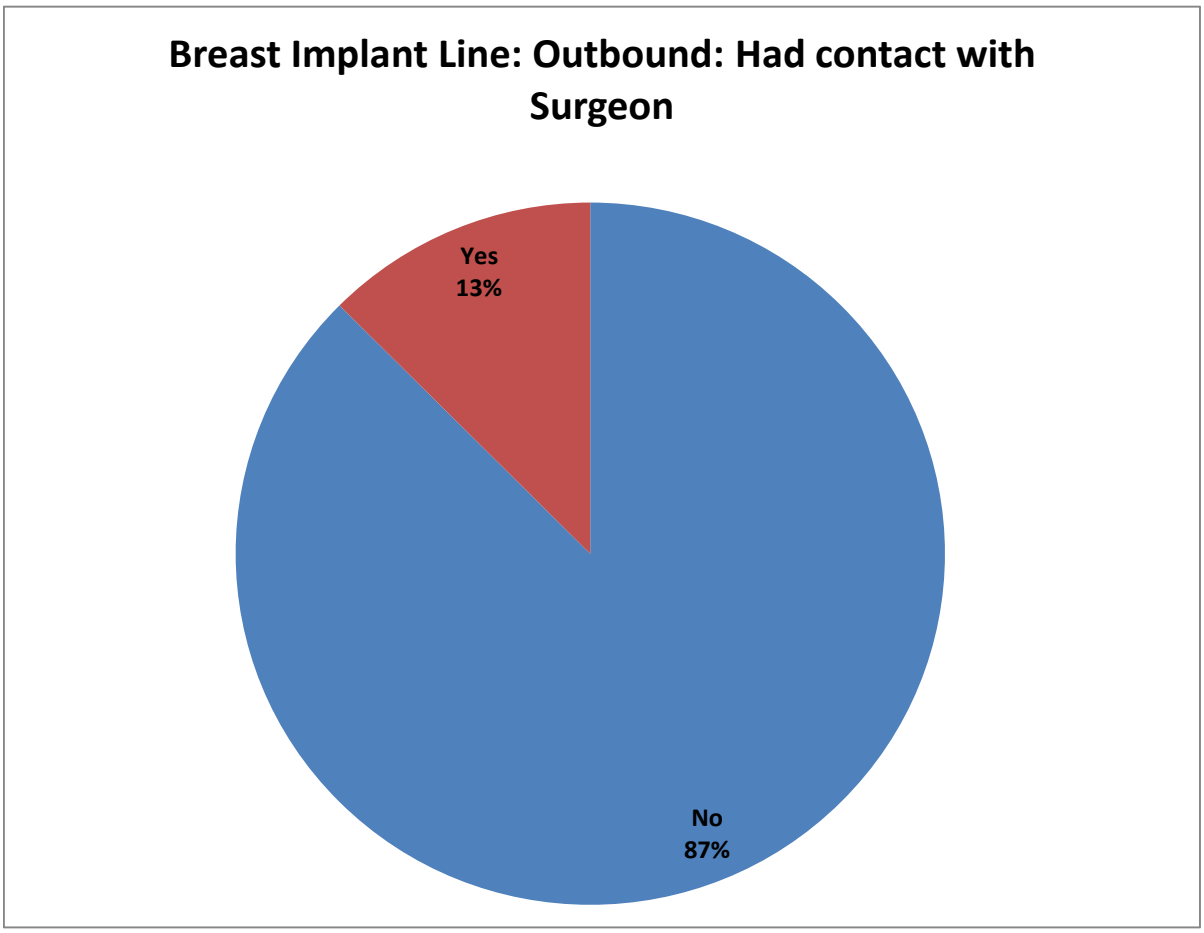
Received sufficient information	Number of Encounters	% of Total Encounters
Yes	12	75.0%
No	4	25.0%
Total	**16**	

Of the 4 callers that did not think they had received enough information, the responses are listed below.

What further information is still required	Number of Encounters	% of Total Encounters
cost of removal and replacement	3	75.0%
not stated	1	25.0%
Total	**4**	

16.14 Outbound Calls: had contact with Surgeon

The callers were asked whether they had contact with their Surgeon since the last time they called the Breast Implant Information Line.



Had contact with surgeon	Number of Encounters	% of Total Encounters
No	14	87.5%
Yes	2	12.5%
Total	**16**	

[62]

[62] Unknown Contact with Surgeon reflects call encounters where the data was not collected.

Abbreviations

ACCS	Australasian College of Cosmetic Surgeons
ACSMD	Advisory Committee on the Safety of Medical Devices
AFSSAPS	Agence française de sécurité sanitaire des produits de santé
AIMD	Active Implantable Medical Devices
ALCL	Anaplastic Large Cell Lymphoma
ARGMD	Australian Regulatory Guidelines for Medical Devices
ACSOM	Advisory Committee on Safety of Medicines
ARTG	Australian Register of Therapeutic Goods
ASPS	Australian Society of Plastic Surgeons
CAB	Conformity Assessment Body
CAC	Clinical Advisory Committee
CHO	Chief Health Officers of states and territories
CMO	Chief Medical Officer
DoHA	Department of Health and Ageing
EC	European Commission
FDA	Food and Drug Administration
FTIR	Fourier transform infrared spectroscopy
GC-MS	Gas chromatography-mass spectrometry
GHTF	Global Harmonisation Task Force
GP	General Practitioner
GPC	Gel permeation chromatography
ICP-MS	Inductively coupled plasma mass spectrometry
ISO	International Organization for Standardization
ITPP	International Testing Panel for PIP breast implants
IVD	In vitro diagnostic
MBS	Medical Benefits Schedule
MDEC	Medical Devices Evaluation Committee
MDIRC	Medical Devices Incident Review Committee
MHRA	Medicines and Healthcare products Regulatory Agency
MRI	Magnetic Resonance Imaging
NCAR	National Competent Authority Report
NHCCN	National Health Call Centre Network Ltd
PIP	Poly Implant Prothese
PMS	Precise Medical Supplies
QMS	Quality Management Scheme
RACS	Royal College of Surgeons
SAS	Special Access Scheme
TGA	Therapeutic Goods Administration
TGA	Thermogravimetric analysis
UPI	Unique Product Identifier
URPTG	Uniform Recall Procedure for Therapeutic Goods