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## Opportunities to reduce reoperations and to improve inter-facility profiling after initial breast-conserving surgery for cancer. A report from the NCDB



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### ABSTRACT

**Background:** Repeat operations after breast-conserving surgery (BCS) for cancer have been termed “epidemic.” To aid improvement activities, we sought to identify those National Cancer Data Base (NCDB) characteristics that were associated with reoperations.

**Methods:** A retrospective cohort of patients with invasive breast cancer undergoing initial BCS in the NCDB from 2004 to 2015 were identified. Univariate, multivariate, ranking (effect size and  $R^2$ ), and time-trend methods were used to assess associations between patient, facility, tumor, treatment, and calendar-year characteristics with reoperation.

**Results:** In 1226 facilities, 84,462 (16.1%) of 524,594 patients underwent reoperations after BCS [range 0–75%; 10th/90th performance percentiles = 6.6%/25%]. Of 18 factors associated with reoperations, facility ID was the highest-ranked. Its estimated impact on the odds of reoperation was more than 10 times greater than any other factor considered, followed by tumor size, neo-adjuvant chemotherapy receipt, patient age, cancer histology, and nodal status. Reoperations after the year of the SSO-ASTRO margin guideline declined significantly compared with prior years. Significant inter-facility reoperation variability persisted after risk adjustment for more than a dozen distinct patient, facility, tumor, and treatment characteristics.

**Conclusion:** In the NCDB, significant inter-facility variability exists regardless of case volume, case mix, and risk adjustment. There were fewer reoperations after the SSO-ASTRO guideline. An endorsed target rate of 10% was achieved by only 1 in 4 facilities. The most impactful determinant of reoperation was the facility itself. Thus, all stakeholders should consider participation in improvement activities. Such activities will benefit from risk-adjusted profiling; the relevant adjusters were identified.

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### Introduction

About one patient in five undergoing an initial breast-conserving surgery (BCS) for breast cancer requires a second operation, and rates of reoperation range from 5% to more than 80% [1–16]. Despite national and international efforts to measure and reduce rates, an incomplete understanding of the causes of high

rates persists.

The goal of the current study was to identify predictors of reoperation that could be incorporated into performance initiatives that aimed to reduce reoperations. To do so, we first sought to identify and hierarchically rank those patient, facility, tumor, and treatment characteristics in the National Cancer Database (NCDB) that were associated with reoperations after BCS. With a reoperation rate time-trend analysis, we also sought to determine the impact of the publication of the Society of Surgical Oncology (SSO)-American Society of Radiation Oncologists (ASTRO) margin guideline for invasive cancer on reoperations [15,17].

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## Methods

The National Cancer Data Base (NCDB) is a joint project of the Commission on Cancer and the American Cancer Society [18,19]. The NCDB files are de-identified and considered exempt from review by the Institutional Review Board of our institution.

The 2004–2014 NCDB was accessed. Facilities with <10 cases/year and patients with stage 0 and IV or with unknown values for reoperation were excluded. Patients with missing values for an independent variable were assigned an “unknown” status for that variable and included.

The primary outcome was reoperation within 60 days of initial surgery. The reoperation rate was reported as the number of patients undergoing reoperation divided by the number of patients undergoing initial breast-conserving surgery. Since reoperation, reasons for reoperation, re-excision for margins, and type of initial surgery are not data fields in the NCDB; reoperations were identified by the fields “First Surgical Procedure, Days from Diagnosis (DFD)” and “Definitive Surgical Procedure, DFD” [3,14,16]. If the latter value was greater than the former, then a repeat operation occurred. If the values were equal and the final surgical code was BCS or mastectomy, then the patient had an initial BCS or mastectomy, respectively, with no reoperation. If DFD to first surgery were < DFD to definitive surgery and the final surgical code was BCS, then the patient's first surgery was BCS followed by reoperation. If DFD to first surgery were < DFD to definitive surgery and the final surgical code was mastectomy, then the patient's first surgery may have been BCS or mastectomy followed by reoperation. The following cases were excluded: DFD to initial or definitive surgery unknown; DFD to first surgery = 0, indicating an excisional, not a needle biopsy for diagnosis; DFD to first surgery > DFD to definitive surgery (nonsensical); and DFD to first surgical procedure = DFD to definitive surgical procedure and the surgical code for the definitive procedure was a mastectomy, indicating that the patient had an initial mastectomy without reoperation.

Chi-square tests assessed the association of each independent variable with reoperations. A multiple logistic mixed model was then fit using reoperation as the response. The 18 patient, tumor, treatment, and facility characteristics in Table 1 were all included as fixed categorical factors for risk adjustment, and this multivariate model was reported with odds ratios and 95% confidence intervals; facility ID served as a random factor. This model was hierarchical, with patients nested within facilities. A semi-partial  $R^2$  was used to rank the relative impact of each of the fixed factors [20]. Maximum effect sizes (max effect - min effect) were then used to rank the impact of the random facility ID factor on adjusted reoperation rates relative to all of the fixed factors. The estimated random effects for each facility ID from the multiple logistic mixed model were used to determine the percentile scores of facilities. Percentile scores were also computed for facilities based on unadjusted reoperation rates, then based on a partially adjusted model (same logistic mixed model, except only including the top 5 ranked predictor variables based on the semi-partial  $R^2$ ). P-values <0.05 were considered significant. Because of the hierarchical nature of the data set with patients nested within facilities, the unadjusted decile computations within facility factor levels were done differently from the decile computations for other factors. Decile tables for facility factors were computed using the reoperation rate of each facility. For the decile tables of patient and tumor factors, we computed the reoperation rate for each facility by predictor variable categories.

To determine any association between the publication date of the SSO-ASTRO guideline with reoperation rates, a time-trend approach at the patient level was applied to annual reoperation rates to assess whether the years 2014 and 2015 could be predicted

from the 2004–2013 data. This model used a multiple logistic mixed model comparable to that mentioned above, with the addition of “year of diagnosis” as a numeric predictor variable. With this model, there would be no evidence of guideline impact if the model results in the years before the margin guideline correctly forecasted the years after the guideline. Conversely, if reoperations after the guideline were lower than those predicted by pre-guideline data, then an impactful intervention, such as the margin guideline, would be supported. For the time-trend approach, the patient cohort was extended to the year 2015 but restricted to those case types that were specified in the SSO-ASTRO guideline [patients with pathologic stage I-II cancer receiving whole-breast irradiation] [17]. These data were split into a training set (random 70% of cases from 2004 to 2013), a validation set (remainder of 2004–2013 cases), and a test set (2014–2015 cases) [21]. The model that was constructed with the training data was applied to the validation and test sets to generate predicted probabilities of reoperation for each patient in the validation and test sets. A Receiver Operating Characteristic Curve (ROC) and the associated area under the curve assessed how closely the predictions of the training model aligned with actual reoperations in the validation and test sets.

All analyses were performed with SAS software, version 9.3 (SAS Institute Inc., Cary, NC, USA).

## Results

Patients and exclusions are shown in Fig. 1. There were 1226 unique facilities and 524,594 cases.

The overall reoperation rate (unadjusted) at the patient level was 16.1% (84,462/524,594). At the facility level, the mean and median were 15.3% [SD 7.6%] and 14.5% [range 0–75%]. The unadjusted 10th and 90<sup>th</sup> percentiles of performance were 6.6% and 25%, a 3.8 X-fold difference.

The breast-conserving surgery (BCS) rate per facility mean [SD] in 524,594 patients was 54.3% [9%]; the minimum/maximum was 10.7%/83.2%. The breast cancer case volume (mastectomy + BCS) per annum per facility mean [SD] was 184 [183]; the range was 12–2339.

Twenty-five percent (307/1226) of facilities had a reoperation rate of less than or equal to 10%.

The associations and hierarchical ranking of independent variables with reoperations are in Tables 1 and 2. There were differences between the 10th and 90<sup>th</sup> performance percentiles for facilities stratified by each of 18 independent variables, ranging from a 2.6-fold difference (integrated facility type) to a 12.3-fold difference (number of patient comorbidities) (Table 1). Inter-facility reoperation variability and profiling (including models for case volume, facility type, and BCS rate) are shown in Figs. 2 and 3.

The profiling of facilities into different tiers of reoperation performance changed with risk adjustment. After partial risk adjustment using the 5 highest ranked factors affecting repeat surgery, 132 (11%) of 1226 facilities moved to a different quartile of reoperation performance compared with no risk adjustment. No facility moved by more than one quartile. In comparing partial-risk with full-risk adjustment for 18 factors associated with repeat surgery, 254 (21%) and 3 (<1%) of 1226 facilities changed by 1 and 2 quartiles of reoperation performance, respectively. In comparing unadjusted to the full-risk adjustment model, 302 (25%) and 5 (<1%) of 1226 facilities changed by 1 and 2 quartiles, respectively.

By the time-trend model to assess the impact of the SSO-ASTRO margin guideline [by date of publication], reoperations were less than “expected” after 2013, compared with 2004–2013 (Fig. 4). The area under the ROC was 0.67 and 0.64 for the validation and the test set, respectively, a statistically significant decline (p-value <0.0001).

**Table 1**  
Univariate and multivariate association of patient, tumor, facility, and treatment factors with reoperation rate after breast-conserving surgery.

Variables	Unadjusted				Adjusted				90/10 ratio		
	N Reoperation	N Total	Reoperation rate, %	p-value	Odds ratio	95% confidence interval		p-value	X-fold differences		
						Lower	Upper		10th Percentile	90th Percentile	X-fold
<b>Overall</b>	84462	524594	16.1						0.07	0.25	3.8
<b>Age</b>											
<40	3171	14046	22.6	<0.0001	Reference			<0.0001	0.05	0.41	7.5
40–49	15061	72119	20.9		0.91	0.87	0.95		0.07	0.33	4.9
50–59	22472	127436	17.6		0.74	0.71	0.78		0.06	0.28	4.4
60–69	23605	152263	15.5		0.66	0.63	0.69		0.06	0.26	4.6
70–79	14398	105892	13.6		0.58	0.55	0.61		0.04	0.24	5.9
≥80	5755	52838	10.9		0.43	0.40	0.45		0.00	0.20	*
<b>Insurance</b>											
Medicaid	4229	25701	16.5	<0.0001	0.88	0.85	0.92	<0.0001	0.04	0.29	6.8
Medicare	28580	210757	13.6		0.93	0.91	0.95		0.05	0.23	4.6
Other Government	802	4617	17.4		1.01	0.94	1.10		0.05	0.33	6.7
Private	48733	269431	18.1		Reference				0.07	0.28	4.2
Uninsured	1288	7911	16.3		0.90	0.85	0.96		0.04	0.35	8.8
Unknown	830	6177	13.4		0.83	0.77	0.90		0.00	0.27	*
<b>Income</b>											
Less than \$38 K	10557	69353	15.2	<0.0001	0.96	0.93	0.99	0.0036	0.05	0.26	5.2
\$38–<48 K	16191	106804	15.2		0.98	0.96	1.00		0.05	0.27	5.1
48–<63 K	21885	140504	15.6		0.97	0.95	0.99		0.06	0.26	4.4
63 K+	35262	204433	17.2		Reference				0.07	0.27	4.1
Unknown	567	3500	16.2		0.92	0.84	1.01		0.06	0.36	6.1
<b>Race</b>											
Black	8739	51756	16.9	<0.0001	0.98	0.95	1.01	0.012	0.06	0.29	5.1
White	71397	449111	15.9		Reference				0.06	0.25	4.0
Other	181	1253	14.4		0.91	0.77	1.08		0.03	0.25	8.3
Unknown	4145	22474	18.4		1.07	1.03	1.11		0.05	0.33	6.7
<b>Ethnicity</b>											
Hispanic	3749	23062	16.3	<0.0001	1.04	1.00	1.08	0.0448	0.05	0.31	5.9
Non-Hispanic	75890	474013	16.0		Reference				0.07	0.25	3.9
Unknown	4823	27519	17.5		1.03	0.99	1.08		0.05	0.31	6.7
<b>Number of comorbidities</b>											
0	72028	443918	16.2	<0.0001	Reference			<0.0001	0.07	0.25	3.8
1	10357	66581	15.6		1.05	1.03	1.08		0.05	0.27	5.7
2+	2077	14095	14.7		1.02	0.97	1.08		0.02	0.29	12.3
<b>Neo-adjuvant Chemotherapy</b>											
No or unknown	81214	498858	16.3	<0.0001	Reference			<0.0001	0.07	0.25	3.8
Yes	3248	25736	12.6		0.38	0.36	0.40		0.00	0.25	*
<b>Neo-adjuvant Endocrine Therapy</b>											
No or unknown	83735	519368	16.1	<0.0001	Reference			<0.0001	0.07	0.25	3.8
Yes	727	5226	13.9		0.75	0.69	0.81		0.00	0.33	*
<b>Her2 Status</b>											
Negative	45846	300674	15.2	<0.0001	0.80	0.77	0.82	<0.0001	0.05	0.24	4.6
Positive	5978	32721	18.3		Reference				0.05	0.33	6.3
Unknown	32638	191199	17.1		0.89	0.86	0.92		0.06	0.28	5.0
<b>Hormone receptor status</b>											
Negative	10763	74390	14.5	<0.0001	0.80	0.78	0.82	<0.0001	0.04	0.26	6.5
Positive	72854	444312	16.4		Reference				0.07	0.25	3.8
Unknown	845	5892	14.3		0.88	0.81	0.95		0.00	0.29	*
<b>Histologic subtype</b>											
Invasive ductal	60147	405867	14.8	<0.0001	Reference			<0.0001	0.06	0.24	4.1
Invasive lobular	10286	42082	24.4		1.91	1.87	1.96		0.09	0.38	4.2
Invasive other	3527	27109	13.0		0.98	0.94	1.02		0.00	0.25	*
Invasive mixed	10502	49536	21.2		1.51	1.48	1.55		0.07	0.35	5.1
<b>Node status</b>											
Negative	73052	478395	15.3	<0.0001	0.54	0.53	0.56	<0.0001	0.06	0.24	4.1
Positive	9361	37052	25.3		Reference				0.08	0.44	5.8
Unknown	2049	9147	22.4		0.83	0.78	0.88		0.06	0.40	6.8
<b>Tumor size</b>											
<2 cm	58658	397120	14.8	<0.0001	Reference			<0.0001	0.06	0.24	4.2
2–5 cm	20803	106900	19.5		1.34	1.31	1.37		0.07	0.32	4.8
>5 cm	2475	8117	30.5		2.83	2.67	2.99		0.09	0.50	5.5
Unknown	2526	12457	20.3		1.46	1.39	1.53		0.07	0.38	5.4
<b>Grade</b>											
1	17976	139194	12.9	<0.0001	Reference			<0.0001	0.04	0.22	6.1
2	38840	223606	17.4		1.33	1.30	1.35		0.07	0.28	4.2
3	22556	133727	16.9		1.30	1.27	1.33		0.06	0.28	4.9
4	198	1190	16.6		1.29	1.10	1.52		0.00	0.38	*
Unknown	4892	26877	18.2		1.30	1.25	1.35		0.05	0.32	6.4
<b>Facility Type</b>											
Community	7647	52828	14.5	<0.0001	Reference			0.7894	0.05	0.25	4.9
Comprehensive	38257	249475	15.3		1.01	0.93	1.09		0.07	0.25	3.8

**Table 1** (continued)

Variables	Unadjusted				Adjusted				90/10 ratio		
	N Reoperation	N Total	Reoperation rate, %	p-value	Odds ratio	95% confidence interval		p-value	X-fold differences		
						Lower	Upper		10th Percentile	90th Percentile	X-fold
Academic/NCI	26030	146205	17.8		1.03	0.92	1.15		0.08	0.27	3.5
Integrated	9487	55792	17.0		1.12	0.93	1.35		0.10	0.25	2.5
Multiple/Unknown	3041	20294	15.0		0.97	0.77	1.22		0.08	0.22	2.8
<b>Facility Location</b>											
New England	7408	39678	18.7	<0.0001	Reference			<0.0001	0.10	0.26	2.6
Mid Atlantic	13849	83556	16.6		0.75	0.65	0.87		0.07	0.26	3.8
South Atlantic	17056	109496	15.6		0.69	0.60	0.80		0.07	0.24	3.6
E N Central	16545	100233	16.5		0.74	0.64	0.85		0.07	0.23	3.5
E S Central	3612	26385	13.7		0.58	0.48	0.70		0.06	0.24	3.9
West N Central	6343	35789	17.7		0.81	0.68	0.96		0.08	0.27	3.3
West S Central	4991	32543	15.3		0.57	0.48	0.69		0.05	0.26	5.2
Mountain	4034	25861	15.6		0.72	0.59	0.88		0.08	0.25	3.4
Pacific	10624	71053	15.0		0.65	0.55	0.75		0.06	0.25	4.4
<b>BCSR</b>											
<40%	2633	15295	17.2	<0.0001	Reference			<0.0001	0.06	0.34	5.9
40–49%	17216	104198	16.5		0.87	0.75	1.02		0.07	0.26	3.7
50–59%	41295	251758	16.4		0.78	0.67	0.91		0.07	0.24	3.5
60–69%	20603	134833	15.3		0.71	0.60	0.83		0.07	0.23	3.5
70+%	2715	18510	14.7		0.63	0.50	0.80		0.05	0.25	5.3
<b>Volume<sup>a</sup></b>											
<200	27892	190942	14.6	<0.0001	0.81	0.57	1.15	0.431	0.06	0.25	4.3
200–499	37777	231121	16.3		0.89	0.63	1.27		0.08	0.25	3.0
500–999	13728	76694	17.9		0.96	0.66	1.39		0.09	0.31	3.5
1000+	5065	25837	19.6		Reference				0.10	0.28	2.8

Summary – With multivariate analysis, 16 of 18 patient, tumor, facility, and treatment factors were found to be associated with reoperations after breast-conserving surgery for cancer. When comparing facilities in the 10th to those in the 90<sup>th</sup> performance percentiles for reoperations, there were 2.6–12.3-fold differences between facilities for each independent variable; i.e., inter-facility variability persisted across all case types.

Abbreviations: NCI, National Cancer Institute; BCSR, breast-conserving surgery rate.

<sup>a</sup> Facility Volume is based on Stage 0–IV breast cancer cases/year/facility [any type surgery]; all other independent variables were at the patient level (Stage I–III that underwent surgery).

## Discussion

### Background

Repeat surgery in patients undergoing initial BCS for breast cancer is common and exceed those in patients undergoing other oncologic operations [22]. In the current study, the overall reoperation rate in 1226 facilities (524,594 cases) was 16.1% and ranged from <5% to >70%. In most reports outside the NCDB, rates are higher [1–15]. As a result, reoperations after BCS have been described as “epidemic,” “over-treatment,” “over-surgery,” and a “disutility” [23–26]. Moreover, an international group recommended universal auditing of rates, Europeans endorsed a single operation as a quality indicator, and other stakeholders developed guidelines, convened consensus conferences, and launched improvement initiatives [17,25,27–33].

### Opportunities to lower rates and to improve risk-adjusted profiling of facilities into different tiers of performance

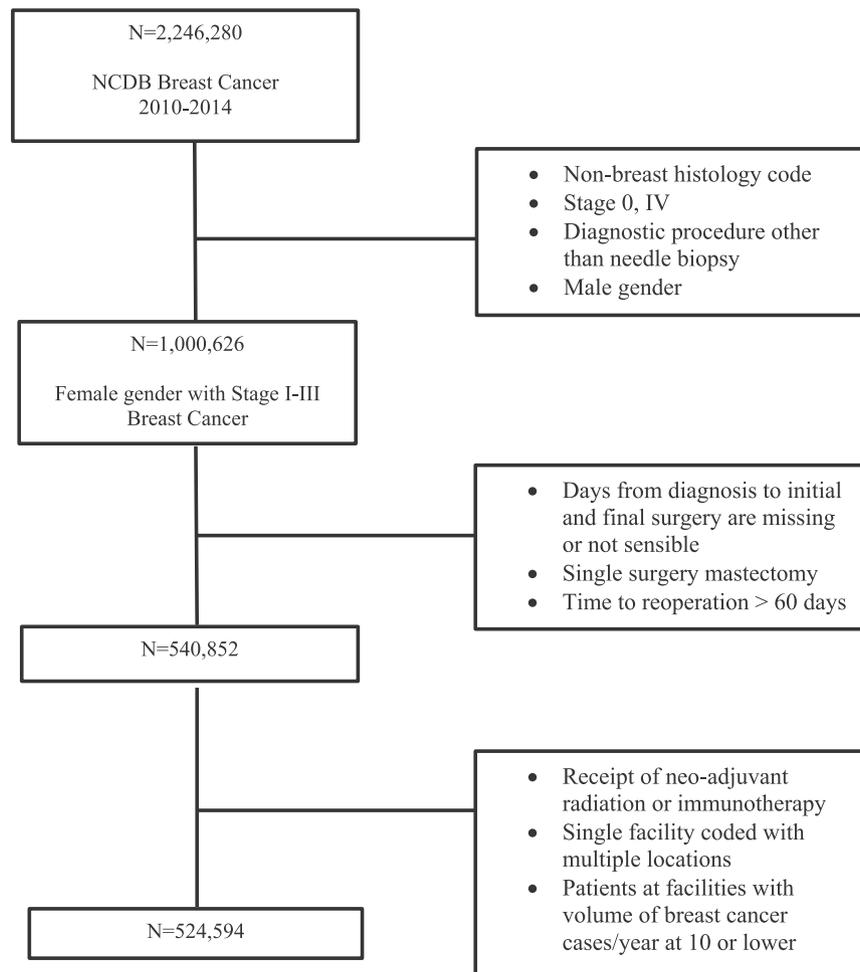
In the NCDB, reoperation rates after the date of the SSO-ASTRO guideline were lower than those predicted by a time-trend analysis of rates before the guideline (Fig. 4). This finding is congruent with most single-institution studies, two national patient registry studies, and a recent meta-analysis [6,7,10,11,13,15,16]. The SSO-ASTRO guideline recommended that surgeons omit re-excisions more widely than no ink on tumor in patients with invasive cancer undergoing whole breast irradiation. Our findings support that the lower rates observed after 2014 were directly attributable to the guideline but cannot prove attribution because “margin distance” and “guideline compliance” are not data fields in the NCDB. However, when margin distance has been reported, “close” [but ink-

negative] margins are the major driver of reoperations [4,7]. Additionally, Morrow et al. recently reported that more than 30% of surgeons [by survey] would still re-excite to achieve margins wider than no ink on tumor [6]. As such, further efforts to increase compliance with the guideline should lead to even lower rates.

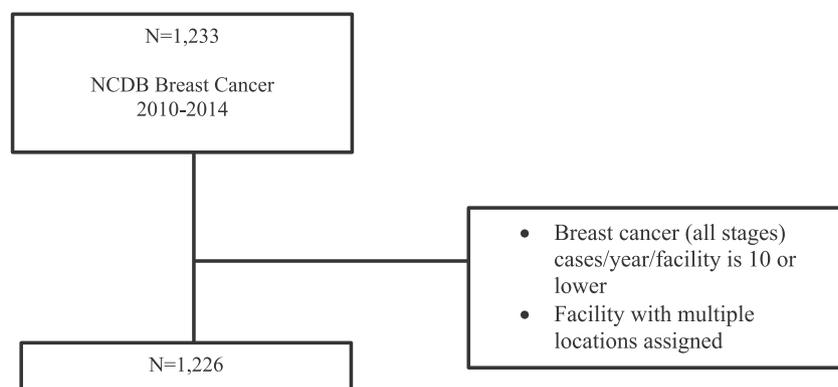
Eighteen other independent factors were found in the NCDB to be significantly associated with reoperations (Tables 1 and 2). For example, similar to past studies, young age, lobular histology, larger tumor size, and positive nodal status were associated with higher rates. The overall unadjusted rates of reoperation varied little (<5%) for patient income, insurance, race and ethnicity factors and for facility type, regional location, and case-volume characteristics. In contrast, the variation between individual facilities was extreme (Fig. 2) and persisted after statistical risk adjustment for all the patient, facility, tumor, and treatment factors listed in Table 1. In other words, the variation in inter-facility reoperation rates was not explained by differences in case-mix.

All the covariates used in the analysis herein could be incorporated into existing or new quality improvement initiatives. Most are immutable; these are the presenting patient and tumor factors. These factors are not actionable to lessen reoperations, but they can be used for risk adjustment to increase fairness when facilities are profiled into different tiers of performance, a policy endorsed by many stakeholders [34–38]. We tested the effect of such risk adjustment on reoperation rates. Facility profiling changed after adjustment. Further, for the parsimony of the number of risk adjusters to collect to lessen the burden of data collection—as discussed by Ong et al.—we also developed models that limited risk adjustment to the 5 most impactful factors influencing reoperations [25]. In doing so, profiling changed but did not match the fully risk-adjusted model. Further, in comparing partially-adjusted with fully adjusted models, about 1 in 5 facilities changed by either 1 or 2

## Patients (Hierarchical variable ranking model)



## Facilities (Hierarchical variable ranking model)



**Fig. 1.** Flow diagram of patients and facilities.

reoperation performance quartiles.

In reoperation initiatives, stakeholders can potentially control 3 of the 18 variables in the NCDB associated with reoperations: the facility to receive care, the BCS rate, and receipt of neo-adjuvant chemotherapy. The receipt of neo-adjuvant chemotherapy was strongly associated with fewer reoperations in the current study (OR 0.38; CI 0.36–0.4). Further, in a prior report of more than

70,000 matched stage I-III patients receiving chemotherapy, the reoperation rate was 11.4% versus 20.3% in those patients receiving it before surgery as opposed to after surgery (OR 0.53; CI 0.49–0.57) [14]. Consequently, during shared the decision making with eligible patients, providers can inform them that an advantage of neo-adjuvant chemotherapy [beyond the known benefits of decreasing mastectomies and full axillary dissections] is fewer

Patients (SSO-ASTRO impact analysis)

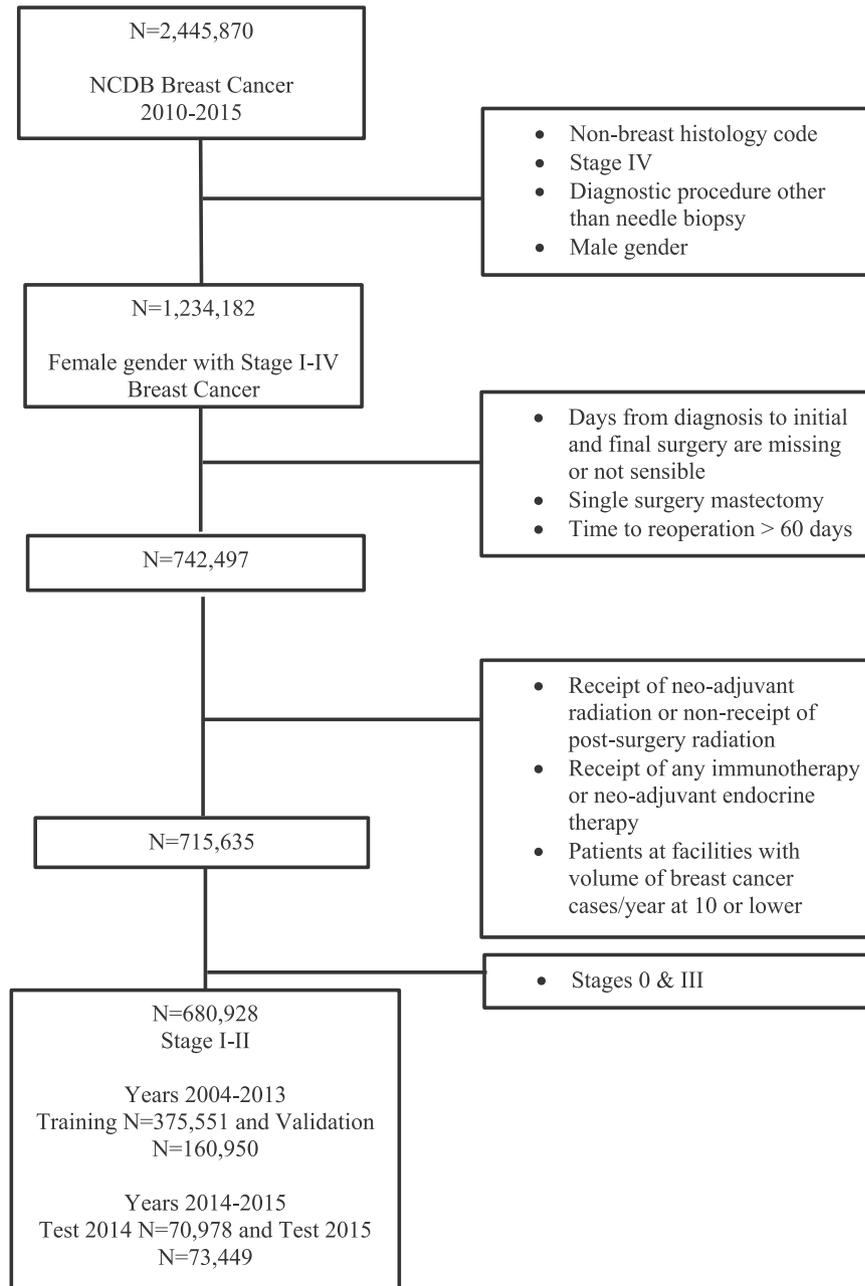


Fig. 1. (continued).

reoperations [14,39,40]. If regionalization of care were to be considered as an option, then the facility itself is the second NCDB factor associated with reoperations that is potentially modifiable. However, in the NCDB, most breast-conserving surgeries are performed outside those centers in the top quartile of performance. Regionalizing care to those centers with the lowest reoperation rates could limit patient access, prolong time to treatment, and increase travel distance. Further, based on our findings, regionalization would only achieve a proposed reoperation target goal of 10% in one of four facilities. Moreover, reoperations are only one part of a quality assessment of a breast center [25,41]. For all these

reasons, a policy of reoperations being used as the primary driver for the destination of care is not supported. The BCS rate was the third potentially modifiable factor that was associated with reoperation rates in the NCDB. Higher rates of BCS were associated with fewer reoperations. Endorsing an ideal BCS rate is complex and out of scope here [42].

*Hierarchical ranking of factors associated with repeat surgery*

In alignment with recommendations to move beyond the use of p-values to determine associations between independent variables

**Table 2**  
Hierarchical ranking of patient, tumor, facility, and treatment factors for their effect on reoperations after breast-conserving surgery.

Ranking based on maximum effect size to include facility ID				Ranking based on semi-partial R <sup>2</sup> excluding facility ID	
Independent variable	Maximum effect size <sup>a</sup>	Odds Ratio (worst to best-case) <sup>b</sup>	Relative size of facility impact when compared with each predictor variable <sup>c</sup>	Independent variable	Semi-partial R <sup>2d</sup>
Facility <sup>e</sup>	3.4	30.6	1	Histologic subtype	0.006
Tumor size	1.0	2.8	11	Node status	0.004
Neo-adjuvant chemotherapy	1.0	2.6	12	Tumor size	0.004
Age	0.9	2.3	13	Neo-adjuvant chemotherapy	0.004
Histologic subtype	0.7	2.0	16	Age	0.003
Node status	0.6	1.9	17	Grade	0.002
Facility location	0.6	1.7	18	Her2 status	0.001
BCSR	0.5	1.6	19	Hormone receptor status	0.001
Neo-adjuvant endocrine therapy	0.3	1.3	23	Insurance	<0.001
Grade	0.3	1.3	23	Neo-adjuvant endocrine therapy	<0.001

Summary – As a contributing factor to reoperation, the facility ID ranks higher than patient, tumor, and treatment factors.

Abbreviations: BCSR; breast-conserving surgery rate.

<sup>a</sup> The difference between logistic model predictions for the two most extreme categories—best- and worst – case scenarios for each independent variable.

<sup>b</sup> The estimated odds ratio of reoperation under the two most extreme categories for each independent variable. For example, the predicted odds of reoperation multiply by 30.6 when switching from the best-to worst-case facility and by 2.8 when switching from the best- (<2 cm) to worst-case (>5 cm) tumor size, assuming all other predictor variables are fixed.

<sup>c</sup> Compares the estimated odds ratio of each of the independent variables to that associated with facility ID. For example, the estimated maximum potential impact of facility ID on the odds of reoperation are 11 times that of tumor size and 12 times that of neo-adjuvant chemotherapy.

<sup>d</sup> After excluding facility ID, the hierarchical ranking of the fixed independent variables based on the semi-partial R<sup>2</sup> value [20]. Note that the top five ranked fixed independent variables are also in the top rankings based on maximum effect size.

<sup>e</sup> For effect of the facility itself on reoperations, a conservative approach of using the difference in the 10th and 90<sup>th</sup> percentiles—rather than the full range of effects—was calculated. The 90/10 effect size was 1.3 (associated odds ratio = 3.5), muting the magnitude of the facility impact, but retaining its top-ranked position.

with the response of interest [reoperations], the study here used effect size and R<sup>2</sup> methodology to hierarchically rank the most impactful factors affecting reoperations [20]. Of 18 factors associated with reoperations, the facility itself had the greatest impact. The predicted odds of reoperation multiply by more than 30 when comparing the facility with the lowest reoperation rate with the highest. The impact of facility ID on the odds of reoperation was more than 10 times that of tumor size. After facility ID and tumor size, the most impactful predictors were tumor histology, patient age, nodal status, and receipt of neo-adjuvant chemotherapy.

#### What is the cause of variation of care?

Inter-facility variation of reoperations persisted irrespective of academic affiliation, case volume, BCS rate, and case mix (Table 1, Figs. 2 and 3). There was a > 3-fold difference between facilities in the 10th and 90<sup>th</sup> performance percentiles for reoperations for each of these factors. Variability also persisted in best-case scenarios, such as non-lobular histology, negative nodes, and T1 cancers, all with at least a 4-fold difference between the 10th and 90<sup>th</sup> percentiles. Overall, these findings argue against differences in case-mix as the cause of inter-facility variation.

#### What is the benchmark?

In 2010, European centers specified a “target” goal of 90% for “single operation” success in patients with invasive cancer [28]. In 2015, 10 of 15 participants in the American Society of Breast Surgeons Consensus Conference on reoperations recommended a goal <20% and a majority recommended ≤10% for reoperations after BCS [27]. Although achievable, few providers have met a 10% target [13,43–45].

#### Moving forward

Action plans to improve performance in healthcare commonly use a cyclical framework that begins with measurement and peer comparison (benchmarking) [1–10,22,25,29,33,43,45–47]. The observed results are then used to determine improvement

strategies [if needed], such as the development and dissemination of guidelines or consensus statements [17,27,30–32]. Subsequently, to assess the effectiveness of these efforts, measurement is repeated. Such initiatives are commonly called “plan-do-study-act” cycles [47]. Regional, national, and international stakeholders have developed these to reduce reoperations [1,2,5,25,27,29,33,46].

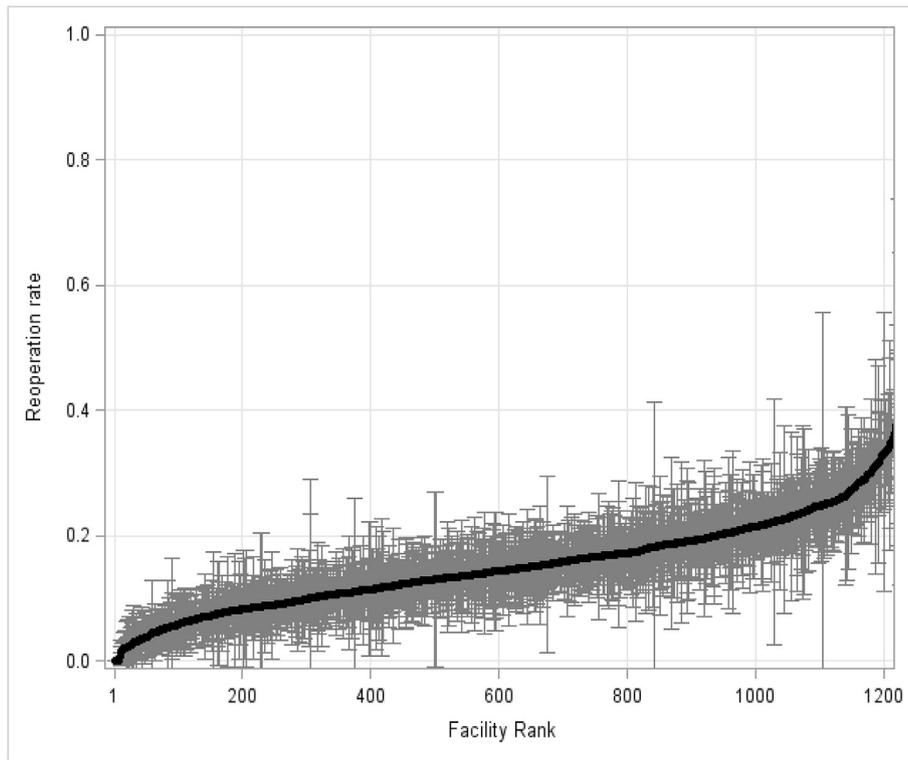
Beyond measurement and benchmarking, reducing reoperations requires increased diffusion of evidence- and consensus-based recommendations into all practice settings [17,27,31]. This includes increasing compliance with the SSO-ASTRO margin guidelines and by adopting those processes of care that are associated with fewer reoperations, such as intra-operative frozen section analysis, cavity shaving, oncoplastic surgery, and, as demonstrated here, receipt of neo-adjuvant chemotherapy in eligible patients, a policy recently endorsed by the St. Gallen Consensus Panel for surgical “de-escalation” [7,10–17,27,31,43,44,48–52]. Multiple initiatives are already underway [17,25,27,30–33]. For those that provide benchmarking, the independent factors associated with reoperations found in the current study can be utilized for risk adjustment. Even then, variability persisted in NCDB facilities in our analysis, suggesting there are potential technical variations among surgeons that we have yet to identify and remediate. Novel investigations with video recording of other types of operations have demonstrated a link between video findings and surgical outcomes [53]. To address reoperations, breast surgeons could consider similar initiatives.

In addition to the large sample size afforded by the NCDB, strengths of the current study include [to our knowledge] the first use of hierarchical ranking strategies to determine which factors most affect reoperation rates and the finding that an endorsed benchmark of 10% is achievable, but not yet achieved in 3 of 4 facilities.

#### Limitations

The limitations of the NCDB are well described elsewhere and apply here, too [3,14,16,19,54]. Some data fields may be misclassified and “receipt of reoperation” is not a data field. Repeat operations were calculated by algorithms described here and elsewhere [3,14,16]. Also, no data were available after 2015, the last

A. Unadjusted reoperation rate by facility (error bars depict 95% binomial confidence intervals)



B. The estimated impact on odds of reoperation for each facility based on the adjusted logistic model (error bars depict 95% confidence intervals for these estimated random effects)

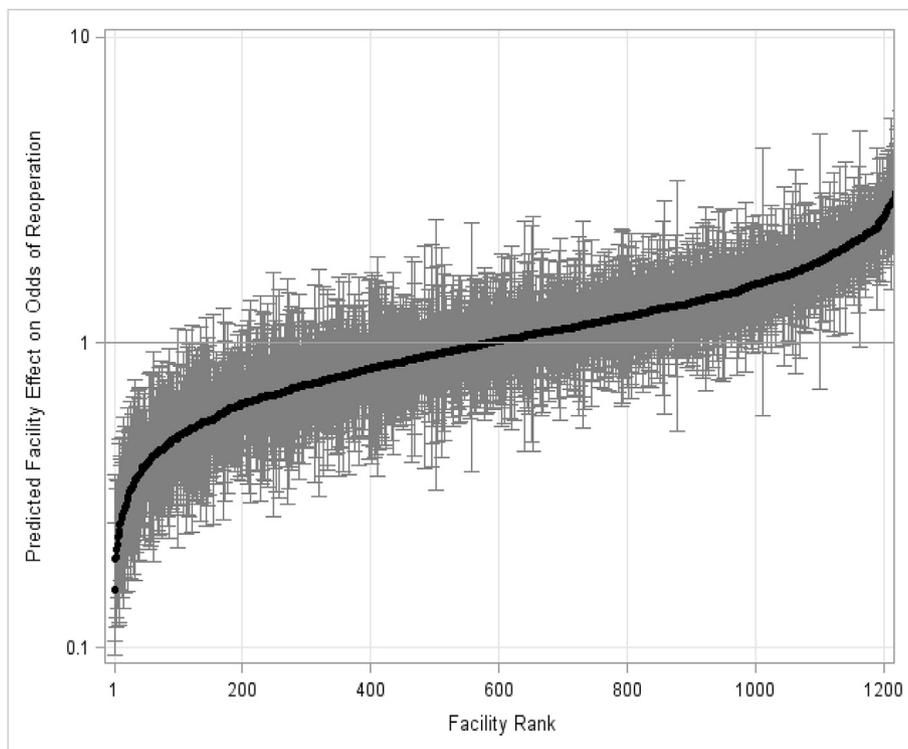
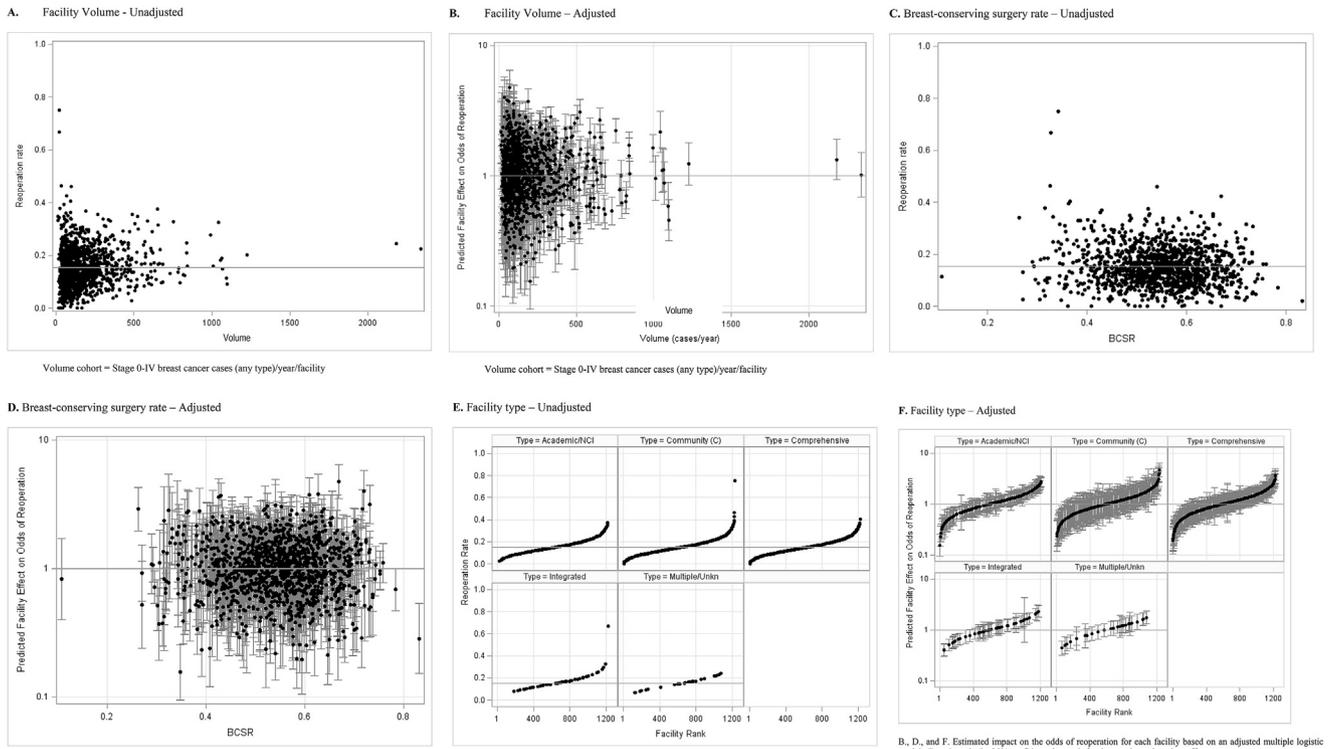


Fig. 2. Inter-facility variation of reoperations after initial breast-conserving surgery\*.



B., D., and F. Estimated impact on the odds of reoperation for each facility based on an adjusted multiple logistic model. Error bars depict 95% confidence intervals for these estimated random effects.

Fig. 3. Unadjusted and adjusted inter-facility reoperation rate variation.

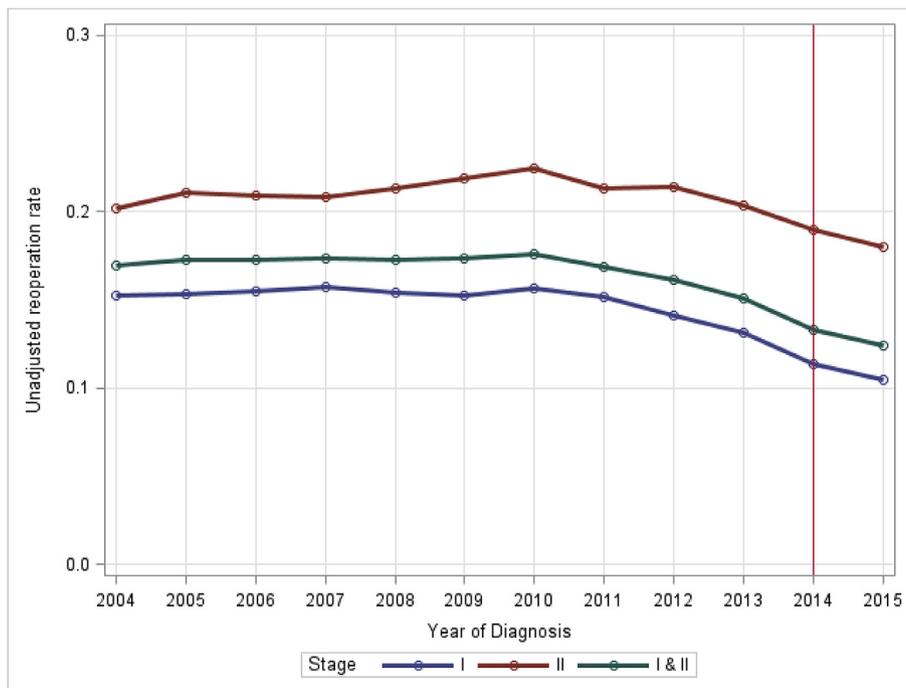


Fig. 4. Reoperation rates after breast-conserving surgery before and after the date of the SSO-ASTRO Margin Guideline for patients with invasive cancer.

available year of NCDDB data. Another limitation is that the NCDDB does not specifically record “all” reasons for reoperation to include margin width and processes of care, such as cavity shaves. We are unaware of any patient registry that does so. As such, all registries that contain reoperations as a response variable have unmeasured

confounders. Lastly, the ranking of predictor variable impact via maximum effect size and  $R^2$  methods is limited in that these metrics are sensitive to associations among the predictor variables being compared.

## Conclusion

After review of more than half a million patients undergoing breast cancer surgery at more than 1000 facilities, high rates of repeat surgery and unacceptable inter-facility variation were documented. The most impactful determinant of reoperation was found to be the facility itself, more than 10 times greater than 18 other patient, tumor, treatment, and facility characteristics. As such, facility ID was a distinguishing characteristic of receipt of reoperations. After 2013, adjusted rates of reoperation were lower than predicted by 2004–2013 data. These findings are consistent with the anticipated benefit of the SSO-ASTRO margin guideline to reduce unnecessary re-excisions in patients with negative margins [15]. Given all these findings, stakeholders should continue to measure, participate, and launch new reoperation initiatives to reduce variability among breast surgeons and centers.

## Declarations of interest

None.

## Disclosures

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