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How to improve patient safety and quality of care in breast implant surgery? First outcomes from the Dutch Breast Implant Registry (2015-2017)

P.E.R. Spronk[a,b,1,*], B.E. Becherer[b,c,1], J. Hommes[d], X.H.A. Keuter[d,e], D.A. Young-Afat[f], M.J. Hoornweg[g], M.W.J.M. Wouters[b,h], M.A.M. Mureau[c], H.A. Rakhorst[i]

[a] *Department of Surgery, Leiden University Medical Center, Albinusdreef 2, 2333 ZA Leiden, the Netherlands*
[b] *Scientific bureau, Dutch Institute for Clinical Auditing (DICA), Leiden, the Netherlands*
[c] *Department of Plastic and Reconstructive Surgery, Erasmus MC, University Medical Center Rotterdam, Rotterdam, the Netherlands*
[d] *Department of Plastic, Reconstructive and Hand Surgery, Maastricht University Medical Center, Maastricht, the Netherlands*
[e] *Department of Plastic, Reconstructive and Hand Surgery, VieCuri Medical Center, Venray, the Netherlands*
[f] *Department of Plastic, Reconstructive and Hand Surgery, Amsterdam University Medical Center, location VU medical center, Amsterdam, the Netherlands*
[g] *Department of Plastic and Reconstructive Surgery, Antoni van Leeuwenhoek, Amsterdam, the Netherlands*
[h] *Department of Surgical Oncology, Antoni van Leeuwenhoek, Amsterdam, the Netherlands*
[i] *Department of Plastic, Reconstructive and Hand Surgery, Medisch Spectrum Twente, Enschede, the Netherlands*

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KEYWORDS
Breast implants;
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Summary *Background:* Although the use of breast implants is generally considered to be safe, breast implants are associated with short- and long-term complications. To evaluate and improve the quality of breast implant surgery, and increase our knowledge of implant performance, the national Dutch Breast Implant Registry (DBIR) was established in 2015. DBIR

[1] Both authors contributed equally to this work.

* Corresponding author at: Department of Surgery, Leiden University Medical Centre, Albinusdreef 2, 2333 ZA Leiden, the Netherlands.
E-mail address: p.e.r.spronk@lumc.nl (P.E.R. Spronk).

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Implant registry;
Quality of care

is one of the first up-and-running breast implant registries worldwide and follows an opt-out structure.
Objective: This article provides an overview of the first outcomes and experiences of the DBIR.
Methods: The national coverage of DBIR was studied using data from the Dutch Health and Youth Care Inspectorate. The incidence rate of breast implants was calculated for 2016 and 2017, and patient, device, and surgery characteristics were compared between cosmetic breast augmentations or reconstructive indications. Four infection control, measures were selected to demonstrate the variation in the Dutch clinical practice.
Results: In 2016, 95% of the hospitals and 78% of the private clinics participated in DBIR. Between 2015 and 2017, a total of 15,049 patients and 30,541 breast implants were included. A minimum breast implant incidence rate of 1 per 1,691 women could be determined for 2017. The majority of devices were inserted for a cosmetic indication (85.2%). In general, patient, device, and surgery characteristics differed per indication group. Substantial variation was seen in the use of infection control measures (range 0–100%).
Conclusion: Preliminary results obtained from DBIR show high national participation rates and support further developments toward the improvement of breast implant surgery and patient safety.

Introduction

Since the introduction of breast implant surgery approximately six decades ago, numerous studies have evaluated the health effects and safety of breast implants.[1] These studies suggested that breast implants are to be considered safe. Nonetheless, a variety of surgical complications may occur following breast implant surgery, such as infection, implant rupture or deflation, late seroma, and capsular contracture.[2–4]

Recently, an association between anaplastic large cell lymphoma (ALCL) of the breast has been found.[5–7] Furthermore, the debate on possible associations between silicone exposure and various autoimmune diseases or connective tissue diseases continues (e.g., ASIA, an autoimmune/inflammatory syndrome induced by adjuvants).[8–12] Therefore, the outcomes of "real-world" data are becoming of increasing scientific and clinical importance to assess the effect of various intraoperative techniques and the use of different types of breast implants, while controlling for confounding factors adequately.[13,14]

In response to this, several countries have developed breast devices registries, among which is the Dutch Breast Implant Registry (DBIR).[15–20] In April 2015, the DBIR started to register all patients undergoing breast implant surgery in the Netherlands (both implantations and explantations).[21] Currently, the audit provides hospitals and private clinics with weekly updated, benchmarked information of their performance. Additionally, the registry can be used as a track-and-trace system in case of an implant recall and identify patients who have the implant(s) of interest. DBIR follows an opt-out construct, which is unique compared to other breast implant registries worldwide.

Recent research has shown that the estimated prevalence of women with breast implants was 3.3% in the Netherlands in 2015.[5] However, incidence rates and further details on surgery techniques used, types of inserted devices, and national trends are not known yet. By using data of the DBIR, this study aims to provide more insight into the patient characteristics of women undergoing breast implant surgery in the Netherlands, the different types of inserted devices, and the nationwide variation in surgical techniques used.

Methods

Registry methods

Governance

The Dutch Breast Implant Registry (DBIR), founded in 2014, was an initiative of the Netherlands Society for Plastic Surgery (NVPC).[22] It provides an audit system for plastic surgeons on outcomes of breast implant surgery and serves as a track-and-trace system for breast implants. More information of the establishment, organization, and funding of the registry can be found in the paper of Rakhorst et al. and the annual report.[21,23]

Quality indicators

The primary purpose of the DBIR is to provide healthcare providers with reliable, benchmarked information of structure, process, and outcome parameters. These quantitative measures cover different aspects of breast implant surgery: patient characteristics, information about intraoperative techniques, and short- and long-term outcomes of implants. A first set of quality indicators was defined by the DBIR group and external stakeholders (e.g., Dutch Health and Youth Care Inspectorate (IGJ), healthcare insurance companies, the Federation of hospitals, and patient advocates). For 2018, three quality indicators will be made publically transparent for all hospitals and private clinics performing breast implant surgery in the Netherlands: (1) participation in the registry, (2) percentage of registered breast implants compared to the actual inserted/explanted devices, and (3) percentage of completely registered records.

Data collection

Data are entered in the DBIR by plastic surgeons (in training) or under supervision by (research) nurses or physician assistants. Data entry can be done in 2 ways: by electronic exchange between the Electronic Patient Record and the registry or by using an Internet-based program. Data are stored at a central server.[24] The dataset consists of four levels: (1) general patient information (e.g., anonymized patient identification number, age), (2) patient characteristics during surgery (e.g., date of surgery, ASA classification, smoking, body mass index (BMI), (3) surgery techniques at the breast level (e.g., indication; incision site; flap cover; or, when applicable, the indication for revision), and (4) iImplant characteristics (e.g., manufacturer, serial number, lot number, texture, fill, shape).

Data verification and participation rate

The quality of the DBIR database is evaluated at three levels: (1) national coverage: the participation of all Dutch hospitals and private clinics participating in breast implant surgery, (2) completeness: the number of registered procedures versus the actual number of procedures performed at each center, and (3) validity: the quality of the data compared to that in the patient electronic medical records in the hospitals.

In this study, the national coverage was assessed by comparing the number of institutions in DBIR to the number of eligible institutions known by the Dutch Health and Youth Care Inspectorate (IGJ).

No gold standard is known for the evaluation of completeness of the DBIR yet. By now, data from the industry are far from complete, and national insurance data do not include cosmetic procedures. Therefore, this could not be determined in the current study.

Study methods

Patient selection

Per record (i.e., breast), information of the date of birth, date of surgery, type of surgery (insertion/replacement/explantation only), and device type was minimally required to be eligible for analysis. The minimum incidence rate was calculated using the total number of women between 20 and 80 years of age in the Netherlands, in 2016 and 2017.[25]

For further analysis, all patients who had received a breast implant from the start of the DBIR on April 1, 2015, until the end of the second complete registration year on December 31, 2017, with a known indication (either reconstructive or cosmetic), were included. Patients who had received a tissue expander were excluded from the analysis. The population was divided into two cohorts: cosmetic and reconstructive. The cosmetic group included all patients with a breast augmentation. The reconstructive group included all patients with the following indication: reconstruction post (prophylactic) mastectomy, reconstruction for a benign condition, or reconstruction for a congenital deformity. To identify differences between hospital and clinics and to identify where improvement can be made, four examples of used infection control measures were selected: glove change before implant handling, antiseptic rinse before insertion, the use of postoperative drains, and the use of prophylactic antibiotics.

Analyses

Differences in patient characteristics, device characteristics, and surgical techniques are described using percentages, means, and medians (depending on the distribution). Records with a missing indication (either cosmetic or reconstructive) are presented separately. Categorical variables were analyzed using the chi-square test, and continuous variables were analyzed using Student's *t*-test. Nationwide variation in the use of the four selected operative techniques was calculated in percentages per hospital per year and is visualized by scatterplots including the national mean. All analyses were performed using SPSS version 24.0 (SPSS Inc., Chicago, IL, USA).

Results

Nationwide participation rate DBIR

In the first full registration year (2016), 101 institutions were included in DBIR, of which 73 hospitals and 28 private clinics. This means coverage of 95% of the hospitals and 78% of the private clinics when compared with the number of the eligible institutions known by the IGJ (Figure 1).

Patients and minimum breast implantation incidence rates

In total, 48,493 records (i.e., breasts) have been registered with an operation date between the start of DBIR on April 1, 2015, and December 31, 2017, of which 48,026 (99.0%) were eligible for analysis (Supplementary Figure 1). Of these, 41,919 were registered for the insertion of a breast implant. In 2016, 7528 women received one or more permanent breast implant(s), accounting for a minimum incidence rate of one per 1649 women. In 2017, the minimum incidence rate was one per 1691 women (number of insertions: 7391).

For further analysis, the indication for surgery needed to be known (either reconstructive or cosmetic). Therefore, 11,378 of the 41,919 records (27.1%) were excluded (36.8% in 2015, 32.8% in 2016, and 15.1% in 2017). Eventually, 15,049 unique patients, 16,574 surgical procedures, and 30,541 breasts were included (Figure 2).

Patient characteristics

Patient characteristics per unique surgical procedure are presented in Table 1. In general, patients who had undergone a cosmetic breast augmentation were younger and had a lower ASA score than patients who received a breast reconstruction (all *ps* <0.001). Information of smoking and body mass index (BMI) has been collected since September 2017. However, this information was missing in more than 5% of the records for both indications. Supplementary Table 1a presents all patient characteristics of the records in which no indication was specified.

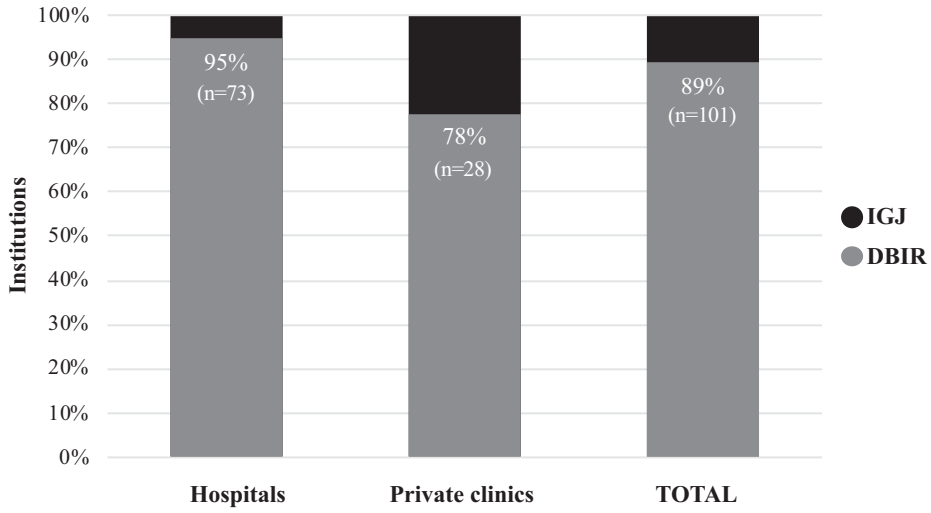

Fig. 1 Nationwide participation rate DBIR (2016). IGJ indicates Dutch Health & Youth Care Inspectorate.

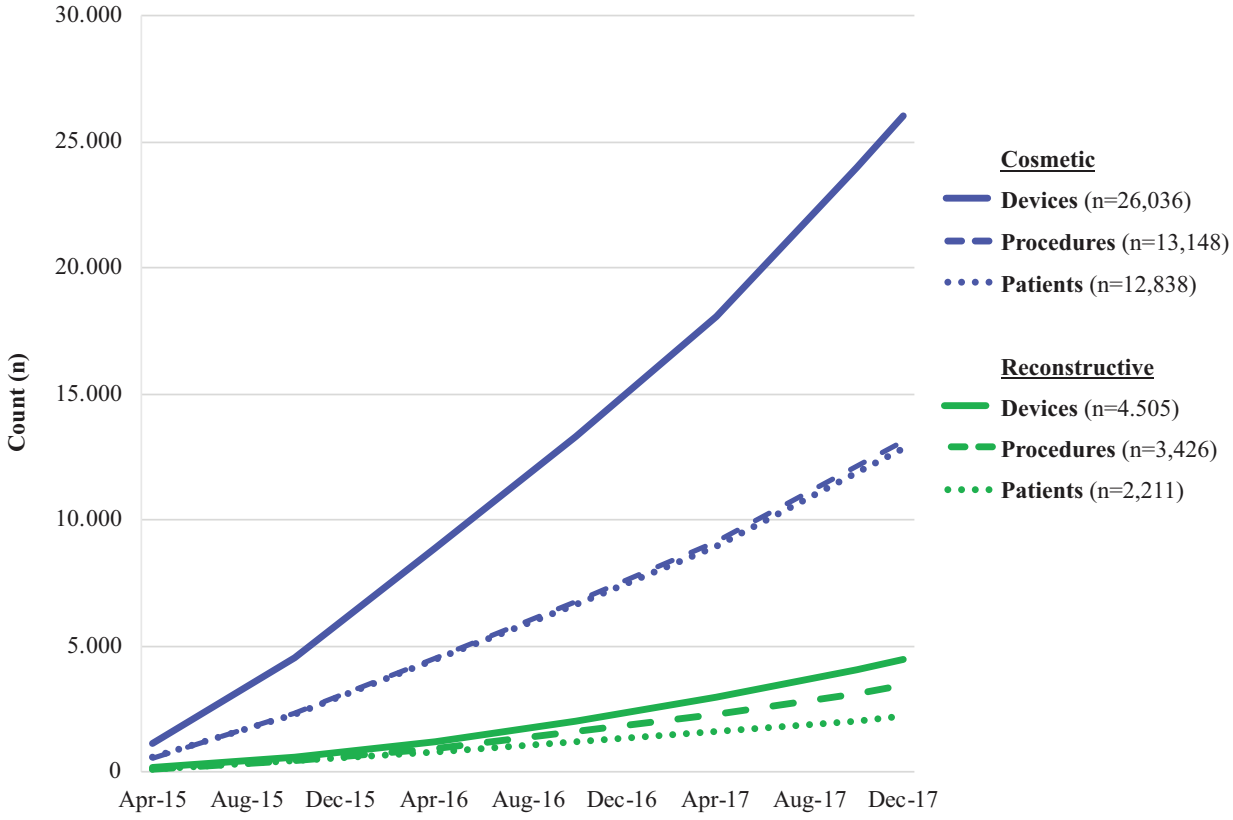

Fig. 2 Cumulative number of registered patients, procedures and inserted breast implants (2015-2017).

Device characteristics

Between April 2015 and December 2017, 26,036 (85.2%) breast implants were inserted for a cosmetic breast augmentation and 4505 (14.8%) for a breast reconstruction. In both cosmetic and reconstructive indications, most devices had a textured shell (93.1% and 92.5%, respectively) with a silicone coating (96.3% and 91.6%, respectively) and with silicone filling (97.2% and 82.6%, respectively). Implants used in reconstructive indications were more often anatomically shaped instead of round (86.0% versus 30.6%, $p < 0.001$). The median volume of inserted implants was higher in the reconstructive group (415 cc, IQR 325-520) than in the cosmetic group (350 cc, IQR 300-405; $p < 0.001$).

Between 2016 and 2017, a decrease in the use of textured implants was seen for both indication groups

Table 1 Patient characteristics per surgical procedure, presented at the patient level (2015-2017).

	Cosmetic		Reconstructive		*P*
	n	%	*n*	%	
Patients[a]	13,148		3426		
Age (years)					<0.001
<30	6227	47.4	205	6.0	
30-39	4140	31.5	488	14.2	
40-49	1794	13.6	876	25.6	
50-59	783	6.0	1112	32.5	
>60	204	1.6	745	21.7	
ASA classification					<0.001
I	12,493	95.0	2235	65.2	
II	532	4.0	1040	30.4	
III-IV	30	0.2	90	2.6	
Unknown	*93*	*0.7*	*61*	*1.8*	
Smoking[b]					<0.001
Yes	218	10.5	61	9.9	
No	1028	49.5	383	62.1	
Unknown	*830*	*40.0*	*173*	*28.0*	
BMI[b] (kg/m^2)					<0.001
<18.5	109	5.3	11	1.8	
18.5-25	1529	73.7	273	44.2	
25-30	218	10.5	148	24.0	
>=30	32	1.5	55	8.9	
Unknown	*188*	*9.1*	*130*	*21.1*	

ASA: American Society of Anesthesiologists. BMI: Body Mass Index.
[a] Patients per unique surgical procedure, no unique patients.
[b] Registered since September 2017. Percentages are calculated for a smaller population: $n = 2.076$ (cosmetic), $n = 617$ (reconstructive).

(cosmetic: 96% to 89%, $p < 0.001$; reconstructive: 94-92%, $p = 0.04$) (Figure 3). A similar trend was observed for the use of silicone-coated devices (cosmetic: 98-95%, $p < 0.001$; reconstructive: 95-90%, $p < 0.001$). Furthermore, in the reconstructive group, an increase in the use of round implants (11-15%, $p < 0.001$) and silicone-filled implants (78-85%, $p < 0.001$) was found. Characteristics of the 11,378 devices inserted for no specified indication are listed in Supplementary Table 1b.

Surgery characteristics

In patients with a known indication for surgery, 26,036 (85.2%) breast implants were inserted for a cosmetic breast augmentation. Almost all cosmetic procedures were performed bilaterally (99.0%). Patients in the reconstructive group, however, more frequently underwent a unilateral procedure (52.1%, 2349 of the 4505 devices). As shown in Table 2, the incision site for a cosmetic breast augmentation was most frequently the inframammary fold (93.7%), while in reconstructive procedures, the mastectomy scar was used in most cases (53.1%). For both cosmetic and reconstructive indications, most devices were placed with full coverage of the pectoral muscle (26.2% and 39.6%, respectively) or dual plane (47.4% and 33.6%, respectively). Autologous flap cover, fat grafting, and a MESH or acellular dermal matrix

Table 2 Surgery characteristics, presented at the breast level (2015-2017).

	Cosmetic		Reconstructive	
	n	%	*n*	%
Breasts[a]	26,036		4505	
Incision site				
Inframammary	24,404	93.7	854	19.0
Mastectomy scar	194	0.7	2391	53.1
Axillary	55	0.2	1	0.0
Areolar	109	0.4	370	8.2
Latissimus Dorsi	0	0.0	218	4.8
Other	1072	4.1	344	7.6
Unknown	*202*	*0.8*	*327*	*7.3*
Plane				
Subglandular	3584	13.8	173	3.8
Subfascial	1823	7.0	34	0.8
Sub flap	13	0.0	360	8.0
Subcutaneous	20	0.1	52	1.2
Full pectoral muscle	6830	26.2	1783	39.6
Dual plane	12,343	47.4	1512	33.6
Unknown	*1423*	*5.5*	*591*	*13.1*
Mastopexy				
Yes	935	3.6	212	4.7
No	24,567	94.4	3659	81.2
Unknown	*534*	*2.1*	*634*	*14.1*
Autologous flap cover				
Yes	95	0.4	511	11.4
No	25,386	97.5	3362	74.6
Unknown	*555*	*2.1*	*632*	*14.0*
Fat grafting				
Yes	14	0.1	87	1.9
No	25,486	97.9	3791	84.2
Unknown	*536*	*2.1*	*627*	*13.9*
Mesh/ADM use				
Yes	16	0.1	333	7.4
No	25,487	97.9	3776	83.8
Unknown	*533*	*2.0*	*396*	*8.8*

ADM: Acellular Dermal Matrix.
[a] Breasts per unique surgical procedure, no unique breasts.

(ADM) were not often used for both indications. See Supplementary Table 1c for all surgery characteristics of the records in which no indication was specified.

National variation in the use of infection control measures

A wide variation was observed between hospitals and clinics in the use of four selected perioperative infection control measures (all ranged 0-100%) (Figure 4). From 2016 to 2017, the proportion of procedures (per breast) in which surgeons changed their gloves before the insertion of an implant increased from 88% to 89% in reconstructive indications and from 61% to 80% in cosmetic augmentations. Furthermore, an increase was observed regarding rinsing the breast implant with an antiseptic solution before insertion (from 70% to 78% (reconstructive), and from 78% to 85% (cosmetic)). Increased use of prophylactic intravenous antibiotics before

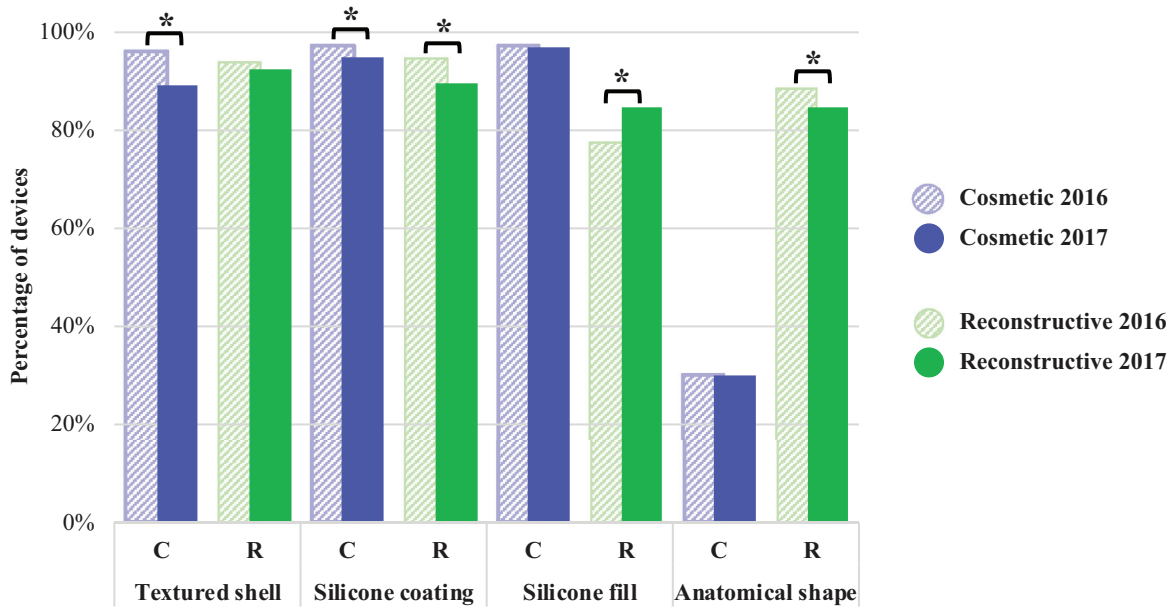

Fig. 3 Device characteristics per inserted device (2015-2017).
Textured vs smooth shell, silicone vs polyurethane coating, silicone vs saline fill, anatomical vs round shape.
2015 was not a complete registration year, and is therefore not included in this figure.
Cosmetic (2016 $n = 8995$; 2017 $n = 11,253$), Reconstructive (2016 $n = 1546$; 2017 $n = 2175$), <5% missing characteristics.
$^{*}p < 0.001$.

the incision was noticed too, from 95% to 97% (reconstructive) and from 91% to 93% (cosmetic). The use of drains decreased in reconstructive procedures (80-78%) but increased in cosmetic augmentations (14-16%).

Discussion

This study provides an overview of the first outcomes and experiences of the Dutch Breast Implant Registry (DBIR), one of the first opt-out breast implant registries in the world. Since the national rollout in April 2015, information of 41,919 breast implants has been registered, including details of patients, devices, and procedures. The participation rate of hospitals (95%) and private clinics (78%) is high compared to that of other breast implant registries in the world with a maximum participation rate of 80% (or unknown capture rates).[15-18] For the first time, we were able to calculate the minimum breast implantation incidence rate in the Netherlands. In 2016 and 2017, at least one per 1649 women or one per 1691 women, respectively, received one or more breast implant(s). However, it must be realized that this incidence rate is an underestimation, considering the current nationwide coverage of procedures.

Essentially, there were two groups of patients undergoing breast implant surgery with significant differences in characteristics: elective patients undergoing augmentation for cosmetic reasons who are generally young, healthy adults versus more complex patients requiring reconstructive surgery (mainly) after breast cancer treatment. Within our population, there was a predominance of textured silicone gel implants used for both indications, which is in line with other European countries but in contrast to the United States.[26,27] However, a significant increase in the use of smooth implants was observed, which appears to coincide with the critical issue of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL), a rare cancer of the immune system believed to be causally associated with textured breast implants.[28,29] In recent research of Becherer and de Boer et al., data of the DBIR and the Dutch Nationwide Network and Registry of Histo- and Cytopathology (PALGA) were combined, resulting in a dataset with pathological, clinical, and implant-related information. This demonstrates the potential of DBIR as an important tool for health risk assessments of implants.[30]

The main purpose of the DBIR is to improve the quality of breast implant surgery in the Netherlands by providing benchmarked information of a set of process and outcome measures (quality indicators). Several other clinical audits have preceded, leading to substantial improvements in quality of care.[31-33] As an example of possible interesting process indicators, the national variation in the use of 4 infection control measures was presented (the use of antibiotics, antiseptic rinse of the implant, glove change before implant handling, and the use of postoperative drains). A wide variation from 0% to 100% between hospitals and clinics in the use of these measures was seen. Understanding the nature of this variation and the effect of infection prevention on clinically relevant outcomes, is paramount in decision-making about improvement efforts.

A balance is required between capturing all valuable information, on the one hand, and spending an acceptable amount of time needed for data entry, on the other hand. To reduce the administrative burden and minimize the

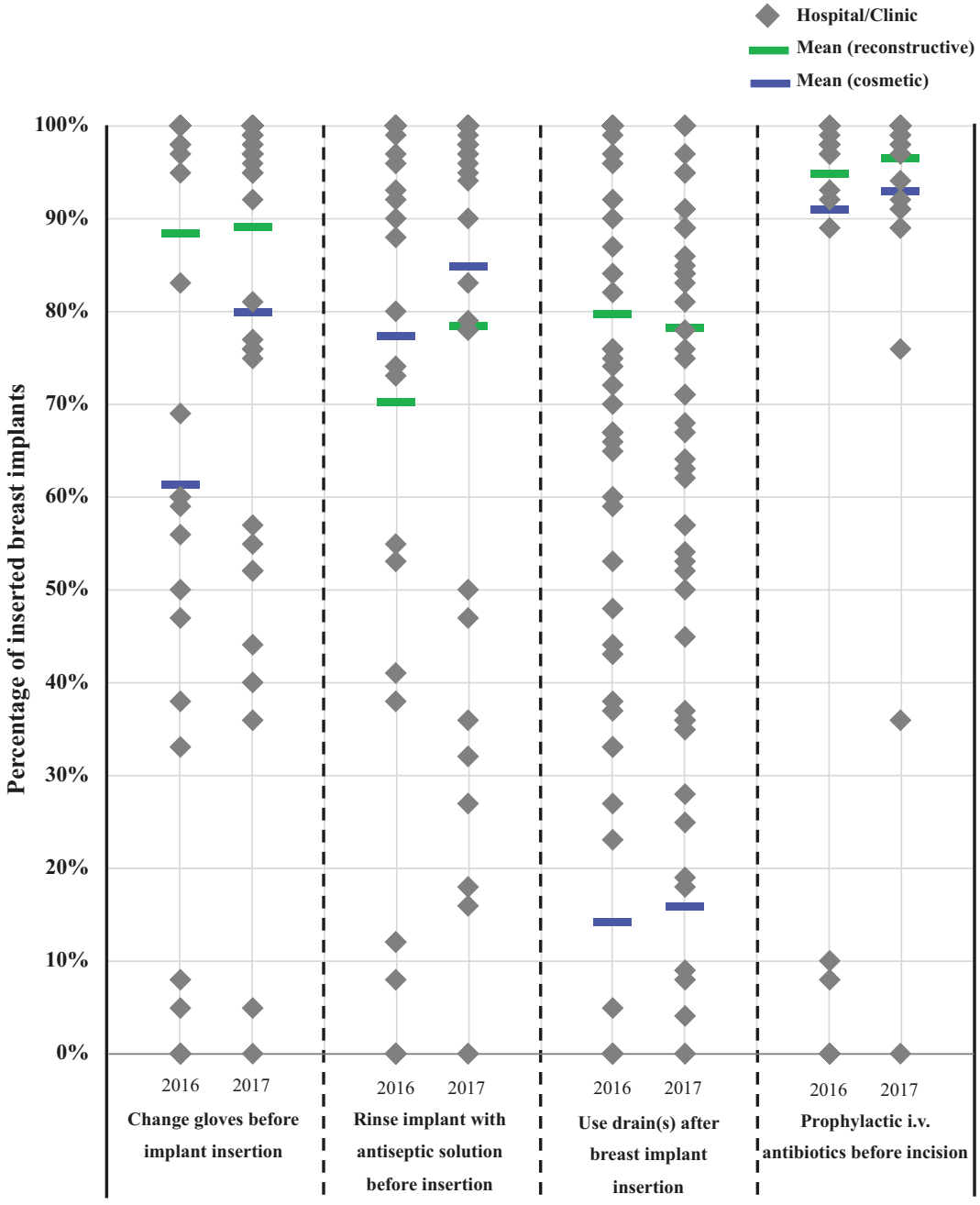

Fig. 4 Nationwide variation for a selection of infection control measures (2016–2017), presented on breast level. 2015 was not a complete registration year, and is therefore not included in this figure.

chance of typing errors, the GS-1 barcode system was implemented in the online data form of DBIR. With the help of this barcode, relevant implant characteristics, including the unique device identification (UDI) number, is automatically retrieved and registered. This will also help to decrease the amount of missing information of implant characteristics. Fortunately, an increasing amount of implant manufacturers are using a correct GS1 barcode in the Netherlands.

In general, completeness of the DBIR data has increased during the last three years.[23] It can be deduced from our results that missing data are not random but patient records in certain hospitals. The DBIR online system provides already instant feedback on missing records using a "list of errors." Further, a data verification project to evaluate the validity of the data will be scheduled shortly.

Future perspectives

To provide clinicians with outcome information and recommendations for change in practice in the near future, research projects with more mature data are scheduled and other outcome indicators are being evaluated. Potential outcome indicators are the percentage of explanations due to complications within an *x* number of days or implant rupture rates. Additionally, the DBIR plans to add

patient-reported outcome measures to the registry. For this, the registry awaits the BREAST-Q Implant Surveillance module, which contains 5 questions, particularly developed to measure patient-reported outcomes in women with breast implants.[34]

Internationally, the International Collaboration of Breast Registry Activities (ICOBRA) has defined an internationally agreed minimum core set of data points to be used by all breast device registries globally.[35] This dataset is integrated into the DBIR dataset. A future step is to combine breast implant registries globally to perform implant surveillance and evaluate clinical outcomes at an international level. Long-term data will eventually reveal the actual health effects of breast implants and breast implant surgery.

Conclusions

The opt-out DBIR is one of the first up-and-running breast implant registries worldwide, which is the result of collaborative and conjoint efforts from clinicians, health care providers, and policymakers. First experiences with DBIR and its preliminary results show that DBIR has the potential to provide answers to clinically relevant questions and to provide quality assurance and outcome research for breast implant surgery.

Declaration of Competing Interest

The authors declare that there are no conflict of interest and financial disclosure.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.bjps.2019.06.023.

CRediT authorship contribution statement

P.E.R. Spronk: Conceptualization, Data curation, Formal analysis, Writing - original draft, Validation. **B.E. Becherer:** Conceptualization, Data curation, Formal analysis, Writing - original draft, Validation. **J. Hommes:** Conceptualization, Data curation, Formal analysis, Writing - original draft, Validation. **X.H.A. Keuter:** Conceptualization, Data curation, Formal analysis, Writing - original draft, Validation. **D.A. Young-Afat:** Conceptualization, Data curation, Formal analysis, Writing - original draft, Validation. **M.J. Hoornweg:** Conceptualization, Data curation, Formal analysis, Writing - original draft, Validation. **M.W.J.M. Wouters:** Conceptualization, Data curation, Formal analysis, Writing - original draft, Validation. **M.A.M. Mureau:** Conceptualization, Data curation, Formal analysis, Writing - original draft, Validation. **H.A. Rakhorst:** Conceptualization, Data curation, Formal analysis, Writing - original draft, Validation.

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