An initial benchmark of the quality of the diagnosis and surgical treatment of breast cancer in South Africa

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Background. Monitoring quality indicators to improve breast cancer care is well established in high-income countries. This is the first evaluation of diagnostic and surgical quality indicators for initial benchmarking of breast cancer care in South Africa (SA).
Objective. To measure the adherence rates to quality indicators among women with breast cancer in SA.
Methods. Ten quality indicators were evaluated for 3 545 breast cancer patients across four SA surgical breast units using a shared electronic patient record system. Data quality and adherence rates with differences between units were determined. The effect of HIV status on adherence was assessed by multivariate Poisson regression analyses.
Results. Our electronic patient record reliably measured most quality indicators. Rates of positive margins (5.7%), overall axillary surgery (95.8%) and appropriate treatment sequencing in locally advanced breast cancer patients (98.4%) consistently reached minimum international standards. Rates of multidisciplinary team discussion (72.2%), radiotherapy (66.7%) and sentinel node biopsy (39.6%) showed wide cross-site variance. Histopathology reporting (62.0%), breast-conserving surgery (19.4%) and number of nodes excised with axillary dissection (47.3%) and sentinel node biopsy (82.7%) were consistently below minimum standards. Unit volumes were achieved consistently in Gauteng Province, but only for some years in KwaZulu-Natal Province; surgeon volumes were achieved across all units. HIV status did not affect adherence levels. Most quality indicators were well measurable, but data quality on reoperations and surgeon volumes was poor.
Conclusion. We evaluated local quality indicators for an initial benchmark, and the most emergent gaps in care are the receipt of radiotherapy and underutilisation of sentinel node biopsy.

Keywords: breast cancer, quality indicators, low- to middle-income countries, electronic patient records

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Quality indicators (QIs) for breast cancer treatment have been measured in high-income countries (HICs), and used to monitor and improve the quality of patient care over time.[1,2] Data on the quality of breast cancer care in low- to middle-income countries (LMICs) are scarce, but suggest lower and variable quality of care depending on the patient's socioeconomic background and geographical location, along with the associated availability of treatment services.[3,4]

Breast cancer is a complex and heterogeneous disease, and is best treated in multidisciplinary teams (MDTs) with specialist expertise and resources from each treatment modality to achieve the best patient outcomes. Quality of care is defined as the degree to which health services increase the likelihood of desired health outcomes and are consistent with current professional knowledge. QIs have classically been divided into the Donabedian model of structural, process and outcome measures.[5] Structural indicators examine the ability of the healthcare system to provide a service, such as the provision of resources, staffing, or expertise, and have been used extensively in accreditation processes. Process indicators permit the evaluation of adherence rates to recommended healthcare processes and are the most commonly used indicators to measure quality of care. Outcome measures such as disease-free survival and quality of life are often regarded as the gold standard in cancer care, but these are difficult to measure because of long follow-up requirements and the potential influence of various patient and clinical factors.[6]

In 2019, a critical set of 10 QIs for the diagnosis and surgical treatment of breast cancer was established in South Africa (SA) through expert consensus.[7] The present study now evaluates the data quality of these QIs within the existing electronic patient record (EPR) data, and adherence to them in patient cohorts. This is the first investigation of diagnostic and surgical breast cancer QIs in sub-Saharan Africa.

Methods

The SA Breast Cancer and HIV Outcomes (SABCHO) study has prospectively collected information on access to healthcare, as well as numerous components of patient and disease factors to develop evidence-based guidelines on the management of breast cancer in HIV-positive and negative women, as well as to improve breast cancer treatment in a resource-constrained environment.[8] An EPR system was implemented in 2015 at all study sites to collect prospective

clinical data. We retrospectively reviewed all patients enrolled in the SABCHO study between 1 July 2015 and 31 August 2020.[8] To mitigate any potential impact on the quality metrics, we chose the time of the first COVID-19 wave in SA as a cut-off. The sites included Chris Hani Baragwanath Academic Hospital (CHBAH), Charlotte Maxeke Johannesburg Academic Hospital (CMJAH), Grey's Hospital (GH) and Durban complex (Inkosi Albert Luthuli Central Hospital, Addington Hospital and Ngwelezana Hospital (IALCH)). CHBAH and CMJAH are in Johannesburg, Gauteng Province, while Durban complex and GH are in KwaZulu-Natal (KZN) Province. All are public sector academic surgical breast units, but they serve different populations and have different staff resources (Table 1).

Data entry was made prospectively on OncoDB, an EPR initiated in 2008 at CHBAH that has since grown into a purposefully designed comprehensive breast database. Both clinicians and SABCHO research staff entered data, although some fields are only used by clinicians and others only by research staff. The extent of OncoDB use differed across sites (Table 1).

The selection process, definitions as well as the nominators and denominators of the 10 QIs were previously described.[7] For QI 1, histopathology reports were considered complete if they included the following parameters for core biopsy: histological type; tumour grade; oestrogen receptor (ER) status; progesterone receptor (PR) status; human epidermal growth factor receptor-2 (HER-2) with a confirmatory *in situ* hybridisation test if HER-2 was equivocal; and proliferative Ki67 score. In addition to the above parameters, the following were required for QI 2 on surgical specimens: pathological stage; size in millimetres for the invasive component; peritumoural lymphovascular invasion; and distance to the nearest invasive margin. Receptors did not require repeating as they are routinely done on core biopsy. We defined a Ki67 cut-off of 20% to define immunohistochemical surrogates for molecular subtypes.[9] A reoperation (QI 4) was defined as a second surgery on the same side within 6 months. For QI 6 we only included patients who had primary surgery, as neoadjuvant therapy affects the number of nodes excised. For QI 8, inoperable locally advanced breast cancer (LABC) was defined as T4a, c or d or N3, and neoadjuvant systemic therapy had to precede surgery to fulfil appropriate modality sequencing.

The reliability and validity of EPR measures are evaluated by data completeness, data accuracy, timeliness or 'currency,' clinical specificity or 'granularity,' and data comparability.[10] We graded our data quality based on *a*) data entry personnel, which was either the clinician or research staff driven, with better data completeness, accuracy, currency and comparability when entered by research staff; *b*) a structured data cleaning process by research staff; and *c*) the use of structured v. unstructured data with improved completeness, accuracy, currency and granularity with structured data. We then classified reliability and validity as good (3 points), varied (1 - 2 points), or poor (0 points) to reflect the integrity of our results.

We described the frequency and percentages of adherence to the 10 mandatory QIs among the different sites. Site differences were evaluated with a χ^2 test for categorical variables and one-way analysis of variance (ANOVA) for continuous variables, and the effect of HIV status on adherence levels was evaluated with multivariate Poisson regressions, adjusting for age, hospital site, stage of disease and intrinsic subtype of breast cancer. All participants provided written informed consent for data collection and analysis. The SABCHO study and this project are overseen by the Human Research Ethics Committees of the University of the Witwatersrand (Johannesburg) and the University of KwaZulu-Natal (Durban), and separate ethical clearance was obtained for this substudy (ref. no. M180761).

Results

A total of 3 545 patients with invasive breast cancer were included. The mean age was 55.7 years, 34.4% of patients were in early stages (stage 1 - 2), 47.8% were locally advanced (stage 3) and 17.8% were metastatic (stage 4) at presentation. Of the 3 545 patients, 2 271 underwent surgery during their treatment process (64.1%). A total of 21.9% were HIV positive, with higher rates in CHBAH and GH. Table 2 displays the detailed distribution based on immunohistochemical surrogates and patient characteristics, as well as the significant differences across sites.

Table 3 tabulates data source and entry, structure, reliability and validity. Most QI data were well measurable, with good validity and reliability. Operative notes to evaluate reoperations were inconsistent across sites, only entered by clinicians, and contained unstructured data, with poor reliability and validity for reoperation and surgeon volume QIs. Clinicians across sites inconsistently entered reoperations measured by pathology reports and MDT discussions, and reliability and validity were varied despite the use of structured fields. Table 4 tabulates the results of QI adherence, and Fig. 1 illustrates the highest and lowest adherence levels and their relation to international minimum standards.

Complete histopathological characterisation was achieved in 62.0% of initial core biopsy specimens, and 65.6% of surgical specimens. Adherence varied across sites from 91.9% to 5.7% and 82.1% to 22.0%, respectively (p>0.001). Breast-conserving surgery (BCS) rate overall was 19.4%, and 31.6% for patients with early-stage breast cancer; rates were highest in Durban and lowest at GH (p>0.001). The positive margin rate was 5.7%, with no significant cross-site variance. The reoperation rate was 2.9% on evaluating pathology reports, and 8.0% on evaluating operation notes. Surgical operation notes were only entered by the Gauteng sites, and therefore not measurable across sites; reliability and validity were poor. Of patients who underwent surgery, 95.8% had axillary surgery, with little cross-site variation. Sentinel lymph node biopsy (SLNB) only in clinically node-negative patients was recorded in 39.6%, with a wide site variation between 71.9% and 1.9% (p>0.001). HIV-positive patients were less likely to have a SLNB (p=0.008, odds ratio (OR) 0.58 (0.38 - 0.86)).

The percentage of patients with axillary lymph node dissection (ALND) with ≥10 nodes was 47.3%, while 82.0% of patients with SLNB had ≤5 nodes dissected. GH achieved the highest rate (72.6%), while IALCH recorded none (0%). However, only four patients had primary surgery and ALND in this unit, as they mainly treated node-positive patients with neoadjuvant therapy. Radiotherapy receipt after BCS was documented in 66.7%, with site variance of 92.7% - 44.7% (p>0.001). HIV-positive patients were less likely to receive adjuvant radiotherapy (p=0.010, OR 0.52 (0.31 - 0.85)). Neoadjuvant therapy was given to 98.4% of 440 inoperable locally advanced cancer patients prior to surgery. MDT discussion was documented in 72.2%, with site variance between 92.2% and 14.3%. Data reliability and validity were varied.

Discussion

The levels of QI adherence varied across sites, and were mostly inferior to minimum standards in HICs (Table 4 and Fig. 1). Nevertheless, they represent an inital benchmark in our resource-constrained setting, and a starting point from which to identify gaps and improve quality of care over time.

QIs fulfilling international standards across sites

The rate of positive margins, overall axillary surgery and appropriate treatment sequencing for LABC consistently achieved international minimum standards across sites. Margins in breast cancer

Table 1. Study site characteristics

Site	Residential demographics	Surgical staff, *n*	Research staff, *n*	OncoDB use
CHBAH	Soweto (3 million), urban	3	10	Main record-keeping tool; clinical management and research
CMJAH	Johannesburg East and Central (1.5 million), urban	2	5	Main record-keeping tool; clinical management and research
GH	Western KwaZulu-Natal (3.5 million), urban/rural mix	1	2	Only used for study purpose; not all functions used
Durban complex	Durban Metropolitan (3.5 million), urban; Uthungulu, Umkhanyakude, Zululand (3 million), rural	1	3	Only used for study purpose; not all functions used

CHBAH = Chris Hani Baragwanath Academic Hospital; CMJAH = Charlotte Maxeke Johannesburg Academic Hospital; GH = Grey's Hospital; Durban complex = Inkosi Albert Luthuli Central Hospital, Addington hospital and Ngwelezana Hospital.

Table 2. Clinical characteristics of cohort, *N*=3 545

Characteristic	Overall, *n* (%)*	CHBAH, *n* (%)*	CMJAH, *n* (%)*	GH, *n* (%)*	Durban complex, *n* (%)*	*p*-value
Enrolled patients	3 545 (100)	1 455 (41.0)	931 (26.3)	530 (15.0)	629 (17.7)	
Age, mean (SD), years	55.7 (14.2)	55.1 (14.5)	54.5 (13.5)	57.6 (14.4)	57.2 (14.1)	<0.001
Stage 1 - 2	1 221 (34.4)	546 (37.5)	309 (33.2)	176 (33.2)	190 (30.2)	<0.001
Stage 3	1 693 (47.8)	724 (49.8)	484 (52.0)	212 (40.0)	273 (43.4)	
Stage 4	631 (17.8)	185 (12.7)	138 (14.8)	142 (26.8)	166 (26.4)	
Received surgery	2 271 (64.1)	984 (67.6)	547 (58.8)	362 (68.3)	378 (60.1)	<0.001
Luminal A†	829 (23.4)	228 (15.7)	240 (25.8)	130 (24.5)	231 (36.7)	<0.001
Luminal B†	1838 (51.8)	885 (60.8)	456 (49.0)	255 (48.1)	242 (38.5)	
HER-2 negative	1 241 (35.0)	580 (39.9)	315 (33.8)	194 (36.6)	152 (24.2)	
HER-2 positive	597 (16.8)	305 (21.0)	141 (15.1)	61 (11.5)	90 (14.3)	
HER-2 enriched†	235 (6.6)	83 (5.7)	73 (7.8)	32 (6.0)	47 (7.5)	
Triple-negative†	548 (15.5)	216 (14.8)	148 (15.9)	95 (17.9)	89 (14.1)	
Unspecified	95 (2.7)	43 (3.0)	14 (1.5)	18 (3.4)	20 (3.2)	
HIV positive	775 (21.9)	359 (24.7)	163 (17.5)	137 (25.8)	116 (18.4)	<0.001
HIV negative	2 713 (76.5)	1 071 (73.6)	741 (79.6)	393 (74.2)	508 (80.8)	
HIV unknown	57 (1.6)	25 (1.7)	27 (2.9)	0 (0.0)	5 (0.8)	

CHBAH = Chris Hani Baragwanath Academic Hospital; CMJAH = Charlotte Maxeke Johannesburg Academic Hospital; GH = Grey's Hospital; Durban complex = Inkosi Albert Luthuli Central Hospital, Addington Hospital and Ngwelezana Hospital; SD = standard deviation.
*Unless otherwise indicated.
†Luminal A was defined as oestrogen receptor (ER)/progesterone (PR) positive, ki67 ≤20%. Luminal B as ER and/or PR positive, Ki67 ≥20%, human epidermal growth factor receptor-2 (HER-2) negative or positive. HER-2 enriched as ER/PR negative, HER-2 positive. Triple-negative as ER/PR/HER-2 negative.

excisions have been subject to many debates, but the most recent recommendation is 'no tumour on ink'.[13] Historically, re-excision rates have been reported as 25% - 40%,[14] and our positive margin rate is comparatively low at 5.7%. This is likely due to the early adoption of the new margin definition and liberal use of advanced oncoplastic techniques in our units, which allows for greater volume resections and lower re-excision rates.[15] The axilla was evaluated surgically in 95.8% of cases. Non-resectable LABC was appropriately treated with neoadjuvant therapy before surgery in 98.4% of cases, reflecting safe patient evaluation and treatment.

QIs with site variance to international standards

It is alarming that only 66.7% of patients received radiotherapy after BCS, with Gauteng sites significantly less likely to deliver than KZN sites. Patients at CHBAH had the lowest adherence level, at 44.7%. One of the possible barriers may have been the need to travel to CMJAH, as radiotherapy is unavailable onsite. However, CMJAH patients, who shared an exact breast clinic location with radiation oncology within the hospital, only received radiation in 65.1% of cases. This starkly contrasts with KZN, where both units achieved the minimum target of 90%. These results point to a specific barrier to radiation care in Gauteng that needs to be addressed urgently.

Critical case volumes for units and surgeons are well described. A breast unit should treat at least 150 newly diagnosed patients annually, while a surgeon should operate on at least 50 cases annually.[17] Surgeon volumes were consistently achieved across sites, but unit volumes were achieved only in Gauteng sites for all years of the full assessment, whereas KZN sites fell short in some years. It is important to note that actual unit volumes were larger than recorded, as foreign patients were not included in SABCHO.

The MDT discussion is a critical process to ensure the review of each patient and to form a complete treatment pathway; it results in better evidence-based clinical decision-making and higher quality of treatment.[17] This QI was a clinician-driven data entry, and was not reliably entered across sites. Adherence level was 72.2% overall, but IALCH was the only unit to consistently document MDT discussion and achieve the >90% standard. GH did not routinely enter the discussions on the EPR (14.3%), but routine MDT meetings were held, which points to differences between documentation and received treatment. Adherence levels are generally higher than measured, a described pitfall in using EPRs to assess quality.[18]

Table 3. Quality indicator data quality

QI number	QI title		Raw data source	Data entry	Data field structure	Cleaned	Reliability and validity
1	Complete histopathological characterisation of invasive breast cancer						
		1i. On core biopsy	Pathology report	Research staff	Structured	Yes	Good
		1ii. On surgical specimen	Pathology report	Research staff	Structured	Yes	Good
2	BCS						
		BCS rate	Pathology report	Research staff	Structured	Yes	Good
		BCS rate among stages 1 and 2	Pathology report	Research staff	Structured	Yes	Good
3	Rate of positive margins after BCS		Pathology report	Research staff	Structured	Yes	Good
4	Reoperation rate						
		4i. On pathology reports	Pathology report	No routine entry	Structured	No	Varied
		4ii. On operation notes	Operation note function	Clinicians	Unstructured	No	Poor
5	Appropriate axillary surgery						
		5i. Rate of axillary surgery in invasive breast cancer	Pathology report	Research staff	Structured	Yes	Good
		5ii. Sentinel node biopsy only in clinically node-negative disease	Pathology report	Research staff	Structured	Yes	Good
6	Number of nodes excised during axillary surgery						
		6i. Lymph node dissection ≥10 nodes	Pathology report	Research staff	Structured	Yes	Good
		6ii. Sentinel node biopsy ≤5 nodes	Pathology report	Research staff	Structured	Yes	Good
7	Receipt of radiotherapy after BCS		Treatment functions	Research staff	Structured	Yes	Good
8	Appropriate treatment sequencing in inoperable LABC		Initial diagnostic workup function and treatment functions	Research staff	Structured	Yes	Good
9	Case volume						
		9i. Breast unit ≥150 newly diagnosed cases per annum	New patient entry	Research staff	Structured	Yes	Good
		9ii. Surgeon volume ≥50 breast cancer cases per annum	Operation note function or single surgeon units	Clinicians	Unstructured	No	Poor
10	Multidisciplinary team discussion		Follow-up function	Clinicians	Structured	No	Varied

QI = quality indicator; BCS = breast-conserving surgery; LABC = locally advanced breast cancer.

Improving the documentation of MDT discussions is important, particularly in our healthcare system where patients may need to visit various hospitals to receive different treatments, and encounter different healthcare providers during each visit.

QIs below international standards

The completeness of histopathology was overall low, but Gauteng sites were significantly more compliant in assessing core biopsy and surgical specimens. Our recent publication[19] describes these findings

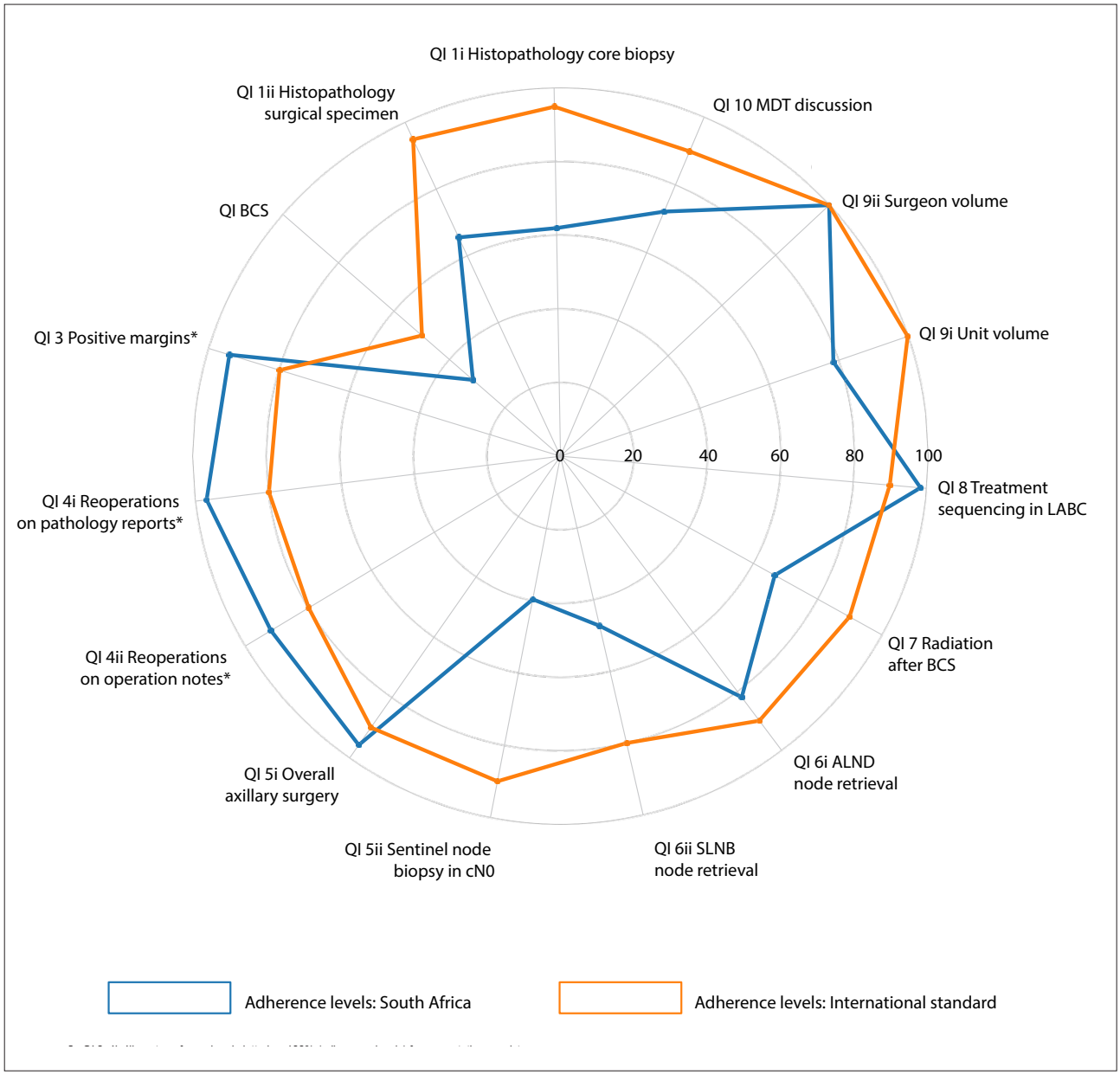

Fig. 1. Radar chart comparing South African adherence levels to international standards. (QI = quality indicator; MDT = multidisciplinary team; LABC = locally advanced breast cancer; BCS = breast-conserving surgery; SLNB = sentinel lymph node biopsy; ALND = axillary lymph node dissection; cN0 = clinically node-negative.)
**QI 3, 4i, 4ii are transformed and plotted as 100% (adherence levels) for presentation consistency.*

in more detail, and emphasises the need to improve reporting of tumour grade, HER-2 confirmatory tests, excision margins, pathological staging and lymphovascular invasion. Reporting standards differ among laboratories, and it is overdue to establish an SA pathology consensus and introduce the routine use of data sheets and synoptic reports to enhance completeness and clear communication of the results with the clinician.[19]

BCS rates were 19.4% overall, and 31.6% for patients with early-stage breast cancer; none of the sites was close to international standards of >50%.[12] BCS requires greater resources and expertise, especially with impalpable tumours, after neoadjuvant therapy and with advanced oncoplastic techniques. In addition, BCS requires postoperative radiotherapy, a factor that may have influenced the rates in Gauteng. At GH, some patients were not offered the option of BCS owing to limited radiotherapy availability, where treatment would fall outside of the recommended treatment time period. This strengthens our opinion that BCS should be seen as an outcome and not a pure process measure in our setting, as it is impacted heavily by factors external to the surgical units.[7]

Only 39.6% of clinically node-negative patients received an SLNB only, with significant variance noted among sites. GH had the lowest rate at 1.9%, as they did not have resources to trace sentinel nodes. We have previously reported on the low use of SLNB in our Gauteng units, and the potential reasons for this such as large tumour size, the intraoperative impression of nodal involvement with conversion to ALND, or non-availability of critical consumables or equipment.[20] We also hypothesised that HIV status may influence nodal assessment and surgery, but this was not proven in this cohort (risk ratio 0.91). Given the ever-expanding applications for SLNB, suspicious lymph nodes should ideally be confirmed with fine needle aspiration, and

Table 4. Quality indicator adherence

QI number	QI title		International minimum standard (%)	Overall documented adherence, *n* (%)	CHBAH, *n* (%)	CMJAH, *n* (%)	GH, *n* (%)	Durban, *n* (%)	*p*-value*	HIV effect on overall adherence, *p*-value
1	Complete histopathological characterisation of invasive breast cancer									
		1i. On core biopsy	>95[1]]	2 199/3 545 (62.0)	1 240/1 455 (85.2)	856/931 (91.9)	30/530 (5.7)	73/629 (11.6)	<0.001	0.832
		1ii. On surgical specimen	>95[1]	1 490/2 271 (65.6)	808/984 (82.1)	353/547 (64.5)	246/362 (68.0)	83/378 (22.0)	<0.001	0.741
2	BCS									
		Breast-conserving surgery rate	-	441/2 271 (19.4)	161/984 (16.4)	126/547 (23.0)	41/362 (11.3)	113/378 (29.9)	<0.001	0.051
		Breast-conserving surgery rate among stages 1 and 2	>50[11]	332/1 051 (31.6)	121/465 (26.0)	92/257 (35.8)	31/164 (18.9)	88/165 (53.3)	<0.001	0.071
3	Rate of positive margins after breast-conserving surgery		<20[12]	26/456 (5.7)	13/169 (7.7)	10/128 (7.8)	1/42 (2.4)	2/117 (1.7)	0.084	0.664
4	Reoperation rate									
		4i. On pathology reports	<20[1]	66/2 271 (2.9)	47/984 (4.8)	9/547 (1.6)	7/362 (1.9)	3/378 (0.8)	<0.001	0.741
		4ii. On operation notes	<20[1]	123/1 531 (8.0)	78/984 (7.9)	45/547 (8.2)	-	-	0.836	0.039; 0.57 (0.33 - 0.97)†
5	Appropriate axillary surgery									
		5i. Rate of axillary surgery in invasive breast cancer	>90[1]	2 176/2 271 (95.8)	948/984 (96.3)	522/547 (95.4)	348/362 (96.1)	358/378 (94.7)	0.546	0.998
		5ii. Sentinel node biopsy only in clinically node-negative disease	>90[1]	319/806 (39.6)	124/361 (34.3)	111/226 (49.1)	2/105 (1.9)	82/114 (71.9)	<0.001	0.648
6	Number of nodes excised during axillary surgery									
		6i. Lymph node dissection ≥10 nodes	>80[12]	245/518 (47.3)	86/251 (34.3)	24/77 (31.2)	135/186 (72.6)	0/4 (0.0)	<0.001	0.858
		6ii. Sentinel node biopsy ≤5 nodes	>90[1]	228/278 (82.0)	110/133 (82.7)	100/117 (85.5)	1/2 (50.0)	17/26 (65.4)	0.064	0.910
7	Receipt of radiotherapy after breast-conserving surgery		>90[1]	294/441 (66.7)	72/161 (44.7)	82/126 (65.1)	38/41 (92.7)	102/113 (90.3)	<0.001	0.253

(Continued ...)

Table 4. (continued) Quality indicator adherence

QI number	QI title	International minimum standard (%)	Overall documented adherence, *n* (%)	CHBAH, *n* (%)	CMJAH, *n* (%)	GH, *n* (%)	Durban, *n* (%)	*p*-value*	HIV effect on overall adherence, *p*-value
8	Appropriate treatment sequencing in inoperable LABC	>90[1]	440/447 (98.4)	126/130 (96.9)	136/137 (99.3)	100/102 (98.0)	78/78 (100.0)	0.274	0.820
9	Case volume‡								
	9i. Breast unit ≥150 newly diagnosed cases per annum	>150 cases[1]	100 (78.6)	2016 - 2019 (100)	2016 - 2019 (100)	2017 (33.3))	2016-2017 (66.6%)	-	-
	9ii. Surgeon volume ≥50 breast cancer cases per annum	>50 cases[1]	>50 (100)	2016 - 2019 (100)	2016 - 2019 (100)	2016 - 2018 (100)	2016 - 2018 (100)	-	-
10	Multidisciplinary team discussion	>90[1]	2 560/3 545 (72.2)	1 198/1 455 (82.3)	706/931 (75.8)	76/530 (14.3)	580/629 (92.2)	<0.001	0.476

QI = quality indicator; CHBAH = Chris Hani Baragwanath Academic Hospital; CMJAH = Charlotte Maxeke Johannesburg Academic Hospital; GH = Grey's Hospital; Durban complex = Inkosi Albert Luthuli Central Hospital, Addington Hospital and Ngwelezana Hospital; RR = relative risk; CI = confidence interval; LABC = locally advanced breast cancer. LABC = locally advanced breast cancer.
*Pearson's χ^2 test was used to test for differences in adherence between the study sites.
†RR; 95% CI. Multivariate Poisson regressions, adjusting for age, hospital site, stage of disease and intrinsic subtype of breast cancer, were used to assess the impact of HIV status on overall adherence.
‡Case volumes calculated for full calendar-year enrolments: 2016 - 2019 for CMJAH and CHBAH; 2016 - 2018 for GH and IALCH.

resources need to be provided and the use of SLNB expanded across all sites.[21] Historically, the number of nodes dissected during ALND has been set at ≥10.[22] Our overall rate was low at 47.3%, and although the indicator measures technical surgical success, its clinical utility is questionable owing to factors such as the pathologist's variation in specimen review and the current clinical shift towards more preserving surgery.

QIs with poor data reliability and validity

We attempted to measure reoperations with operative and pathology records. However, operative notes were only entered by clinicians in Gauteng; IALCH and GH entered operative notes on their separate hospital EPR. A common challenge in using EPRs is that data entry is more likely to be of poor quality when entered by busy frontline staff, and when it requires duplication of work processes.[23] Analysis of Gauteng operative notes show a reoperation rate of 8%. The data using histopathology are also flawed, as specimens would only be sent for re-excision or early recurrence, but not for emergent reoperations such as sepsis or bleeding. Furthermore, entry of the second pathology report was also less consistent than the first pathology report, as it did not form part of the routine data entry protocols for research staff. As expected, the reoperation rate based on pathology reports is lower, at 2.9%, and is not representative. The database will require an update for reoperations with structured data fields. This underlines our experience that building EPRs for clinical management and research purposes is an iterative rather than a linear process, requiring many revisions.

QIs within the context of our resource-constrained health system

We hypothesised that we would be more prone to interference, especially in the complex multidisciplinary treatment of breast cancer, where indicators are not solely dependent on the quality of a surgical practice but are interlinked with patient and health system factors.[7] Our results reflect this expected process when starting the quality control process. The commitment to quality improvement, audit, accreditation and structured guideline-adherent breast care dates back to the 1990s in Europe. The gradual improvements in quality through investigation and benchmarking and repeated internal and external audits have been well documented; a review of European centres showed compliance in 8 out of 13 QIs in 2006, compared with complete compliance in 2015.[24] Similarly, radiation after BCS improved from 75.8% to 95.8% after the initiation of an audit process by the National Quality Forum in the USA.[25] We hope this audit will also trigger a series of gradual improvements in SA.

EPR and study strengths and limitations

Our study shows the unique benefits of EPRs in research, such as access to already collected data, large sample sizes, reduced administrative efforts, reduced costs and sample selection bias.[23] The challenges are that our QI data fields were not predefined, and were not all collected specifically for research or quality control purposes. Functions were not uniformly used across sites, especially when this required clinician entry or duplication of workflow. Although structured data are best for research, the clinical nuances of cancer care often require unstructured data fields, the evaluation of which is flawed even with natural language processing methods.[17] It is critical to understand clinical workflow so that routine EPRs do not increase workload, but instead aid the clinician. Many routine data points require administrative research staff for reliable data collection in a busy clinic, and cannot be entered by frontline staff. Therefore, the success of EPRs and quality control measures depends on the synergy

between clinicians, administrators, researchers and informaticians. A further limitation of this study is that it only includes data from the public sector and two provinces, limiting representation. The time of enrolment was set for an initial benchmark, and offers no time trends in adherence, which will be assessed in a future publication.

Conclusion

Adherence to QIs varied widely across sites, and was mostly inferior to HIC standards. We achieved international standards in the volume criteria for surgeons, and unit volumes in Gauteng, and showed very low positive margin rates, likely due to the generous use of oncoplastic techniques. Our results highlight gaps in breast cancer care; the most urgent are the lack of radiation delivery in Gauteng and the underutilisation of SLNB. BCS rates must be improved, but reliable radiotherapy and sufficient resources are required. MDT discussion requires better documentation to assist patients with complex breast cancer treatment pathways. EPRs are essential in continuous QI monitoring and require adjustment within the EPR to document QI adherence directly. Reliable data collection calls for administrative research staff to avoid overburdening busy frontline workers.

Data availability. Study data are available from the first author on request.

Declaration. This study forms part of SN's PhD (Surgery) degree at the University of the Witwatersrand.

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Author contributions. Concept and design: SN, SAN, PR; data collection: SN, HC, IB, BP, CC, MJ, PR; data analysis: SN, WCC; write up and revisions: SN, HC, SC, IB, BP, SAN, WCC, MJ.

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