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Optimizing breast reconstructive surgery in the Netherlands using clinical audit data

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CHAPTER 2

Clinical auditing as an instrument for quality improvement in breast cancer care in the Netherlands

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ABSTRACT

Background: In 2011, the NABON Breast Cancer Audit (NBCA) was instituted as a nation-wide audit to address quality of breast cancer care and guideline adherence in the Netherlands. The development of the NBCA and the results of 4 years of auditing are described.

Methods: Clinical and pathological characteristics of patients diagnosed with invasive breast cancer or in situ carcinoma (DCIS) and information regarding diagnosis and treatment are collected in all hospitals (n=92) in the Netherlands. Thirty-two quality indicators measuring care structure, processes and outcomes were evaluated over time and compared between hospitals.

Results: The NBCA contains data of 56,927 patients (7,649 DCIS and 49,073 invasive cancers). Patients being discussed in pre- and post-operative multidisciplinary team meetings improved (2011: 83% and 91%; 2014: 98% and 99%, respectively) over the years. Tumor margin positivity rates after breast conserving surgery for invasive cancer requiring re-operation were consistently low (~5%). Other indicators, for example, the use of an MRI-scan prior to surgery or immediate breast reconstruction following mastectomy showed considerable hospital variation.

Conclusions: Results show an overall high quality of breast cancer care in all hospitals in the Netherlands. For most quality indicators improvement was seen over time, while some indicators showed yet unexplained variation.

INTRODUCTION

Quality of health care has become subject of public debate. Until recently, quality of breast cancer care was merely enhanced by national organizations such as the National Breast Cancer Organization Netherlands (NABON) that defined and distributed guidelines that contained multidisciplinary criteria for providing good quality breast cancer care as well as actual treatment guidelines.¹ Today's society demands transparency, resulting in a call for the evaluation of quality of care as provided by the individual institutions.

In the Netherlands, the Dutch Health Care Inspectorate started querying surgical departments a decade ago for a number of quality aspects and national media began to report on the observed variation of hospital-specific indicator results. In 2008, the Dutch Health Care Inspectorate observed a high rate of tumor-positive margins after breast conserving surgery in a number of hospitals in the Netherlands², urging the need for a national audit for the monitoring of the quality of breast cancer care in individual hospitals. Concurrently, clinicians of various disciplines were seeking benchmarked performance information to monitor the quality of their delivered breast cancer care which could catalyze quality improvements in the care delivered to their patients.³

The aims of the present study were to describe the development of the NABON Breast Cancer Audit (NBCA) and report on the results of the first 4 years of nationwide clinical auditing of multidisciplinary breast cancer care in the Netherlands.

METHODS

The creation of the NABON Breast Cancer Audit (NBCA)

Close cooperation of the NABON, the Comprehensive Cancer Organization the Netherlands (IKNL) and the Dutch Institute for Clinical Auditing (DICA) led to the institution of the NBCA in 2011.⁴ NABON is a Dutch breast cancer working group that aims to improve breast cancer care in the Netherlands by developing

national guidelines, defining quality indicators and standards of care, and by organizing post-graduate symposia. IKNL is a quality institution for oncological and oncological palliative care, which hosts the Netherlands Cancer Registry (NCR), in which data of all newly diagnosed malignancies in the Netherlands are registered since 1989. Information regarding treatment and outcomes of breast cancer is extracted from the medical records by specially trained data-managers in each hospital in the Netherlands. Moreover, IKNL is the NABON and NBCA secretary. DICA was founded in 2011 with the objective to facilitate the start-up of new nation-wide clinical audits, following the successful initiation of the Dutch Surgical Colorectal Audit (DSCA) in 2009.⁵

In 2009, the NABON established a scientific committee to initiate the NBCA. The scientific committee consisted of mandated members of all medical associations involved in breast cancer care in order to constitute a national clinical audit: the Dutch Radiological Society (NVvR), the Dutch Society for Pathology (NVvP), the Association of Surgeons of the Netherlands (NVvH), the Netherlands Society for Plastic Surgery (NVPC), the Dutch Society of Radiotherapy and Oncology (NVRO) and the Dutch Society of Medical Oncology (NVMO). The Breast Cancer Patients Association (BVN) participated to represent the patients' voice. Later, a representative of the Dutch health care insurance companies (ZN) joined the scientific committee and in 2015 a mandated member of the Dutch Society for Clinical Genetics (VKGN) joined the working group.

The primary goal of the NBCA is the nation-wide monitoring of quality of care and the provision of feedback to the participating individual hospitals on their outcomes in relation to "real-time" national benchmark information as a first step to improve the quality of breast cancer care in the Netherlands by enabling institutions to evaluate their data and start improvement projects. The aforementioned scientific committee is responsible for the draft and development of a multidisciplinary set of indicators used to express and monitor the various qualitative aspects of care. Other tasks include in-depth outcomes research and preparation of annual reports for public use to improve transparency.

Quality indicators: monitoring of the structure, process and outcome of breast cancer care

Quality indicators are as much evidence-based as possible. These quality indicators are used to evaluate guideline adherence and outcomes of breast cancer care and they cover different aspects of the multidisciplinary care path for breast cancer patients, from diagnostic work-up to the different treatment options. For 2015, 32 quality indicators measuring structure, processes and outcomes of breast cancer care are available for benchmarked feedback and public transparency. Each indicator consists of a nominator and a denominator, the latter describing the selection of patients under consideration (**Supplementary Appendix 1**). For 10 indicators, a professional standardized norm is available, that is, a generally accepted cut-off value, implying that a hospital should perform above (e.g., in case of pre-operative multi-disciplinary team [MDT] meeting) or below (e.g., in case of tumor-positive margins) a predefined standard. These norms are based on consensus of the multidisciplinary scientific committee. For some indicators, such as tumor-positive margins, norms are based on national guidelines/international literature. For other indicators, where total adherence was expected and desirable, thresholds were set at 90%. Other indicators were merely defined to explore institutional variation in treatment patterns. Standardized cut-off values denominating a level of quality are not (yet) available for these indicators. The NBCA quality indicators are evaluated annually by the scientific committee on their validity and existing indicators may be adapted or removed when considered redundant whereas new indicators are developed based on new insights. Currently, some indicators are merged (pre- and post-operative MDT meeting with a more strict norm), others are deleted (estrogen and progesterone receptor positivity), while others are adjusted (such as the frequency of tumor-positive margins which will be presented in relation to the proportion of patients who subsequently undergo re-excisions).

Dataset and registration of NBCA data

All surgically treated patients diagnosed with primary invasive breast cancer or ductal carcinoma in situ (DCIS) in the Netherlands are included in the NBCA. Patients diagnosed with lobular carcinoma in situ, phyllodes tumors, sarcomas and lymphomas are not included. Patients are included based on the date of the

histological confirmed diagnosis. Information regarding diagnostic procedures, surgery, reconstructive surgery, radiotherapy, neo-adjuvant and adjuvant systemic treatment is collected. For case-mix adjustment, baseline characteristics of the patient (e.g., age, previous breast surgery) and tumor characteristics (e.g., histology, tumor stage, receptor status) are collected. Depending on the treatments given, a maximum of 75 items is registered per patient.

Participating hospitals can either register the data themselves (facilitated by the web-based data-collection system of DICA) or have the data registered by IKNL-data-managers. A manual is available to secure uniform data acquisition. When data are registered by IKNL, hospitals can check the indicators and data on patient level for possible inconsistencies before the data are transferred to the DICA-system, in which data of all participating hospitals are gathered. Patient information is anonymized before transfer of the data to the national database. Hospitals registering the data themselves (through data-managers or specialized nurses) enter the data directly into the secured web-based system of DICA.⁵ A third trusted party de-identifies data directly after data entry.⁶ Data are continuously collected. Entry and accuracy of data remain the responsibility of the participating hospitals.

Benchmarking and transparency of quality indicator results

Throughout the year, individual hospitals have continuous insight into their own performance on the quality indicators, along with other baseline information such as patient, tumor and treatment characteristics that are updated weekly on their secured MyNBCA website. The quality indicators are nationally benchmarked against the other (anonymously presented) hospitals. Funnel plots are used to present indicator results in conjunction with the benchmark results. Annually, comprehensive reports with performance on all quality indicators of all institutions are disclosed to other parties, such as the national health care inspectorate and health care providers. In addition, an annual report with in depth research is available online for the public.

Analyses

Information of all patients who were operated for invasive breast cancer or DCIS between 1 January 2011 and 30 September 2014 was available for analysis. Results

of the 32 quality indicators were calculated for all 92 institutions and changes over the 4-year-period were evaluated using a χ^2 trend test. Since information regarding adjuvant treatments requires a longer period (~9 months) to be completed, information of the quality indicators involving adjuvant treatments was not available for 2014. A P-value <0.05 is considered statistically significant. Comparisons of indicator results between the individual hospitals are visualized by funnel plots and presented in relation to the mean or norm (if applicable) using funnels to represent 95% confidence intervals. Boxplots with median hospital performance and interquartile ranges were used to analyze changes over the years. All analyses were performed using SPSS 20 (IBM-SPSS, Inc., Chicago, IL).

RESULTS

Hospitals

In the Netherlands, breast cancer care is provided in 92 hospitals. Full participation of all hospitals was realized in 2012, the second year of registration. One hospital stopped treating breast cancer patients in 2012, and one new hospital was founded in 2013. About one third of the hospitals registered the data themselves and a high rate of case ascertainment was found after comparing data with those registered by the NCR for these hospitals (data not shown).

Patient and tumor characteristics

After 4 years of auditing the NBCA database contained data of 56,927 patients: 7,649 patients with DCIS, 49,073 with invasive cancer (**Table 1**). In 205 patients (0.4% of all patients), DCIS or invasive cancer was not specified. Most patients were aged between 50 and 65 years (57% for DCIS and 43% for invasive breast cancer, respectively) at the time of diagnosis. Patients diagnosed with invasive breast cancer most frequently had relatively small tumors (pT1, 63%) and the majority had no axillary lymph node metastases (pNo, 64%).

Quality indicators

An overview of the overall results for all NBCA-indicators per year is displayed in **Table 2**.

Table 1. Patient, tumor and treatment characteristics of patients included in the NABON Breast Cancer Audit (NBCA) stratified by invasive breast cancer and ductal carcinoma in situ (DCIS) (2011–2014).

			DCIS		Invasive breast cancer	
			(n=7,649)	% ^a	(n=49,073)	% ^a
Patient	Age	Below 50	990	13%	9,587	20%
		50 - 65	4,323	57%	21,100	43%
		65 or above	2,334	31%	18,368	37%
	Gender	Female	7,621	100%	48,774	99%
		Male	28	0%	299	1%
Tumor	BI-RADS classification	BI-RADS 0	19	0%	95	0%
		BI-RADS 1 - 2	230	3%	392	1%
		BI-RADS 3 - 5	7,127	93%	47,739	97%
		Unknown	273	4%	847	2%
	Palpable	No	6,176	81%	17,057	35%
		Yes	1,308	17%	31,340	64%
		Unknown	165	2%	676	1%
	Multifocal	No	7,044	92%	41,443	85%
		Yes	605	8%	7,630	16%
	Histology	Ductal	7,164	94%	39,822	81%
		Lobular	0	0%	5,465	11%
		Combination	141	2%	1,264	3%
		Unknown	344	5%	2,522	5%
	Grade	1	1,188	16%	11,127	23%
		2	2,691	35%	20,783	42%
		3	3,323	43%	12,726	26%
		Unknown	447	6%	4,437	9%
	TNM-pT	pT0 / cTx / Unknown	n.a.	n.a.	2,359	5%
		pT1	n.a.	n.a.	30,996	63%
		pT2	n.a.	n.a.	13,644	28%
pT3		n.a.	n.a.	1,636	3%	
pT4		n.a.	n.a.	438	1%	
TNM-pN	pNx / Unknown	n.a.	n.a.	1,981	4%	
	pN0	n.a.	n.a.	31,193	64%	
	pN1	n.a.	n.a.	11,996	24%	
	pN2	n.a.	n.a.	2,463	5%	
	pN3	n.a.	n.a.	1,440	3%	

Table 1. Patient, tumor and treatment characteristics of patients included in the NABON Breast Cancer Audit (NBCA) stratified by invasive breast cancer and ductal carcinoma in situ (DCIS) (2011–2014). (continued)

			DCIS		Invasive breast cancer	
			(n=7,649)	% ^a	(n=49,073)	% ^a
Treatment	Neo-adjuvant therapy	Yes	n.a.	n.a.	6,262	13%
	Type of first surgery	Breast conserving surgery	5,210	68%	29,070	59%
		Ablative surgery	2,381	31%	19,506	40%
	Immediate reconstruction ^b	Yes	1,012	43%	3,364	17%
	Sentinel node procedure	Yes	4,844	64%	39,839	82%
	Axillary lymph node dissection	Yes	86	1%	12,388	25%
	Postoperative chemotherapy ^c	Yes	n.a.	n.a.	12,423	40%
	Postoperative radiotherapy ^c	Yes	3,169	52%	24,454	63%

BI-RADS, Breast Imaging-Reporting and Data System; n.a., not applicable.

^aPercentages are rounded off, which in some cases leads to a total of above 100;

^bin case of ablative surgery;

^ccalculated for 2011, 2012 and 2013 only.

Table 2. Quality indicators for breast cancer health care in the NABON Breast Cancer Audit (NBCA) and mean percentages per year from 2011 to 2014.

Discipline	Indicator	Pre-defined norm	2011 (n=12,562)	2012 (n=15,929)	2013 (n=16,451)	2014 ^a (n=11,985)	P-value ^b
Radiology	BI-RADS classification used in radiology report	>90%	97%	98%	98%	99%	<0.001
	Breast MRI in patients treated with neo-adjuvant chemotherapy		n.a. ^f	83%	87%	89%	<0.001
Pathology	Breast MRI in patients treated with primary surgery		n.a. ^f	28%	30%	31%	<0.001
	Pathology report as defined ^c	>90%	83%	93%	97%	97%	<0.001
	HER-2 positive measurement		12%	15%	13%	13%	<0.001
	Estrogen positive measurement		83%	83%	85%	84%	<0.001
	Progesterone positive measurement		65%	67%	69%	69%	<0.001
Surgery	Tumor positive margins after first breast conserving surgery for invasive breast cancer after neo-adjuvant therapy ^e		5,0%	8,3%	6,5%	6,8%	0.193
	Tumor positive margins after first primary breast conserving surgery for invasive breast cancer ^d	<15%	5,9%	5,4%	4,8%	4,6%	0.007
	Tumor positive margins after first primary breast conserving surgery for DCIS ^e	<30%	2,5%	2,0%	2,2%	1,8%	0.002
	Sentinel node procedure for pNo(i-) tumors, with more than 5 nodes excised	<5%	2,3%	1,9%	1,9%	1,7%	0.274
	Sentinel node procedure for pNo(i+) tumors, with more than 5 nodes excised	<5%	4,6%	2,6%	1,9%	3,7%	0.123
	Breast conserving surgery for invasive breast cancer without a re-intervention		9,4%	9,2%	9,3%	9,3%	0.004
Breast conserving surgery for DCIS without a re-intervention							0.054

Table 2. Quality indicators for breast cancer health care in the NABON Breast Cancer Audit (NBCA) and mean percentages per year from 2011 to 2014. (continued)

Discipline	Indicator	Pre-defined norm	2011 (n=12,562)	2012 (n=15,929)	2013 (n=16,451)	2014 ^a (n=11,985)	P-value ^b
Plastic surgery	Immediate reconstructions with first ablative surgery for invasive breast cancer (total)		14%	16%	19%	21%	<0.001
	Immediate reconstructions with first ablative surgery for DCIS (total)		4.1%	38%	45%	46%	0.013
Radiotherapy	Prior to neo-adjuvant chemotherapy seen by radiation oncologist		36%	42%	46%	n.a. ⁹	<0.001
	Radiotherapy for locally advanced breast cancer (excluding T3No) treated with mastectomy		75%	80%	81%	n.a. ⁹	<0.001
	Radiotherapy for DCIS treated with breast conserving surgery		75%	81%	84%	n.a. ⁹	<0.001
Systemic therapy	Neo-adjuvant chemotherapy for invasive Mo breast cancer		8%	9%	12%	14%	<0.001
	Post-operative chemotherapy for invasive Mo breast cancer		34%	32%	31%	n.a. ⁹	<0.001
	Neo-adjuvant or post-operative chemotherapy for invasive Mo breast cancer		42%	40%	42%	n.a. ⁹	<0.001
	Number of records completed in NBCA	>90%	97%	98%	99%	99%	<0.001
Multi-disciplinary	Pre-operative multi-disciplinary team meeting including digital report	>90%	83%	94%	97%	98%	<0.001
	Post-operative multi-disciplinary team meeting including digital report	>90%	91%	97%	99%	99%	<0.001

Table 2. Quality indicators for breast cancer health care in the NABON Breast Cancer Audit (NBCA) and mean percentages per year from 2011 to 2014. (continued)

Discipline	Indicator	Pre-defined norm	2011 (n=12,562)	2012 (n=15,929)	2013 (n=16,451)	2014 ^a (n=11,985)	P-value ^b
Transit times							
	Transit time ≤ 5 weeks between diagnosis and start neoadjuvant chemotherapy		66%	74%	79%	81%	<0.001
	Transit time ≤ 5 weeks between diagnosis and primary surgery (without immediate reconstruction)	>90%	81%	85%	85%	88%	<0.001
	Transit time ≤ 5 weeks between diagnosis and primary surgery (with immediate reconstruction)		43%	47%	50%	56%	<0.001
	Transit time ≤ 5 weeks between final operation and start radiotherapy		38%	43%	51%	n.a. ⁹	<0.001
	Transit time ≤ 5 weeks between end chemotherapy and start radiotherapy		77%	77%	82%	n.a. ⁹	<0.001
	Transit time ≤ 5 weeks between final operation and start chemotherapy		65%	66%	64%	n.a. ⁹	<0.001
	Transit time ≤ 5 weeks between end radiotherapy and start chemotherapy		93%	93%	94%	n.a. ⁹	<0.001

NABON, National Breast Cancer Consultation Netherlands; BI-RADS, Breast Imaging-Reporting and Data System; MRI, magnetic resonance imaging; DCIS, ductal carcinoma in situ.

See **Supplementary Appendix 1** for definitions of quality indicators.

^a 2014 consists of 9 months: January–October.

^b Using χ^2 tests.

^c Pathology report addresses estrogen receptor-, progesterone receptor-, and HER2-status, malignancy grade, tumor size, margin involvement and number of positive lymph nodes (when sentinel node procedure or axillary node dissection was performed).

^d Tumor positive for invasive breast cancer is defined as tumor cells (>4 mm) in the surgical resection.

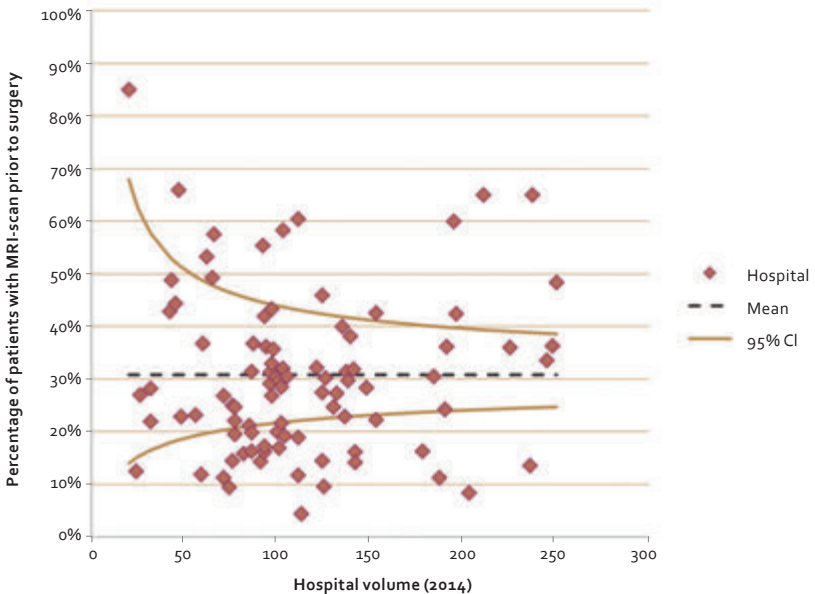
^e Tumor positive for DCIS is defined as any tumor present in a surgical resection margin.

^f n.a.: not applicable, registration of use of MRI-scan started in 2012.

^g n.a.: not applicable, for adjuvant indicators there are no results yet available for 2014.

Radiology. A final Breast Imaging-Reporting and Data System (BI-RADS) classification was used in breast imaging reports in 98% of the patients (97% in 2011 and 99% in 2014; see **Table 2**). Over the years 2011–2014, the percentage of patients who underwent breast MRI increased (from 83% to 89% before neo-adjuvant treatment and from 28% to 31% before upfront surgery). The use of breast MRI varied largely between hospitals both for patients undergoing primary surgery (2014: range 4–84%; **Figure 1**) as well as for patients treated with neo-adjuvant systemic treatment (2014: range 0–100%).

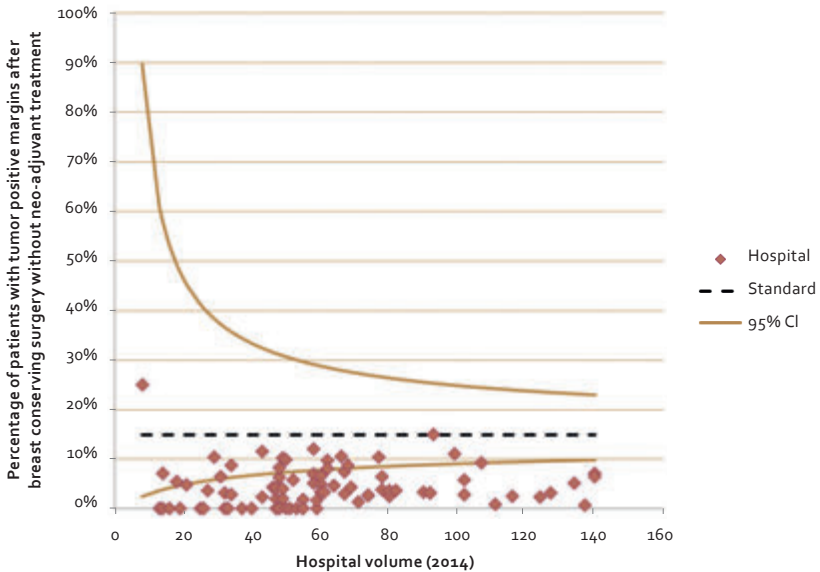
Figure 1. Funnel plot of variation between hospitals in the percentage of patients with invasive Mo breast cancer or ductal carcinoma in situ (DCIS) having a Magnetic Resonance Imaging (MRI)-scan prior to surgery in 2014. The 95% confidence intervals are displayed around the mean (31%).



Pathology. The proportion of patients with complete pathology reports increased significantly over the years. In 2014, 97% of the pathology reports contained all required pathology items (**Table 2**), and nearly every hospital (90 out of 92) reached the norm of 90% for this indicator compared to 66% of the hospitals reaching this norm in 2011.

Surgery and reconstructive surgery. Fifty-nine percent and 68% of the patients underwent breast conserving therapy for invasive breast cancer and DCIS, respectively (**Table 1**). The percentage of patients with tumor involved resection margins requiring re-operation after initial breast conserving surgery for invasive breast cancer was stable over the years: ~5% (**Figure 2**). After neo-adjuvant chemotherapy, this percentage was higher (7%) and highest for patients undergoing breast conserving surgery for DCIS (20%). All hospitals had results significantly below the predefined norm of 15% for invasive breast cancer and 30% for DCIS.

Figure 2. Funnel plot of variation between hospitals in the percentage of patients with invasive breast cancer and more than focal tumor-positive margins after breast conserving surgery without neo-adjuvant treatment (2014). The 95% confidence intervals are displayed around the standard (15%).



An immediate breast reconstruction was performed in 17% (range 0–66%) of patients with invasive cancer and in 43% (range 0–84%) of patients diagnosed with DCIS who underwent a mastectomy. The percentage of patients receiving an immediate breast reconstruction increased over the years with a 50% relative

increase over the 4 years for invasive breast cancer (14–21%), and 12% relative increase for DCIS (41–46%).

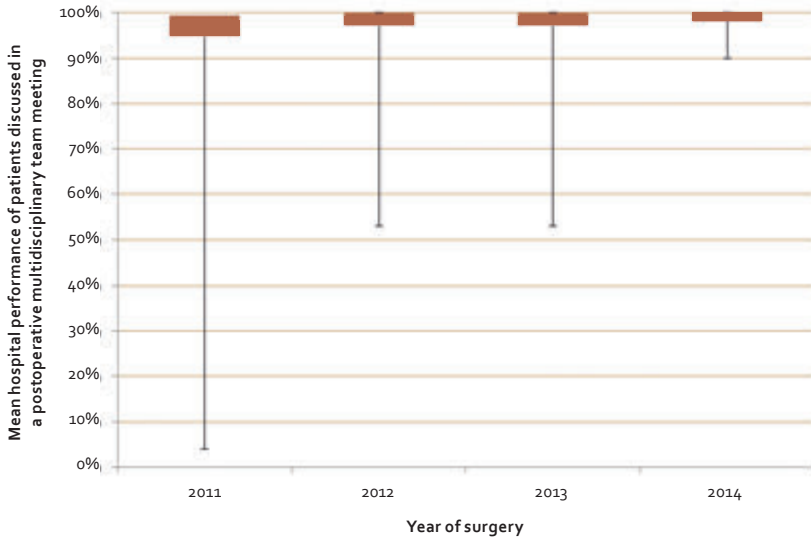
Radiotherapy. Eighty-one percent of the patients diagnosed with locally advanced breast cancer who underwent a mastectomy received additional radiotherapy in 2013. Of the patients undergoing breast conserving surgery for DCIS, 84% received radiotherapy.

(Neo-)adjuvant systemic therapy. Neo-adjuvant chemotherapy was increasingly administered over the study period (from 8% in 2011 to 14% in 2014, **Table 2**), and there was a significant variation between hospitals (0–48% in 2014). In 2014, 9% of the patients diagnosed with a cT2 tumor received neo-adjuvant chemotherapy (range 0–57%). The proportion of patients who received either adjuvant or neo-adjuvant chemotherapy decreased slightly over the years (**Table 2**).

Multidisciplinary care process. Ten quality indicators provide insight in the multidisciplinary care process logistics, and four of them have a standardized cut-off value (**Table 2**). Compared to 2011, more patients were discussed in pre- and post-operative MDT meetings: pre-operative this percentage rose from 83% to 98%, postoperative from 91% to 99%. In addition, variation between the hospitals decreased; in 2014, none of the hospitals discussed significantly less patients than the 90% norm in a post-operative MDT meeting (**Figure 3**). A similar trend was observed for the pre-operative MDT meeting.

Transit times. Time between diagnosis and primary treatment improved, more patients were treated within the predefined time frame of 5 weeks. An immediate breast reconstruction negatively affected the proportion of patients being operated within 5 weeks since diagnosis: from 56% to 88% when immediate breast reconstruction was not performed. The proportion of patients operated timely was lower in hospitals with larger patient volumes. However, an improvement over the years was observed for all time intervals.

Figure 3. Boxplot of variation between hospitals in the percentage of patients with either invasive breast cancer or ductal carcinoma in situ (DCIS) discussed in a post-operative multidisciplinary team meeting, and digital report available (2011–2014) with median hospital performance and interquartile ranges. 2014 contains 9 months; from January 2014 to October 2014.



DISCUSSION

This paper describes the implementation of a system monitoring the quality of breast cancer care in the Netherlands via a nationwide multidisciplinary audit. All 92 hospitals currently delivering breast cancer care in the Netherlands participate in the NBCA and the results of the first 4 years of auditing show an overall high quality of care, areas where clear improvement has been achieved as well as unexplained variation.

The collection of data in all hospitals in the Netherlands resulted in 56,927 patients for whom detailed information regarding their work-up and treatment was available for analysis. Several initiatives have shown that improvement of quality of care can be established by measuring quality indicators over time^{7–12}; however, to the best of our knowledge we are the first to report on a nationwide breast cancer audit with full participation of all hospitals. The use of quality indicators embedded in a

national audit providing benchmark information to participating hospitals catalyzes quality improvement and insurance on various levels in the healthcare system.¹³ An example of improvement on hospital level is a hospital that recognized itself as an outlier on the indicator “frequency of HER2-positive tumors”. Having observed a significant higher frequency they evaluated their pathology processes and found out that their laboratory used a different method of tracking HER2 positivity. This was subsequently adjusted. Another hospital observed low rates of patients discussed in a pre-operative MDT meeting, identifying that this was associated with a lack of meetings during holiday periods and they changed their clinic days to make sure every patient is discussed in an MDT meeting. On another level, regional cancer centers have organized network meetings reflecting on observed differences between the institutions within the network.

Apart from the actions of the individual hospitals that were triggered by benchmarking their results, the comprehensive audit outcomes have led on a national level to in depth research into hospital variation in breast MRI use and immediate breast reconstruction facilitated by research grants of the Dutch Cancer Society. As such, the NBCA serves as a monitor to identify variation as well as a database that identifies factors explaining variation and eventually ought to catalyze guideline adjustments.

The absence of consistency between indicator sets used by different other audits internationally is a limitation of individual audits as only uniform definitions of quality indicators can enable international benchmarking.^{7-9,14,15} Nevertheless, guidelines may well differ between countries and therefore differences in quality parameters will remain, as the main goal of an audit is the quality assurance in a particular area.

Process indicators

A number of trends were observed since the introduction of the audit in 2011. For most quality indicators with a predefined quality norm, the mean value of all hospitals improved and the variation between the hospitals decreased, as was observed at an earlier moment in the Netherlands.¹⁶ Significant changes were

seen for the indicators reflecting the process of provided care. Over time, all hospitals reached the norm of 90% of patients being discussed in MDT meetings. This demonstrates that a multidisciplinary approach is widely adopted in the Netherlands as is advised by national guidelines. A similar study reported a variety of patients being discussed in an MDT meeting in Belgium, with improvement from 61.4% in 2003 to 80% in 2006.⁷ Although a slight improvement was seen in the time to operation, in 2014 still a number of hospitals were not able to reach the 90% norm of patients undergoing surgical treatment within 5 weeks after diagnosis. It was also shown that a number of factors, such as combining surgical resection with reconstructive surgery, affect this process indicator.

Outcome indicators

The consistent low rate of tumor-positive margins in patients who underwent breast conserving surgery for invasive breast cancer is remarkable as well as reassuring, since concerns about the rate of incomplete resections were one of the drivers to initiate this clinical audit. Compared to earlier studies in the Netherlands, improvement was observed, although various definitions of margin involvement have been applied over the years, making direct comparison difficult.¹⁷ The NBCA adheres to the current guideline, defining a positive margin for invasive breast cancer as a margin that is more than focally (>4 mm) involved, because this is the cut off where re-excision or continuation of treatment with radiotherapy is advised. Altogether, a positive margin rate for invasive breast cancer of 5% in the 4 years' study period, with no hospital performing significantly worse than the 15% norm was seen. Room for further improvement seems limited. The same applies to the positive margin rate following breast conserving surgery for DCIS.

Apart from the quality indicators with a standardized norm, other indicators were designed to explore current patterns of care. Some of these indicators showed large variation between hospitals and its causes and clinical relevance need to be explained. The preoperative use of breast MRI varied from 4% to 85% between hospitals. Routine use of breast MRI in the preoperative setting is discouraged by national guidelines, while MRI is considered to be indicated in patients who receive chemotherapy in a neo-adjuvant context (for patients treated with neo-

adjuvant chemotherapy it is recommended to perform breast MRI prior to the start of therapy as the optimal means to monitor response to treatment).¹⁸ Apparently, interpretation of this definition varies between hospitals as demonstrated by the observed variation. Another example is the proportion of patients undergoing an immediate reconstruction following a mastectomy for invasive breast cancer or DCIS and variation in neo-adjuvant chemotherapy. The NBCA may serve as a database to identify factors explaining the observed hospital variation. Identifying areas of variation provides insight, opens discussions among clinicians and enables further research to understand the variation, allowing future guideline recommendations and improving quality of care for all breast cancer patients.

Limitations

Participation of all hospitals in the audit enables valid comparisons. However, completeness of the data by all participating hospitals is required in order to understand observed differences. Especially in the first year of registration, not all data were complete or correctly coded in the system. For example, it was difficult to retrieve from hospital records by IKNL-trained registrars whether a patient was discussed in an MDT meeting in the first year of registration. We chose not to make missing data an advantage; in case that a hospital had not reported if patients were discussed in an MDT meeting, it was assumed that these patients were not discussed in such a meeting. The results should be interpreted within this context and can only lead to an underestimation of actual performances. Furthermore, the present results also underline that the NBCA remains “work-in-progress” as reproducible quality indicators were not available for all involved disciplines, this is expected to change within the next few years. Lastly, it is of note that the observed trends cannot be attributed fully to the audit, as these improvements may well be the result of other changes in breast cancer practice such as new operation techniques to reduce tumor-positive margins or awareness for immediate breast reconstructions. Moreover, indicators for patients without surgery should be defined and these patients should be included in future.

Future directions of the audit

A future challenge is the development of more robust and reproducible quality indicators for all disciplines involved in the treatment of patients with breast cancer. At the moment, the NBCA has a data verification process to achieve reliable hospital comparisons. In the near future, more extensive data verification will be done in order to secure the quality of the data. For indicators without norms, reasons for the observed variation should be addressed by evaluating the audit data and further in-depth research. The availability of these data enables us not only to investigate and understand the variation found, but also to inspect hospitals on their performances and learn from best practices to further improve quality of breast cancer care for each hospital, throughout the country.

Furthermore, a balance is required between capturing all valuable information on the one hand and spending an acceptable amount of time needed for data entry on the other hand. At the moment, the 32 current quality indicators are calculated based on 75 registered items. Developing new quality indicators of interest should be accompanied by deleting indicators that have become redundant. A modest and acceptable investment of time (and finances) is one of the major challenges for the NBCA. Various ways to reduce the registration burden are explored.

Lastly, since patient-centered care is becoming more and more focused on the perceived quality of care, the NBCA will start measuring patient-reported outcome measures (PROMs) in order to evaluate the patient's outcomes with the care delivered, also on a longer term. PROMs will be implemented in 2016 and the dataset will be aligned with other initiatives focusing on patient-centered care such as the International Consortium for Health Outcomes Measurement (ICHOM).²⁹ This leads to an increased number of outcome indicators along with the process indicators and opportunities for international comparisons. The outcome indicators for recurrent disease will become available after 5 years.

CONCLUSION

The goals of the NBCA to establish a nation-wide multidisciplinary evaluation of quality parameters in breast cancer care, to evaluate guideline adherence and to facilitate benchmarking have been achieved within 4 years' time with full participation of all hospitals. Present results show an overall high quality of breast cancer care in the Netherlands and provide insight in fields and items for improvement. Future challenges include the development of robust quality indicators and understanding the variation of several indicators, accurate data verification and reducing the time necessary for data collection. With these efforts, we will be able to monitor and improve breast cancer care in the Netherlands.

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SUPPLEMENTARY APPENDIX 1

Overview of 32 quality indicators and their definitions used in the NABON Breast Cancer Audit

Radiology

BI-RADS classification described in radiology report (Standard >90%)

- Numerator: Number of patients with BI-RADS category reported in diagnostic phase on mammography, ultrasound or breast MRI.
- Denominator: Number of patients surgically treated for invasive breast cancer or DCIS.

Breast MRI prior to neo-adjuvant chemotherapy

- Numerator: Number of patients with breast MRI exam prior to neo-adjuvant chemotherapy.
- Denominator: Number of patients with invasive breast cancer treated with neo-adjuvant chemotherapy.

Preoperative breast MRI

- Numerator: Number of patients with preoperative breast MRI exam.
- Denominator: Number of patients with invasive breast cancer or DCIS treated with primary surgery.

Pathology

Pathology report as defined (Standard >90%)

- Numerator: Number of patients with standard pathology report including information about estrogen receptor percentage, progesterone receptor percentage, HER2, grade, tumor size, resection margin and number of positive lymph nodes.
- Denominator: Number of patients with a pathology report of invasive breast cancer of at least 1cm without neo-adjuvant therapy.

HER-2 positive measurement

- Numerator: Number of patients with HER2 positive tumor.
- Denominator: Number of patients with primary invasive breast cancer and availability of HER2 status.

Estrogen positive measurement

- Numerator: Number of patients with estrogen receptor positive tumor ($\geq 10\%$ of the tumor cells is positive).
- Denominator: Number of patients with primary invasive breast cancer and availability of estrogen receptor status.

Progesterone positive measurement

- Numerator: Number of patients with progesterone receptor positive tumor ($\geq 10\%$ of the tumor cells is positive).
- Denominator: Number of patients with primary invasive breast cancer and availability of progesterone receptor status.

Surgery

Tumor positive margins after first breast conserving surgery for invasive breast cancer after neo-adjuvant therapy

- Numerator: Number of patients with more than focal (>4 mm) tumor in resection margin after first breast conserving surgery.
- Denominator: Number of patients treated with neo-adjuvant therapy and breast conserving surgery for invasive breast cancer.

Tumor positive margins after first primary breast conserving surgery for invasive breast cancer (Standard $<15\%$)

- Numerator: Number of patients with more than focal (>4 mm) tumor in resection margin after first breast conserving surgery.
- Denominator: Number of patients treated with breast conserving surgery for invasive breast cancer.

Tumor positive margins after first primary breast conserving surgery for DCIS (Standard $<30\%$)

- Numerator: Number of patients with focal or more than focal (>4 mm) tumor in resection margin after first breast conserving surgery.
- Denominator: Number of patients treated breast conserving surgery for DCIS.

Sentinel node procedure for pNo(i-) tumors, with more than 5 nodes excised (Standard <5%)

- Numerator: Number of patients with removal of more than 5 lymph nodes.
- Denominator: Number of patients with pNo(i-) after primary surgical treatment with sentinel node biopsy without axillary lymph node dissection of a primary pT1-2NoMo breast cancer.

Sentinel node procedure for pNo(i+) tumors, with more than 5 nodes excised (Standard <5%)

- Numerator: Number of patients with removal of more than 5 lymph nodes.
- Denominator: Number of patients with pNo(i+) after primary surgical treatment with sentinel node biopsy without axillary lymph node dissection of a primary pT1-2NoMo breast cancer.

Breast conserving surgery for invasive breast cancer without a re-intervention

- Numerator: Number of patients with one breast conserving surgery as final surgical treatment.
- Denominator: Number of patients with invasive breast cancer treated surgically (either one or multiple times) of whom the first operation was breast conserving without prior neo-adjuvant systemic treatment.

Breast conserving surgery for DCIS without a re-intervention

- Numerator: Number of patients with one breast conserving surgery as final surgical treatment.
- Denominator: Number of patients with DCIS treated surgically (either one or multiple times) of whom the first operation was breast conserving.

Plastic surgery

Immediate reconstructions with first ablative surgery for invasive breast cancer (total)

- Numerator: Number of patients with immediate breast reconstruction.
- Denominator: Number of patients with a primary mastectomy for invasive breast cancer.

Immediate reconstructions with first ablative surgery for DCIS (total)

- Numerator: Number of patients with immediate breast reconstruction.
- Denominator: Number of patients with a primary mastectomy for DCIS.

Radiotherapy

Prior to neo-adjuvant chemotherapy seen by radiation oncologist

- Numerator: Number of patients seen by radiotherapist prior to neo-adjuvant systemic treatment.
- Denominator: Number of patients with invasive breast cancer treated with neo-adjuvant systemic therapy, surgery and postoperative radiation therapy.

Radiotherapy for locally advanced breast cancer (excluding T₃No) treated with mastectomy

- Numerator: Number of patients receiving radiotherapy.
- Denominator: Number of patients with primary invasive locally advanced breast cancer (clinical T₃, T₄, any N, Mo and T, N₂₋₃, Mo) treated with mastectomy.

Radiotherapy for DCIS treated with breast conserving surgery

- Numerator: Number of patients receiving radiotherapy.
- Denominator: Number of patients with DCIS treated with breast conserving surgery.

Systemic therapy

Neo-adjuvant chemotherapy for invasive Mo breast cancer

- Numerator: Number of patients receiving neo-adjuvant chemotherapy.
- Denominator: Number of patients with invasive breast cancer treated surgically.

Post-operative chemotherapy for invasive Mo breast cancer

- Numerator: Number of patients receiving post-operative chemotherapy.
- Denominator: Number of patients with invasive breast cancer treated surgically.

Neo-adjuvant or post-operative chemotherapy for invasive Mo breast cancer

- Numerator: Number of patients receiving neo-adjuvant or post-operative chemotherapy.
- Denominator: Number of patients with invasive breast cancer treated surgically.

Multi-disciplinary

Number of records completed in NBCA (Standard >90%)

- Numerator: Number of patients of whom the information in the registry is complete and approved by the breast cancer care team.
- Denominator: Number of surgically treated patients with primary invasive breast cancer or DCIS.

Pre-operative multi-disciplinary tumor board meeting including digital report (Standard >90%)

- Numerator: Number of patients discussed in a pre-operative MDT and the report is electronically available.
- Denominator: Number of patients surgically treated for primary invasive breast cancer or DCIS.

Post-operative multi-disciplinary tumor board meeting including digital report (Standard >90%)

- Numerator: Number of patients discussed in a post-operative MDT and the report is electronically available.
- Denominator: Number of patients surgically treated for primary invasive breast cancer or DCIS.

Transit times

Transit time ≤ 5 weeks between diagnosis and start neo-adjuvant chemotherapy

- Numerator: Number of patients receiving neo-adjuvant chemotherapy within ≤ 5 weeks after diagnosis (date of biopsy).
- Denominator: Number of patients with neo-adjuvant chemotherapy for invasive breast cancer.

Transit time ≤ 5 weeks between diagnosis and primary surgery (without immediate reconstruction) (Standard >90%)

- Numerator: Number of patients receiving surgery within ≤ 5 weeks after diagnosis (date of biopsy).
- Denominator: Number of patients with primary surgery without immediate breast reconstruction for invasive breast cancer or DCIS.

Transit time ≤ 5 weeks between diagnosis and primary surgery (with immediate reconstruction)

- Numerator: Number of patients receiving surgery within ≤ 5 weeks after diagnosis (date of biopsy).
- Denominator: Number of patients with primary surgery with immediate breast reconstruction for invasive breast cancer or DCIS.

Transit time ≤ 5 weeks between final operation and start radiotherapy

- Numerator: Number of patients receiving radiotherapy within ≤ 5 weeks after surgery.
- Denominator: Number of patients with invasive breast cancer or DCIS treated with surgery and radiotherapy (without chemotherapy between the two treatments).

Transit time ≤ 5 weeks between end chemotherapy and start radiotherapy

- Numerator: Number of patients receiving radiotherapy within ≤ 5 weeks after chemotherapy.
- Denominator: Number of patients with invasive breast cancer with chemotherapy and radiotherapy.

Transit time ≤ 5 weeks between final operation and start chemotherapy

- Numerator: Number of patients receiving chemotherapy within ≤ 5 weeks after surgery.
- Denominator: Number of patients with invasive breast cancer with surgery and chemotherapy (without radiotherapy between the two treatments).

Transit time ≤ 5 weeks between end radiotherapy and start chemotherapy

- Numerator: Number of patients receiving chemotherapy within ≤ 5 weeks after radiotherapy.
- Denominator: Number of patients with invasive breast cancer with radiotherapy and chemotherapy.

Abbreviations

NABON: National Breast Cancer Consultation Netherlands;

BI-RADS: Breast Imaging-Reporting and Data System;

MRI: Magnetic Resonance Imaging;

DCIS: Ductal Carcinoma in Situ.