Quality assurance in breast cancer care and breast implant surgery

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CHAPTER 8

From the ICOBRA initiative: A globally agreed minimum data set for breast implant surgery.

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ABSTRACT

Objective: To identify an internationally agreed minimum set of data points and their definitions to be used by all breast device registries globally.

Background: The Poly Implant Prothese (PIP) incident and breast implant associated Anaplastic Large Cell Lymphoma (ALCL) have raised awareness of the need for developing uniform device registries for breast implants. A uniform set of data points and data definitions is key to monitoring the performance of breast implants and collecting comparable information about procedures and outcomes of breast device surgery on an international level.

Methods: The International Collaboration of Breast Registry Activities (ICOBRA) convened an international multidisciplinary working group of surgeons, consumer representatives, specialist nurses, registry experts and medical device regulators. Data points collected by all currently operating breast implant registries were reviewed. A list of items to be used in the consensus process was defined. A modified Delphi approach was used, with surveys requiring the panellists to rate the importance of each data point to be included in the global minimum data set on a six point Likert scale.

Results: Data points from six different national breast implant registries were compared. Data points were divided into nine categories: clinical, implant related, and patient-reported findings, operation details (including antibiotics) and implanting technique details, patient characteristics, unique device identifiers (UDIs), unique patient identifier (UPI), and clinical demographics. A total of 52 data points which were collected by over 33% of currently national running registries were identified for the consensus (Delphi) process. After five rounds, 34 data points formed the global dataset and 17 data points were classified as the optional dataset for registries to collect globally. Data definitions were subsequently agreed upon.

Conclusion: We defined an internationally agreed minimum dataset to be used in breast device registries. This collaborative approach to share data will allow datasets to be combined and will provide a more effective global early warning system of implant-related problems.

INTRODUCTION

Breast implants are increasingly popular worldwide for breast reconstruction as well as breast augmentation.[1] In the Netherlands, the estimated prevalence of breast implants is 3,3% of the adult female population.[2] The safety and health effects of breast implants have been debated since their introduction over 50 years ago.[3,4,5] It has been observed that the longer breast implants remain in situ, the greater the likelihood of complications or adverse events.[6,7] Recently, Anaplastic Large Cell Lymphoma which, although a rare disease, has been shown to be associated to breast implants (BIA-ALCL).[8,2] In order to determine the health effects of breast implants and to determine implant performance, reliable long-term systematically collected data are needed.

Registry data provide a pragmatic source of evidence to address such issues of public health and safety. However, insufficient capture rates or dependence on implant producers made previous national and international patient registries unreliable.[9,10] Stakeholders including the UK Medicines and Healthcare Products Regulatory Agency, the Food and Drug Administration and the Australian Therapeutic Goods Administration have highlighted the importance of well-organized clinical registries that can provide early warning of underperforming devices such as breast devices, independent from the industry.[11,12,13,14] They are also an effective tool for recall procedures in the case of an adverse event. An example of this followed the recent withdrawal of Silimed implants from the market. Within a few hours the number of Silimed implants in the Dutch Breast Implant Registry could be determined, thereby providing clarity for patients, institutions as well as governmental organizations, and reassuring the vast majority who were unaffected.[15]

In 2012, the International Collaboration of Breast Registry Activities (ICOBRA) was established to improve breast device registries by sharing datasets and connecting organizations.[16] The members of ICOBRA include national plastic surgery societies or multidisciplinary breast implant registries of several countries, including Australia, Austria, Canada, France, Germany, Ireland, Italy, the Netherlands, New Zealand, South Africa, the United Kingdom, and the United States.

A number of countries have independent registries that are using largely similar datasets. Harmonization of these data points and data definitions is key to be able to compare and pool data from registries. Pooling is crucial to amplify the data and reduce the time needed to identify implants performing well and those associated with higher rates of adverse events, such as BIA-ALCL or capsular contraction. Therefore, we aimed to identify and define an internationally agreed minimum set of data points to be used by all breast device registries globally.

METHODS

Selection of data points

Registries for breast implants and tissue expanders were included in our study. Methods of enrolment, estimated total market of implants/100.000 adult female inhabitants, number of registered implants and capture rates were collected but were not part of this Delphi process.

Through ICOBRA, the six eligible countries with functioning breast device registries were invited to share their data sets, including the Australian Breast Device Registry (ABDR),[14] the Dutch Breast Implant Registry (DBIR),[15] the Bröstimplantatregistret of Sweden (BRIMP),[17] the Austrian Breast Implant Register (ABIR),[18] the Breast and Cosmetic Implant Registry of the United Kingdom (BCIR),[19] and the US National Breast Implant Registry (NBIR). In addition, all invitees provided their data definitions.

Data points were divided into nine categories: clinical, implant related, and patient-reported findings, operation (including antibiotics) and implanting technique details, patient characteristics, unique device identifiers (UDIs), unique patient identifier (UPI), and clinical demographics. Data points collected identically by the various registries were divided into three groups based on the percentage of registries that collect a specific data point. Groups were >66% , 33-66% and <33%.

On the 7th and 8th of April 2017, ICOBRA organized an in-person meeting at Monash University in Prato, Italy and 26 participants from eleven countries attended, representing clinicians, regulators, registry science experts, data managers and administrators; Australia (8), Austria (1), Germany (1), the Netherlands (3), New Zealand (1), Russia (1), Saudi (2), South Korea (2), Spain (1), Sweden (2), the United Kingdom (4), the United States (1). The theme of the meeting was "Consensus planning". The categorized data points were shared and the Delphi method was introduced. It was agreed that the number of data points should be reduced to a minimum and that a minimum overlap of 33% was required for a data point to become a candidate for the global minimum data set using a Delphi process.

Modified Delphi Process to obtain consensus on the core Tier 1 data points

The consensus process followed a modified Delphi approach,[20] which took place between July and November 2017. This process consisted of four rounds of online surveys using Qualtrics,[21] with each round of survey followed by a video teleconference. A pilot data collection form which included the global data set was designed and circulated among all the clinicians in the Delphi panel. All clinicians were encouraged to test the form by filling it out after their procedures. Clinicians provided feedback after trialling the form during 5-10 procedures, and suggested additional data points, so one further round was organised in November 2018 which included additional data points identified during testing of the dataset.

Expert panel members were selected to represent a wide range of stakeholders. The panel was international and multi-disciplinary, with representatives from each of the functioning breast implant registries (Australia, Austria, the Netherlands, Sweden, UK, US), other specialists in breast device surgery (breast surgeons and cosmetic surgeons and a breast-care nurse), two consumer representatives to confirm that the dataset would identify outcomes that were important for them, national regulators to help maximize the utility of the dataset and ensure the work aligned with other international registries, biostatisticians to ensure the statistical rigor of the methodology, and was chaired by a registry science expert.

The survey required the panelists to rate the importance of each data point on a six point Likert scale to be included in the global minimum data set. Data points were considered when they met the following criteria: (i) median score of 5 or 6, (ii) more than 70% of the panel scoring a 5 or 6, and (iii) no disagreement according to the RAND criteria.[22]

After each round, results from the survey were shared with the panel members prior to the next teleconference. As feedback and preparation for teleconferences, panel members received their own individual score and the overall group score (median) for each data point. If consensus was not reached to include a data point in the global data set, it became part of the optional set for each country to use at liberty.

Data definitions for Tier-1 and Tier-2 data points

Data definitions for all the data points included in the modified Delphi process were then finalized. The ABDR data definitions, which were obtained from established standard sources where they existed, or adapted from the medical literature, were used as the starting point. If no definitions were available from the ABDR data definitions, the definitions for those data points were developed by the ICOBRA team. The Delphi panel voted on these definitions as being 'acceptable' or 'requiring amendment'. This process consisted of 2 rounds of online surveys with each round of survey followed by a video teleconference, until the majority of panel members agreed to all definitions, with the same process used for further additions from the November 2018 round. Ethics approval was obtained from Monash University Human Research Ethics Committee. All panelists consented to participating in the study.

RESULTS

General characteristics of the six included national, functioning breast device registries are listed in **Table 1**. The results of the categorization of data points are listed in **Table 2**. The highest number of items were collected on implant related findings, operation details, and Unique Device Identifiers (UDI). Fewer similarities in data points were detected on patient characteristics and patient-reported outcomes.

Table 1. General characteristics of the current running breast device registries

Breast Device Registry	Since	Method of enrollment	Implants per 1,000 inhabitants[a] per year	Registrations per year	Capture rate
ABDR	2015	Opt-out	0.4 – 0.8	10,000-15,000	*not known yet*
DBIR	2015	Opt-out	1.2 – 2.9	15,000 – 25,000	80%-90%
BRIMP	2014	Opt-out	< 1.0	< 5,000	61% -70%
ABIR	2004	Opt-in	< 1.1	< 5,000	*not known yet*
BCIR	2016	Opt-in	0.8 – 1.5	25,000 – 50,000	*not known yet*
NBIR	2018	Opt-out	1.3 – 1.7	175,000 – 225,000	*not known yet*

ABDR: Australian Breast Device Registry, DBIR: Dutch Breast Implant Registry, BRIMP: Bröstimplantatregistret of Sweden,
ABIR: Austrian Breast Implant Register, BCIR: Breast and Cosmetic Implant Registry of the UK,
NBIR: US National Breast Implant Registry

Table 2. Overlap in data points in the six current running nationwide breast device registries Bold = 100% overlap.

	> 66% overlap	33% - 66% overlap	< 33% overlap
CLINICAL FINDINGS	**Infection** Seroma / hematoma (Newly diagnosed) breast cancer ALCL	Reason for revision; *(complication, asymptomatic, patient preference)* Skin necrosis Skin Scarring problems	Removing PIP implant Need for biopsy/suspect tumor Flap problem/loss Wound problems Bleeding ASIA syndrome
IMPLANT RELATED FINDINGS	**Capsular contracture (baker)** **Device rupture** **Device deflation** **Device malposition/rotation** Silicone extravasation		Axillary lymph node involvement Wrinkling/rippling
PATIENT-REPORTED FINDINGS	Asymmetry Patient dissatisfied with volume/ shape	Breast pain Worried for implant/desire to remove Due to recommendation LMV	Because of pregnancy Swollen breast Hard breast Ptosis
OPERATION DETAILS	Systemic/preoperative antibiotics **Laterality/side** Indication for surgery **Type of intervention (primary, revision, explant only)** Implant position/plane **Incision site** Capsulectomy Fat grafting	Postoperative Antibiotics Timing reconstruction (immediate/delayed) Occlusive nipple shields Nipple absent Flap cover	Neo-pocket formation Fat volume AB selection Steroids selection
IMPLANTING TECHNIQUE DETAILS	**Drain use** Antiseptic rinse of the pocket	Nipple Guards Glove change before insertion Sleeve/funnel (Keller funnel)	Type of rinse solution
PATIENT CHARACTERISTICS	Previous radiotherapy Date of birth Gender	ASA classification before Operation Smoking Height Weight Diabetes	History of medical issues Breast surgery prior to present operation Patients experience before surgery Post Radiotherapy planned
UDI	UDI (unique device identifier) **Device manufacturer** **Device serial no.** **Device catalogue reference no.** Device LOT no. Texture/ shell Fill Mesh or ADM used	Device distributor Shape Volume of implant Volume of TE Date of insertion of removed implants Device details of explanted device Volume of implant removed	Coating Max. volume of TE Markers/medical record of explant available Removing implant inserted other location UDI/details of MESH/ ADM

ALCL: *Anaplastic Large Cell Lymphoma*, ASIA: Auto Immune/Inflammatory *Syndrome* induced by Adjuvants, TE: Tissue Expander,
UDI: Unique Device Identification, ADM: *Acellular Dermal Matrix*, ASA: American Society of Anaesthesiologists physical status classification, AB: Antibiotics, LMV: Competent Authority *Sweden* (LäkeMedelsVertet*)*

Delphi analysis on data points

The Delphi process included five rounds of surveys and videoconferences. The videoconferences focused on the importance of collecting the data point based on its usefulness and the feasibility of collecting. The results and the participation from the panel at each round is shown in **Figure 1**. All data points that (i) were modified or (ii) did not achieve consensus in one round were included in the next round. The five rounds resulted in 34 data points (78 including sub-points) that were voted in the global data set by the panel (see **Table 3**). The optional data set consisted of 17 data points which are listed in **Table 4**.

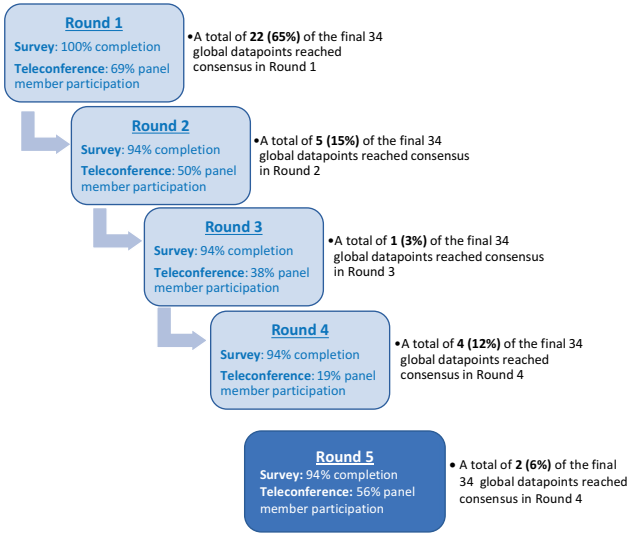

Figure 1. Modified Delphi process flow diagram.

Webconferences lead to renaming of datapoints

Discussions in webinars resulted in rewording of some data points (includes data points already in the global data set), introduction of some new data points to capture more meaningful information from multiple data points, and the inclusion of additional information. One data point (device malposition/rotation) and four sub-points (Infection leading to explantation, seroma, hematoma, risk reducing mastectomy) that had achieved consensus in round 1 had the wording clarified in the second round. Another data point 'Antiseptic rinse of the pocket' was changed during round 3 into 'Rinse of

Table 3. List of the global data points

Domain	No.	Data point	Voted in the global dataset during round
CLINICAL FINDINGS	1.	Reason for revision/explantation	Round 1
		a) *Patient preference*	Round 2
		b) *Asymptomatic*	Round 1
		c) *Complication*	Round 1
	2.	Infection leading to explantation	Round 1&2*
	3.	Seroma	Round 1&2*
	4.	Hematoma	Round 1&2*
	5.	Capsular contracture	Round 1
	6.	BIA-ALCL	Round 1
		a) *Suspected*	Round 5
		b) *Confirmed*	Round 5
IMPLANT RELATED FINDINGS	7.	Device rupture	Round 1
	8.	Device malposition/rotation	Round 1&2*
PATIENT REPORTED FINDINGS	9.	Breast pain	Round 4
OPERATION DETAILS	10.	Postoperative antibiotics	Round 1
	11.	Preoperative antibiotics	Round 2
	12.	Laterality	Round 1
	13.	Indication for surgery	Round 1
		a) *Cosmetic augmentation*	Round 1
		b) *Reconstruction post-risk reducing mastectomy*	Round 1&2*
		c) *Reconstruction (benign)*	Round 1
		d) *Reconstruction post-mastectomy for cancer*	Round 1
	14.	Type of intervention	Round 1
		a) *Primary*	Round 1
		b) *Secondary*	Round 1
		c) *Revision*	Round 1
		d) *Explant only*	Round 1
	15.	Timing of reconstruction	Round 5
		a) *Immediate*	Round 5
		b) *Delayed*	Round 5

Table 3. List of the global data points (continued)

Domain	No.	Data point	Voted in the global dataset during round
OPERATION DETAILS	16.	Implant position/plane	Round 1
		a) Sub glandular	Round 1
		b) Sub pectoral	Round 1
		c) Sub fascial	Round 1
		d) Sub flap	Round 1
		e) Sub cutaneous	Round 1
		f) Dual plan	Round 1
		g) Others (please specify)	Round 1
	17.	Incision site	Round 2
		a) Inframammary	Round 2
		b) Periareolar	Round 2
		c) Axillary	Round 2
		d) Mastectomy scar	Round 2
		e) Others (please specify)	Round 3
	18.	Nipple sparing	Round 1
	19.	Flap cover	Round 1
	20.	Fat grafting	Round 1
	21.	Concurrent mastopexy	Round 5
	22.	Capsulectomy	Round 1&4*
		a) Partial capsulectomy	Round 2
		b) Full capsulectomy	Round 3
IMPLANTING TECHNIQUE	23.	Rinse of the pocket	Round 3
		a) Antibiotics	Round 3
		b) Antiseptics	Round 3
		c) Others (please specify)	Round 3
	24.	Drain use	Round 2
	25.	Glove change before insertion	Round 2
PATIENT CHARACTERISTICS	26.	Previous radiotherapy	Round 1
	27.	Date of birth/Age of patient	Round 4
	28.	Height	Round 4
	29.	Weight	Round 4

Table 3. List of the global data points (continued)

Domain	No.	Data point	Voted in the global dataset during round
	30.	Device details[#]	Round 1
		a) Device manufacturer	Round 1
		b) Device serial number	Round 1
		c) Catalogue reference number	Round 1
		d) Device lot number	Round 1
		e) Texture	Round 1
		f) Fill	Round 1
		g) Shape	Round 1
UDI (incl. MESH/ADM)		*h) Volume of implant*	Round 1
	31.	ADM/Mesh used	Round 1
		a) Device details of the ADM/Mesh used	Round 1
	32.	Date of insertion of removed implants	Round 1
	33.	Device details of explanted device	Round 1
		a) Texture	Round 1
		b) Fill	Round 1
		c) Shape	Round 1
	34.	Marker/Medical record of explanted device if known	Round 2

BIA-ALCL: Breast Implant Associated Anaplastic Large Cell Lymphoma, **ADM:** Acellular Dermal Matrix, **UDI:** Unique Device Identification
Please note:
* Data point voted on in earlier round and wording confirmed in later rounds
[#] This data point will be changed to UDI when it has been implemented

the pocket with options to include antiseptics, antibiotics and other' (see **table 5** for details on these changes). The global data points that required multiple rounds of discussion were either in the 'Patient characteristics' category or the 'Patient reported findings' category. With date of birth/age of patient, the discussion showed that different formats are used and that the European Union does not allow the international transfer of such identifiable information, so age of patient will be used instead. The panel had concerns about the collection of height and weight relating to the reliability of data obtained.[23] Breast pain, which is a patient reported finding, was seen to be subjective and difficult to define. Another data point, 'Capsulectomy', which did not have a consistent definition, also required four rounds of discussion before it was voted in the global dataset.

Table 4. List of the optional data points

Domain	No.	Data point	% of registries collecting
CLINICAL FINDINGS	1.	(Newly diagnosed) Breast cancer	>66%
	2.	Skin scarring problem	33-66%
	3.	Flap problem	33-66%
	4.	Double capsule (Panellist suggestion)	33-66%
	5.	Autoimmune Syndrome Induced by Adjuvants (ASIA)	NA
IMPLANT RELATED FINDINGS	6.	Silicone extravasation	>66%
PATIENT REPORTED FINDINGS	7.	Asymmetry	33-66%
	8.	Changing implant size	33-66%
	9.	Desire to remove/change implant	33-66%
ANTIBIOTICS/ OPERATIONS DETAILS	10.	Neopocket formation	33-66%
IMPLANTING TECHNIQUE	11.	Occlusive nipple shields	33-66%
	12.	Nipple absent	33-66%
PATIENT CHARACTERISTICS	13.	ASA Classification before operation	33-66%
	14.	Smoking	33-66%
	15.	Gender	33-66%
UDI (incl. MESH/ADM)	16.	Volume of tissue expander	33-66%
	17.	Volume of removed implant	33-66%

ADM: *Acellular Dermal Matrix*, **UDI:** Unique Device Identification, **ASA:** American Society of Anaesthesiologists physical status classification

Table 5. Changes made to data points

Data points	Modification
Infection	Wording changed to 'Infection leading to explantation'.
Seroma/Hematoma	Split into two separate data points, 'Seroma' and 'Hematoma'.
ALCL	Changed to 'BIA-ALCL' (not included in the round 2 survey as the modification was minor)
Device malposition	Changed to 'Device malposition/rotation'
Capsulectomy	Included two sub-points, 'Full capsulectomy' and 'partial capsulectomy'
Prophylactic mastectomy	Changed to 'Risk reducing mastectomy'
Changing implant size and Desire to remove/change implant	A data point 'Patient preference' will be sufficient to capture meaningful information relating to these two data points
Antiseptic rinse of the pocket	Changed to 'Rinse of the pocket with options to include antiseptics, antibiotics and other'

BIA-ALCL: Breast Implant Associated Anaplastic Large Cell Lymphoma

The round 3 teleconference slides compared the results for each of the data points under consideration across the three rounds. This was done to evaluate whether further consensus could be achieved for the data points. It was decided during the teleconference that further consensus on the remaining data points would be unlikely after the next round, and therefore any remaining data points would be included in the optional dataset.

An additional round included data points that were identified during pilot testing of the dataset by the panel. The additions made were 'timing of surgery' and 'concurrent mastopexy' which were both voted in as global data points in the survey and 'Autoimmune/inflammatory Syndrome Induced by Adjuvants (ASIA)' was included as an optional data point.

Delphi analyses on data definitions

The first round of survey included 72 data points with definitions and the response rate was 93%. The definitions for 31 data points received no comments from the panellists and were voted as 'acceptable'. The definitions for the remaining 41 data points were discussed in the teleconference which had participation from 60% panellists and resulted in definition options for each of the 41 data points. The second round of survey included all the definition options for the data points and the most popular definition was chosen as the preferred definition. The final round also included definitions for the additional data points. The panel considered a number of published definitions of ASIA[24,25,26], but were unable to reach consensus, largely as the causative role of silicone in ASIA remains unproven, therefore this data point does not currently have a working definition. See **table 6** for the list of definitions for all other data points.

DISCUSSION

We have outlined the process undertaken by ICOBRA, an international multidisciplinary group with expertise in breast device registries including consumer representatives, national regulators and biostatisticians, to develop a global minimum dataset for breast implant registries, to enhance patient safety and quality of care. After the Delphi process, consensus was reached on a list of 34 data points (78 with sub-points) to

Table 6. List of finalised definitions for all data points

		The global dataset
No.	**Data point**	**Definition**
1.	Reason for revision/ explantation	The main reason for undertaking revision of a breast implant
a	Patient preference	The choice of the patient
b	Asymptomatic	Procedure performed due to a device recall, or a planned revision, or asymmetry, or revision due to a complication on the other breast
c	Complication	Any deviation from the normal post-operative course
2.	Infection leading to explantation	An infection associated with a breast implant in place, which leads to its explantation. Usually involves redness, localised pain or tenderness, abscess or persistent serous liquid formation around the implant even with distinct clinical signs it might be culture-negative
3.	Seroma	An abnormal accumulation of serum around the device
4.	Hematoma	A collection of blood outside the blood vessels which can be localised in an organ, space, or tissue
5.	Capsular contracture	The shrinkage of the foreign body encapsulation scar tissue that forms around artificial implants imbedded in body tissues
6.	BIA-ALCL	A current or previous diagnosis (pathology based) of breast implant associated anaplastic large cell lymphoma (BIA-ALCL), where BIA-ALCL is a CD30+, ALK-, T-cell derived lymphoma within the non-Hodgkin lymphoma group. This data point to include (a) Suspected and (b) Confirmed.
7.	Device rupture	Loss of implant shell integrity
8.	Device malposition/ rotation	Any instance in which the implant is outside its intended position
9.	Breast pain	As noted by the patient
10.	Preoperative antibiotics	Use of antibiotics provided IV, Orally, or IM before incision
11.	Postoperative antibiotics	Use of antibiotics provided IV, Orally, or IM at any time after 3 hours post-surgery
12.	Laterality	The left or the right breast
13.	Indication for surgery	The reason for surgery
a	Cosmetic augmentation	A cosmetic procedure for enlarging breasts
b	Reconstruction post risk reducing mastectomy	Surgery to remove one or both breasts to reduce the risk of developing breast cancer
c	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, congenital deformity, tuberous breasts, or gender reassignment surgery
d	Reconstruction post mastectomy for cancer	Surgical procedures performed to recreate a breast after one or both breasts are removed as a treatment for breast cancer
14.	Type of intervention	Type of intervention to include sub-points primary, secondary, revision, or explant only.
a	Primary	An initial insertion of a new device, i.e. an implant or expander
b	Secondary	Removal of an expander and insertion of an implant
c	Revision	Revision of an in situ device, i.e. an implant or an expander revision
d	Explant only	Removal of an implant

Table 6. List of finalised definitions for all data points (continued)

15.a	Timing of reconstruction Immediate	Breast reconstruction carried out at the time of mastectomy
15.b	Timing of reconstruction Delayed	Breast reconstruction carried out at a later time than the mastectomy
16.	Implant position/plane	The surgical plane in which an implant is inserted. This data point to include sub-points (i) Sub glandular, (ii) Sub pectoral, (iii) Sub fascial, (iv) Sub flap, (v) Sub cutaneous, (vi) Dual plane, and (vii) Others (please specify)
17.	Incision site	The site where the incision is placed
a	Infra-mammary	An incision in, or beneath, the infra-mammary fold
b	Periareolar	An incision around the areola
c	Axillary	An incision in the axilla
d	Mastectomy scar	An incision at the site of an existing mastectomy incision
e	Others (please specify)	Any other incision site
18.	Nipple sparing	Removal of the breast tissue with preservation of the breast skin envelope and the nipple and areola complex
19.	Flap cover	Any type of flap used for breast reconstruction (concurrent or previous) that covers an implantable breast device or adds volume to the breast mound
20.	Fat grafting	Transfer of aspirated fat to the breast region
21.	Concurrent mastopexy	Indicating whether the procedure involves a mastopexy (breast lift)
22.	Capsulectomy	Removal of the encapsulating scar tissue surrounding the breast implant
a	Partial capsulectomy	Surgical release and/or partial removal of the capsule
b	Full capsulectomy	Complete removal of the capsule including thoracic part of the capsule
23.	Rinse of the pocket	Rinse of the surgically created pocket before implant insertion
a	Antiseptics	Intraoperative wash of the surgical pocket with an antiseptic solution
b	Antibiotics	Intraoperative wash of the surgical pocket with an antibiotic solution
c	Other (please specify)	Any other type of rinse used
24.	Drain use	Intra-operative insertion of drains
25.	Glove change before insertion	Change of gloves immediately prior to insertion of the implant
26.	Previous radiotherapy	Radiotherapy to the breast or chest wall at any time prior to the current device operation
27.	Date of birth OR Age of patient	As identified in the medical record
28.	Height	A person's self-reported height, measured in centimetres (or inches)
29.	Weight	The weight (body mass) of a person measured in kilograms (or lbs)
30.	Device details / Unique Device Identifier (UDI)	Details of the implanted device / Unique Device Identifier
a	Device manufacturer	Name of the manufacturer of the implanted device
b	Device serial number	Serial number of the implanted device
c	Catalogue reference number	Catalogue reference number of the implanted device
d	Device lot number	Lot number of the implanted device

Table 6. List of finalised definitions for all data points (continued)

e	Texture	The surface texture of the device being inserted or explanted
f	Fill	The material used to fill the breast implant: saline solution, silicone gel, or other
g	Shape	The shape of the device being inserted into or explanted from the breast; where the shape of the device is either **Round:** implant is shaped like a flattened sphere or **Shaped:** a contoured shape that re-creates the more teardrop outline of a mature breast
h	Volume of implant	As determined by the manufacturer or measured intraoperatively by weight, or displacement, or fill volume
31.	ADM / Mesh used	The use of either an 'absorbable or non-absorbable synthetic mesh' or 'acellular dermal matrix' which are medical devices used in breast implant surgery where the mesh or matrix provide a soft tissue scaffold
a	Device details of the ADM / Mesh used	Details of the ADM / Mesh
32.	Date of insertion of removed implants	Date the explanted implants were inserted (known or estimated)
33.	Device details of explanted device (UDI)	Any available details of the implant at the time of explantation
34.	Marker / medical record of explanted device (if known)	The explanted device's specific markings indicating type, manufacturer, serial number or lot number
		The optional dataset
No.	**Data point**	**Definition**
1.	Newly diagnosed breast cancer	*Recommend not using this data point; hence no definition*
2.	Skin scarring problem	An abnormal or suboptimal cutaneous or dermal scarring. Includes keloid formation, hypertrophic scarring, poor scar contour or orientation causing distortion or compromise of the reconstructive or aesthetic result. Does not include capsular contracture
3.	Flap problem	When a flap is used as part of a reconstruction, includes but not limited to one or all of the following problems: Total flap loss, partial flap loss, vessel thrombosis, flap hematoma, flap infection, sub-flap seroma, flap fat necrosis, size mismatch resulting in incomplete coverage. Does NOT include donor site complications
4.	Double capsule	A second thin tissue layer encasing the usually textured implant subsequently leading to permanent separation from the outer capsule
5.	Autoimmune Syndrome Induced by Adjuvants (ASIA)	No accepted definition as yet – kindly refer to Tervaert, J. W. C. (2018). Autoinflammatory/autoimmunity syndrome induced by adjuvants (ASIA; Shoenfeld's syndrome): A new flame. *Autoimmunity reviews.*
6.	Silicone extravasation	Extrusion of silicone beyond the limits of the capsule
7.	Asymmetry	As determined by the patient and identifiable by the surgeon
8.	Changing implant size	Patient preference to change the size of implant
9.	Desire to remove / change implant	As determined by the patient

Table 6. List of finalised definitions for all data points (continued)

10.	Neopocket formation	Formation of a new pocket
11.	Occlusive nipple shields	The use of adhesive film dressing covering the nipple-areola complex to prevent perioperative expression of bacteria from nipple ducts contaminating the operative field
12.	Nipple absent	Absence of the nipple at the time of device insertion
13.	ASA classification	A system used by anaesthesiologists' to stratify severity of patients' underlying disease and potential for suffering complications from general anaesthesia
14.	Smoking	As identified by the patient
15.	Gender	Self-identified gender (options to include male, female, other)
16.	Volume of tissue expander	Intraoperative fill volume, as determined by the surgeon at the time of the procedure
17.	Volume of removed implant	As determined (or estimated) by the surgeon at the time of the procedure

be included in the global dataset. Data points for which consensus was not achieved and were not voted into the global dataset, became the optional dataset. Consensus definitions for all data points were achieved, using the ABDR data definitions as the starting point, with the exception of ASIA, for which no definition is currently provided. It is expected that the global dataset will be adopted by currently operating breast device registries within two years and by all new breast implant registries in the ICOBRA network.

The use of the global set and the optional set ensures that countries can maintain their independence in selecting data points that suit them. The global dataset can be described as a "data spine", and will be reviewed every three years in light of new evidence. The optional dataset can be described as a "data rib" and encompasses all other data points collected by any country, which may be used to reflect regional preferences or to further investigate a clinical issue, and can be expanded upon.

Consensus for the majority of data points was easily achieved in the first round, while some others required multiple rounds of discussion before consensus for inclusion in the global dataset was achieved. Although not everyone could be present at the video teleconferences, all participants were able to add their remarks beforehand and all contributions were discussed. Approximately 56% of the global data points were al-

ready being collected by >66% of registries, meaning that for the currently functioning registries, incorporation of these data points will be straightforward.

The ICOBRA global dataset is designed as a minimum dataset. The data collection itself should facilitate the documentation for the clinical personnel at the frontline of medical/operative documentation, instead of posing another burden. The dataset is epidemiologically sound, meaning that clinical judgement is not required to collect the data, such as might be required for example with the Baker grading of capsular contracture. Ideally data collection is built into a routine workflow in an institution's electronic patient record system. Incorporating the ICOBRA global dataset into the electronic medical record also eliminates double/redundant documentation and facilitates bulk-uploading to the registry. Combining it with administrative databases improves the quality of the data overall, and diminishes a cherry-picking type of record keeping.

The value of the ICOBRA global dataset is clear. Pooling data from breast implant registries will allow active surveillance and comparative outcomes evaluation, providing denominator data for adverse events to identify under-performing devices earlier. This will safeguard the health of recipients of breast implants by preventing implantation of defective devices, reducing risks and costs associated with early revision, and providing manufacturers with greater ability to deliver safe products to the market.[27] Further, collecting comparable information about procedures and outcomes feeds into clinical auditing and facilitates benchmarking on an international level, which can drive quality improvement at participating institutions, again reducing complications and costs.[28] In the absence of high-quality, randomized controlled trials to assess the effect of various intraoperative techniques, such as the use of antiseptic rinse, glove change prior to implant handling, and the use of nipple guards and postoperative drains, registry data provide a pragmatic alternative source of evidence (clinical practice based evidence).[29,30] Best surgical techniques can be identified in a real-world environment and new implant technologies can be reliably evaluated. Importantly, the use of large pooled international datasets is the only way we can address the critical issue of BIA-ALCL[2], a rare cancer of the immune system believed to be causally associated with breast implants. Moreover, this information will be of great value empowering patients to be effective advocates for their health, so that they can make informed decisions.

There are significant complexities and practical hurdles when transferring large datasets internationally.[31] Care must be taken to protect the privacy of patients as well as the security of data when bringing together the ICOBRA global dataset. Regulations vary according to region with the use of de-identified data. European Union regulations do not allow the export of identifying information including date of birth, with the threat of heavy fines.[32] It remains to be determined whether de-identified data (with the risk of re-identification) or aggregate analyses will be combined.

Now that a global minimum dataset for breast implant surgery has been established, further international initiatives should be undertaken. The ICOBRA network collaborates on research projects and post-market surveillance of breast implants, similar to the work of the International Consortium of Orthopedic Registries,[33] and aims to establish a global patient-reported outcome measure (PROM) to provide early warning of under-performing devices using patient reports of breast symptoms. In addition, there is potential for breast device registries to support low-cost randomized controlled trials.[34] Collaboration with industry can lead to benefits such as a reduced registration load by prefilling device characteristics using a Unique Device Identifier (UDI). Uniform barcode processing with accepted international standards will increase patient safety and further reduce the burden of data entry. Further, the usage of stock and supply information functions as valuable validation system of the registry database to calculate the capture rate on a nationwide level.

CONCLUSIONS

We have defined a global minimum dataset to be collected for breast implant surgery in routine clinical practice. Datasets will be combined in the future with the aim of early detection of under-performing breast devices and to guide treatment protocols. This will provide better information about outcomes of breast implant surgery and overcome national borders, thereby strengthening international collaborations.

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