DUTCH BREAST IMPLANT REGISTRY (DBIR) ANNUAL REPORT 2018

DBIR

DUTCH BREAST IMPLANT REGISTRY

DICA
DUTCH INSTITUTE FOR CLINICAL AUDITING

NVPC
Nederlandse Vereniging voor Plastische Chirurgie
handchirurgie, reconstructieve en esthetische chirurgie

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CONTENTS

1. FOREWORD

Dear reader,

Hereby we present to you the second annual report from the DBIR.

We are proud and thankful to all plastic surgeons who endorse us on a daily basis and are actively registering all the cases in which breast implants and tissue expanders are used.

While on the one hand, a survey amongst our users has shown that all plastic surgeons in the Netherlands find the DBIR of vital importance to monitor and improve quality of breast implant surgery, on the other hand, the administrative burden was shown to be significant. This burden needs to be reduced.

Today this reduction in administrative burden is of vital importance and many strategies are being explored including bar code technologies, uploads from electronic patient files, and development of a national breast implant catalogue where, after entering vendor and catalogue number, all implant specific data are filled in automatically.

Besides facing challenges, we should also be proud of our accomplishments thus far. The number of registered implants, the completeness of our data, and the number of surgeons and clinics that are actively registering are inspiring. We are one of the world's leaders in the field of breast implant registries. Our data are shared with all our close friends by using the International Collaboration of Breast Registry Activities (ICOBRA) as a connecting organization. From this, our annual report is aligned with the reports of Sweden, the United Kingdom, and Australia. We are designing standard output to be able to compare our registries without sharing the actual datasets. This is the first step towards pooled outcomes, which exponentially adds value to our registries for all our patients around the world.

Let's keep our work growing in quality to improve the quality and safety of breast implant surgery for our patients. Let's keep on reducing our administrative burdens to a minimum.

Best regards,
On behalf of the DBIR Clinical Audit Board & DBIR Scientific Committee,

Hinne Rakhorst
Chair DBIR committee

H.A. Rakhorst MD PhD
M.A.M. Mureau MD PhD
J.E. Hommes MD PhD
X.H.A. Keuter MD PhD
M.J. Hoornweg MD PhD
P.L.T. Liem MSc
D.A. Young-Afat MD PhD
A.C.M. van Bommel MD
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2. REGISTRY PERSONNEL

The clinical content of DBIR is managed by a delegation of plastic surgeons from the Netherlands Society of Plastic Surgery, subdivided in a Clinical Audit Board and a Scientific Committee. Daily management of the registry is facilitated and administered by DICA, the Dutch Institute for Clinical Auditing.

DBIR Clinical Audit Board (as at November 2019)

- Mr. H.A. Rakhorst MD PhD, chairman, plastic surgeon at Medisch Spectrum Twente, Enschede & Ziekenhuis Groep Twente, Almelo.
- Mr. M.A.M. Mureau MD PhD, vice-chairman, plastic surgeon at Erasmus MC, University Medical Center Rotterdam, Rotterdam.
- Ms. J.E. Hommes MD PhD, secretary, plastic surgery resident, Maastricht University Medical Center +, Maastricht.

DBIR Scientific Committee (as at November 2019)

- Mr. H.A. Rakhorst MD PhD, chairman, plastic surgeon at Medisch Spectrum Twente, Enschede & Ziekenhuis Groep Twente, Almelo.
- Mr. M.A.M. Mureau MD PhD, vice-chairman, plastic surgeon at Erasmus MC, University Medical Center Rotterdam, Rotterdam.
- Ms. J.E. Hommes MD PhD, secretary, plastic surgery resident at Maastricht University Medical Center +, Maastricht.
- Ms. B.E. Becherer MD, Medical researcher at Dutch Institute for Clinical Auditing, Leiden & PhD candidate at Erasmus MC, University Medical Center Rotterdam, Rotterdam.
- Ms. M.J. Hoornweg MD PhD, plastic surgeon at Antoni van Leeuwenhoek hospital, Amsterdam.
- Mr. X.H.A. Keuter MD PhD, plastic surgeon at Viecuri, Venlo & Maastricht University Medical Center +, Maastricht.
- Ms. P.L.T. Liem MSc, director of the Netherlands Society of Plastic Surgery, Utrecht.
- Mr. D.A. Young-Afat MD PhD, plastic surgery resident at VU Medical Center, Amsterdam.
- Ms. A.C.M. van Bommel MD, plastic surgery resident at University Medical Center Utrecht, Utrecht.

Former members

- Mr. M. Cromheecke MD PhD, plastic Surgeon at Zipper Clinics, Apeldoorn, Enschede, Zwolle.
- Mr. Prof. R.R.J.W. van der Hulst MD PhD, plastic surgeon at Maastricht University Medical Center +, Maastricht.
- Ms. Prof. I.M.J. Mathijssen MD PhD, plastic surgeon at Erasmus MC, University Medical Center Rotterdam, Rotterdam.
- Ms. L. Moojen-Zaal MD PhD, plastic surgeon at Velthuiskliniek, Hilversum.
- Ms. P.E.R. Spronk MD PhD, general surgery resident at Alrijne Ziekenhuis, Leiderdorp.

3. HIGHLIGHTS 2018

- *In 2017, 96% of the hospitals and 69% of the private clinics eligible for breast implant surgery participated in DBIR. (**chapter 4**)*

- *On the website www.impantaatcheck.nl, patients can check whether their breast implant has been registered in DBIR and if it has been subject to a recall or not. (**chapter 4**)*

- *In 2018, approximately 3,000 unique patients were registered in DBIR to have received one or two breast device(s) for a reconstructive indication. This accounts for approximately 3,500 procedures and 4,500 devices. More than 6,300 unique patients received one or two breast device(s) for an aesthetic indication, which accounts for approximately 6,500 procedures and 12,500 devices. (**chapter 6**)*

- *Of the ±7,500 permanent breast implants and ±5,500 tissue expanders, which have been inserted for reconstructive indications (and could be traced over time since April 2015), 4% and 3%, respectively, have been revised (unplanned) within 12 months. (**chapter 6**)*

- *Of the ±38,000 permanent implants and ±90 tissue expanders, which have been inserted for an aesthetic indication (and could be traced over time since April 2015), 1% and 6%, respectively, have been revised (unplanned) within 12 months. (**chapter 6**)*

- *The average nationwide result of the quality indicator "Completely registered device records per health care institution" appeared to be high, namely 93%. (**chapter 7**)*

- *Since the summer of 2019, clinicians are provided with a new, interactive dashboard at which users can zoom in on specific patient populations, used breast devices, or applied surgical techniques when they look at their own results of performed implant surgery. (**chapter 9**)*

- *The numbers presented in this report will also be used for an upcoming ICOBRA-annual report. (**chapter 9**)*

4. BACKGROUND

Rationale for the registry

Since April 2015, the Dutch Breast Implant Registry (DBIR) has registered characteristics of patients, surgical procedures, and breast implants to monitor, benchmark, and improve the quality of breast implant surgery in the Netherlands. In addition, it can be used as a track and trace system for recall purposes.

Healthcare providers can gain insight into their quality of care and complications by anonymously comparing results of their clinic to other centers in the Netherlands (i.e., benchmarking). In this way, the provided care can be evaluated, and points of improvement identified. Every year a selection of quality indicators is published on the Transparency Calendar, making this information publicly available (**Chapter 7**). Additionally, participants of the registry can also use data from the registry for scientific research (www.dica.nl/dbir/onderzoek).

Governance

The DBIR was developed by commission of the Netherlands Society of Plastic Surgery (NVPC). A delegation of the NVPC, which is split into a Clinical Audit Board and a Scientific Committee, manages the content of the registry and safeguards the quality of the analyses and the interpretation of data.

The daily management of the registry is facilitated by the Dutch Institute for Clinical Auditing (DICA). DICA is an independent institution founded in 2009. DICA manages and supports clinical outcome registries in the Netherlands, aiming at quality improvement, transparency, and cost savings in health care. The DBIR is financially covered by a fixed fee per implant (EUR 25). This fee is paid either by the national health insurance (ZN) for patients receiving reconstructive breast implant surgery, or by private clinics in case of a cosmetic breast augmentation.

Patients are involved

Patients can check whether their doctor has registered their breast implant(s) in DBIR. On the website www.implantaatcheck.nl, patients may enter the unique combination of the manufacturer name and the serial number of their implant. Subsequently, the website provides information on the registration status of the device. Additionally, the website serves as an information tool for patients during an implant recall, stating whether the breast implant is involved in the recall or not.

Registry participation

DBIR is a national, prospective, opt-out registry, with mandatory registration for all board-certified plastic surgeons in the Netherlands. In contrast to other countries, only board-certified plastic surgeons are allowed to perform breast implant surgery in the Netherland. Breast implant surgery is performed in either a hospital or private clinic.

For the first full registration year (2016), the nationwide coverage of participating institutions was 89% (95% of the hospitals, 78% of the private clinics) relative to the eligible number of institutions known by the Dutch Health and Youth Care Inspectorate (IGJ). For 2017, the nationwide coverage was 88% (96% of the hospitals, 69% of the private clinics) (**Figure 1**). The IGJ has not yet released the numbers of 2018. Besides initiatives to increase the national participation rate, another future step is to evaluate the completeness and quality of the data being entered by all participating institutions (**chapter 9**).

Figure 1. *Coverage of DBIR in the Netherlands (2017)*

** ziekenhuizen = hospitals, zelfstandige klinieken = private clinics*

Methodology

The dataset of the DBIR is based on a core dataset developed by the International Collaboration of Breast Registry Activities (ICOBRA). All patients undergoing implantation or explantation of a breast implant (including tissue expanders) are eligible for inclusion in DBIR. Health care institutions may register their data using an online portal (Survey) or via automated batches from electronic patient records. A methodological council, consisting of statisticians, epidemiologists, doctors, and data scientists, develops and secures the statistical methods used for analyses. To remain up to date, the quality registries of DICA undergo yearly updates, including removal, adjustments, or modification of the data points.

Privacy

A certified Trusted Third Party (MRDM), appointed by the healthcare institutions and serving as an extension of the healthcare institutions, processes the data before they are forwarded to DICA. The data which DICA receives can no longer be traced back to individual patients. This process complies with the General Data Protection Regulation (GDPR, or AVG in Dutch).

GS1 standards in DBIR

Since the start of DBIR, the industrial partners who distribute breast implants in the Netherlands have been actively invited to embrace standardized barcodes and product identifiers. According to European regulations, GS1 is one of the two techniques to provide a Unique Device Identifier (UDI) to a medical device. This UDI is unique for every single implant and contains information about the Global Trade Item Number (GTIN), serial number, batch number, and expiration date. With the support of GS1, DBIR has incorporated barcode scanning technology for data entry in the online environment (Survey). By scanning the standardized GS1-barcode, the UDI, serial number, batch number, and expiration date will be automatically registered. In the future, this same GS1-barcode will also be used to automatically register implant specific details such as texture, fill, and shape. Therefore, this technology is crucial for the reduction of the administrative burden and typing errors in our registry.

Currently, 4 of the 6 suppliers (5 of the 7 brands) have embraced our joint choice for GS1 and actively started adding GS1 barcodes to the boxes of their breast implants (**Table 1**). We thank GS1 and all industrial parties that have included a GS1 compatible barcode on their implant boxes, and we hope the remaining parties will follow this example in the near future.

Table 1. *Implementation of GS1 standards and participation to the DBIR SUPPLIERS registry, per breast implant brand and supplier (November 2019)*

Supplier	Brand	Implementation GS1-barcode on implant box	Registration in DBIR SUPPLIERS
Allergan	Allergan (Natrelle)	--	--
Aleamed	Polytech	Yes	Yes
BlooMEDical	Mentor	Yes	Yes
Contourion	Arion Laboratoires (Monobloc)	--	--
EmdaPlast	Eurosilicone	Yes	Yes
	Nagor	Yes	Yes
Motiva Benelux	Motiva	Yes	Yes

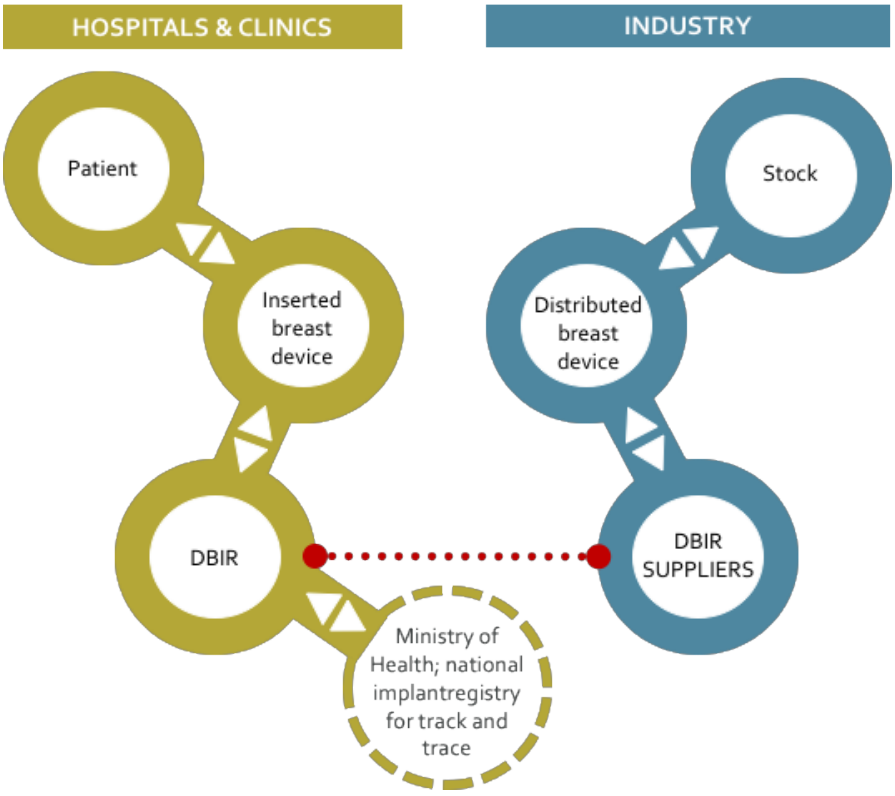
DBIR SUPPLIERS registry

Additionally, the DBIR has a unique feature by having a separate industrial registry. This registry is called the DBIR SUPPLIERS. **Figure 2** describes the relationship between the DBIR and DBIR SUPPLIERS registries in more detail.

The DBIR SUPPLIERS is a system in which vendors of breast implants in The Netherlands register the implants that are delivered to health care institutions. Because many clinicians order more than one implant per breast, as the choice of the definitive implant is frequently made during the operation, many implants are returned to the vendor. Once the vendor has received the returned implants, the number of net delivered implants is corrected in the DBIR SUPPLIERS. The result is an overview of

how many implants and of what type were delivered per health care institution, per year.
Additionally, the suppliers are asked for a selection of other data points, such as implant characteristics (fill, texture, coating), and the Unique Device Identifier (UDI) consisting of a Global Trade Item Number (GTIN), serial number, batch number, and expiration date. Currently, 4 of the 6 suppliers (5 of the 7 brands) participate in this registry (**Table 1**).
Once the DBIR SUPPLIERS contains sufficient and valid data of each brand, this system can be used to validate the devices registered in DBIR, provide suppliers with objective and reliable results of the quality of their devices in vivo (with results from the DBIR), and help to minimalize the registration burden for the clinicians registering in DBIR by pre-filling implant characteristics.

Figure 2. *Relationship between DBIR and DBIR SUPPLIERS registries*

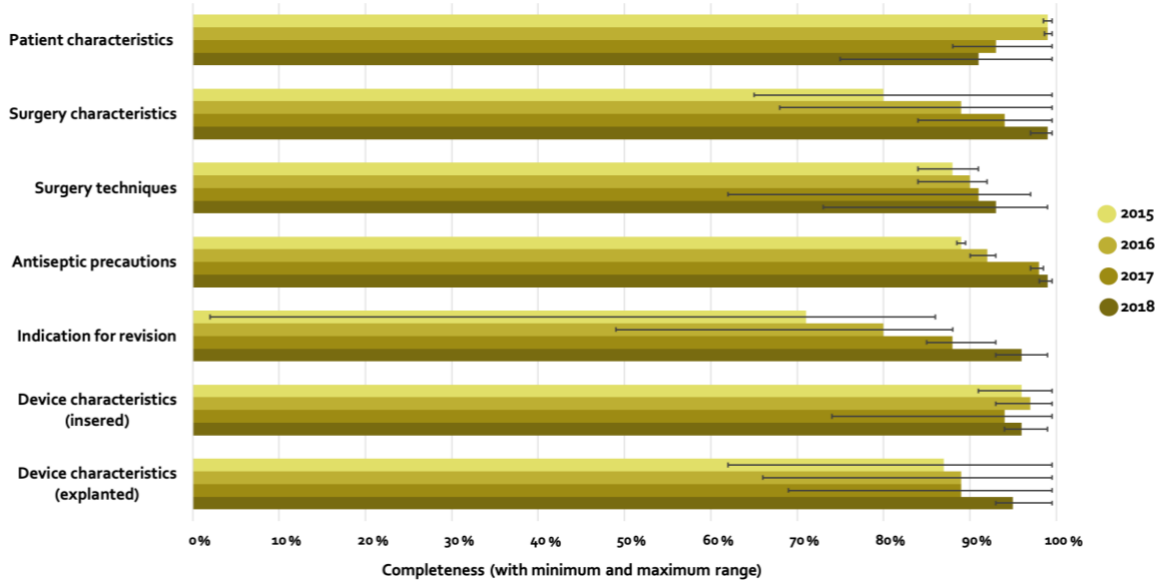


5. DATA COMPLETENESS

In order to improve data completeness and data quality, DBIR uses an opt-out structure. Additionally, three quality control mechanisms have been incorporated:

- During the online registration process (via Survey), immediate feedback is provided on missing, erroneous, or unlikely data.
- After data entry, all remaining patients with missing or erroneous data are collected and appear on an institution-specific and surgeon-specific signaling list, which can be used to rectify these records.
- A daily updated online platform is available for all participating institutions, presenting their outcomes compared to a Dutch benchmark to facilitate the clinical auditing process. This report also includes records with missing data (**chapter 9**).

Figure 3. *Data completeness (2015 - 2018)*



In general, the completeness of all variables has increased over the last three years (**Figure 3** & **Table 2**). However, the completeness of patient characteristics is decreasing. This is caused by a lower percentage of records with "Smoking status" and "Body Mass Index", and the introduction of the GDPR, after which some health care institutions decided not to register Social Security Numbers (BSN in Dutch) anymore. Overall, in 2018, the completeness of most variables was >90%. The variables "Smoking status" and "Manufacturer of ADM/Mesh" were the only variables with a completeness of less than 90%.

Table 2. *Data completeness (2016-2018)*

	Complete (%)		
	2016	**2017**	**2018**
Total number of device records	n = 23,599	n = 23,628	n = 22,320
Patient characteristics (Patient level)			
Date of birth	100%	99%	100%
ASA classification	99%	100%	93%
Smoking		95%	75%
Length		88%	92%
Weight		88%	92%
Body Mass Index		88%	92%
Surgery characteristics (Breast level)			
Operation date	100%	100%	100%
Hospital	100%	100%	100%
Laterality	100%	100%	100%
Intervention	100%	100%	100%
Indication	68%	84%	99%
Timing reconstruction	72%	85%	98%
RTx (preop)	87%	93%	97%
RTx (postop)		88%	97%
Surgery techniques (Breast level)			
Incision site	92%	97%	97%
Plane	84%	88%	95%
Capsulectomy	90%	94%	96%
Mastopexy	90%	95%	97%
Autologous flap cover	90%	95%	97%
Fat grafting	90%	95%	97%
Drains	91%	98%	99%
ADM/Mesh use	92%	95%	97%
ADM/Mesh manufacturer		62%	75%
Antiseptic precautions (Breast level)			
Systemic AB (preop)	93%	98%	99%
Systemic AB (postop)	91%	97%	97%
Antiseptic rinse of implant	93%	98%	100%
Antiseptic rinse type	99%	98%	98%
Sleeve/Funnel	92%	98%	100%
Nipple guards	90%	98%	100%
Glove change	90%	98%	100%

	Complete (%)		
	2016	**2017**	**2018**
Total number of device records	n = 23,599	n = 23,628	n = 22,320
Indication for revision (Breast level)			
Change TE for implant		91%	94%
Flap problem	85%	89%	96%
Skin necrosis	49%	85%	95%
Skin scarring	85%	89%	96%
Deep wound infection	85%	89%	96%
Seroma/Hematoma	85%	88%	95%
Capsular contracture		93%	94%
Capsular contracture grade	81%	85%	99%
Breast cancer	84%	88%	96%
BIA-ALCL	82%	85%	96%
ASIA	82%	85%	96%
Breast pain	84%	88%	95%
Asymmetry	84%	89%	95%
Dissatisfaction with volume	49%	86%	95%
Device rupture/deflation	88%	92%	93%
Silicone extravasation		91%	94%
Silicone extravasation type	84%	89%	99%
Device malposition	86%	89%	95%
Device characteristics (Device level, inserted)			
Device type	100%	100%	100%
Texture	93%	95%	94%
Coating	97%	97%	95%
Fill	94%	96%	95%
Shape	96%	98%	96%
Volume/Weight		97%	95%
Max. volume TE		95%	94%
Intraoperative volume TE		74%	95%
Manufacturer	99%	94%	99%
Device characteristics (Device level, explanted)			
Device type	100%	100%	99%
Texture		88%	93%
Coating		88%	94%
Fill		90%	94%
Shape		91%	93%
Manufacturer	66%	69%	95%
Inserted abroad	100%	98%	99%

** Total number of device records represents the total number of inserted and explanted device records.*

** ASA: American Society of Anesthesiologists, RTx: radiotherapy, Preop: preoperatively, Postop: postoperatively, ADM: Acellular Dermal Matrix, AB: antibiotics, TE: tissue expander, BIA-ALCL: Breast Implant Associated - Anaplastic Large Cell Lymphoma, ASIA: Autoimmune Syndrome Induced by Adjuvants.*

** For 2015 data: see Annual Report (2015-2017).*

6. REGISTRY OUTPUT

Indications for breast implant surgery

In this report, breast implants or breast devices are defined as both tissue expanders as well as permanent breast implants.

Clinical differences were found between patients who opted for a cosmetic breast augmentation and patients who received an implant for a reconstructive indication. Therefore, the results in this report are presented separately for these two groups.

- **Part 1 - Reconstructive procedures**, includes the indications:
  - *Reconstruction after mastectomy for cancer (surgery to recreate a breast after one or both breasts are removed as a treatment for breast cancer).*
  - *Reconstruction after prophylactic mastectomy (surgery to recreate a breast after one or both breasts are removed to reduce the risk of developing breast cancer).*
  - *Reconstruction benign (surgery to restore or create shape and symmetry in patients with loss or absence of all or some breast tissue due to benign breast conditions or gender reassignment surgery).*
  - *Congenital deformity (surgery to restore or create shape and symmetry in patients with loss or absence of all or some breast tissue due to a congenital deformity, such as tuberous breasts).*

- **Part 2 - Aesthetic procedures**, includes solely:
  - *Cosmetic augmentations (cosmetic surgery for breast enlargement).*

Table 3. *Indications for breast implant surgery (2018)*

	Patients		Procedures		Devices	
	n	(%)	n	(%)	n	%
Reconstructive						
Reconstruction after mastectomy for cancer	2,668	(27%)	3,129	(30%)	5,304	(24%)
Reconstruction after prophylactic mastectomy	264	(3%)	320	(3%)	759	(3%)
Reconstruction benign	196	(2%)	237	(2%)	540	(2%)
Congenital deformity	38	(0%)	41	(0%)	91	(1%)
Aesthetic	6,550	(67%)	6,692	(64%)	15,460	(69%)
Not stated	70	(1%)	84	(1%)	162	(1%)
TOTAL	9,786	(100%)	10,503	(100%)	22,316	(100%)

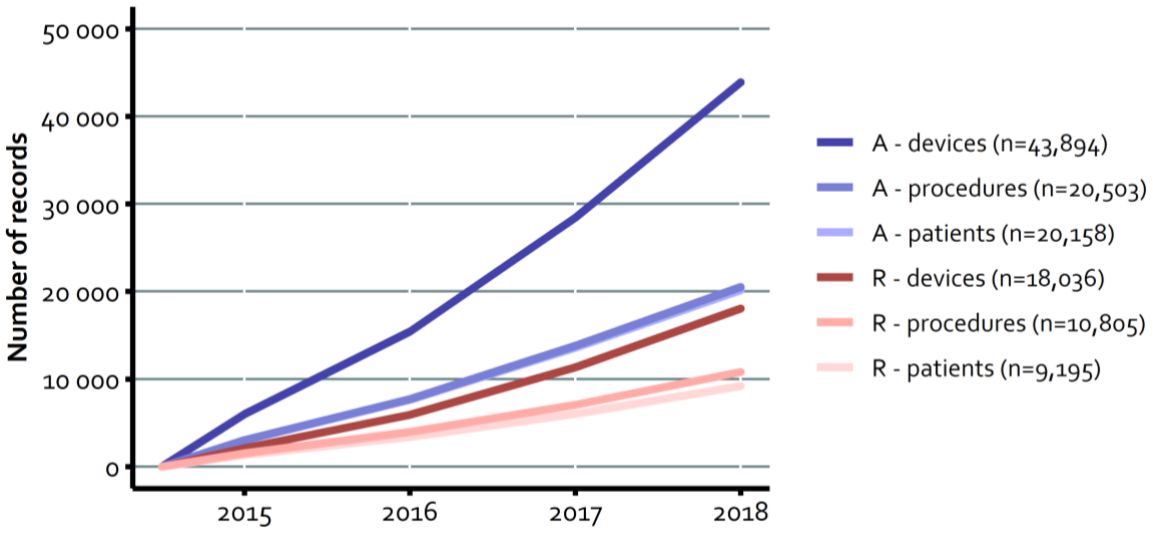
** Patients and procedures are presented as unique patients and unique procedures. Some patients had multiple surgeries.*

** Devices are measured on breast level.*

Records for which the indication was not stated, were excluded from further analysis in this report (70 patients, 84 procedures, and 162 devices). In total, since the start of the registry in April 2015 until the end of 2018, information of approximately 30,000 patients, 31,000 procedures, and 62,000 breast

implants has been registered in DBIR (**Figure 4**). This includes insertion only procedures, replacement surgeries, and explantation only procedures with both tissue expanders and permanent implants, of which the indication was known (aesthetic or reconstructive). **Figure 4** also illustrates that patients with a reconstructive indication are more likely to undergo multiple operations when compared to patients with an aesthetic breast augmentation. Generally, the majority of aesthetic patients received breast implants bilaterally and reconstructive patients unilaterally.

Figure 4. *Cumulative number of registered patients, procedures and devices (2015 – 2018)*



** A: Aesthetic, R: Reconstructive*

In the two following chapters (i.e., reconstructive indications and aesthetic indications), results are presented for three types of interventions.

- **Insertion only** includes:
  - Initial insertion of a new device.
  - Insertion of a new device in a patient who has had previous implant surgery.
- **Replacement surgery** includes:
  - Removal of an in situ device and insertion of the same or new device.
  - Replacement of TE with an implant.
  - Replacement of an in situ device with autologous tissue.
- **Explantation only** includes:
  - Explantation of an in situ device without replacement of a new device or autologous tissue.

PART 1 – RECONSTRUCTIVE INDICATIONS

6. REGISTRY OUTPUT

Part 1 – Reconstructive indications

In 2018, a total of 3,727 operations (3,166 unique patients) were performed for a reconstructive indication, of which 1,880 insertion only procedures (1,601 unique patients), 1,552 replacement surgeries (1,336 unique patients), and 295 explantation only procedures (229 unique patients).

Laterality ***(Table 4** & **Figure 5)***

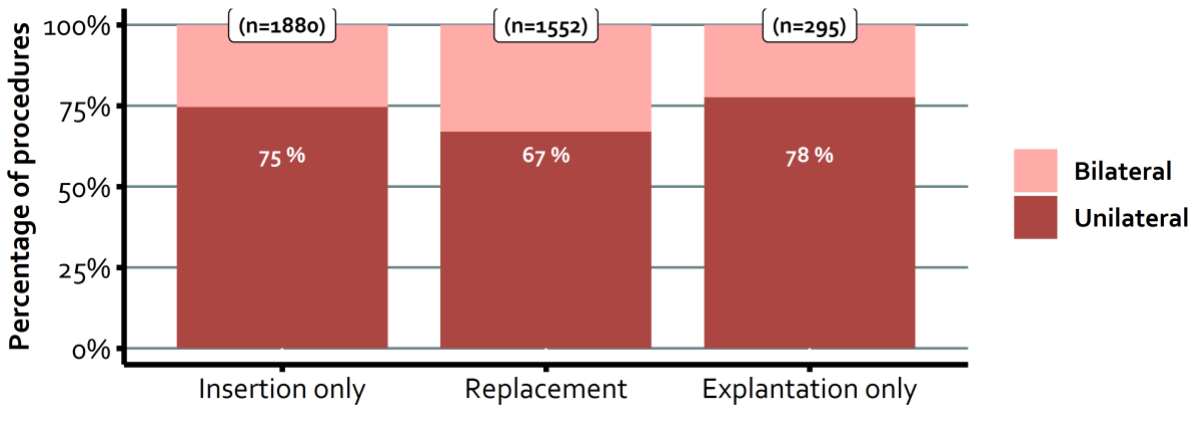
The majority of the reconstructive procedures were unilateral (72%). This is best explained by the vast majority of reconstructive procedures being performed after a mastectomy for breast cancer, which occurred mostly unilaterally (80%). When looking at **table 4** in more detail, it is clear that the other indications were more often performed bilaterally.

Table 4. *Laterality of reconstructive procedures (2018)*

	Unilateral		Bilateral		Total	
	n	(%)	n	(%)	n	%
Reconstructive procedures	**2,672**	**(72%)**	**1,055**	**(28%)**	**3,727**	**(100%)**
Reconstruction after mastectomy for cancer	2,489	(80%)	640	(20%)	3,129	(100%)
Reconstruction after prophylactic mastectomy	81	(25%)	239	(75%)	320	(100%)
Reconstruction benign	80	(34%)	157	(66%)	237	(100%)
Congenital deformity	22	(54%)	19	(46%)	41	(100%)

** Presented as procedures on patient level. Some patients had multiple operations.*

Figure 5. *Laterality of reconstructive procedures (2018)*

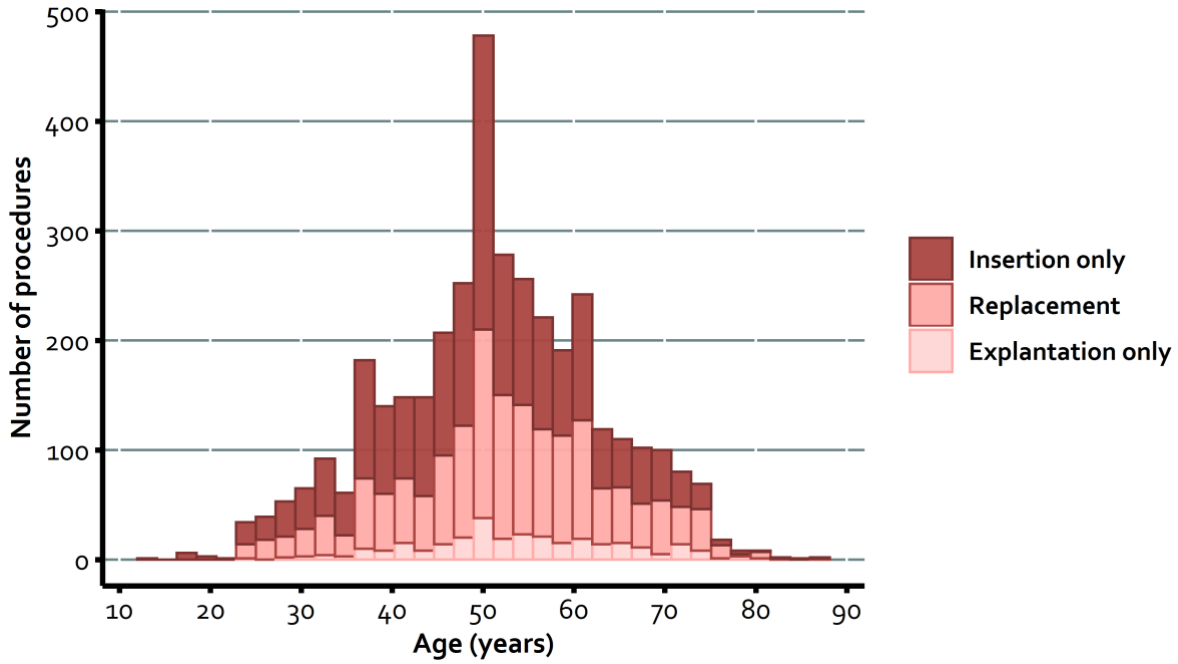


** n is the total number of procedures per year.*

Age ***(Figure 6)***

The mean age of patients undergoing an insertion only procedure was 50 years (SD 12), the mean age of patients undergoing a replacement procedure was 52 years (SD 12), and the mean age of patients undergoing an explantation only procedure was 54 years (SD 11).

Figure 6. *Distribution of patient age at time of reconstructive surgery (2018)*



Smoking ***(Table 5)***

The percentage of smokers at the time of reconstructive surgery was between 10% and 16%. In 13% to 18% of the cases, the variable "Smoking" was not registered. The reasons for these missing values are unclear, but they are higher compared to other variables.

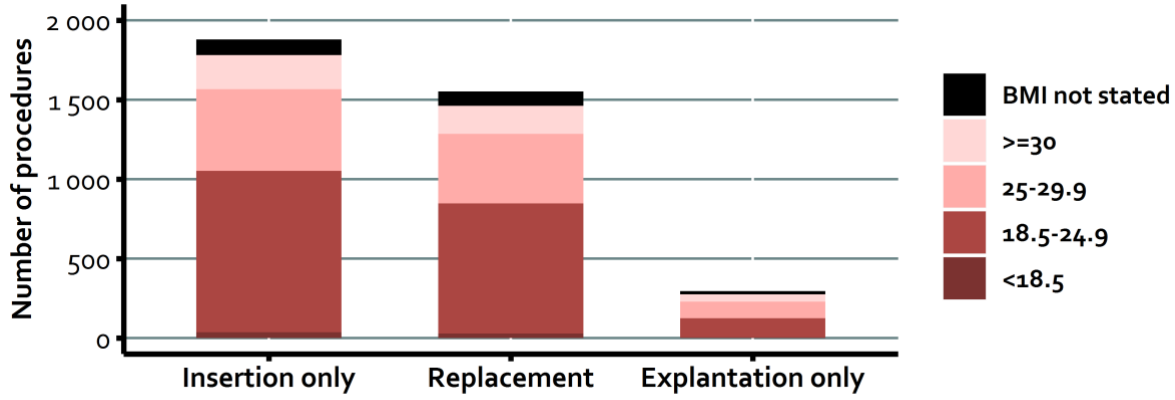
Table 5. *Percentage of patients smoking at time of reconstructive surgery (2018)*

	Insertion only	Replacement	Explantation only
Smoking			
No	70%	74%	71%
Yes	12%	10%	16%
Not stated	*18%*	*16%*	*13%*

Body Mass Index (BMI) ***(Figure 7)***

For insertion only, replacement, and explantation only procedures, most of the patients had a BMI between 18.5 and 24.9 (54%, 53%, and 41%, respectively) or 25.0 – 29.9 (27%, 28%, and 36%, respectively), followed by a BMI ≥30 (11%, 11%, and 15%, respectively), and <18.5 (2%, 2%, and 1%, respectively). In respectively 5%, 6%, and 7% of the records BMI was missing.

Figure 7. *Patient BMI at time of reconstructive surgery (2018)*



Intraoperative techniques ***(Table 6)***

To improve the quality of care of breast implant surgery in the Netherlands, DBIR provides benchmark information on several topics, among which the use of infection control measures (ICM's) and technical operation details. For some techniques and ICM's, there is scientific evidence it has a positive effect on surgical outcomes, such as the preoperative use of prophylactic systemic antibiotics. For other techniques, however, no consensus has been reached yet. Therefore, DBIR aims to identify best practices by collecting nationwide, patient-based data and surgical outcomes.

The number of records with missing information on the intraoperative techniques was low (±3%), except for the manufacturer (brand) of each ADM/Mesh, which only was registered in 75% of the cases in which an ADM/Mesh was used (**Table 2**).

Table 6. *Intraoperative techniques in reconstructive procedures, per breast (2018)*

		Insertion only	Replacement	Explantation only
Total number of breasts		**(n=2,350)**	**(n=2,071)**	**(n=366)**
Timing reconstruction	Immediate	83%	57%	61%
	Delayed	14%	38%	33%
	Not applicable *(congenital deformity)*	1%	1%	2%
	Not stated	*2%*	*4%*	*4%*
Incision site	Inframammary	13%	24%	21%
	Mastectomy scar	60%	57%	61%
	Axillary	0%	0%	0%
	Areolar	10%	3%	3%
	Latissimus Dorsi	3%	7%	3%
	Other	5%	3%	8%
	Not stated	*9%*	*6%*	*4%*
Plane	Subglandular	2%	4%	
	Subfascial	0%	0%	
	Sub flap	7%	9%	
	Subcutaneous	4%	4%	
	Subpectoral	37%	33%	
	Dual plane or partial cover with PM	38%	42%	
	Not stated	*12%*	*7%*	
Mastopexy	Yes	4%	2%	7%
	Not stated	*12%*	*7%*	*5%*
Capsulectomy	Partial capsulectomy		44%	34%
	Full capsulectomy		10%	21%
	Not stated		*7%*	*5%*
Autologous flap cover	Yes	11%	9%	13%
	Not stated	*11%*	*7%*	*5%*
Fat grafting	Yes	1%	7%	1%
	Not stated	*12%*	*7%*	*5%*
Drains	Yes	93%	71%	71%
	Not stated	*0%*	*0%*	*5%*
Mesh/ADM use	Yes	7%	1%	
	Not stated	*13%*	*8%*	

** ADM: Acellular Dermal Matrix.*

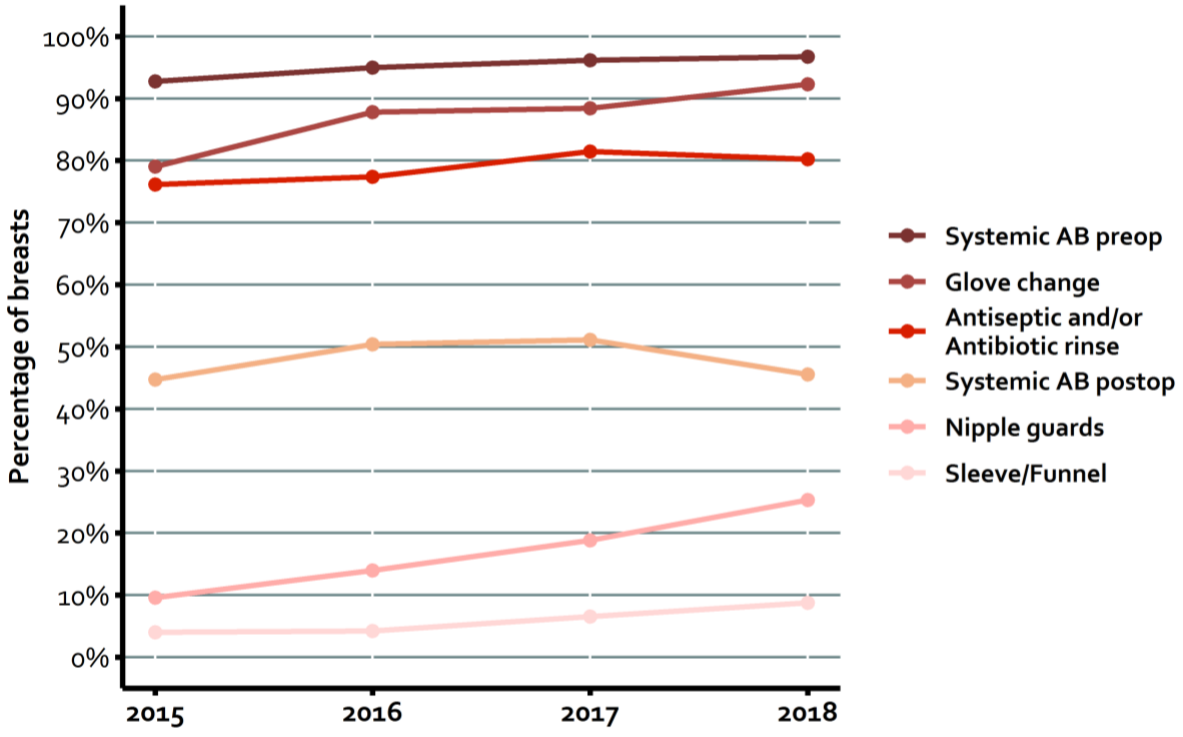
** The variables 'Plane' and 'Mesh/ADM use' were only registered for Insertion only & Replacement procedures.*

** The variable 'Capsulectomy' was only registered for Replacement & Explantation only procedures.*

Infection control measures ***(Figure 8)***

Most of these variables were only registered for the insertion of an implant. Therefore, only the insertion only and replacement procedures are included in **figure 8**. Results are presented per breast. The use of infection control measures (ICM's) slightly increased over the years (2015-2018). However, the percentage of records with information on the use of ICM's also increased over the years from ±93% in 2016 to ±99% in 2018 (**Table 2**). This has to be kept in mind when interpreting these results.
The most frequently used ICM's for reconstructive indications in 2018, were the use of preoperative systemic antibiotics, glove change before implant insertion, and antiseptic and/or antibiotic rinse of the implant. Since 2015, the use of these three ICM's has increased from 93% to 97%, from 79% to 92%, and from 76% to 80%, respectively.
Postoperative systemic antibiotics were provided in ±47% of the procedures between 2015 and 2018. Nipple guards were administered more frequently over the years, increasing from 10% to 25%. A sleeve/Keller funnel was used in less than 10% of the procedures.

Figure 8. *Infection control measures for every reconstructive implant insertion, per breast (2015 – 2018)*



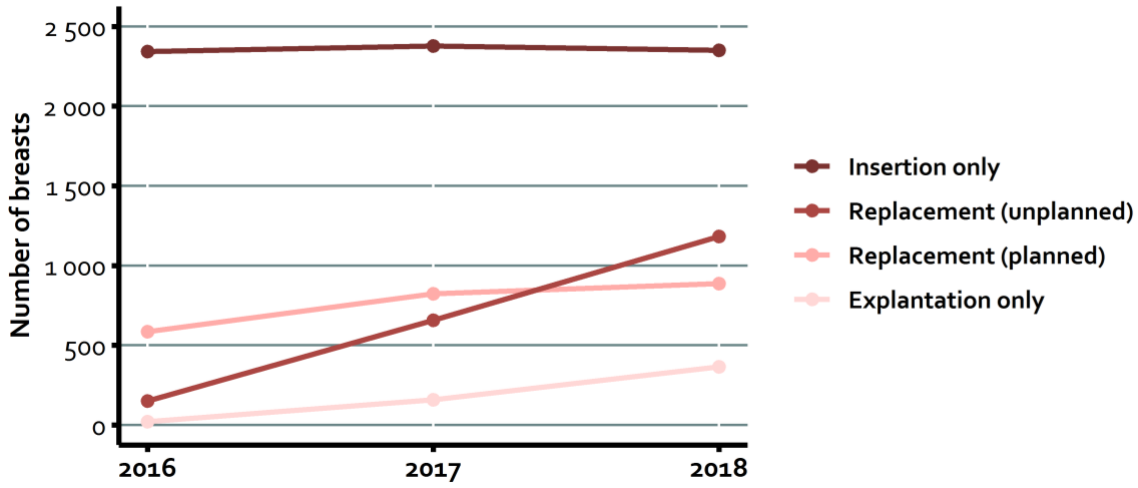
** Infection control measures were only registered for Insertion only & Replacement procedures.*
** AB: antibiotics, Preop: preoperatively, Postop: postoperatively.*

***Note**: It is not known how many of the replacement and explantation procedures in the Netherlands have been registered in DBIR (national denominator), as there has been no gold standard for the validation of explantations yet. Therefore, the presented revision results should be interpreted with caution.*

Revision surgery *(Figure 9)*

Indications for revision surgery were categorized as unplanned or planned. The numbers presented in **Figure 9** are composed of new implants as well as breast implants inserted (and/or explanted) prior to and after the start of the registry. The increasing trend of more replacement and explantation procedures being registered in DBIR that was seen in the previous annual report, was continued in 2018.

***Figure 9.** Distribution of registered reconstructive procedures per year, per breast (2016 – 2018)*



	2016	2017	2018	Total
Insertion only	**2,343**	**2,378**	**2,350**	**7,071**
Replacement (planned)	**586**	**823**	**887**	**2,296**
TE to Implant				
Replacement (unplanned)	**152**	**657**	**1,184**	**1,993**
Implant to Implant	78	511	919	1,508
Implant to TE	32	49	57	138
Implant to Autologous tissue	19	37	32	88
TE to TE	23	38	59	120
TE to Autologous tissue	0	3	48	51
Not stated	*0*	*19*	*69*	*88*
Explantation only	**22**	**159**	**366**	**547**

** TE: tissue expander.*

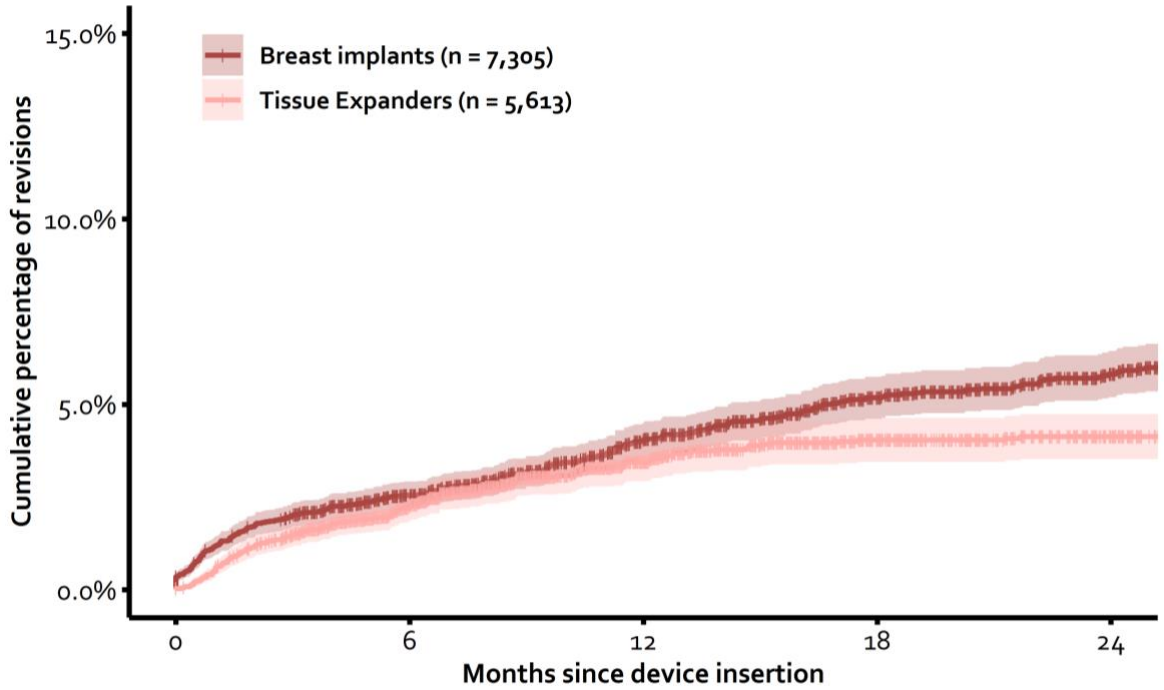
** 2015 was not a full registration year and is therefore not included in the trend line.*

Percentage of revisions *(Figure 10)*

The cumulative percentage of revisions was calculated per device type. These analyses included all devices of which the insertion surgery was registered in DBIR since the start in April 2015. All indications for revision were included, except a replacement of a tissue expander for a permanent breast implant. These procedures were censored. Additionally, only devices with a correct manufacturer and serial number registered at insertion surgery could be traced over time and could, therefore, be included in the calculations. For these analyses, revision was defined as reinsertion of a new device, reinsertion of the same device, replacement with autologous tissue, or explantation without replacement with any device or autologous tissue. The presented cumulative percentages were not adjusted for confounding factors.

Of the 7,305 inserted permanent breast implants which could be traced over time since April 2015, 3% had been revised after 6 months, 4% after 12 months, and 6% after 24 months. Of the 5,613 inserted tissue expanders which could be traced over time since April 2015, 2% had been revised (unplanned) after 6 months, 3% after 12 months, and 4% after 24 months.

Figure 10. *Cumulative revision incidence after reconstructive surgery – unplanned (since April 2015)*



** Only devices of which the insertion surgery was registered in DBIR are included in this figure.*
** Devices that are inserted in 2015, have a longer follow-up time than recently inserted devices.*
** These results should be interpreted carefully (See Note on page 21).*

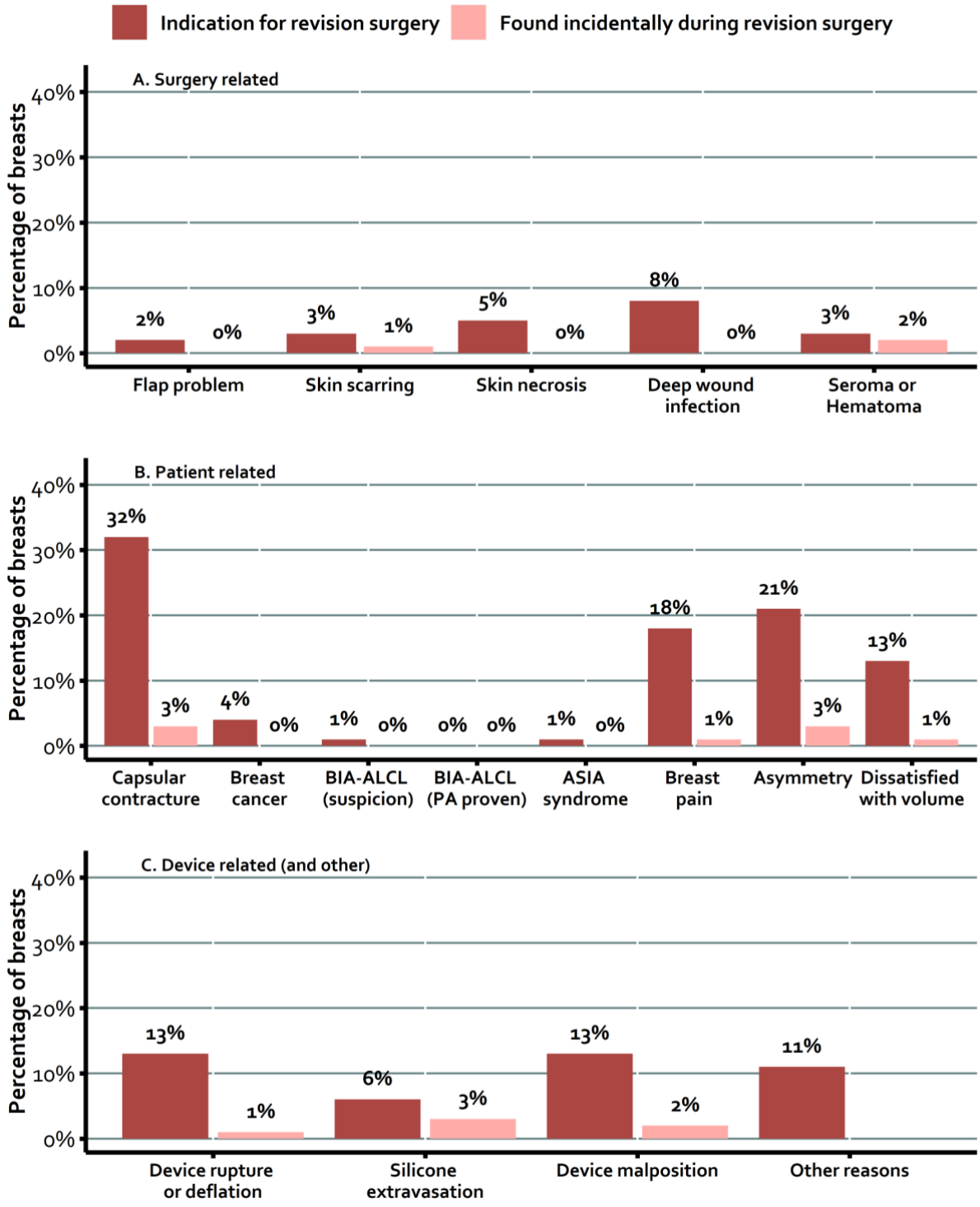
Indications for revision surgery & Incidental findings ***(Figure 11 – next page)***

Of the women with an unplanned replacement or explantation procedure, the indication for revision was stated in 85% of the records. Of these, most revisions were performed due to patient-related indications (0%-32%), followed by device-related indications (6%-13%), and surgery-related indications (2%-8%).

An "Other" reason for revision was registered in 11% of the cases. Most of the time, this appeared to be a revision due to a planned replacement for autologous tissue. Therefore, this indication was added as a separate option in the next DBIR update, to be able to better distinguish between the indications for revision.

All reported issues could also have been found incidentally during a revision procedure, not being the primary indication for revision. Nevertheless, these incidentally found issues were hardly reported. It is not known, however, whether they were less often encountered or that surgeons less frequently registered these issues.

Figure 11. *Indications for replacement or explantation after reconstructive surgery, per breast (2018)*



** Multiple indications could be reported per revision procedure.*

** This figure includes devices that were inserted before and after the start of the DBIR.*

** These results should be interpreted carefully (See Note on page 21).*

Device characteristics *(**Table 7** & **Figure 12**)*

The majority of devices inserted for reconstructive indications were permanent breast implants. Most of the permanent breast implants were anatomically shaped, textured, silicone coated, and silicone filled. The mean volume was between 420cc and 430cc. The inserted tissue expanders were predominantly anatomically shaped, textured, silicone coated, and filled with saline. The mean maximum volume of the tissue expanders was between 470cc and 480cc, and the mean intraoperative filling volume was between 118cc and 132cc.

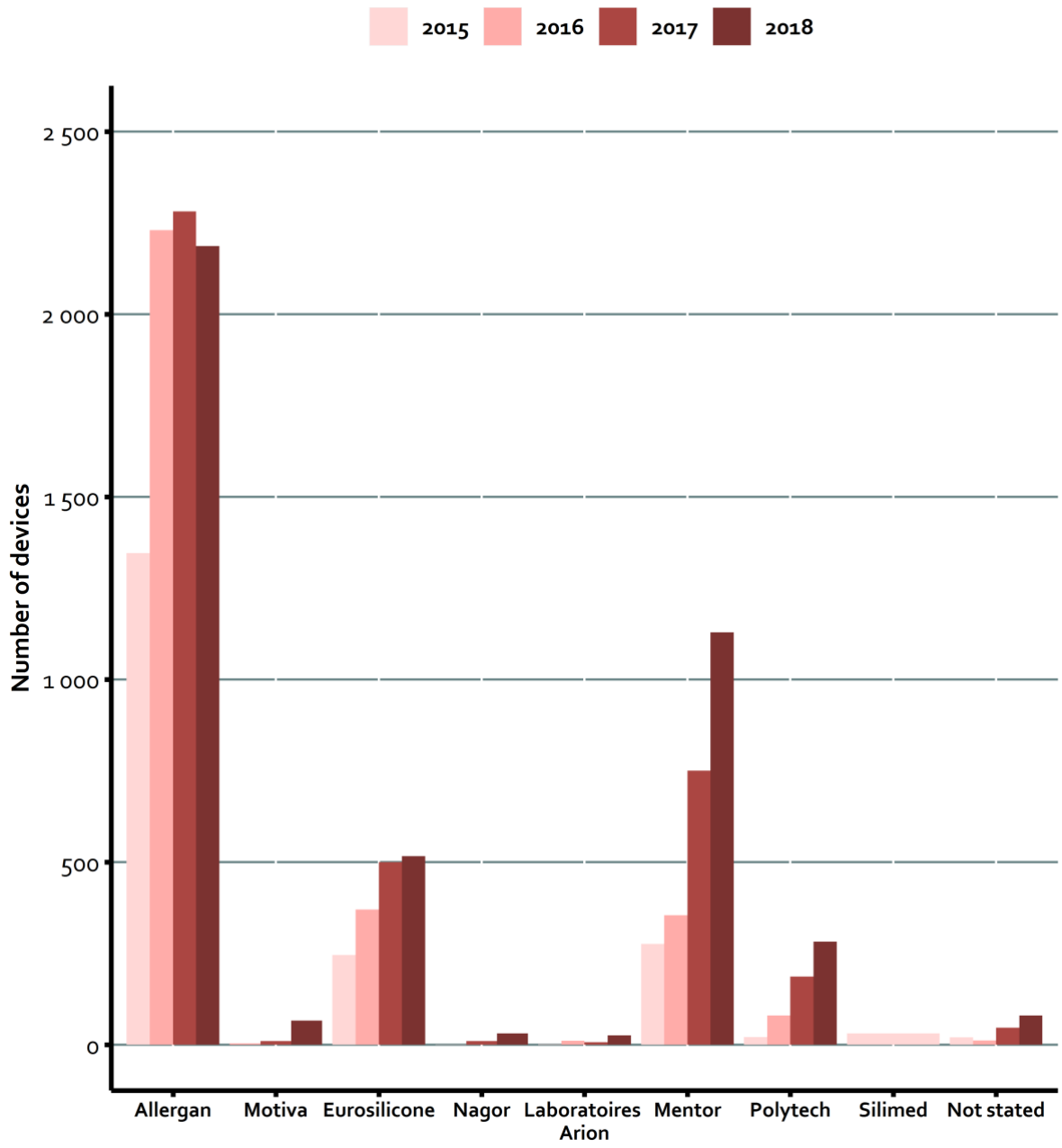
Table 7. *Characteristics of inserted devices for reconstructive indications, per year (2015-2018)*

	Permanent implants				Tissue Expanders			
	2015	**2016**	**2017**	**2018**	**2015**	**2016**	**2017**	**2018**
Inserted devices	n = 807	n = 1,575	n = 2,258	n = 2,773	n = 1,136	n = 1,487	n = 1,533	n = 1,539
Device shape								
Round	10%	9%	13%	17%	11%	7%	4%	5%
Shaped/Anatomical	84%	88%	85%	70%	83%	88%	92%	90%
Not stated	*6%*	*2%*	*2%*	*13%*	*6%*	*5%*	*4%*	*5%*
Device texture								
Textured	89%	94%	93%	81%	92%	96%	94%	92%
Smooth	1%	1%	1%	2%	4%	1%	0%	1%
Not stated	*10%*	*5%*	6%	*17%*	*4%*	*3%*	*6%*	*7%*
Device coating								
Silicone	90%	94%	90%	77%	96%	96%	93%	93%
Polyurethane	5%	4%	7%	9%	0%	0%	0%	1%
Not stated	*5%*	*2%*	*3%*	*14%*	*4%*	*4%*	*7%*	*6%*
Device fill								
Silicone	84%	78%	85%	83%	12%	14%	13%	7%
Saline	7%	7%	4%	3%	74%	70%	77%	86%
Hydrogel	1%	1%	1%	1%	0%	0%	0%	0%
Other	2%	0%	0%	0%	8%	8%	4%	2%
Not stated	*6%*	*14%*	*10%*	*13%*	*6%*	*8%*	*6%*	*4%*
Device volume Mean volume in cc (SD)								
Volume breast implant*			431 (144)	421 (139)				
Not stated			*11%*	*15%*				
Max. volume TE*							474 (129)	481 (129)
Not stated							*4%*	*6%*
Intraoperative filling of TE					128 (84)	118 (75)	132 (93)	127 (85)
Not stated					*37%*	*38%*	*22%*	*5%*

** SD: standard deviation, Max.: maximum, TE: Tissue Expander.*

** The variables 'volume breast implant' and 'max. volume TE' have been registered since September 2017.*

Figure 12. *Number of inserted devices for reconstructive indications per manufacturer, per year (2015-2018)*



PART 2 – AESTHETIC INDICATIONS

6. REGISTRY OUTPUT

Part 2 – Aesthetic indications

In 2018, a total of 6,692 operations (6,548 unique patients) were performed for an aesthetic indication, of which 5,161 insertion only procedures (5,082 unique patients), 1,273 replacement surgeries (1,223 unique patients), and 258 explantation only procedures (243 unique patients).

Laterality *(**Table 8** & **Figure 13**)*

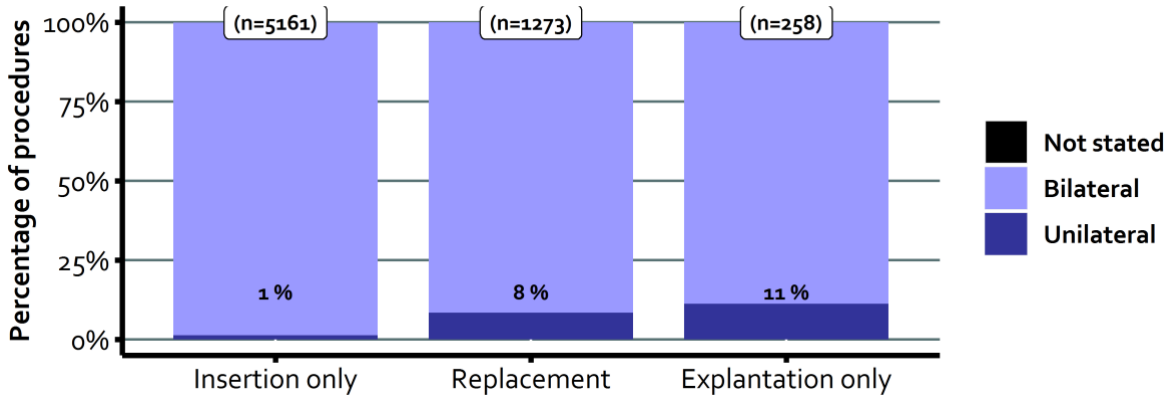
As expected, the majority of aesthetic procedures were bilateral (97%). The distribution of unilateral and bilateral interventions per insertion only procedure, replacement procedure, and explantation only procedure, did not differ when compared to 2017 (2017 was: 2% unilateral, 9% unilateral, and 10% unilateral, respectively) (**Figure 13**). Although there still is an increasing number of replacement and explantation only procedures being registered in DBIR, the distribution of laterality appears to be stabilizing.

Table 8. *Laterality of aesthetic procedures (2018)*

	Unilateral		Bilateral		*Not stated*		Total	
	n	(%)	n	(%)	*n*	*(%)*	n	%
Cosmetic augmentation	**204**	**(3%)**	**6,482**	**(97%)**	*6*	*(0%)*	**6,692**	**(100%)**

** Presented as procedures on patient level. Some patients had multiple operations.*

Figure 13. *Laterality of aesthetic procedures (2018)*

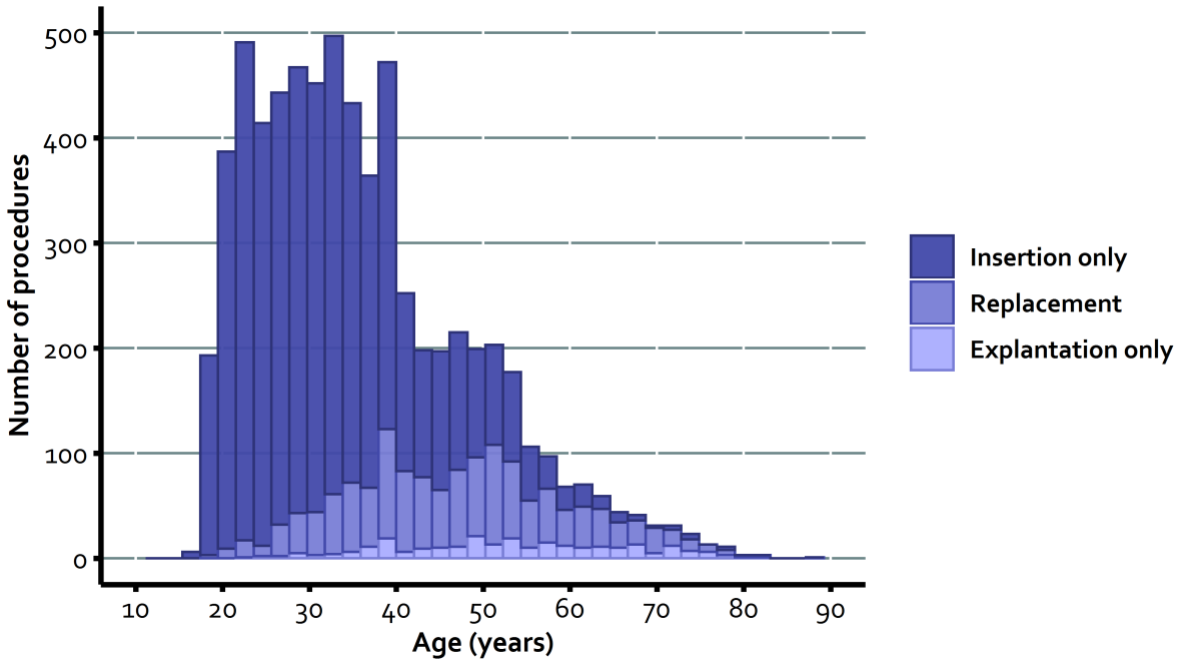


** n is the total number of procedures per year.*

Age (***Figure 14***)

The mean age of patients undergoing an insertion only procedure was 33 years (SD 10), the mean age of patients undergoing a replacement procedure was 47 years (SD 13), and the mean age of patients undergoing an explantation only procedure was 53 years (SD 13).

Figure 14. *Distribution of patient age at time of aesthetic surgery (2018)*



Smoking (***Table 9***)

The percentage of smokers at the time of aesthetic surgery was between 13% and 19%. In 16% to 30% of the cases, the variable "Smoking" was not registered. The reasons for these missing values are unclear, but they are higher compared to other variables.

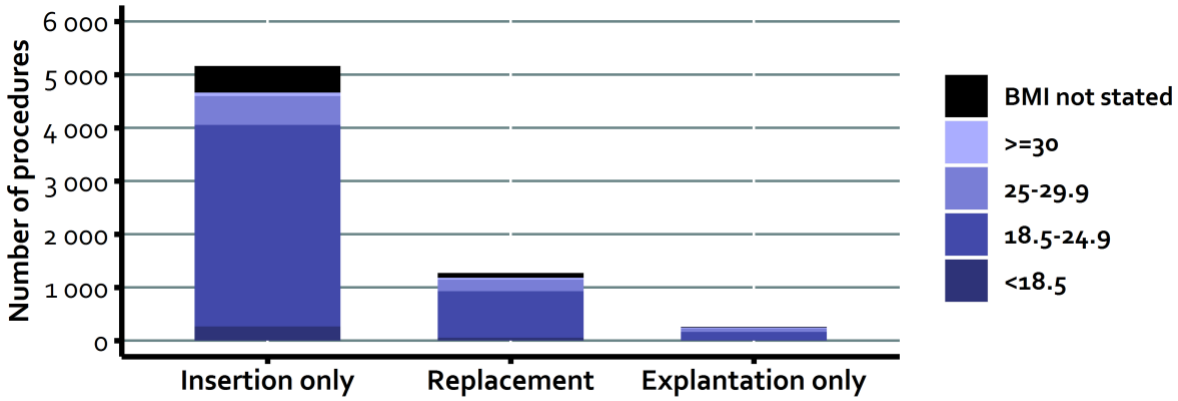
Table 9. *Percentage of patients smoking at time of aesthetic surgery (2018)*

	Insertion only	Replacement	Explantation only
Smoking			
No	57%	65%	67%
Yes	13%	19%	17%
Not stated	*30%*	*16%*	*16%*

Body Mass Index (BMI) *(**Figure 15**)*

For insertion only, replacement, and explantation only procedures, most of the patients had a BMI between 18.5 and 24.9 (73%, 69%, and 60%, respectively) or 25.0 – 29.9 (11%, 17%, and 27%, respectively), followed by a BMI <18.5 (5%, 4%, and 2%, respectively), and ≥30 (1%, 3%, and 8%, respectively). In respectively 10%, 7%, and 3% of the records BMI was missing.

Figure 15. *Patient BMI at time of aesthetic surgery (2018)*



Intraoperative techniques *(**Table 10**)*

To improve the quality of care of breast implant surgery in the Netherlands, DBIR provides benchmark information on several topics, among which the use of infection control measures (ICM's) and technical operation details. For some techniques and ICM's, there is scientific evidence it has a positive effect on surgical outcomes, such as the preoperative use of prophylactic systemic antibiotics. For other techniques, however, no consensus has been reached yet. Therefore, DBIR aims to identify best practices by collecting nationwide, patient-based data and surgical outcomes.

The number of records with missing information on the intraoperative techniques was low (±3%), except for the manufacturer (brand) of each ADM/Mesh, which only was registered in 75% of the cases in which an ADM/Mesh was used (**Table 2**).

Table 10. *Intraoperative techniques in aesthetic procedures, per breast (2018)*

		Insertion only	Replacement	Explantation only
Total number of breasts		**(n=10,222)**	**(n=2,433)**	**(n=482)**
Incision site	Inframammary	97%	95%	90%
	Mastectomy scar	1%	1%	2%
	Axillary	0%	0%	0%
	Areolar	0%	0%	1%
	Other	2%	2%	6%
	Not stated	*0%*	*1%*	*0%*
Plane	Subglandular	20%	32%	
	Subfascial	10%	3%	
	Subcutaneous	0%	1%	
	Subpectoral	2%	6%	
	Dual plane or partial cover with PM	64%	57%	
	Not stated	*3%*	*1%*	
Mastopexy	Yes	4%	9%	20%
	Not stated	*0%*	*1%*	*0%*
Capsulectomy	Partial capsulectomy		41%	26%
	Full capsulectomy		29%	47%
	Not stated		*1%*	*0%*
Autologous flap cover	Yes	0%	0%	0%
	Not stated	*0%*	*1%*	*0%*
Fat grafting	Yes	0%	1%	3%
	Not stated	*0%*	*1%*	*0%*
Drains	Yes	12%	74%	57%
	Not stated	*0%*	*1%*	*0%*
Mesh/ADM use	Yes	0%	0%	
	Not stated	*0%*	*1%*	

** ADM: Acellular Dermal Matrix.*

** The variables 'Plane' and 'Mesh/ADM use' were only registered for Insertion only & Replacement procedures.*

** The variable 'Capsulectomy' was only registered for Replacement & Explantation only procedures.*

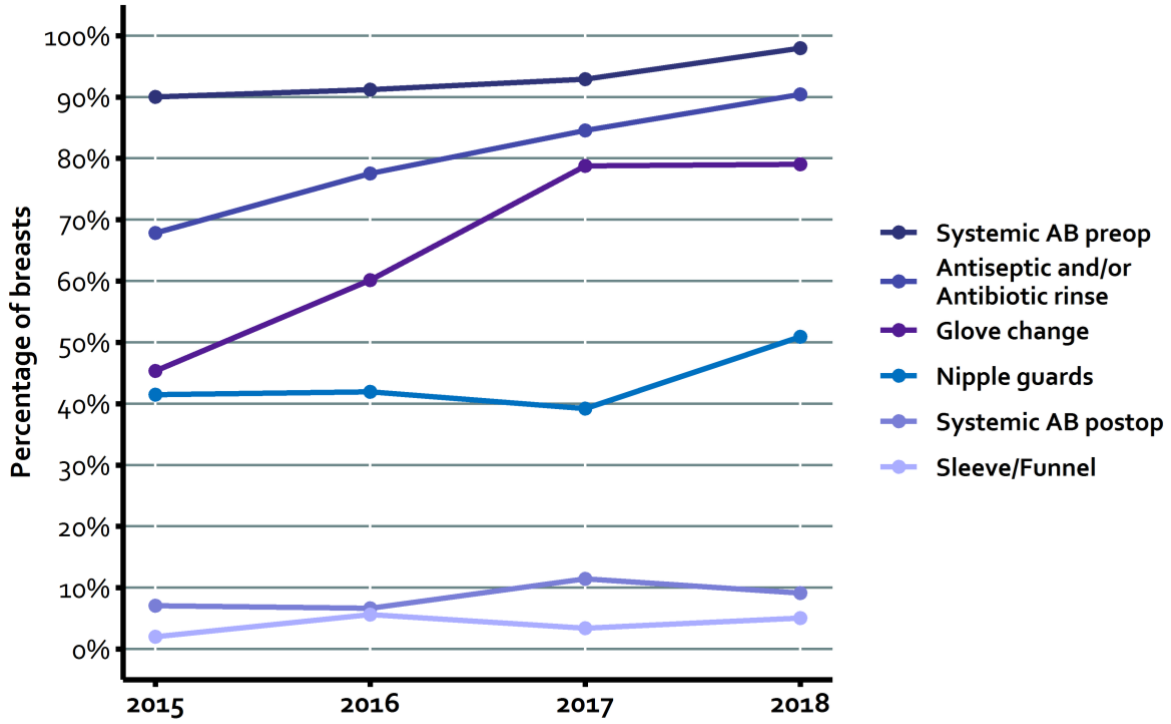
Infection control measures ***(Figure 16)***

Most of these variables were only registered for the insertion of an implant. Therefore, only the insertion only and replacement procedures are included in **figure 16**. Results are presented per breast. The use of infection control measures (ICM's) increased over the years (2015-2018). However, the percentage of records with information on the use of ICM's also increased over the years from ±93% in 2016 to ±99% in 2018 (**Table 2**). This has to be kept in mind when interpreting these results.

The most frequently used ICM's for aesthetic indications in 2018, were the use of preoperative systemic antibiotics, antiseptic and/or antibiotic rinse of the implant, and glove change before implant insertion. Since 2015, the use of these three ICM's has increased from 90% to 98%, from 68% to 90%, and from 45% to 79%, respectively.

Nipple guards were used in ±40% of the procedures between 2015 and 2017. In 2018, the use of this ICM increased to 51%. Postoperative systemic antibiotics or a sleeve/Keller funnel were not used commonly (±9% and ±4%, respectively).

Figure 16. *Infection control measures for every aesthetic implant insertion, per breast (2015 – 2018)*



** Infection control measures were only registered for Insertion only & Replacement procedures.*

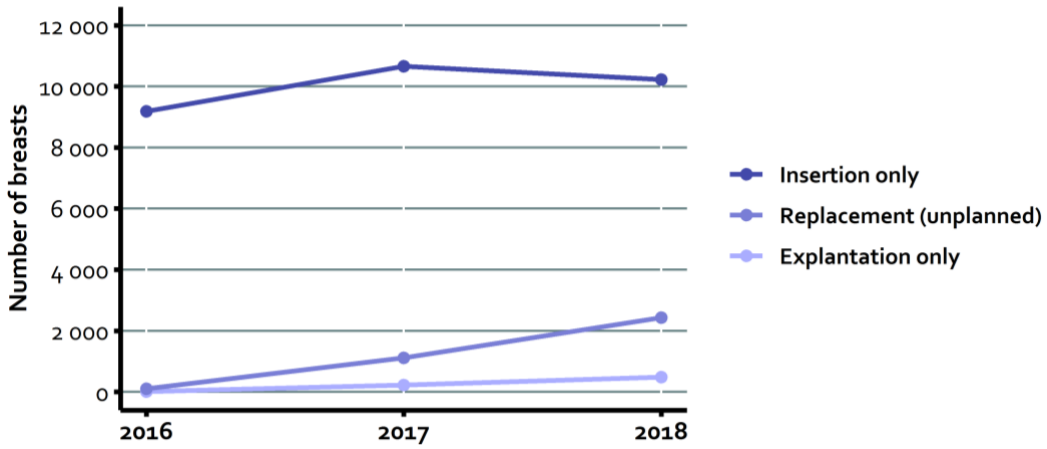
** AB: antibiotics, Preop: preoperatively, Postop: postoperatively.*

***Note**: It is not known how many of the replacement and explantation procedures in the Netherlands have been registered in DBIR (national denominator), as there has been no gold standard for the validation of explantations yet. Therefore, the presented revision results should be interpreted with caution.*

Revision surgery *(Figure 17)*

Indications for revision surgery were categorized as unplanned or planned for reconstructive indications, such as the exchange of a tissue expander for a permanent breast implant. For aesthetic augmentation procedures, however, every revision was considered unplanned. The numbers presented in **figure 17** are composed of new implants as well as breast implants inserted (and/or explanted) prior to and after the start of the registry. The increasing trend of more replacement and explantation procedures being registered in DBIR that was seen in the previous annual report, was continued in 2018.

***Figure 17.** Distribution of registered aesthetic procedures per year, per breast (2016 – 2018)*



	2016	2017	2018	Total
Insertion only	**9,188**	**10,660**	**10,222**	**30,070**
Replacement (unplanned)	**108**	**1,111**	**2,433**	**3,652**
Implant to Implant	82	1,058	2,381	3,521
Implant to TE	0	1	1	2
Implant to Autologous tissue	0	2	0	2
TE to TE	0	0	1	1
TE to Implant	26	17	9	52
Not stated	*0*	*33*	*41*	*74*
Explantation only	**9**	**225**	**482**	**716**

** TE: tissue expander.*

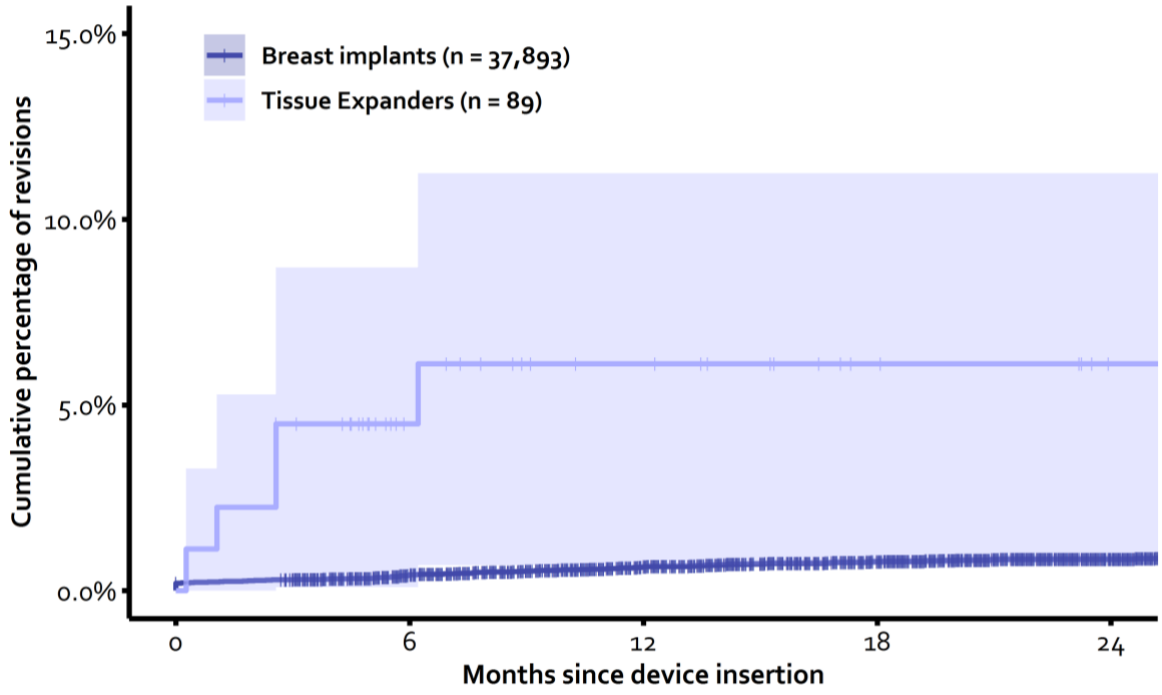
** 2015 was not a full registration year and is therefore not included in the trend line.*

Percentage of revisions *(Figure 18)*

The cumulative percentage of revisions was calculated per device type. These analyses included all devices of which the insertion surgery was registered in DBIR since the start in April 2015. All indications for revision were included, except a replacement of a tissue expander for a permanent breast implant. These procedures were censored. Additionally, only devices with a correct manufacturer and serial number registered at insertion surgery could be traced over time and could, therefore, be included in the calculations. For these analyses, revision was defined as reinsertion of a new device, reinsertion of the same device, replacement with autologous tissue, or explantation without replacement with any device or autologous tissue. The presented cumulative percentages were not adjusted for confounding factors.

Of the 37,893 inserted permanent breast implants which could be traced over time since April 2015, 0% had been revised after 6 months, 1% after 12 months, and 1% after 24 months. Of the 89 inserted tissue expanders which could be traced over time since April 2015, 4% had been revised (unplanned) after 6 months, 6% after 12 months, and 6% after 24 months.

Figure 18. *Cumulative revision incidence after aesthetic surgery – unplanned (since April 2015)*



** Only devices of which the insertion surgery was registered in DBIR are included in this figure.*

** Devices that are inserted in 2015, have a longer follow-up time than recently inserted devices.*

** These results should be interpreted carefully (See Note on page 33).*

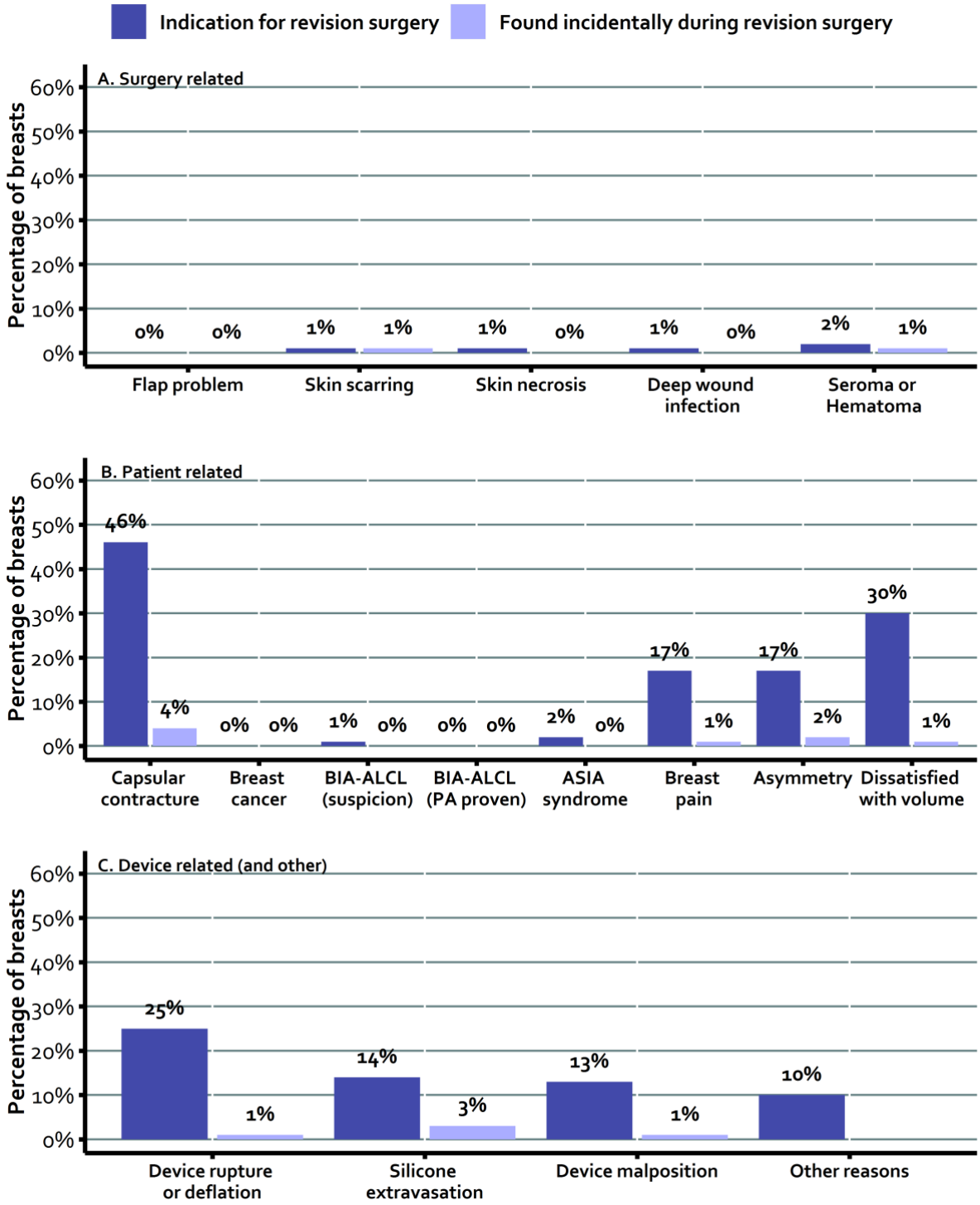
Indications for revision surgery & Incidental findings ***(Figure 19 – next page)***

Of the women with an unplanned breast implant replacement or explantation procedure, the indication for revision was stated in 90% of the records. Of these, most revisions were performed due to patient-related indications (0%-46%), followed by device-related indications (13%-25%), and surgery-related indications (0-2%).

An "Other" reason for revision was registered in 10% of the cases. In case of a reconstructive indication, most of the time, this appeared to be a revision due to a planned replacement for autologous tissue. In the case of an aesthetic indication, the "other" reasons are not entirely known yet.

All reported issues could also have been found incidentally during a revision procedure, not being the primary indication for revision. Nevertheless, these incidentally found issues were hardly reported. It is not known, however, whether they were less often encountered or that surgeons less frequently registered these issues.

Figure 19. *Indications for replacement or explantation after aesthetic surgery, per breast (2018)*



** Multiple indications could be reported per revision procedure.*

** These results should be interpreted carefully (See Note on page 33).*

Device characteristics *(**Table 11** & **Figure 20**)*

The majority of devices inserted for aesthetic indications were permanent breast implants. Most of the permanent breast implants were round, textured, silicone coated, and silicone filled. The mean volume was between 360cc and 370cc. The inserted tissue expanders were predominantly anatomically shaped, textured, silicone coated, and filled with saline. The mean maximum volume of the tissue expanders was between 450cc and 490cc, and the mean intraoperative filling volume was between 110cc and 200cc.

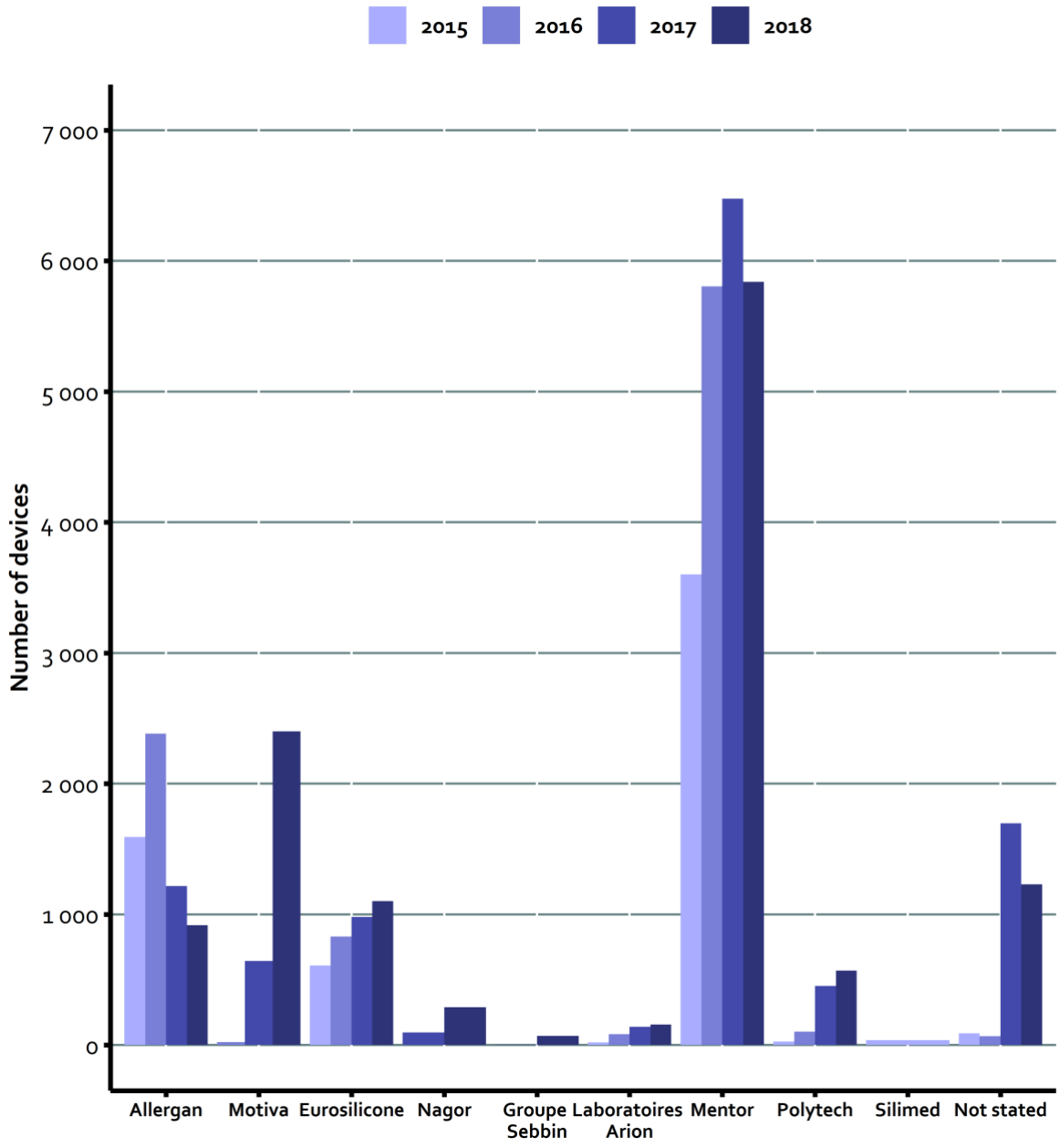
Table 11. *Characteristics of inserted devices for aesthetic indications, per year (2015-2018)*

	Permanent implants				Tissue Expanders			
	2015	**2016**	**2017**	**2018**	**2015**	**2016**	**2017**	**2018**
Inserted devices	n = 5,974	n = 9,285	n=11,664	n=12,539	n = 3	n = 10	n = 40	n = 36
Device shape								
Round	66%	68%	69%	63%	0%	40%	52%	11%
Shaped/Anatomical	32%	30%	30%	35%	33%	60%	45%	86%
Not stated	*2%*	*2%*	*1%*	*2%*	*67%*	*0%*	*3%*	*3%*
Device texture								
Textured	96%	96%	89%	90%	33%	100%	92%	97%
Smooth	1%	1%	8%	7%	0%	0%	5%	3%
Not stated	*3%*	*3%*	3%	*3%*	*67%*	*0%*	*3%*	*0%*
Device coating								
Silicone	97%	97%	95%	94%	33%	100%	98%	100%
Polyurethane	1%	1%	3%	4%	0%	0%	0%	0%
Not stated	*2%*	*2%*	*2%*	*2%*	*67%*	*0%*	*2%*	*0%*
Device fill								
Silicone	98%	97%	97%	96%	100%	100%	68%	28%
Saline	0%	0%	0%	0%	0%	0%	28%	72%
Hydrogel	0%	1%	1%	1%	0%	0%	0%	0%
Not stated	*2%*	*2%*	*2%*	*3%*	*0%*	*0%*	*4%*	*0%*
Device volume Mean volume in cc (SD)								
Volume breast implant*			368 (102)	363 (98)				
Not stated			*1%*	*2%*				
Max. volume TE*							489 (135)	450 (120)
Not stated							*0%*	*0%*
Intraoperative filling of TE					?	?	196 (142)	111 (100)
Not stated					*100%*	*100%*	*55%*	*0%*

** SD: standard deviation, Max.: maximum, TE: Tissue Expander.*

** The variables 'volume breast implant' and 'max. volume TE' have been registered since September 2017.*

Figure 20. *Number of inserted devices for aesthetic indications per manufacturer (x-axis), per year (2015-2018)*



QUALITY INDICATORS, COLLABORATIONS, FUTURE PERSPECTIVES, AND RESEARCH

7. QUALITY INDICATORS

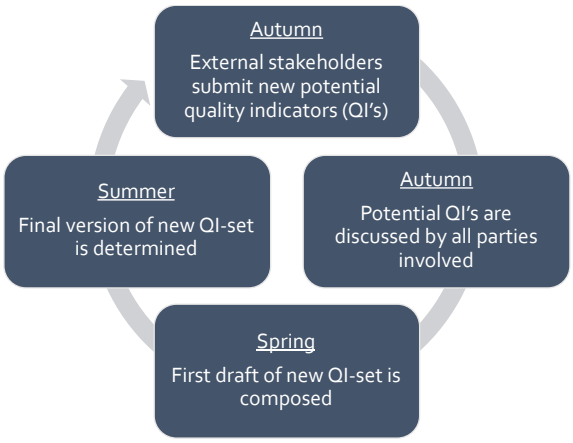
Quality indicators

According to Donabedian's model, there are three types of indicators: structure, process, and outcome indicators. The DBIR quality indicators are defined by the Scientific Committee and constitute the basis for internal data mirroring. After tripartite coordination with patient representatives and health care insurers, indicators can eventually become externally transparent, which means that hospitals make their results publicly available.

Annual cycle ***(Figure 21)***

The cycle for developing quality indicators is a secure trajectory that involves close collaboration between external stakeholders and the Scientific Committee. A potential quality indicator undergoes two phases: internal and external transparency. The first few years, only health care institutions receive feedback about this indicator (internal indicator) to further review and adjust the indicator where needed. After the agreement of all involved stakeholders, it is decided whether or not an indicator will become externally transparent (external indicator) in the yearly Transparency Calendar of the Dutch National Health Care Institute (ZiNL). At that time, the quality indicator should be sufficiently valid to be shared with external parties, such as patients and health care insurers.

Figure 21. *Annual DICA cycle for quality indicators*



Dutch Health and Youth Care Inspectorate (IGJ)

There are multiple parties in the Netherlands that request quality indicators to monitor the quality of care. One of these parties is the Dutch Health and Youth Care Inspectorate (IGJ). These indicators are legally required for health care institutions. For this reason, DBIR tries to collaborate closely with IGJ and other parties regarding the development of new quality indicators to prevent double requests or any ambiguities from the care providers' side.

External quality indicators 2018

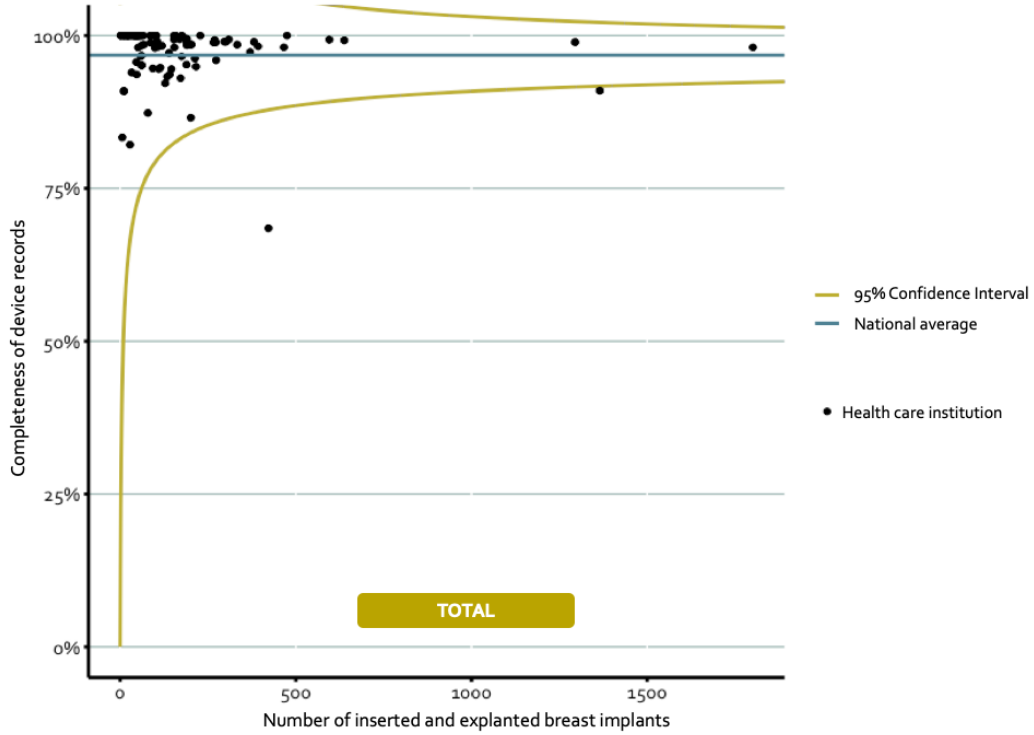
No.	Description	Type
1.	Is this institution registering in DBIR? (YES/NO)	Structure
2.	The percentage of registered breast devices in DBIR.	Process
3.	The percentage of registered breast devices in DBIR with a complete record.	Process

Results of external quality indicator no. 3

In 2018, indicator 3 became externally transparent for the first time. The rationale for this indicator is the need for complete device records to analyze outcome indicators, such as explantation within 60 days, to be able to follow an implant over time, to conduct scientific research, or to carry out a recall action.

The national average of completely registered device records appeared to be high, namely 93% (range 50-100%) (**Figure 22**). For further quality research, this indicator can be divided into two subgroups: inserted and explanted breast implants. If we zoom in on these two subgroups, it appeared that the average record completeness of inserted devices was very high (93%, range 50-100%) **(Figure 22a**). For explanted devices, however, the average record completeness was lower (88%), with a wider range (0-100%) **(Figure 22b**).

Figure 22. *Funnel plot of quality indicator no. 3, inserted and explanted devices (2018)*



Potential for quality improvement

It is known that information from explanted breast implants is often lacking. Data from breast implants that were placed several years ago are difficult to retrieve. However, this was taken into account when analyzing the results of quality indicator 3. Nevertheless, for a large number of health care institutions, there appears to be potential for improvement of the registration of explanted breast implants. Fortunately, the longer the DBIR exists, the more data can be retrieved from the DBIR database to use for quality evaluations.

Figure 22a. *Funnel plot of quality indicator no. 3, inserted devices (2018)*

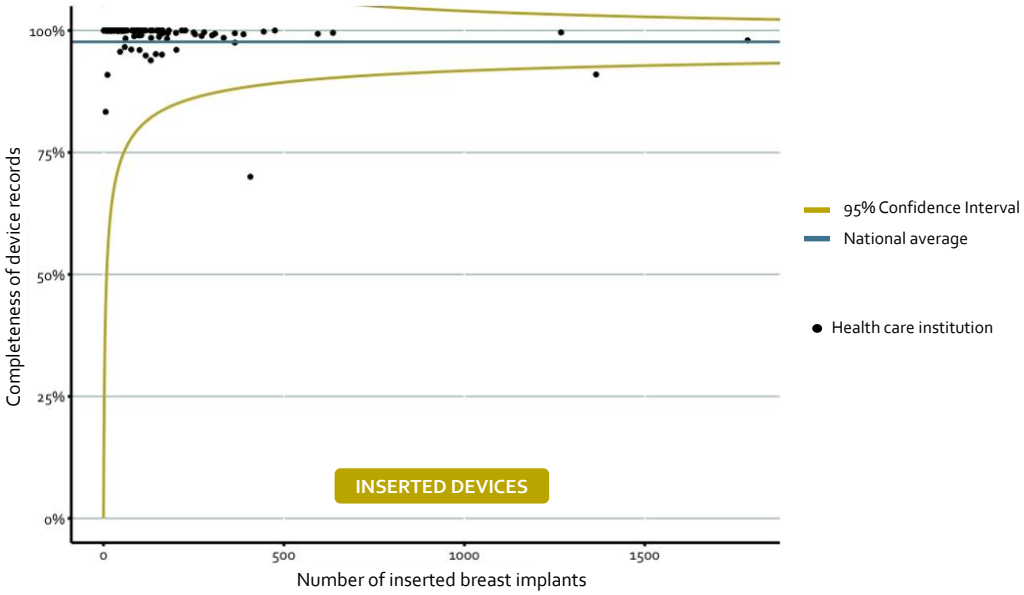
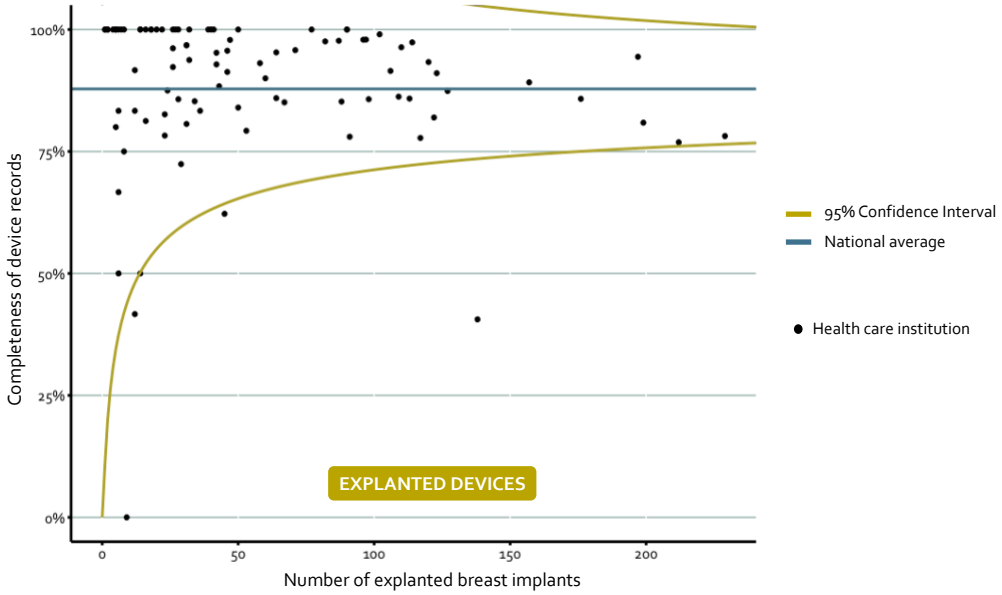


Figure 22b. *Funnel plot of quality indicator no. 3, explanted devices (2018)*



8. COLLABORATIONS

International collaboration with ICOBRA

DBIR collaborates intensively with international partners through ICOBRA (International Collaboration of Breast Registry Activities) (**Figure 23**). ICOBRA was founded in 2012, at the initiative of the Australian Breast Device Registry (ABDR) and under the auspices of the Australasian Foundation for Plastic Surgery. At the heart of the ICOBRA concept resides the core ethic and commitment to improving health outcomes for patients with breast devices globally, in an atmosphere of transparency, and a non-profit setup. Contributing countries have been working towards an internationally agreed comparable core dataset and quality indicators, using standardized and epidemiologically sound data that reflect global best practice.

Additionally, by using harmonized datasets, ICOBRA hopes that future crises related to breast devices can be detected and averted in a timely fashion and that best surgical strategies can be identified. At the beginning of 2020, the first steps in pooling anonymized data between the DBIR and ABDR will be explored.

Combined Annual Report

In the beginning of 2020, the American, Australian, British, French, Dutch, and Swedish breast device registries will present their first combined ICOBRA Annual Report. This report includes data on patient-, surgery-, and device characteristics from each registry.

Figure 23. *Current partners of ICOBRA*

9. FUTURE PERSPECTIVES

Quality Indicators

In addition to the current structural and process indicators which are externally transparent (**chapter 7**), the first outcome indicators are being developed internally. These include explantation within 60 days due to complications, explantation within one year due to complications, or the adherence to national guidelines such as the use of preoperative systemic antibiotic prophylaxis.

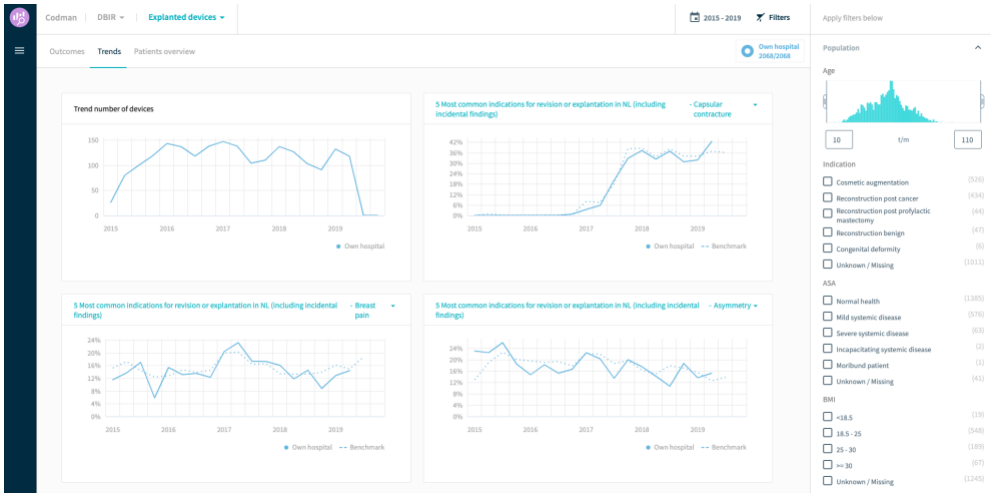
Patient Feedback

In addition to measuring clinical outcomes, it may be of added value to incorporate the patients' perspective. DBIR is exploring options to measure these 'patient reported outcomes' (PROs) with the Implant Surveillance Module of the BREAST-Q (BREAST-Q IS). Eventually, by linking these PROs to the clinical data, more insight is gained into the quality of the provided care and all registered breast implants. Currently, BREAST-Q IS is still under development. Once BREAST-Q IS becomes available, its potential and added value will be evaluated by the Scientific Committee of DBIR.

Interactive Codman Dashboard

Since the summer of 2019, the users of DBIR have access to an interactive dashboard: the Codman Dashboard. In this dashboard, the results of their external and internal quality indicators, together with an overview of their treated patients is provided (**Figure 24**). Users are able to zoom in on specific patient populations, used breast implants, or applied surgical techniques when they look at the results of their performed implant surgery. All results are presented versus a national benchmark. At the moment, this dashboard is live with the first beta-version. Next year, this dashboard will be extended with more features.

Figure 24. *Screenshot of the new, interactive Codman Dashboard (with dummy data).*



Coverage and quality of the DBIR database

A requirement for accurate quality evaluations is optimizing capture rates and the data quality. Therefore, at the end of 2019, a data verification project will start. During this project, registered data points from the DBIR will be compared with actual data points from the Electronic Patient Records in a representative selection of health care institutions.

More implant brands with unique and scannable barcodes

The close collaboration between GS1 Healthcare, implant manufacturers, implant distributors, and the DBIR committee, resulted in 5 of the 7 brands having a standardized, unique barcode on all of their breast implant boxes in The Netherlands. These brands are Eurosilicone, Mentor, Motiva, Nagor, and Polytech. Besides a reduction of typing errors, these implants can be registered in DBIR by scanning the barcode, leading to a reduction of registration burden.

Decreasing the registration burden

Just like last year, the reduction of the administrative burden is one of the top priorities of DBIR and DICA. Therefore, DBIR and DICA co-operate in projects that invest in the registration of information uniformly, so that data can be extracted automatically from electronic patient records for various purposes, based on the FAIR principles (Findable, Accessible, Interoperable, Reusable). Also, we are aiming for a breast implant catalogue containing breast implant characteristics from all manufacturers based on the reference number, reducing the registration burden by clinicians.

Linkage with other registries and databases

Currently, all breast cancer patients undergoing implant-based breast reconstruction, are being registered in the NBCA (the NABON Breast Cancer Audit) and DBIR. The same applies to patients with Breast Implant Associated - Anaplastic Large Cell Lymphoma (BIA-ALCL), who are registered in the Dutch nationwide pathology database PALGA and DBIR. Ideally, overlapping information between these groups is registered only once. Therefore, DBIR tries to set up collaborations. However, in all these linking processes, current privacy issues have to be considered and overcome.

International Perspectives

Parallel to these nationwide initiatives, we will continue our teamwork with the partners of ICOBRA regarding the ICOBRA core dataset, GS1 barcodes, combined analysis, annual reports, lining up the development of quality indicators, and patient reported outcome measures (PROMs).

Privacy issues in improving patient care

Sharing aggregated data with other registries nationally and internationally helps to identify areas of improvement for individual patient care. However, with the introduction of new privacy legislation, clinical quality registries are under pressure. The DBIR scientific committee notices differences in the interpretation of laws between health care institutions, legal advisors, and privacy officers within European countries as well as the rest of the world. These issues will be addressed, and an open mind towards the use of data, with respect for the individual's privacy, will be essential for future quality improvement.

10. RESEARCH OUTPUT

The primary goal of DBIR is improving the quality of care and breast implants using benchmark information and quality indicators, rather than providing a large database solely for research purposes. However, the Scientific Committee of DICA and the DBIR Committee believe that scientific research contributes to improving the quality of care, identifying best practices, and evaluate device performance. Therefore, all participants of the registry (e.g. plastic surgeons) have the possibility to conduct research with the data, and are encouraged to submit research proposals. These research proposals are managed by the Scientific Committee of DBIR and the statistical department of DICA, to check the validity and relevance of the proposal, and the availability of the requested data items.

Previous research:

- Spronk PER*, Becherer BE*, Hommes J, Keuter XHA, Young-Afat DA, Hoornweg MJ, Wouters MWJM, Mureau MAM, Rakhorst HA. How to improve patient safety and quality of care in breast implant surgery? First outcomes from the Dutch Breast Implant Registry (2015-2017). J Plast Reconstr Aesthet Surg. **2019**.;72(10):1607-15. DOI: 10.1016/j.bjps.2019.06.023. *(*first two authors contributed equally to this article)*
- Becherer BE*, de Boer M*, Spronk PER, Bruggink AH, de Boer JP, van Leeuwen FE, Mureau MAM, van der Hulst RRJW, de Jong D, Rakhorst HA. The Dutch Breast Implant Registry: Registration of Breast Implant-Associated Anaplastic Large Cell Lymphoma – A proof of concept. Plast Reconstr Surg. **2019**;143(5):1298-1306. DOI: 10.1097/PRS.0000000000005501 *(*first two authors and last two authors contributed equally to this article)*
- Becherer BE, Spronk PER, Mureau MAM, Mulgrew S, Perks AGB, Stark B, Pusic AL, Lumenta DB, Hopper I, Cooter RD, Rakhorst HA. High risk device registries: Global value, costs, and sustainable funding. J Plast Reconstr Aesthet Surg. **2018**;71(9):1362-80. DOI: 10.1016/j.bjps.2018.05.048
- Rakhorst HA, Mureau MAM, Cooter RD, McNeil J, van Hooff M, van der Hulst R, Hommes J, Hoornweg M, Moojen-Zaal L, Liem P, Mathijssen IMJ. The new opt-out Dutch Breast Implant Registry – Lessons learnt from the road to implementation. J Plast Reconstr Aesthet Surg. **2017**;70(10):1354-60. DOI: 10.1016/j.bjps.2017.04.003
- Hommes J, Mureau MAM, Harsmen M, Rakhorst HA. 'Which breast implant do I have?' The importance of the Dutch Breast Implant Registry'. Ned Tijdschr Geneeskd. **2015**;160:A9728.

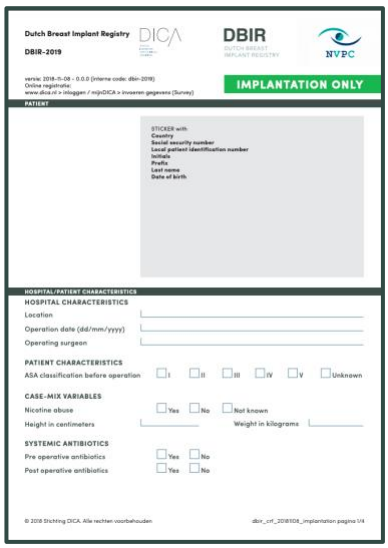
APPENDIX

Case report forms

The paper Case Report Forms (CRF) are accessible by clicking one of the images below, or by visiting one of the websites:

- https://dica.nl/dbir/about-dbir
- https://documents.mrdm.nl/showcase/downloaden

IMPLANTATION ONLY



REPLACEMENT PROCEDURE

EXPLANTATION ONLY

Scan the QR-code to read the digital version of the DBIR Annual Reports

Annual Report (2015-2017)

Annual Report (2018)

DBIR

DUTCH BREAST IMPLANT REGISTRY

DICA MAKE CARE COUNT

Annual report DBIR 2018