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Defining Quality Indicators for Breast Device Surgery: Using Registries for Global Benchmarking

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Background: Breast device registries monitor devices encompassing breast implants, tissue expanders and dermal matrices, and the quality of care and patient outcomes for breast device surgery. Defining a standard set of quality indicators and risk adjustment factors will enable consistency and adjustment for case-mix in benchmarking quality of care across breast implant registries. This study aimed to develop a set of quality indicators to enable assessment and reporting of quality of care for breast device surgery which can be applied globally.

Methods: A scoping literature review was undertaken, and potential quality indicators were identified. Consensus on the final list of quality indicators was obtained using a modified Delphi approach. This process involved a series of online surveys, and teleconferences over 6 months. The Delphi panel included participants from various countries and representation from surgical specialty groups including breast and general surgeons, plastic and reconstructive surgeons, cosmetic surgeons, a breast-care nurse, a consumer, a devices regulator (Therapeutic Goods Administration), and a biostatistician. A total of 12 candidate indicators were proposed: Intraoperative antibiotic wash, intraoperative antiseptic wash, preoperative antibiotics, nipple shields, surgical plane, volume of implant, funnels, immediate versus delayed reconstruction, time to revision, reoperation due to complications, patient satisfaction, and volume of activity.

Results: Three of the 12 proposed indicators were endorsed by the panel: preoperative intravenous antibiotics, reoperation due to complication, and patient reported outcome measures.

Conclusion: The 3 endorsed quality indicator measures will enable breast device registries to standardize benchmarking of care internationally for patients undergoing breast device surgery. (*Plast Reconstr Surg Glob Open* 2019;7:e2348; doi: 10.1097/GOX.0000000000002348; Published online 19 August 2019.)

INTRODUCTION

Breast implants are one of the most commonly used medical implants in healthcare. Estimating the prevalence

of breast implants remains a challenge; however, in a study from 2018, an estimated 3.3% of all women in The Netherlands have a breast implant.¹ A number of breast device clinical quality registries (CQRs) have been established around the world.^{2–4} CQRs record a minimum dataset relating to surgery involving breast implants, tissue expanders and additional elements such as the use of acellular dermal matrices and dermal meshes.

Breast device CQRs are designed to monitor the long-term safety and performance of breast devices, track patient health outcomes, and benchmark the quality of surgery.⁵ CQRs provide a credible means to monitor healthcare processes and outcomes.⁶ The provision of feedback of timely, relevant, and reliable information on patient care

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to clinicians drives improvements in healthcare quality,⁷ and benchmarking outcomes can identify variation in outcomes to further improve healthcare quality.^{7,8}

The International Collaboration of Breast Registry Activities (ICOBRA) brings breast device registries together worldwide with the aim of monitoring the safety of breast devices over time and benchmarking the quality of care for breast device surgery.⁹ To achieve this, clinical quality indicators (QIs) for breast device surgery are needed. QIs measure performance and assess quality of care by examining the incidence of specific events.¹⁰ Importantly, they measure the quality of healthcare with little interobserver and intraobserver variability so that they are suitable for comparisons between professionals and institutions.¹¹

QIs fall into 3 categories: structure, process, and outcome indicators.¹² Process indicators reflect what a provider does, outcome indicators reflect the impact of the medical care on the health status patient, and structural indicators reflect the setting in which the care is delivered.¹³ QIs must be both (1) valid—it must capture the quality of breast device surgery and (2) feasible—easy to collect.¹⁴

Risk adjustment factors (RAFs) are also important to allow a fair comparison across providers. Risk adjustment is the process of statistically accounting for differences in patient case-mix that influences healthcare outcomes.¹⁵ These are often patient risk factors that can be added to statistical models to control for their contribution to the outcome of interest, thus residual differences in outcomes can be attributed to provider quality once this adjustment is performed.¹⁵

Currently, there is no consensus on the appropriate QIs and RAFs to benchmark the quality of breast device surgery. We aimed to develop a set of QIs and RAFs applicable to patients undergoing both augmentation and reconstruction surgery with breast devices, which can be used by breast device registries worldwide to benchmark the quality of breast device surgery.

METHODS

This study was approved by the Monash University Human Research Ethics Committee.

Literature Review

Identification of QIs and RAFs

Three clinicians (N.D., E.E., M.Mur.) provided clinical input and identified 12 clinical questions that were considered critical to surgery utilizing breast devices. A scoping review of the literature on breast device surgery was done, articles relating to each of the clinical questions were short-listed and used to transform the clinical questions into candidate QIs (refer to Table 1 for list of 12 candidate QIs). Articles referring to RAFs in breast device surgery were also identified and a list of potential RAFs was developed (refer to Table 2 for list of potential RAFs). All panel members were also given an opportunity to modify and/or suggest more candidate QIs or RAFs throughout the Delphi process.

Search Strategies and Data Extraction

Three databases were used (Ovid MEDLINE, EMBASE, and CENTRAL database), with date range 1995

to February 2017. Review articles, gray literature including government reports and guidelines from regulatory agencies were included.¹⁶ Manual reference checking of the bibliographies of all retrieved articles was undertaken. All searches included keywords and corresponding MeSH terms for breast implants, augmentation or reconstruction surgery, and study type. Studies that addressed the clinical questions were included and articles that did not include outcomes of breast device surgeries (ie, breast augmentation or reconstruction using devices) were excluded. Additionally, articles were excluded if the study groups involving autologous surgery, articles that focused solely on breast mastectomy (unless followed up with tissue expander and/or reconstruction), studies with less than 50 patients, and in-vivo/in-vitro studies performed on cells and animals. See table, Supplemental Digital Content 1, which displays a list of indicators voted on across four Delphi rounds, and their voting outcomes, <http://links.lww.com/PRSGO/B167> for detailed search strategies and inclusion/exclusion criteria. Figure 1 details a PRISMA flow diagram¹⁷ summarizing the short-listing procedure and reasons for exclusion of articles.

We summarized the findings from studies on each candidate QI. Evidence assessment for each individual study was performed according to the National Health and Medical Research Council guidelines.¹⁸ Potential RAFs were also included in the consensus process.

Modified Delphi Process

Consensus on the final list of QIs and RAFs was achieved through a modified Delphi approach¹⁹ held over 6 months (June–November 2017), which included online surveys and video teleconferences.

Delphi Expert Panel Selection

The expert panel was selected to represent a diverse range of experience with breast device surgery and breast device registries. A consumer representative was included to ensure the QIs aligned with patient values.²⁰ Invitations to participate were sent out to ICOBRA and ABDR collaborators who consented to take part in this project. The panel comprised 17 members, including elected representatives and practicing clinicians from surgical specialty groups. The panel comprised breast and general surgeons (E.E., C.S.), plastic and reconstructive surgeons (R.D.C., H.R., M.Mur., B.S., N.D., A.D., H.K., M.Mag.), and cosmetic surgeons (R.B., M.H., C.M.), a breast-care nurse (J.B.), a consumer (C.S.-F.), a representative from the national regulator (P.C.) (Therapeutic Goods Administration, Australia) and a biostatistician (A.E.). Countries with functioning breast device registries were represented (Australia, The Netherlands, and Sweden).

Statistical Analyses

Each candidate QI was rated for validity and feasibility as a measure of quality of breast device surgery on a six-point Likert scale, with 1 being least valid (or feasible) and 6 being most valid (or feasible). Validity, defined as

Table 1. Candidate QIs

Number	Quality Indicator	Rationale	Category
1	1a	Intraoperative antibiotic wash (later changed to topical antibiotics)	Process
	1b	Intraoperative antiseptic wash (later changed to topical antiseptics)	
2		Preoperative antibiotics	
3		Nipple shields	
4		Drains	
5		Surgical plane	Outcome
6		Volume of implant	
7	7a	Funnels to reduce CC	
	7b	Funnels to reduce BIA-ALCL	
8	8a	Immediate versus delayed reconstruction	
	8b	Immediate versus delayed reconstruction with RT	
9		Time to revision (combined with reoperation in Round 2)	
10	10a	Reoperation due to complications (augmentation) (combined with time to revision in Round 2)	
	10b	Reoperation due to complications (reconstruction) (combined with time to revision in Round 2)	
11		Patient satisfaction (later changed to patient reported outcome measures)	
12		Volume of activity	Structure

BIA-ALCL, breast implant-associated anaplastic large cell lymphoma; RT, radiation therapy.

Table 2. List of Potential RAFs

RAFs
Indication for surgery
Age
Body mass index
Ethnicity
Smoking
Diabetes
Hypertension
Acellular dermal matrix/mesh
Large size of original breast
Postmenopausal hormone therapy
Radiation therapy
Chemotherapy

the ability of the indicator to capture the quality of breast device surgery, and feasibility defined as the ease of data collection for that candidate indicator.

Three statistical criteria were used for short-listing: (1) a median score of 5/6 or 1/2; (2) no disagreement (disagreement score of <1) according to the Interpercentile Range Adjusted for Symmetry, calculated with the formula provided in the RAND Users' Manual¹⁴; and (3) total of 70% or more panelists voting either 5/6 or 1/2.²¹ A median of 5 or 6 was required for an indicator to be voted as valid or feasible and a median score of 1 or 2 was required for an indicator to be voted out as not valid or not feasible.

Opportunity to comment or suggest additional indicators was included. Nonclinicians were given the option of responding "unsure" which was excluded from analysis. All data were deidentified, with results and comments provided to the panel before each teleconference, enabling comparison of individual responses with group responses. Indicators with disagreement were discussed during the

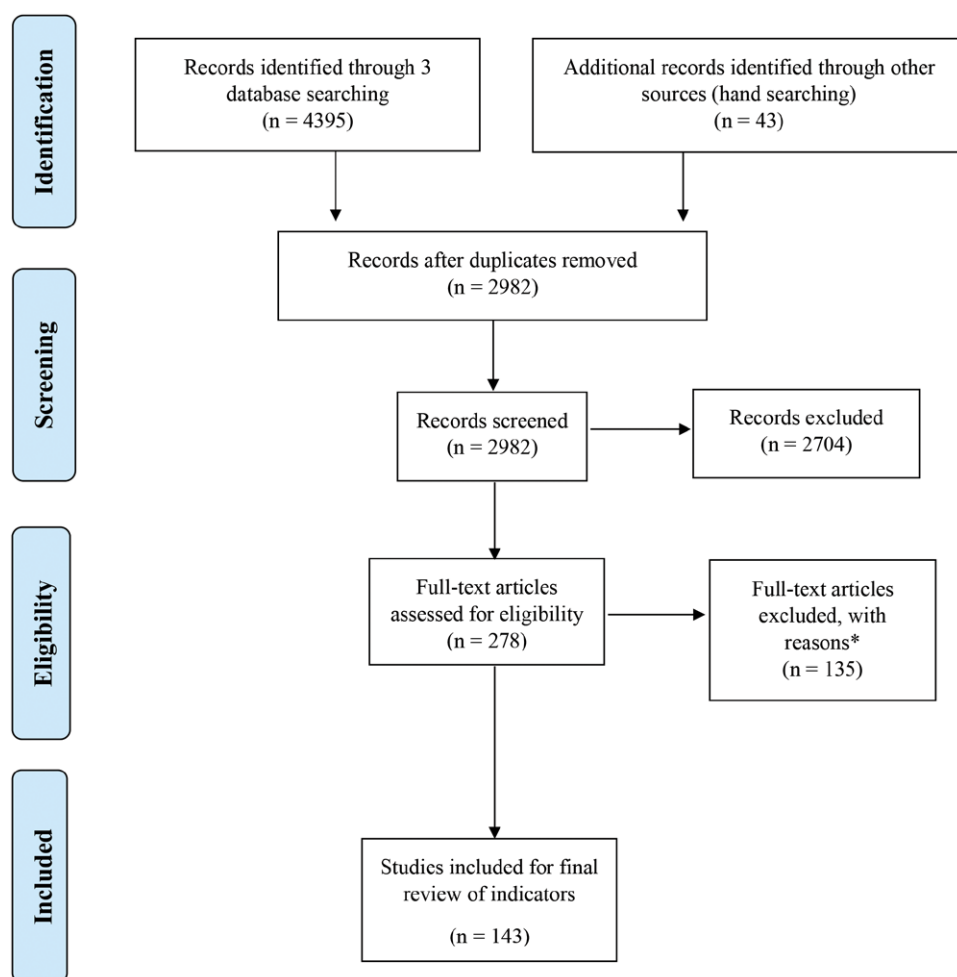


Fig. 1. PRISMA flow diagram. *Full-text articles were excluded due to the following reasons: (1) articles had several study groups and size of study groups was less than 50 for augmentation and/or reconstruction patients; (2) articles did not report data for individual comparison groups; and (3) articles fell under the exclusion criteria listed in the section above.

teleconference. Each RAF was voted on its importance on a 6-point Likert scale.

All data analyses were performed on Microsoft Excel. Online surveys were administered using Qualtrics (Qualtrics, Provo, Utah),²² and Zoom was used for teleconferences. The senior author (I.H.), a registry science expert who heads the Drug and Device Registries at Monash University, chaired the teleconferences.

RESULTS

Literature Review

The scoping literature search resulted in 4,395 abstracts and 43 hand-searched articles. None of the gray literature was relevant. After removal of duplicates and screening based on eligibility criteria, 143 articles were summarized for the QIs with 8 articles of level IV evidence, 111 articles of level III evidence, and 24 articles could not be assessed for level of evidence (review articles, or study type not stated). The majority of articles included in the

literature review were for the outcome QIs. There were no articles found which related to three process QIs (nipple shields, funnels, volume of activity) based on our inclusion/exclusion criteria.

For RAFs, 66 articles were short-listed with 50 articles of Level III evidence and 5 articles of Level II evidence. Eleven articles could not be assessed for level of evidence. There were 12 potential RAFs short-listed (see Table 2).

Delphi Process

There were 4 rounds of online survey and teleconference. A summary of the voting results across all four modified Delphi rounds is provided in Supplementary Digital Content 1 for QIs and Supplementary Digital Content 2 for RAFs. Figure 2 shows the Delphi process and the level of participation during each round. (See table, Supplementary Digital Content 1, which displays a list of indicators voted on across four Delphi rounds, and their voting outcomes, <http://links.lww.com/PRSGO/B167>) (See table, Supplementary Digital Content 2, which displays a list of risk adjustment voted on across three Del-

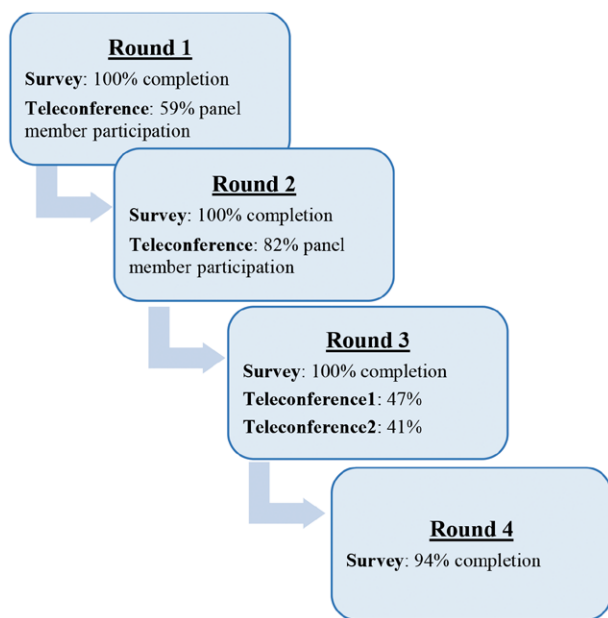


Fig. 2. Panel participation in the 4 Delphi rounds.

phi rounds, and their voting outcomes, <http://links.lww.com/PRSGO/B168>)

In the first round, 3 candidate QIs (intravenous antibiotics, time to revision, and patient satisfaction), and subparts of 2 candidate QIs (intraoperative antibiotics and immediate versus delayed reconstruction with radiotherapy) were voted in as being valid and feasible QIs. Teleconference discussion resulted in 2 outcome indicators (time to revision, complications due to augmentation and reconstruction surgery) being combined into one (reoperation due to augmentation and reconstruction surgery). This new candidate QI included 6 complications as subcategories: infection, capsular contracture (CC), malposition/displacement, rupture/deflation, seroma/hematoma, and implant loss. Intraoperative antibiotics/antiseptics wash was changed to topical antibiotics/antiseptics. Patient satisfaction was changed to Patient Reported Outcome Measure (PROM).

In the second round, 3 QIs (topical antibiotics/antiseptics, preoperative antibiotics, and PROM) were voted as being valid QIs. Reoperation due to complications was also voted in with the exception of the complication “short-term CC.” Eight RAFs (indication for surgery, age, body mass index, smoking, diabetes, acellular dermal matrix/mesh, radiation therapy, and chemotherapy) were voted in as “important.” The panelists suggested 2 additional RAFs, immunosuppressive therapy and previous episode of fat grafting, which were added to the list of potential RAFs. During the teleconference, the issue of antimicrobial resistance was raised, and the panel members requested a consultation with an infectious diseases expert before endorsing topical antibiotics and topical antiseptics as QIs.

In the third round, 7 candidate QIs were voted out (nipple shields, drains, surgical plane, funnels, immediate versus delayed reconstruction, and Surgical volume). One

$$\text{Reoperation due to short-term complication} = \frac{\text{No. of cases of reoperation due to a complication within 60 days of surgery}}{\text{Total no. of operations}}$$

Fig. 3. Method for calculating reoperation due to short-term complication.

$$\text{Reoperation due to long-term complication} = \frac{\text{No. of cases of reoperation due to a complication after 60 days of surgery}}{\text{Total no. of operations}}$$

Fig. 4. Method for calculating reoperation due to long-term complication.

RAF (immunosuppressive therapy) was voted as important and 4 RAFs (ethnicity, hypertension, postmenopausal hormone therapy, and previous fat grafting) were voted as not important and removed. Calculations (Figs. 3 and 4) for the QI “reoperation due to complications (infection, CC, malposition/displacement, rupture/deflation, seroma/hematoma, and implant loss) within 60 days (short term) and after 60 days (long term) for both augmentation and reconstruction surgery” were discussed.

An external expert on infectious disease epidemiology (A.C.) participated in the Round 3 teleconference. There was consensus that topical antibiotics/antiseptics were not an appropriate QI currently, due to weak evidence supporting it, in particular the lack of evidence from randomized control trials. Due to a low percentage of the panel members attending this teleconference, a second Round 3 teleconference with the external infectious diseases expert present (A.C.) was held. It was agreed that topical antibiotics/antiseptics would not be a QI; however, these data would be collected by registries and reviewed again in light of accumulating evidence.

The fourth round resulted in topical antibiotics/antiseptics (previously voted in by the Delphi panel in the second round), being voted out. Consensus on one RAF, large size of original breast, was not achieved in the final round, and was not included in the final list of RAFs.

After 4 rounds of survey and teleconferences, consensus was achieved on 3 QIs (one process indicator and two outcome indicators, Table 3), and 9 RAFs (Table 4) for breast device surgery. The remaining indicators were deemed to require more data collection before they could be considered as potential QI, to be revisited in the future. No structural indicators were in the final list of endorsed QIs. It was agreed that data capture would be reviewed yearly, to monitor these endorsed QIs and feedback processed data provided to participating local sites, with the aim of comparing data internationally across different breast device registries.

DISCUSSION

Following a scoping literature review, we used a Delphi process with a panel of 17 experts representing a broad range of views to reach consensus on 3 QIs and 9 RAFs for reporting on the quality of breast device surgery by

Table 3. Outcomes of All Indicators across 4 Delphi Rounds

Number	Category	Indicator	Included in Final Set
1a	Process	Topical antibiotics	No
1b		Topical antiseptics	No
2		Preoperative IV antibiotics	Yes
3		Nipple shields	No
4		Drains	No
5		Surgical plane	No
6		Volume of implant	No
7a		Funnels to reduce CC	No
7b		Funnels to reduce BIA-ALCL	No
8a		Immediate versus delayed reconstruction	No
8b		Immediate versus delayed reconstruction with RT	No
9	Outcome	Reoperation due to complications	Yes
9ai		List of complications (augmentation-ST)	Yes
		Infection	Yes
		CC	No
		Malposition/displacement	Yes
		Rupture/deflation	Yes
		Seroma/hematoma	Yes
		Implant loss	Yes
9aii		List of complications (augmentation—LT)	Yes
		Infection	Yes
		CC	Yes
		Malposition/displacement	Yes
		Rupture/deflation	Yes
		Seroma/Hematoma	Yes
		Implant loss	Yes
9bi		List of complications (reconstruction—ST)	Yes
		Infection	Yes
		CC	No
		Malposition/displacement	Yes
		Rupture/deflation	Yes
		Seroma/hematoma	Yes
		Implant loss	Yes
9bii		List of complications (reconstruction—LT)	Yes
		Infection	Yes
		CC	Yes
		Malposition/displacement	Yes
		Rupture/deflation	Yes
		Seroma/hematoma	Yes
		Implant loss	Yes
10	Structure	Patient reported outcome measure	Yes
11		Volume of surgical activity	No

BIA-ALCL, breast implant-associated anaplastic large cell lymphoma; LT, long term; RT, radiation therapy; ST, short term.

Table 4. Outcomes of All Risk Adjustment Factors across 3 Delphi Rounds

RAFs	Inclusion in Final Set of RAFs
Indication for surgery	Yes
Age	Yes
BMI	Yes
Ethnicity	No
Smoking	Yes
Diabetes	Yes
Hypertension	No
Acellular dermal matrix/mesh	Yes
Large size of original breast	No
Postmenopausal hormone therapy	No
Radiation therapy	Yes
Chemotherapy	Yes
Previous episode of fat grafting	No
Immunosuppressive therapy	Yes

CQRs. The QIs endorsed in this study are designed to use data from breast device CQRs for benchmarking quality of care. Other proposed QIs or RAFs were not endorsed at this stage, however, will be evaluated again in the future. It is planned that they will be reviewed annually, and revised once every 3 years in light of new evidence.

Benchmarking using data from CQRs may occur at different levels, such as comparing the performance of

different surgical techniques, different types of implants, at the surgeon or hospital level, and between countries. Identification of unwarranted variation and performance outliers has been shown to reduce variation over time, and lead to health care quality improvement.²³ This work does not seek to replace more comprehensive assessments of outcomes of breast augmentation or reconstruction, such as BREAST-Q²⁴; nor does it intend to substitute any existing guidelines for best practice, such as the guidelines for oncoplastic breast reconstruction.^{25,26}

The endorsed QIs in this study include one process and 2 outcome indicators. The selection of outcome measures for breast device surgery differs from quality measures in breast reconstruction surgery, which a recent systematic review²⁷ demonstrated have an overrepresentation of process measures to benchmark quality. Data in CQRs are collected at a population level, thus providing the opportunity to systematically assess outcome measures. However, there are risks that should be considered if undertaking clinician level benchmarking, including low procedural volumes and the potential for clinician avoidance of high-risk patients.²⁸

The Delphi panel endorsed only one process indicator, preoperative intravenous antibiotics. Despite the comparative ease with which process measures are collected at the time of surgery, there is lack of quality data showing a di-

rect link with improved outcomes. Maxwell et al²⁹ reported similar results, finding fewer items, such as drains, reaching consensus as a recommended practice which could then be used to measure quality. In our study, another process measure, topical antibiotics/antiseptics, was initially voted in. However, given the issue of antimicrobial resistance and the lack of high quality studies, the panel reconsidered its decision and decided against including it as a QI at this time. The panel also recognized the need for breast device registries to collect data on these potential process indicators as more information becomes available.

The endorsement of outcome indicator PROMs as a QI reflects the importance of patient satisfaction as a measure of quality in this surgery, which is for the most part, elective. The International Consortium of Health Outcome Measurement breast cancer set also recognizes the importance of PROMS in standardized health outcome measurement; however, it did not include breast device surgery specifically. The International Consortium of Health Outcome Measurement breast cancer set included the BREAST-Q, a validated PROM widely used in breast surgery.³⁰ A 5 question registry-specific version, the Breast-Q Implant Surveillance, has been piloted as a PROM for use by breast device registries globally,³¹ and will be validated in due course.

The other outcome measure to be endorsed was reoperation due to complication. For this QI, the panel also agreed upon the method of calculating and reporting on reoperation, ensuring consistency in reporting of complication rates across breast device registries internationally. The one candidate structural measure in this study, volume of surgical activity, was not voted in as a QI due to lack of evidence linking volume of surgical throughput and surgical outcomes in breast device surgery. It is noteworthy that this was also rejected by the Prostate Cancer Outcomes Registry (Australia),²¹ and has been called into question in other reports.^{32,33}

Over half of the proposed RAFs reached consensus. These factors affect outcomes, and are beyond the control of the surgeon, therefore should be adjusted for in the statistical modeling used in benchmarking. Most RAFs were patient related (age, ethnicity, body mass index, and smoking status) and linked to postoperative outcomes.^{34,35} Others were specific to surgery and concomitant treatments (indication for surgery, radiation therapy, chemotherapy, and postmenopausal hormone therapy) that affect outcomes. Most studies in our literature review reported results separately for cosmetic augmentation and breast reconstruction, and it is clear that these groups should be considered separately for benchmarking.

The modified Delphi approach has been used widely in health research. Examples include selection of QI for hospital-based emergency care,³⁶ and cancer care such as prostate, colorectal, ovarian, and breast cancers.^{37–41} Similar studies performed for breast implants have utilized a modified Delphi approach without the literature reviews²⁹ or have focused only on breast reconstruction.^{27,42,43} This is the first study identifying potential QIs for breast device CQRs for both cosmetic augmentation and breast reconstruction purposes. Additionally, it encompasses both detailed scoping literature reviews and inputs from

an international multidisciplinary panel of experts including all surgical implanters: plastic and reconstructive surgeons, breast and general surgeons, and cosmetic surgeon groups.

The strengths of this process include the four round modified Delphi process in combination with stringent statistical criteria. We used 3 statistical measures instead of the usual 2²¹ to ensure a clear consensus on the key indicators, reflected in the fact that a consensus was reached for all the proposed QIs and all but one of the RAFs. Furthermore, all comments from panelists across the 4 voting rounds were addressed in the teleconference discussion, robust discussions took place in which rephrasing of the proposed QIs, as well as the addition of complications, and risk factors were incorporated.

Most registries already collect data on the QIs that have been voted in this study. The ICOBRA group has also established a global minimum dataset for all registries to collect, which includes Preoperative antibiotics and Complications. Additionally, PROMs are currently being collected by the Australian³¹ and Swedish registries,⁴ with others planning to follow.

The Delphi panel in our study comprised 17 members which, according to a systematic review including 80 studies selecting healthcare quality indicators,¹⁹ is the median number of individuals invited to participate in the Delphi panels. The review did not have any specific recommendations for the size of a Delphi panel, but suggested that a Delphi panel that reflects the full range of stakeholders enhances the credibility and acceptance of QIs. Our study involved diverse representatives with expertise in breast device surgery and importantly, from currently functioning breast device registries, taking the consumer and regulatory perspectives into account, and was independent of industry.

The limitations of this study were a scoping review rather than a comprehensive systematic review was performed, although care was taken to include all relevant articles based on hand searching of literature. Second, indicators were limited to process, outcome and structural measures of care, and preoperative assessment factors, such as patient anatomy, were not included in this study. Finally, video conferencing facilities were used for the teleconferences, which may have caused potential bias, as the discussions are not anonymous. However, the results of the online surveys were anonymized during the teleconference discussions and the moderator (I.H.) ensured that no one person influenced the views of the entire group and encouraged comments from all present. Panelists were also given a chance to write in their views over chat during the teleconference or speak to the moderator separately after the teleconference sessions.

CONCLUSIONS

With the use of a combination of a comprehensive scoping review process and expert input from a panel of clinicians and others, we identified a set of 3 clinical QIs and 9 RAFs for use by breast device CQRs. The 3 endorsed quality indicator measures will enable breast device regis-

tries to benchmark care internationally for patients undergoing breast device surgery. Uniform reporting practices enable registries to ensure continual safety and consistency in the quality of care and improvement in patient outcomes. These indicators will be continually evaluated and refined to reflect new data made available from registries and other large-scale studies.

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