OECD Patient Reported Indicator Surveys (PaRIS) Breast Cancer PROMs Working Group

PATIENT REPORTED OUTCOME MEASURES (PROMS) FOR BREAST CANCER CARE

kronikgune
institute for health services research

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Technical report on data collected between 2020 and 2021

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Acknowledgements

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Acronyms

BC	Breast Cancer
BCT	Breast Conserving Therapy
BWH	Brigham and Women's Hospital
ECOG	Eastern Cooperative Oncology Group
EMC	Erasmus Medical Centre
HCQO	Health Care Quality and Outcomes
ICO	Institut de Cancerologie de l'Ouest
OECD	Organisation for Economic Co-operation and Development
PaRIS	Patient Reported Indicator Surveys
PROM	Patient-Reported Outcome Measure
UK	United Kingdom
US	United States
UWA	University of Western Australia

Abstract

Breast cancer is the type of cancer with the highest incidence among women in all OECD countries, and the second most common cause of cancer death among women. While conventional outcome measures, like survival or mortality rates, are useful these only partially depict the burden caused by breast cancer. Patient-reported outcome measures (PROMs) help capture complementary information on aspects of perceived health status and quality of life of individuals.

With the ambition to make health systems more people-centred, the OECD launched the PaRIS initiative in order to measure outcomes and experiences reported by patients. PaRIS has two main work streams: 1) Upscaling existing PROMs data collections for hip and knee replacement, breast cancer, and mental health; 2) Developing a new international survey of people living with chronic conditions.

Building on the lessons learnt from the pilot data collection in 2019, the PaRIS Breast Cancer Working Group collected PROMs data by using BREAST-Q Breast Satisfaction tool between 2020 and 2021. The results of the data collection were published in the Health at a Glance 2021, and this technical report details further analysis and interpretation of the findings. The report also describes reported limitations in the possibility to have breast reconstruction surgery during the pandemic, notably in England and Sweden.

Compared to the data collected for HAG 2019, the number of countries, sites and patients reported upon increased for the HAG 2021 publication. Despite limitations caused by the pandemic, the potential to compare countries/sites based on the BREAST-Q demonstrated feasible although inference is hindered by small numbers per operation type for various sites and limited availability of reported data for risk-adjustment.

Results confirm though the preliminary findings of higher breast satisfaction outcomes after breast-conserving therapy in some, but not all sites. Consolidated mean crude scores show 21% higher breast satisfaction following breast-conserving therapy compared to reconstruction surgery. The majority of participating sites report the PROMs data collection being part of an established ongoing measurement programme.

The PaRIS Breast Cancer PROMs working group has outlined a preliminary roadmap for the future work on the measurement of PROMs for breast cancer. Strategies and concrete actions to upscale data collection at regional or national level are prioritised, so study results and interpretation are generalisable and internationally comparable.

1 Measuring care outcomes of people with breast cancer

Breast cancer is the cancer with the highest incidence among women in all OECD countries, and the second most common cause of cancer death among women (OECD, 2021[1]). Thanks to better screening for early diagnosis and improved treatment, while incidence rates have increased over the past decades, mortality rates have declined or stabilized across OECD (OECD, 2021[1]). In addition, quality and outcomes of breast cancer care have improved in recent years, as seen in improved survival estimates, with most OECD countries having 5-year net survival rates of 80% (OECD, 2019[2]).

While conventional outcome measures, like survival or mortality rates, are useful, these only partially depict the burden caused by breast cancer. The diagnostic and treatment for breast cancer has several physical, emotional, and social effects proving to be detrimental to the quality of life of many patients. Measures such as patient-reported outcome measures (PROMs) help capture complementary information on aspects of perceived health status and quality of life, including symptoms, functionality, and physical, mental and social health of individuals.

The applicability of PROMs in breast cancer care is expanding beyond clinical purposes and these are now a source of intelligence for improving quality of care and designing actions by policymakers. Many OECD countries are scaling up their breast cancer PROMs initiatives to regional (e.g. Italy) and national (e.g. the Netherlands, Sweden) levels in order to improve quality of care for patients and design health systems that are more people-centred (OECD, 2021[1]).

OECD's PaRIS initiative to improve care for patients with breast cancer

During the Health Ministerial meeting in 2017, health ministers called on the OECD to lead international efforts to make health systems more people-centred. To achieve this goal, the OECD launched the PaRIS initiative[1] in order to measure to what extent health systems deliver what matters most to people. The PaRIS initiative consists of two work axes:

- Increasing uptake of PROMs and PREMs on a number of existing measurement areas such as Hip and Knee Replacement Surgery, Breast Cancer, and Mental Health;
- Developing a new international survey on outcomes and experiences of people living with chronic conditions and managed in primary care (PaRIS survey).

The OECD established the PaRIS Breast Cancer PROMs Working Group in 2018. The main objectives of the Group has been threefold: 1) developing international standards in Breast

[1] PaRIS is the OECD's Patient-Reported Indicator Surveys initiative where countries work together on developing, standardising and implementing a new generation of indicators that measure the outcomes and experiences of health care that matter most to people. For more information, please visit: https://www.oecd.org/health/paris/

Cancer PROMs data collection; 2) assisting national implementations; and 3) creating a forum for exchange of experiences. The initial Terms of References of the group is shared in Annex A.

The Expert Group has over 100 members from 21 countries as well as representatives from patient organizations and industry. The members of the Working Group are listed in Annex B**.** The Expert Group meets twice a year to define data collection standards, discuss interpretability of results, share experiences, and give future directions to the Breast Cancer PROMs work.

OECD co-leads the group in collaboration with Kronikgune Institute of Health Services Research. Kronikgune Institute assists the group methodologically while the OECD is supporting the group activities. The Working Group reports to the Working Party for Health Care Quality and Outcomes (WP-HCQO), the governing body of work on Health Care Quality and Outcomes while the Health Committee composed of official country delegates, provides strategic direction to the overall work.

PaRIS Breast Cancer PROMs pilot data collection (2018-2019)

The Breast Cancer Working Group had its pilot data collection between 2018 and 2019. Eleven sites from eight countries submitted PROMs data by using BREAST-Q tool, an internationally validated instrument used to measure breast surgery outcomes reported by patients (Pusic AL, 2009[3]). The Working Group agreed on using the Breast Satisfaction module of BREAST-Q tool due to its availability in participating sites.

The participating sites reported crude breast satisfaction outcome scores at 6-12 months following breast-conserving therapy and breast reconstruction surgery. The results of the pilot data collection was published in the Health at a Glance 2019 (OECD, 2019[2]). The results of the pilot data collection from 2018-2019 suggested higher breast satisfaction outcomes after breast conserving therapy in some, but not all sites. Nevertheless, analyses were based on relatively small samples, not intending to be representative.

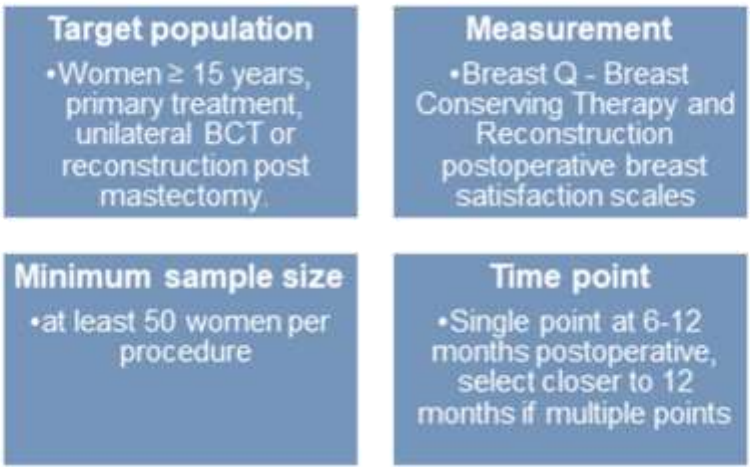
2 Building on the pilot: PaRIS Breast Cancer PROMs 2020-2021 data collection

With the lessons learnt from the pilot data collection, the group had a new round of data collection between 2020 and 2021. The results of the data collection were published in the Health at a Glance 2021 (OECD, 2021[1]). In the following sections, the data collection, further analysis and interpretation are detailed.

Data submission requirements at a glance

Figure 2.1 summarises the data specifications for the data collection 2020-2021. Women included were 15 years old or older (at the date of surgery) that received unilateral breast conserving surgery (i.e. lumpectomy) or immediate reconstructive surgery (autologous or implant reconstruction) at the site after a mastectomy during the primary treatment phase of breast cancer (Box 2.1). Women that received bilateral surgery, surgery for recurrent cancer or where the reconstruction was delayed were excluded from the data collection. Each participating site was asked to provide data on at least 50 women where autologous reconstruction was performed, using a continuous recruitment method based on the date of surgery. This recruitment method was expected to result in a total sample well over 150 women from each site. However, no site was excluded from the data collection based on not being able to meet the 50 case quota for autologous cases and was therefore encouraged to provide all available data by 1 April 2021.

Figure 2.1. Summary of data specifications for the data collection 2020-2021



Source: Authors

Box 2.1. Different procedures in the management of Breast Cancer

Breast conserving therapy (BCT) involves a surgical operation to remove the cancer while leaving as much of the breast as possible – commonly an option in early-stage cancer. This is the primary surgical choice for breast cancer, with 60%–80% of newly diagnosed cancers amenable to breast conservation at diagnosis or after primary systemic therapy for women in Western Europe (Cardoso, 2019).

Mastectomy involves complete removal of the breast surgically and is often undertaken when a woman cannot be treated with breast conserving therapy. However, a woman may prefer a mastectomy over a breast conserving therapy and women at very high risk of getting a second cancer sometimes have both breasts removed.

Breast reconstruction may be chosen by women who have had mastectomy of their breast to rebuild the shape and look of the breast. The two main types of breast reconstruction are:

1) Implant Reconstruction surgery which involves the insertion of a silicone implant after the removal of the woman's breast tissue; and

2) Autologous reconstruction surgery, which uses tissue from other parts of the woman's body, such as her belly, back, thighs, or buttocks to rebuild the breast shape. This form of reconstruction is generally considered to look more natural and behave more like natural breast tissue than breast implants.

Source: (Cardoso et al., 2019[4])

The Breast-Q tool was used to measure and capture the outcome data (Box 2.2). Only data collected from the breast satisfaction scale of two modules of the tool - the post-operative Breast Conserving Therapy and Reconstruction modules - were reported to the OECD, where the surgery was performed within a specified 12-month period and the measurement was taken between 6-12 months after the surgery. The details of the data collection guidelines and data submission template can be found in the Annex C and Annex D

Box 2.2. PaRIS Recommended Breast Cancer PROMs

The BREAST-Q Breast Satisfaction Module is a patient-reported outcome measure designed to evaluate outcomes among women undergoing different types of breast surgery. Items cover breast appearance such as size, symmetry, softness, implant placement, cleavage, and satisfaction with breasts in relation to how a bra fits and how the breasts look when clothed or unclothed. For reconstruction with implant, there are also items specific to implants such as rippling and postoperative issues such as scars. The responses of the patients are transformed into scores that range from 0-100. The scores are computed by adding the response items together and then converting the raw sum scale score to a score from 0-100. A higher score means greater satisfaction. For more information, see Annex E.

Source: (Pusic et al., 2009[5])

Several personal factors can influence a woman's postoperative satisfaction with the outcomes of her breast cancer surgery, including age, smoking, obesity, tumour burden, education level, cultural background as well as overall satisfaction with breasts and physical health before surgery (Kern, 2015[6]). These factors are largely independent of the quality of care delivery and their impact should ideally be considered when comparing the quality of care across sites. Given this, in this study, sites were asked to submit data on key factors (hereinafter called covariates), including age, smoking and pre-operative ECOG performance status.

Moreover, sites were required to submit some metadata. These metadata were referring to various information, including: the periods of data reporting; the context of the measurement programme under which the BREAST-Q data was collected at each site (i.e. whether there was an established ongoing measurement programme or a one-off measurement initiative); the main use of PROMs data at each site; and details about the methods and processes in place for the data collection is implemented.

Characteristics of submitted data in 2020-2021

Fifteen sites from 11 countries submitted data from October 2020 to June 2021 to the PaRIS Breast Cancer PROMs data collection in 2020-2021. Table 2.1 summarises the data submitted by participating sites.

Data from 2,379 patients were submitted to the OECD. Table 2.1 shows that the sample size varied across sites, with US-Sloan Kettering reporting 72 % of the total sample of patients. Five sites – Australia-Flinders, Australia-UWA, Spain-12 Octubre, Portugal and US-BWH – reported sample sizes of 15 patients or less and were excluded from the publication in the Health at a Glance 2021. Nevertheless, data from these sites are included in this technical report.

Sites were required to submit information for a minimum number of patients (50 patients) on each of the three procedures: Breast Conserving Therapy (BCT), Implant Reconstruction Surgery, and Autologous Reconstruction Surgery (Box 2.1). Yet, only US-Sloan Kettering was able to reach the target sample size. In addition, France-ICO Nantes-Anger only provided details of patients following BCT, while other sites, like Australia-Flinders and Italy-Tuscany, only submitted data regarding patients who underwent Reconstruction surgery.

Only eight out of 15 sites– France-ICO Nantes-Anger, Netherlands-EMC, Spain-12 Octubre, Spain-Cruces, Spain-Donostia, Sweden-Stockholm, UK-Manchester and US-BWH – were able

to submit data for all covariates. Five sites – Australia-Flinders, Germany-Charité, Italy-Tuscany, Portugal and US-Sloan Kettering – were able to submit data for age and smoking status but not for ECOG performance status. Switzerland- Basel submitted data for age only while Australia-UWA did not submit data for any covariate. Limitations on sample size and incomplete datasets impeded risk-adjusted analysis.

Table 2.1. Summary of information reported by sites for PaRIS Breast Cancer PROMs data collection

Site	Sample	BCT	Implant	Autologous	Age	Smoking	ECOG performance status
Australia-Flinders	8		✓	✓	✓	✓	
Australia-UWA	5	✓					
France-ICO Nantes-Anger	50	✓			✓	✓	✓
Germany-Charité	48	✓	✓		✓	✓	
Italy-Tuscany	52		✓	✓	✓	✓	
Netherlands-EMC	106	✓	✓	✓	✓	✓	✓
Portugal	6	✓	✓		✓	✓	
Spain-12 Octubre	15	✓	✓	✓	✓	✓	✓
Spain-Cruces	39	✓	✓	✓	✓	✓	✓
Spain-Donostia	29	✓	✓		✓	✓	✓
Sweden-Stockholm	147	✓	✓		✓	✓	✓
Switzerland-Basel	46	✓	✓	✓	✓		
UK-Manchester	93	✓			✓	✓	✓
US-BWH	15	✓	✓	✓	✓	✓	✓
US-Sloan Kettering	1720	✓	✓	✓	✓	✓	

Source: PaRIS Breast Cancer PROMs data collection 2020-2021

Data analysis

Each site submitted a database containing aggregated data, avoiding that any patient level data was exchanged between the sites and the OECD. Data submitted by sites was collated into a master database to support data analysis and visualisation. Descriptive statistics was undertaken to account for the total number of patients, the number and relative percentage of the total patients per procedure, the mean and the standard deviation of PROMs as well as an assessment of the number of cells with missing data.

Mean values for breast satisfaction were calculated as a weighted average based on the sample size of sites. Confidence intervals around the means for breast satisfaction were calculated using the pooled variance based on the sample size of each site. A limitation of these analyses on the whole population is the risk of type I error (rejection of a true null hypothesis).

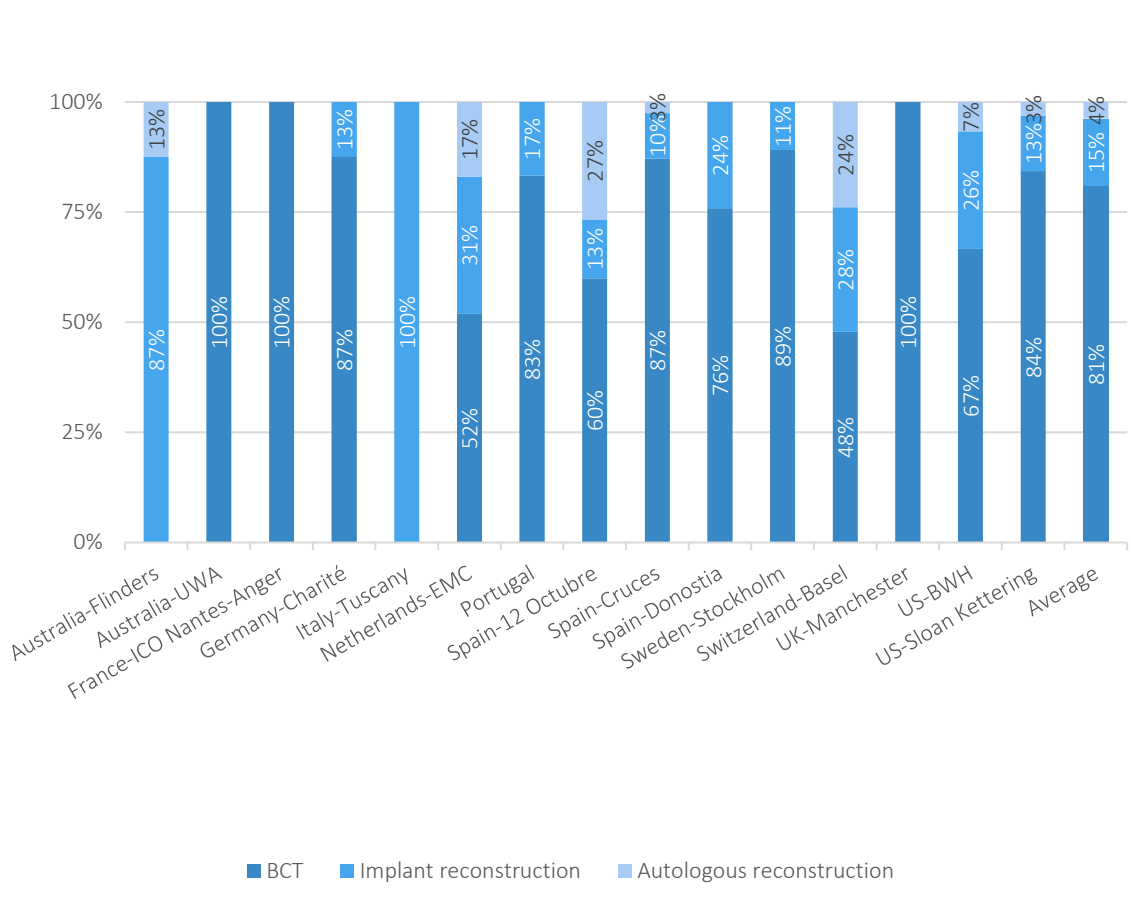
Statistical significance was set at a probability level of 0.05. To evaluate between-group differences for categorical and binary variables chi-square tests were applied, while for

continuous variables t-tests was used. Confidence intervals were used to assess means comparisons for continuous covariates.

Descriptive results

Both Figure 2.2 and Table 2.2 show the proportion of patients undergoing each type of surgery. Results suggest BCT was more common than mastectomy, followed by immediate reconstruction in 12 out of 15 sites. The proportion of BCT varied from 0% in Australia-Flinders and Italy-Tuscany to 100% in Australia-UWA, France-ICO, and UK-Manchester. PROMs from women undergoing autologous reconstruction were only reported in seven out of 15 sites (i.e. Australia-Flinders, Netherlands-Erasmus Medical Center (EMC), Spain-12 Octubre, Spain-Cruces, Switzerland-Basel, US-Brigham and Women's Hospital (BWH) and US-Sloan Kettering). The proportion of patients undergoing autologous reconstruction surgery varied among these seven sites from 3% in Spain-Cruces and US-Sloan Kettering to 27% in Spain-12 Octubre. The proportion of implant reconstruction surgery varied from 0% in Australia- University of Western Australia (UWA), France-Institut de cancérologie de l'Ouest (ICO) and UK-Manchester to 100% in Italy-Tuscany.

Figure 2.2. Sample distribution across sites and procedures in the PaRIS Breast Cancer data collection 2020-2021



Source: PaRIS Breast Cancer PROMs data collection 2020-2021

Table 2.2. Sample distribution across sites and procedures

Site	Total	BCT	Implant	Autologous
Australia-Flinders	8	0	7	1
Australia-UWA	5	5	0	0
France-ICO Nantes-Anger	50	50	0	0
Germany-Charité	48	42	6	0
Italy-Tuscany	52	0	52	0
Netherlands-EMC	106	55	33	18
Portugal	6	5	1	0
Spain-12 Octubre	15	9	2	4
Spain-Cruces	39	34	4	1
Spain-Donostia	29	22	7	0
Sweden-Stockholm	147	131	16	0
Switzerland-Basel	46	22	13	11
UK-Manchester	93	93	0	0
US-BWH	15	10	4	1
US-Sloan Kettering	1,720	1,450	216	54
Total	2,379	1,928	361	90

Source: PaRIS Breast Cancer PROMs data collection 2020-2021

Sample characteristics

The descriptive statistics of the sample helps interpreting the results by examining the differences in characteristics between sites and across procedures. The following data was submitted by type of surgery: mean age, proportion of women who currently smoke, proportion of women who are obese and proportion of women who received post-operative adjuvant radiotherapy. Data reported by sites on these variables is described in Table 2.3.

Patients treated with BCT are on average older than those treated with reconstruction following mastectomy, i.e. 59 years old versus 52 (Figure 2.3). This finding is observed across all included sites. No correlation between age and procedure was found.[2]

[2] As the standard deviation for mean age was not collected from participating sites, it was not possible to make this conclusion.

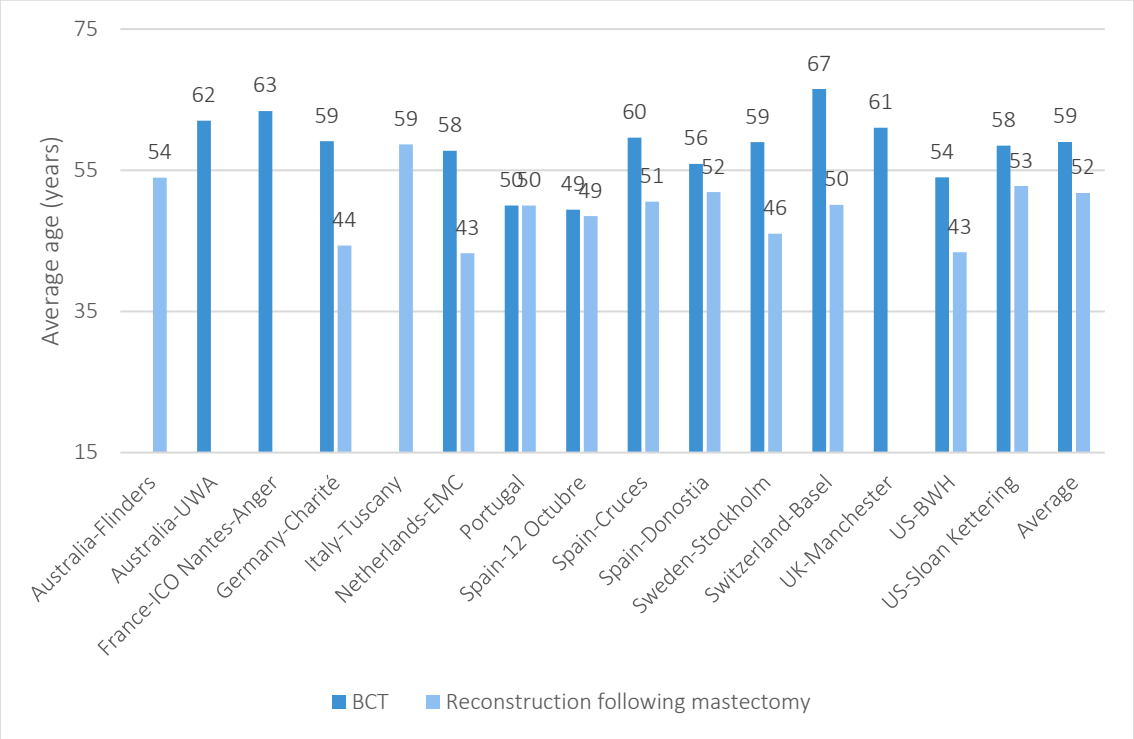
Table 2.3. Sample details across sites and procedure

	Procedure	Australia-Flinders	Australia-UWA	France-ICO Nantes-Anger	Germany-Charité	Italy-Tuscany	Netherlands-EMC	Portugal-Anynymous	Spain-12 Octubre	Spain-Cruces	Spain-Donostia	Sweden-Stockholm	Switzerland-Basel	UK-Manchester	US-BWH	US-Sloan Kettering	Total
Number of women included	BCT	0	5	50	42	0	55	5	9	34	22	131	22	93	10	1450	1918
	Reconstruction	8	0	0	6	52	51	1	6	5	7	16	24	0	5	270	450
Mean age at date of surgery	BCT	-	62.0	63.4	59.1	-	57.7	50.0	49.4	59.6	55.9	59.0	66.5	61.0	54.0	58.5	59.1
	Reconstruction	53.9	-	-	44.3	58.7	43.3	50.0	48.5	50.6	51.9	46.0	50.1	-	43.4	52.7	51.8
% of smokers	BCT	-	NA	22.0	23.8	-	9.1	0.0	44.4	47.1	31.8	51.1	NA	8.6	20.0	5.0	10.7
	Reconstruction	0	-	-	50.0	46.2	9.8	0.0	16.7	40.0	71.4	25.0	NA	-	40.0	3.7	13.1
% of obesity	BCT	-	NA	16.0	14.3	-	20.0	60.0	0.0	29.4	18.2	11.5	NA	51.6	10.0	38.0	34.6
	Reconstruction	25.0	-	-	0.0	7.7	11.8	100.0	0.0	0.0	14.3	12.5	NA	-	0.0	31.5	23.7
% with post-operative adjuvant radiotherapy	BCT	-	60.0	100.0	90.5	NA	100.0	100.0	88.9	82.4	95.5	85.6	NA	72.0	70.0	72.0	75.4
	Reconstruction	12.5	-	-	16.7	NA	3.9	100.0	50.0	40.0	0.0	25.0	NA	-	20.0	15.9	15.5

Note: "-" no value applies; NA: no data reported by site, BCT. Breast Conserving Therapy
Source: PaRIS Breast Cancer PROMs data collection 2020-2021

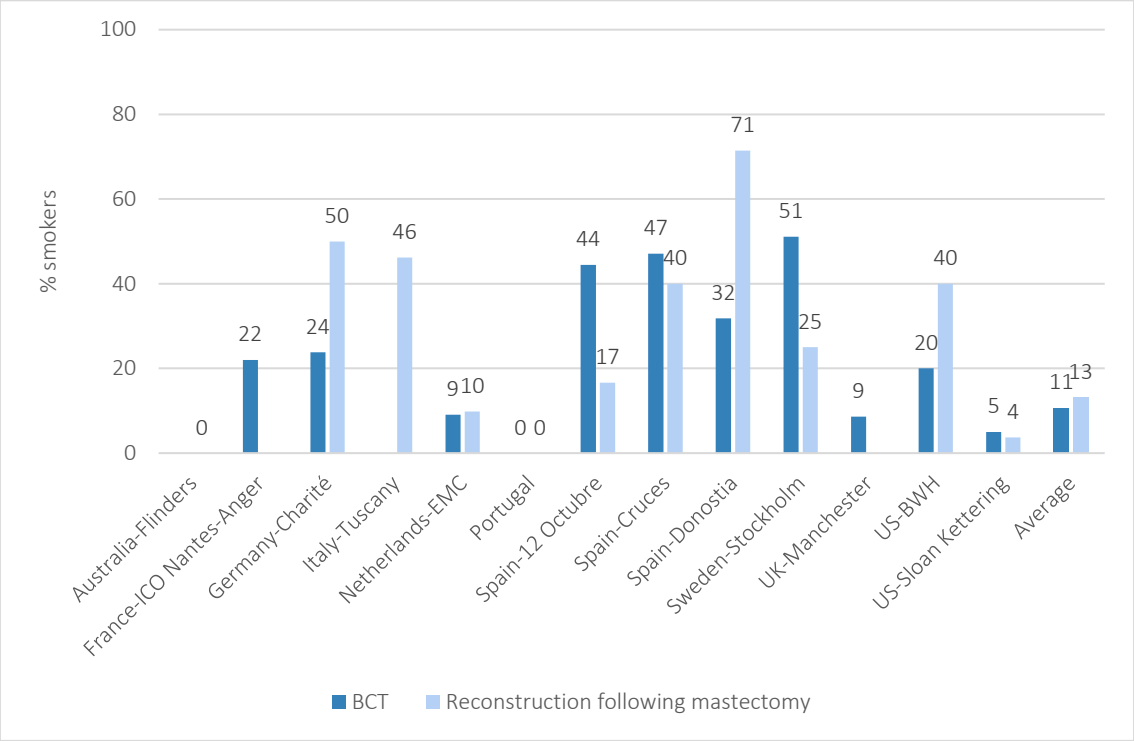
The proportion of smokers varied substantially across sites (Figure 2.4). Sweden-Stockholm reported 48.3% of smokers, while Australia-Flinders and Portugal reported 0%. Nonetheless, no statistically significant difference was found in the proportion of smokers between both procedures (10.7% smokers with BCT, 13.1% smokers with reconstruction surgery, chi-squared test's p-value for the difference between groups is equal to 0.17).

Figure 2.3. Age distribution across sites and procedures



Source: PaRIS Breast Cancer PROMs data collection 2020-2021

Figure 2.4. Smokers' distribution across sites and procedures

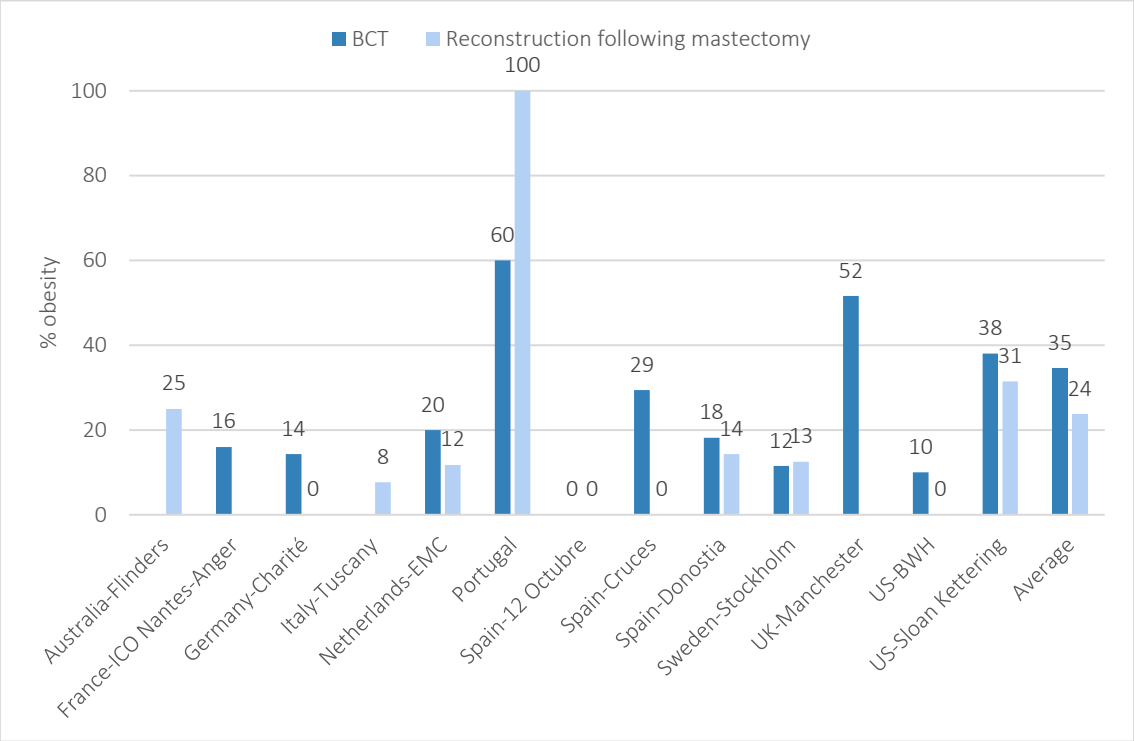


Source: PaRIS Breast Cancer PROMs data collection 2020-2021

The proportion of obesity across analysed women is significantly higher in women undergoing BCT (34.6% obese women) than in those with reconstruction after mastectomy (23.7% obese women) according to the chi-squared test executed ($p<0.05$). (Figure 2.5).

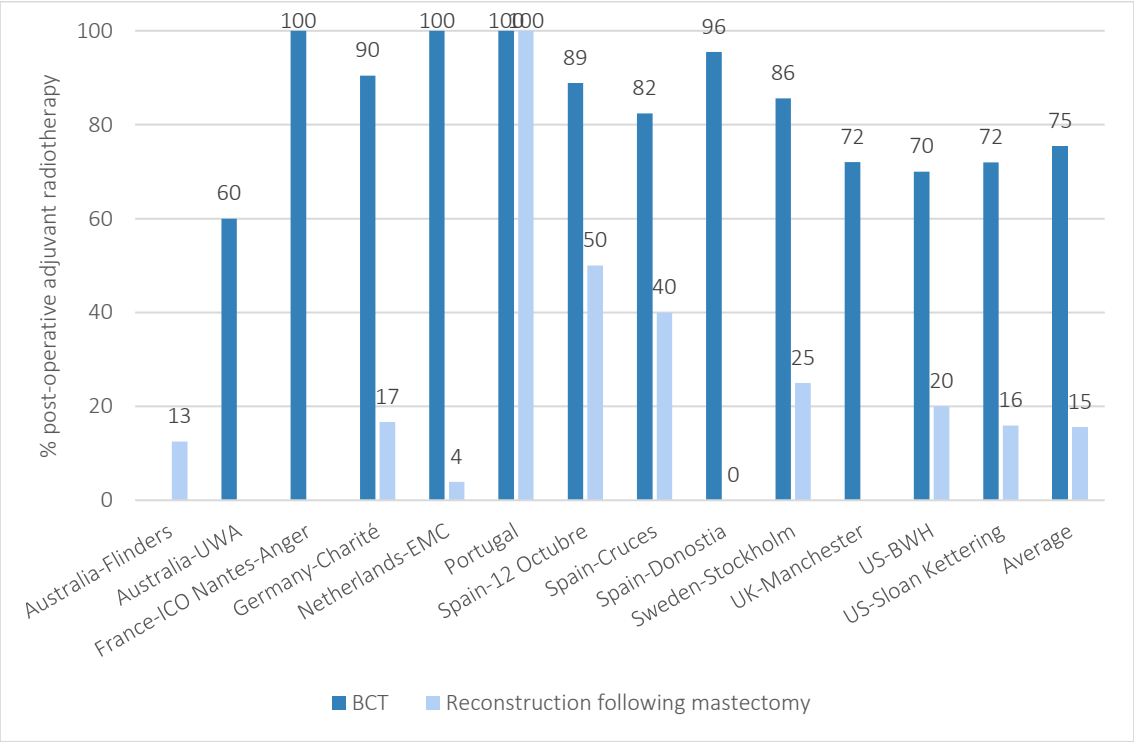
In line with the clinical practice, the percentage of patients with post-operative adjuvant radiotherapy after BCT was over 60% for all sites. Women with reconstruction after mastectomy did not undergo post-operative radiotherapy (on average, only 15% did) (Figure 2.6). Box 2.3 briefly describes post-operative radiotherapy procedure for Breast Cancer (Speers, 2016[7]; Vallis, 2004[8]).

Figure 2.5. Obesity distribution across sites and procedures



Source: PaRIS Breast Cancer PROMs data collection 2020-2021

Figure 2.6. Post-operative adjuvant radiotherapy distribution across sites and procedures



Source: PaRIS Breast Cancer PROMs data collection 2020-2021

Box 2.3. Post-operative radiotherapy for Breast Cancer

Radiotherapy (RT) is defined as the use of high-energy radiation from x-rays, gamma rays, neutrons, protons, and other sources to kill cancer cells and shrink tumors.

When treating early-stage breast cancer, RT is often given after surgery, as it is known to substantially reduce the risk of locoregional recurrence, both when given after mastectomy and after breast-conserving surgery. Surgery is performed to remove the cancer, and radiation is done to destroy any cancer cells that may remain after surgery.

Radiotherapy after BCT for early-stage disease has become an integral part of breast cancer treatment. However, the optimal integration of mastectomy and radiotherapy creates a therapeutic challenge.

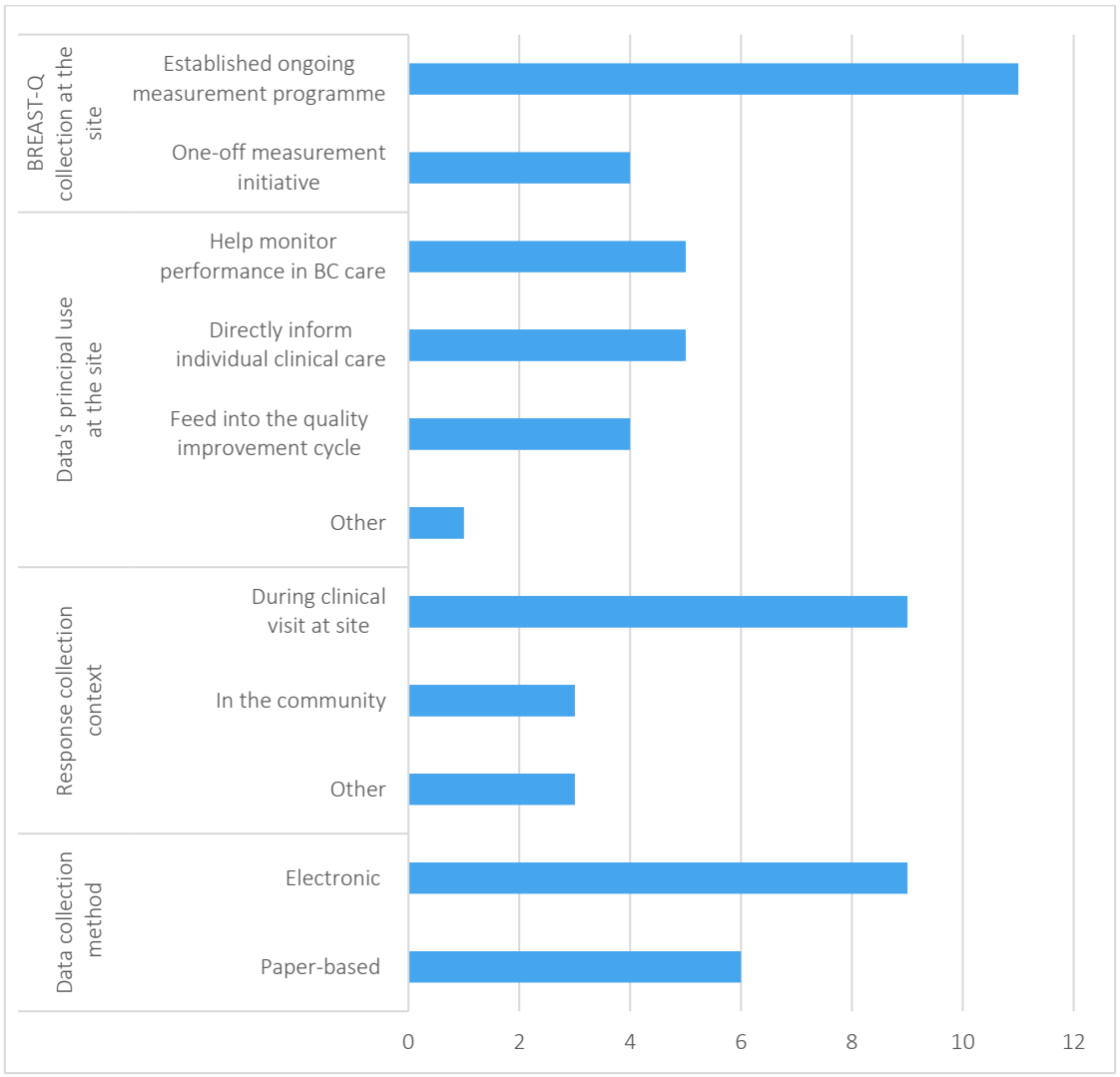
Source: National Cancer Institute and (Speers, 2016[7]; Vallis, 2004[8])

Additional data supporting data interpretation

The collection of data for PROMs in breast cancer care is expanding. This was also reflected in the OECD PaRIS Breast Cancer PROMs data collection (in the pilot data collection in 2019, 10 sites from 7 different countries reported data from 1,807 patients; in 2021, 2,379 patients' data coming from 15 sites of 11 different countries were reported). Figure 2.7 summarises information concerning data collection methods in the participating sites.

In 11 out of 15 sites – Australia-Flinders, Australia-UWA, Germany-Charité, Italy-Tuscany, Netherlands-EMC, Spain-12 Octubre, Spain-Cruces, Spain-Donostia, Sweden-Stockholm, Switzerland-Basel and US-Sloan Kettering – BREAST-Q satisfaction data were collected from an ongoing measurement programme established at the site rather than from a one-time measurement initiative, as was the case of France-ICO Nantes-Anger, Portugal, UK-Manchester and US-BWH. The utility of such measurements is increasingly appreciated and participating sites indicated that the information obtained through the above initiatives is used to help monitor the performance of breast cancer care, directly inform individual clinical care and feed into the quality improvement cycle.

Figure 2.7. Sources and methodology information reported by sites



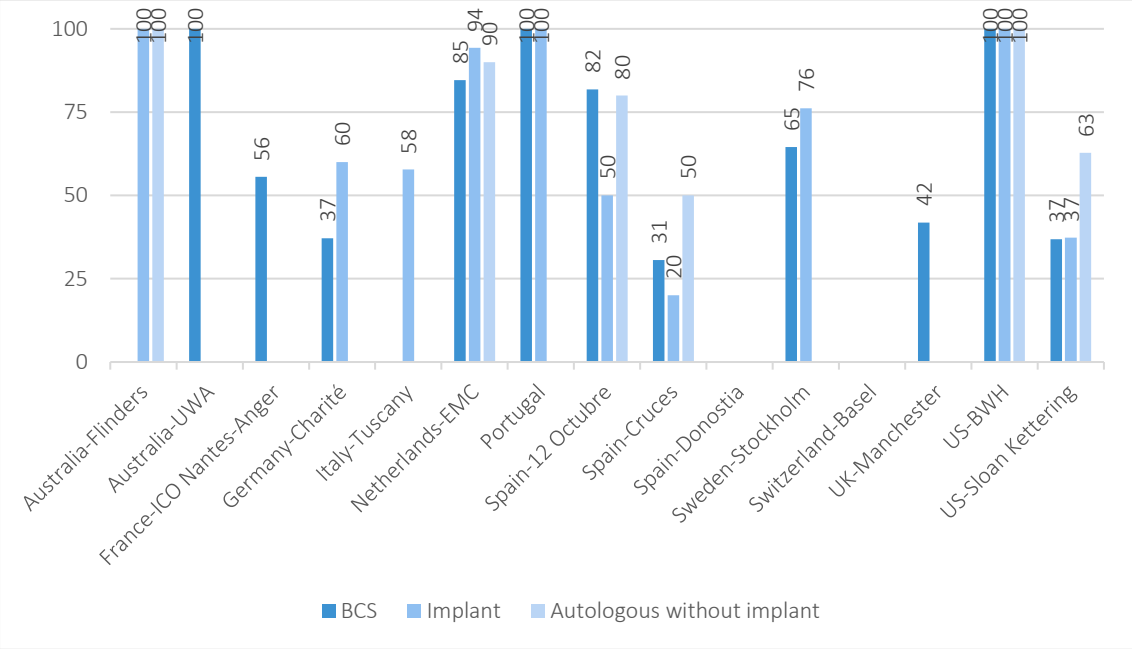
Source: PaRIS Breast Cancer PROMs data collection 2020-2021

PROMs were collected during patient clinic visits in each site but Australia-UWA, France-ICO Nantes-Anger, Germany-Charité, Italy-Tuscany, Sweden-Stockholm and UK-Manchester where data collection was online. Data collection was conducted mainly via electronic means (nine out of 15 sites, i.e. Germany-Charité, Italy-Tuscany, Netherlands-EMC, Portugal, Spain-12 Octubre, Spain-Cruces, Sweden-Stockholm, Switzerland-Basel and US-Sloan Kettering). The remaining sites still gathered data through paper questionnaires (six out of 15). Non-digital means had a negative impact on participation, as reported by sites such as US-BWH. Due to the COVID-19 pandemic, many clinical visits were conducted virtually, so paper forms were not completed. The COVID-19 pandemic has only magnified the benefits to health systems to have in place digitalised systematic collection of data for PROMs.

Eight out of 15 sites – Australia-Flinders, France-ICO Nantes-Anger, Italy-Tuscany, Portugal, Sweden-Stockholm, UK-Manchester, US-BWH and US-Sloan Kettering – extended the established time-window of reporting surgeries performed between 1 February 2019 and 1 August 2020.

Figure 2.8 shows the response rate in each site, which is the percentage of invited women that provided valid BREAST-Q questionnaire that was submitted to the OECD data collection. Note that four sites – Australia-Flinders, Australia-UWA, Portugal and US-BWH – reported a 100% response rate, while others – Germany-Charité, Spain-Cruces, Spain-Donostia and US-Sloan Kettering – reported response rates below 40%. Values from these sites should be interpreted with caution, as sites might have considered different criteria when inviting patients to fill in the questionnaires.

Figure 2.8. Response rate across participating sites



Source: PaRIS Breast Cancer PROMs data collection 2020-2021

Box 2.4. Methodological challenges to descriptive analysis

Some methodological challenges were identified in the descriptive analysis of the data submitted. The following methodological points should be kept in mind while comparing the results of Breast Cancer PROMs scores across the participating sites:

- Small sample sizes;
- Large differences in sample sizes across sites;
- Large differences in distribution of procedures across sites;
- Differences across sites in the distribution of patients with respect to variables of interest – smoking status, obesity and post-operative radiotherapy – which might affect and be directly correlated with satisfaction with breasts;
- Incomplete data submissions regarding metadata that allow limited interpretation of the context of the data submitted.

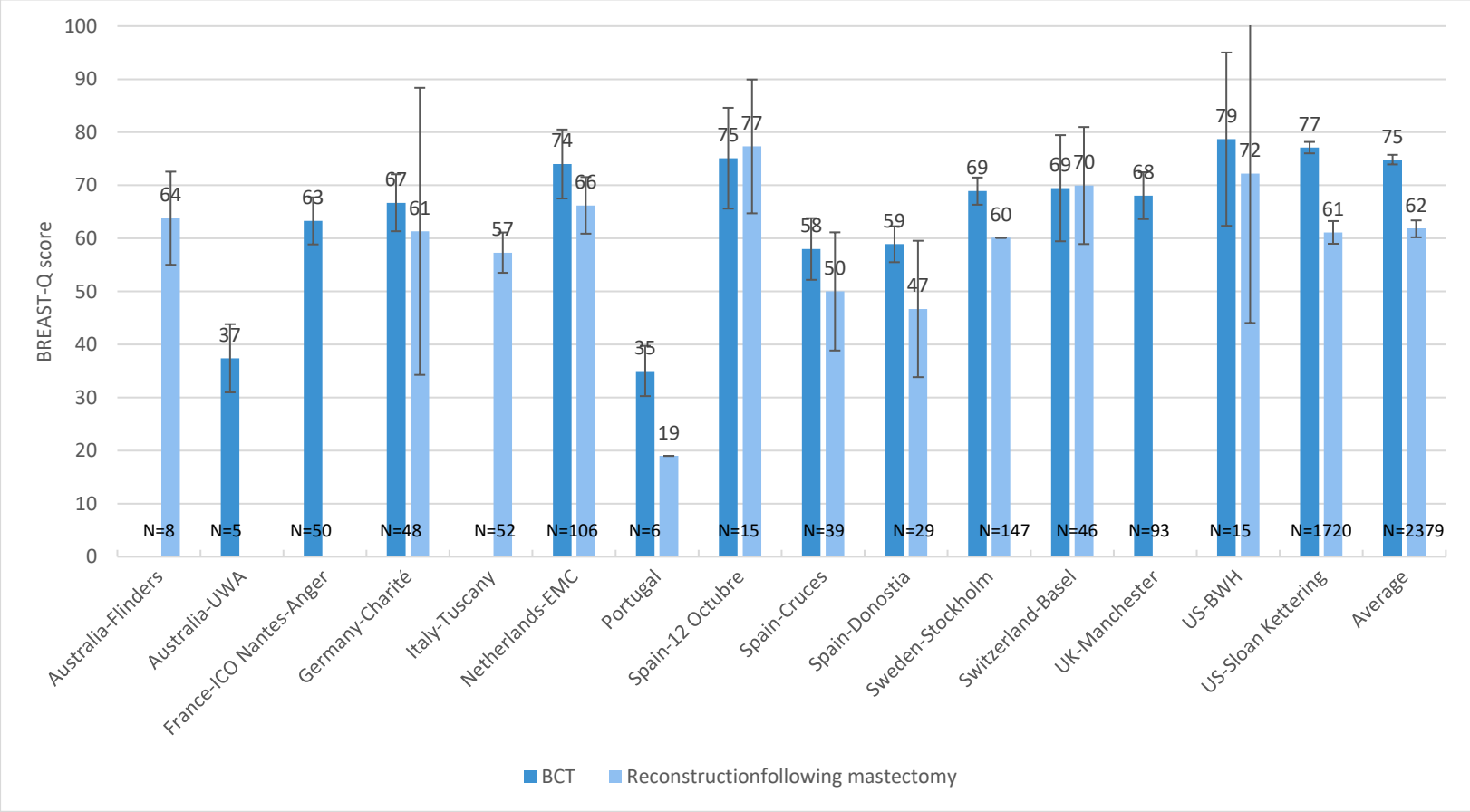
Source: Authors.

Breast satisfaction scores

Figure 2.9 presents crude (unadjusted) breast satisfaction outcome scores at 6-12 months following breast cancer procedures (breast-conserving therapy and reconstruction following mastectomy) for 15 sites in 11 countries.

Overall, patients following breast conserving therapy showed higher levels of satisfaction than patients with reconstructive surgery, which is in line with previous studies and conventional knowledge in the area (Flanagan, 2019[9]). Non-overlapping confidence intervals showed that this difference is statistically significant, such as in Sweden-Stockholm (where BCT patients reported a mean score of 69 points and reconstruction patients reported a mean score of 60 points) and US-Sloan Kettering (where BCT patients reported a mean score of 77 points and reconstruction patients reported a mean score of 61 points). Nevertheless, in Spain-12 October and Switzerland-Basel, reconstructive surgery patients reported higher scores than BCT patients (77 points vs. 75 and 70 vs. 69, respectively). However, overlapping 95% confidence intervals show that these differences were not statistically significant at the 5% confidence level.

Figure 2.9. Self-reported breast satisfaction: crude scores 6-12 months after surgery across sites and procedures



Note: H lines show 95% confidence intervals. Weighted average based on site sample size was used to calculate crude average breast satisfaction

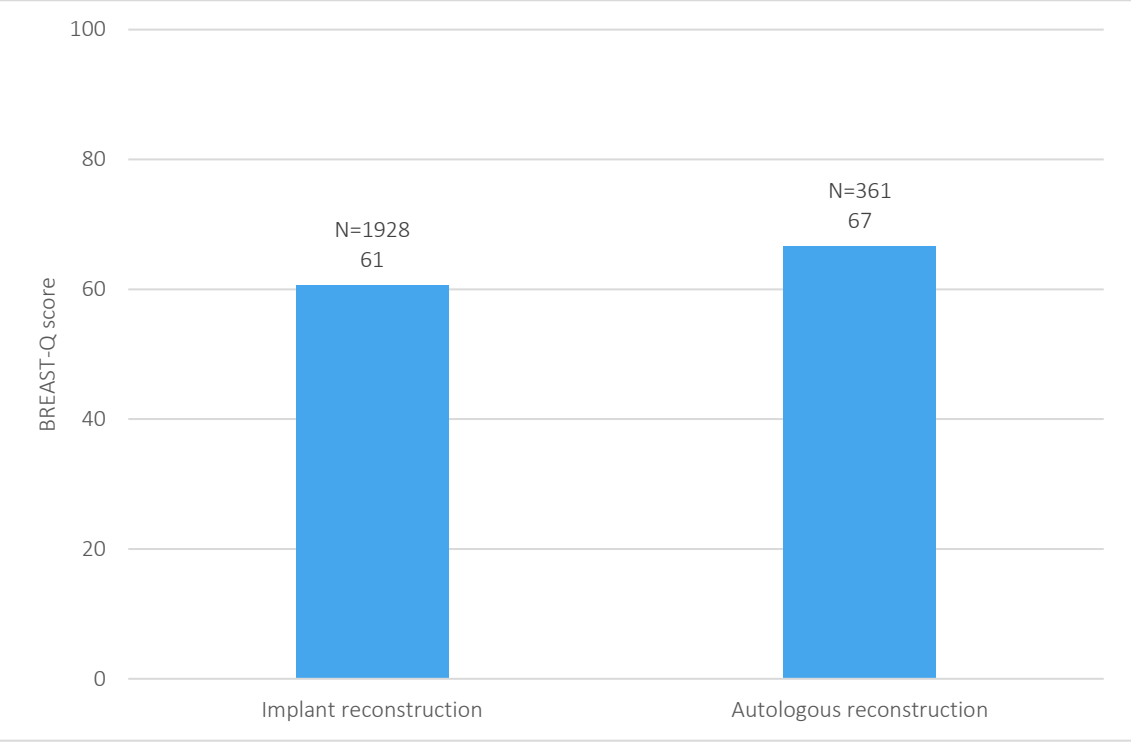
Source: PaRIS Breast Cancer PROMs data collection 2020-2021

According to the average satisfaction scores weighted by site, patients undergoing BCT reported scores on average 13 points higher than patients with reconstruction (75 and 62 points, respectively). Non-overlapping 95%-confidence intervals confirmed that this difference was significant from a statistical point of view.

Caution is advised when comparing the results of the participating sites. Sample sizes varied substantially, which biased to some extent the direct comparability across centres. These differences are reflected in the confidence intervals included in Figure 2.9, as smaller sample sizes result in wider confidence intervals.

Mean breast satisfaction scores differentiated by reconstruction type are presented in Figure 2.10. Results suggested that women are on average 6 points more satisfied with the autologous reconstructive procedure than with the implant surgery. No confidence intervals were calculated, as standard deviations were not collected. It follows that the variation in breast satisfaction scores presented in Figure 2.9 may be influenced, among other factors, by the proportion of women undergoing autologous reconstruction surgery. The higher number of autologous, the higher satisfaction. Further analysis and larger sample size of patients with autologous reconstruction would be needed to draw more robust conclusions. Nevertheless, this result can be an important consideration where choice of surgical intervention is possible.

Figure 2.10. Self-reported breast satisfaction: crude scores 6-12 months after surgery for implant and autologous reconstruction



Source: PaRIS Breast Cancer PROMs data collection 2020-2021

3 Challenges and recommendations

Participating sites faced some challenges during data collection due to the COVID-19 pandemic. Many health systems prioritised urgent care needs and cancer-screening programs were paused (OECD, 2021[1]).This was the for example the case of Sweden-Stockholm, where a reduction of 14.9% in diagnosed cases was observed between 2019 and 2020 for screening ages 40-74. The clinical activities in the participating sites have been substantially deviating from the routine practice resulting in one type of treatment to be dominated by another type or decrease in small volumes. In this field, some countries, including the United Kingdom, suspended all immediate breast reconstruction surgeries and delayed reconstruction to be offered once services returned to normal (Dave, 2021[10]). Sweden-Stockholm also reported changes in treatment options with reductions of 12-16% nationally in performed immediate breast reconstructions. US-BWH stated the cancelation and postponement of surgeries, affecting the OECD data collection. In addition to this, on-site consultations were cancelled or replaced by online consultations hampering paper-based data collection.

Participating sites identified a number of limitations concerning the data specifications:

- Exclusion of women who undergo bilateral surgery;
- Exclusion of delayed reconstruction surgery cases;
- Short time window for application of PROMs questionnaire following a surgery.

Strategies to improve PROMs collection and benchmarking across health systems in breast cancer have been agreed with participating sites and take into consideration two perspectives: **appropriateness** (clinical pertinence of the suggested changes) and **feasibility** (capacity of participating sites to assume the suggested modifications). The challenges and recommendations for improvement are summarized in the following table.

Table 3.1. Challenges and recommendations for the Breast Cancer PROMs working group

Dimension	Challenges	Recommendations
Measurement	• BREAST-Q questionnaire is completed but out of required reporting period (later than 6-12 months) • Some reconstructions are not ready for at least 12 months	• Extended time window (6-24 month) for BREAST-Q measurement • Inclusion of BREAST-Q new modules • Collection of pre-operative PROMs
Coverage	• Small sample sizes due to strict eligibility criteria	Inclusion of patients with bilateral reconstruction, contralateral procedure or delayed reconstruction.
Participation	• Low number of recruited patients • Unbalanced composition of sample (types of procedures reported) across sites • Biased analysis due to differences in sample size and distribution	• Involvement of key healthcare professionals responsible for breast cancer care • Set up mechanisms to invite all eligible patients • Reach out the minimum sample size • Reporting of three types of procedures (BCT, implant reconstruction and autologous reconstruction)
Data collection	• Significant number of incomplete BREAST-Q questionnaires	• Implementation of electronic/remote PROMs collection procedures and tools • Ensure appropriate organizational procedures for timely collection
Data analysis	• Only unadjusted data analysis possible	• Submission of data for all covariates (mean score and standard deviation) and breast satisfaction scores by type of procedure

Source: Authors.

Some of the recommendations included in the table will support the discussions of the Working Group for the preparations of the data collection materials proposed for data to be collected to be published in the *Health at a Glance* 2023.

Future considerations

The PaRIS Breast Cancer PROMs working group has outlined a preliminary roadmap for the future work on the measurement of PROMs for breast cancer. Strategies and concrete actions to upscale the data collection at both regional or national level are prioritised to allow results and its interpretation to be generalisable and internationally comparable.

In order to make health systems more people-centred, it is essential to improve quality of care for patients with breast cancer. Collaboration with key national and international organisations is key to seize the use of PROMs at the health systems and policy level.

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Annex A. Terms of References

TERMS OF REFERENCE OF A WORKING GROUP TO DEVELOP INTERNATIONALLY COMPARABLE PATIENT-REPORTED INDICATORS FOR BREAST CANCER CARE

PREAMBLE

In January 2017, OECD Health Ministers asked the Secretariat to lead efforts to analyse comparative measures of patients' experiences of medical care and health care outcomes.[3] This mandate was given with the full support of the OECD Health Committee and follows the recommendations of a High-Level Reflection Group on Health Statistics (HLRG), convened by the Health Committee in 2015.

The Final Report of the HLRG[4] addressed the need for more information on patient-reported experiences and outcomes of care to better monitor health system performance and drive continuous improvement.

The report concluded that several patient-reported experience measures (PREMs) already exist internationally, but coverage and comparability remain limited.

The challenge is more apparent for patient-reported outcome measures (PROMs), which are at a very early stage of implementation across OECD health systems. A number of instruments exist to collect PROMs in specific conditions and procedures. They are collected in some countries to varying degrees of system coverage, but the existence of multiple concurrent initiatives using a disparate set of instruments risks missing the opportunity for international comparison. In addition, PROMs programmes are noticeably absent for patients with complex needs, suffering from multiple long-term conditions.

The OECD Health Committee, the senior governing body of the OECD's health-related activities, will work to fulfil this mandate through the new Patient Reported Outcomes Indicators Survey (PaRIS) initiative.

PaRIS will comprise two work streams.

1. To support countries in the adoption and reporting of existing patient-reported measures (PROMs and PREMs) that are validated and internationally comparable. The clinical areas, conditions and procedures of potential focus in this work stream will be selected based on the (a) degree of priority, disease burden and volume/expenditure; and (b) existence of national or sub-national PROMs collection programmes and alignment with current OECD data collection. They are likely to include mental health, cancer care, hip

[3] See point 17 of the Ministerial Statement from the 17 January 2017 meeting of OECD Health Ministers, http://www.oecd.org/health/ministerial/ministerial-statement-2017.pdf

[4] See http://bit.ly/2u8B1l1

and knee surgery, and cardiovascular (coronary and stroke) care. This work stream will be guided by the Health Care Quality Indicators (HCQI) Expert Group.

2. To develop a new international survey to address the need to understand the outcomes and experiences of patients with complex conditions. The survey would be of patients receiving primary health care services who have multiple long-term conditions. This work stream will be overseen by the Health Committee.

To progress the *first work stream*, the HCQI Expert Group has recommended the establishment of working groups for each of clinical area, condition and procedure of focus. This document describes the Terms of Reference for the **Working Group on Patient-Reported Indicators for Breast Cancer Care** (the Working Group).

OBJECTIVES

The Working Group will advise the HCQI Expert Group on the development, collection and reporting of patient-reported indicators for breast cancer care. More specifically, the Working Group will:

- Recommend suitable instrument(s) for piloting an international collection of patient-reported indicators for breast cancer care and, if necessary, oversee development of reliable cross-walks between instruments.
- Develop definitions, specifications and standards for these indicators (inclusions, exclusions, collection time points, and risk adjustment protocols) and a minimum data set for collection.
- Steer initial data collection across a subset of countries. This will include guidance on sampling requirements, collection methods (e.g. electronic; paper based) and privacy and security of data.
- Advise on requirements to ensure comparability of results between languages and cultures.
- Advise on international benchmarking and reporting requirements, and on the publication of data.
- Advise on implementation support such as training manuals, protocols, and stakeholder engagement, especially patients and clinicians.
- Share national and international experience in this domain.

The activity of the Working Group will culminate in a report to the HCQI Expert Group on an initial (pilot) collection and publication from the identified subset of countries, including recommendations on scaling up this work over time.

MEMBERSHIP

The Working Group will comprise approximately ten experts including:

- Representatives of patients and providers (e.g. breast cancer patients, oncologists, surgeons, nurses).
- Recognised experts in breast cancer patient-reported measures.
- Representatives of countries prepared to participate in the initial data collection.

The Working Group Chair will be nominated by the OECD Secretariat in consultation with the HCQI Expert Group Bureau.

The Working Group will be supported by the OECD Secretariat who will undertake research, develop and refine documents, and organise meetings and Web-conference calls.

TIMELINE & MEETINGS

The Working Group will be constituted in the latter half of 2017. Three to four meetings will be held per year. Meetings will be conducted virtually by web- or video-conference. The activity of the Working Group will cease following the report and recommendations to the HCQI Expert Group, expected in late 2019. The table below sets out the key milestones of the Working Group.

Milestone	Date
Working Group established	Nov 2017
Confirm participating countries for initial data collection	Mar 2018
Confirm and agree recommended instruments, specifications, time-points and other standards for initial data collection.	May 2018
Guidelines for initial data collection finalised	Dec 2018
Initial data collection commences	Jan 2019
Agreement on publication and benchmarking parameters based on initial data collected and existing programmes	Jun 2019
Initial data published	Nov 2019
Report the HCQI EG	Nov 2019
Publication at Health at a Glance 2019	Nov 2019
Planning ongoing methodological R&D for guidelines for second data collection	Jan-Sep 2020
Confirm participating countries for second data collection	Feb 2020
Confirm and agree specifications, time-points and other standards for second data collection.	May-Sep 2020
Guidelines for second data collection finalised	Sep 2020
Second data collection commences	Oct 2020
Prepare input for publication at Health at a Glance 2021	May-Oct 2021

Annex B. PaRIS Breast Cancer PROMs Working Group members

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	Richard Price	ECCO, Head of Policy
	Sema Erdem	ECCO, Patient Advisory Committee
	Lorenza Marotti	EUSOMA representative

Annex C. Guidelines for International Data Collection 2020-2021

OECD Breast Cancer Patient Reported Outcomes Working Group Guidelines for International Data Collection 2020

This document seeks to provide information and guidance for the people from each participating site coordinating the preparation of the data for submission to the OECD data collection on Breast Cancer Patient Reported Outcome Measures (PROMs) in 2020.

Objective

The principal objective of this second international data collection is to advance data collection efforts by OECD and collaborating countries to capture comparable patient reported outcomes on breast cancer care. The data collection forms part of a broader body of work being undertaken by the OECD to promote national measurement capacity and international comparison of PROMs, with more comprehensive data collections anticipated as methodological developments progress and the capacity of ongoing data collections within countries increase.

Timeframe

The data collection will be conducted from 1 October 2020 through to 1 February 2021. The OECD Working Party of Health Care Quality and Outcomes will undertake initial consideration of early data outcomes in 2021, with a view to assessing the feasibility and appropriateness of reflecting selected data outcomes in the 2021 publication of the OECD Health at a Glance.

Measurement

The Breast Q tool will be used to measure and capture the outcome data. Only data from the use of the breast satisfaction scale of the post-operative Breast Conserving Therapy and Reconstruction modules of the tool will be reported to the OECD, where the surgery was performed within a specified 12-month period and the measurement was taken between 6-12 months after the surgery. Where more than one measurement is made for a woman within this period, the measurement closest to 12 months will be reported.

Assuming the data collection closes on 1 February 2021, this means the surgery must have been performed during the period between 1 February 2019 and 1 February 2020 in order to enable measurement at 12 months postoperative and between 1 August 2019 and 1 August 2020 to enable measurement at 6 months postoperative.

Coverage

The data collection will include all women aged 15 years or older (at the date of surgery) that received unilateral breast conserving surgery (i.e. lumpectomy) or immediate reconstructive

surgery (autologous or implant reconstruction) at the site after a mastectomy during the primary treatment phase of breast cancer. Women that received bilateral surgery, surgery for recurrent cancer or where the reconstruction was delayed will be excluded from the data collection. This means that any woman that received breast surgery (either to the same breast of the other breast) subsequent to the initial surgery and during the 6-12 month follow-up period will also be excluded.

Participation

The data collection will be open to all OECD and collaborating countries where data is available from at least one hospital or clinical site. Given the formative nature of data collection efforts in many countries at this time, it is not expected that nationally representative data or data that covers the full scope of patient eligibility for this data collection will be available in all instances.

Each participating site will be asked to provide data on at least 50 women where autologous reconstruction was performed, using a continuous recruitment method based on the date of surgery. The continuous recruitment method will require sites to select a date before 1 February 2021 and then look back to sequentially select cases by date of surgery. The sites will select cases for all three types of surgery (breast conserving surgery, implant reconstruction and autologous reconstruction) until 50 autologous reconstruction cases are identified, with an option to go back further and provide more cases if they are available.

Given the utilisation of autologous reconstruction surgery is likely to be significantly less than implant reconstruction or breast conserving surgery at any site during the relevant reporting period, this recruitment method will result in a total sample that is well over 150 women from each site. However, no site will be excluded from the data collection based on not being able to meet the 50 case quota for autologous cases and will therefore be encouraged to provide all available data by 1 February 2021. While this may result in data from some sites being excluded from selected site level analyses, these data will still make an important contribution to the overall data analyses and outcomes.

Data

It is noted that only aggregated data will be requested by the OECD during this data collection. It is not anticipated that any patient level data will be exchanged between the sites and the OECD. Further, the data collection has been carefully specified to minimise the risk of requesting sites to exchange data with small cells size.

The data from each site will include:

1. Population Characteristics by type of surgery and total:
    - Number of women meeting the inclusion criteria during the specified reporting period
    - Of these women, the total number invited by the site to complete the relevant Breast Q modules between 6-12 months post-surgery.
    - Of these women, the total number that provided a valid response to the site.
2. Sample Characteristics

Of the sample from all the women that provided a valid response to the site, the average score, standard deviation (SD) and number of women (N) by type of surgery and total by following variables:

- Age group
- Smoking status

- Pre-operative performance - Eastern Cooperative Oncology Group (ECOG) Performance Status

Variables

A number of variables were considered for inclusion in the data collection, including age, smoking status, pre-operative performance, BMI, postoperative adjunct therapy, tumour burden, diabetes status, deprivation and postoperative month of measurement. The variables of age, smoking and pre-operative performance were selected based on their relative impact on patient reported breast satisfaction and the likely feasibility of sites being able to provide related data.

To avoid the exchange of data with small cell size, it has been necessary to constrain the number of variables and categories per variable to be requested. Accordingly, the following data structure will be used to create 24 data stratum per site where:

Smoking Status

- Yes (includes current and previous smokers)
- No

Pre-operative Performance

- High (ECOG Scores 0-2)
- Low (ECOG Scores 3-5)

Adjustment

It is intended that the variables age, smoking status and pre-operative performance be used to adjust the average breast satisfaction scores for each type of surgery and the total. The risk adjustment will seek to remove the impact of key casemix differences between sites and across procedures and thereby improve the comparability of the quality of care.

After taking into account the nature of the outcome variable, the anticipated number of participating sites, the size of the sample per site and the limitations on the number of variables and categories per variable, a simple direct standardisation method has been selected to risk adjust the average scores.

The method of calculating the risk-adjusted scores is as follows:

1. Calculation of the Average Score

For each stratum for each site divide the total scores by the number of cases.

2. Calculation of the Standard Population Proportion

For each strata sum the number of cases across all sites and divide by the total number of cases across all stratum

3. Calculation of the Weighted Average Score

For each strata for each site multiple the standard population proportion with the average score.

4. Calculation of the Adjusted Score

Sum the weighted average score for all the strata per site.

5. Calculation of the Crude Average Score

Divide the sum of the total average scores by the total number of cases for all the strata per site.

Variation

The standard deviation of the breast satisfaction scores will be collected for each strata to enable the calculation of confidence intervals for the average scores. Along with risk-adjustment of the average scores, the confidence intervals will improve the comparability of the data by highlighting the variability of the average scores and allowing the identification of where the average scores across sites or types of surgery are statistically different.

Program

Information regarding the measurement program including, duration of the program, use of Breast Q and other tools, mode of administration and compliance with the data collection specifications will also be collected from sites.

Process

The data collection materials, including the guidelines and data collection sheets (a draft copy is attached at Annex D), will be distributed through the Breast Cancer PROMS online community on 1 October 2020 along with an invitation to all countries to provide data for sites with relevant data available.

Annex D. Templates for International Data Collection 2020-2021

POPULATION-SAMPLE DETAILS

Please specify the reporting period of the data provided here, by date of surgery

START DATE

END DATE

		All	Breast Conserving Surgery	Immediate Reconstruction Surgery	
				Implant	Autologous without implant
Population	1. Number of women meeting the inclusion criteria during the specified reporting period?				
	2. Number of these women invited to complete the breast satisfaction scales 6-12 months after surgery?				
	3. Number of these women that provided the site with a valid response?				
Sample	4. Number of these women included in the data reported here?				
	5. Number of months after surgery that breast satifaction was generally measured for these women?				
	6. Mean breast satisfaction score for these women?				
	7. Mean age of these women at date of surgery?				
	8. Proportion of these women who currently smoke?				
	9. Proportion of these women who are obese?				
	10. Proportion of these women who received post-operative adjuvant radiotherapy?				

BREAST SATISFACTION SCORE DATA															
Strata			BREAST-Q™ BCT Breast Satisfaction Scale				BREAST-Q™ Reconstruction Breast Satisfaction Scale				All			
			Breast Conserving Surgery				Reconstruction Surgery							
Age group	Smoking status	Pre-operative ECOG Performance Status	Total of Scores	Total Women	Mean Score	Standard Deviation	Total of Scores	Total Women	Mean Score	Standard Deviation	Total of Scores	Total Women	Mean Score	Standard Deviation
MEA														
ES (fi														
MS) F														
REA														
ANC														
ARE														

Annex E. Breast-Q Patient Reported Outcomes collection tool

The Breast-Q suite of tools is one of the more widely used amidst the range of instruments currently in use internationally to measure patient-reported outcomes from breast cancer surgery (Tevis et al., 2018[11]).

The breast satisfaction scales of the Breast Q tools measure body image in terms of a woman's satisfaction with her breasts and asks questions regarding how comfortably bras fit and how satisfied a woman is with her breast area both clothed and unclothed. Postoperative items ask about breast appearance (e.g., size, symmetry, softness), clothing issues (e.g., how bras fit; being able to wear fitted clothes) and location and appearance of scars. There are separate modules for lumpectomies, mastectomies and reconstructions, with each module consisting of multiple separate scales covering such issues as psychosocial wellbeing, sexual wellbeing, physical wellbeing, satisfaction with breasts and satisfaction with care. There are also implant-specific items, including the amount of rippling that can be seen or felt.

The scores from each scale of the breast conserving therapy and reconstruction scales, along with the other Breast-Q scales can be transformed to an Equivalent Rasch Transformed Score of 1-100 to allow direct comparison between scales (higher scores denoting better outcomes).

For this data collection, Breast-Q Postoperative Breast Satisfaction Scales were selected, based on the criteria of a group of experts (including patients, clinicians, policymakers and industry representatives).

See http://qportfolio.org/breast-q/breast-cancer/ for more details.

BREAST-Q - RECONSTRUCTION MODULE (POSTOPERATIVE) SATISFACTION WITH BREASTS:

If you have had a mastectomy and reconstruction of both breasts, answer these questions thinking of the breast you are least satisfied with. With your breasts in mind, in the past week, how satisfied or dissatisfied have you been with:

	Very Dissatisfied	Somewhat Dissatisfied	Somewhat Satisfied	Very Satisfied
a. How you look in the mirror clothed?	1	2	3	4
b. The shape of your reconstructed breast(s) when you are wearing a bra?	1	2	3	4
c. How normal you feel in your clothes?	1	2	3	4
d. The size of your reconstructed breast(s)?	1	2	3	4
e. Being able to wear clothing that is more fitted?	1	2	3	4
f. How your breasts are lined up in relation to each other?	1	2	3	4
g. How comfortably your bras fit?	1	2	3	4
h. The softness of your reconstructed breast(s)?	1	2	3	4
i. How equal in size your breasts are to each other?	1	2	3	4
j. How natural your reconstructed breast(s) looks?	1	2	3	4
k. How naturally your reconstructed breast(s) sits/hangs?	1	2	3	4
l. How your reconstructed breast(s) feels to touch?	1	2	3	4
m. How much your reconstructed breast(s) feels like a natural part of your body?	1	2	3	4
n. How closely matched (similar) your breasts are to each other?	1	2	3	4
o. How you look in the mirror unclothed?	1	2	3	4

BREAST-Q – BCT MODULE (POSTOPERATIVE) SATISFACTION WITH BREASTS:

	Very Dissatisfied	Somewhat Dissatisfied	Somewhat Satisfied	Very Satisfied
a. How you look in the mirror clothed?	1	2	3	4
b. The shape of your lumpectomy breast when you are wearing a bra?	1	2	3	4
c. How normal you feel in your clothes?	1	2	3	4
d. Being able to wear clothing that is more fitted?	1	2	3	4
e. How your lumpectomy breast sits/hangs?	1	2	3	4
f. How smoothly shaped your lumpectomy breast looks?	1	2	3	4
g. The contour (outline) of your lumpectomy breast?	1	2	3	4
h. How equal in size your breasts are to each other?	1	2	3	4
i. How normal your lumpectomy breast looks?	1	2	3	4
j. How much your breasts look the same?	1	2	3	4
k. How you look in the mirror unclothed?	1	2	3	4