# Optimizing the Quality of Breast Cancer Care at Certified German Breast Centers

## A Benchmarking Analysis for 2003–2009 with a Particular Focus on the Interdisciplinary Specialty of Radiation Oncology

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**Purpose:** A voluntary, external, science-based benchmarking program was established in Germany in 2003 to analyze and improve the quality of breast cancer (BC) care. Based on recent data from 2009, we aim to show that such analyses can also be performed for individual interdisciplinary specialties, such as radiation oncology (RO).

**Methods:** Breast centers were invited to participate in the benchmarking program. Nine guideline-based quality indicators (QIs) were initially defined, reviewed annually, and modified, expanded, or abandoned accordingly. QI changes over time were analyzed descriptively, with particular emphasis on relevance to radiation oncology.

**Results:** During the 2003–2009 study period, there were marked increases in breast center participation and postoperatively confirmed primary BCs. Starting from 9 process QIs, 15 QIs were developed by 2009 as surrogate indicators of long-term outcome. During 2003–2009, 2/7 RO-relevant QIs (radiotherapy after breast-conserving surgery or after mastectomy) showed considerable increases (from 20 to 85% and 8 to 70%, respectively). Another three, initially high QIs practically reached the required levels.

**Conclusion:** The current data confirm proof-of-concept for the established benchmarking program, which allows participating institutions to be compared and changes in quality of BC care to be tracked over time. Overall, marked QI increases suggest that BC care in Germany improved from 2003–2009. Moreover, it has become possible for the first time to demonstrate improvements in the quality of BC care longitudinally for individual breast centers. In addition, subgroups of relevant QIs can be used to demonstrate the progress achieved, but also the need for further improvement, in specific interdisciplinary specialties.

**Key Words:** Breast cancer · Benchmarking · Quality of care · Quality assurance · Radiotherapy

### Onkologische Qualitätsoptimierung in der Mammakarzinomversorgung an zertifizierten deutschen Brustzentren: eine Benchmarkinganalyse für 2003–2009 unter besonderer Berücksichtigung eines Querschnittsfaches, der Radioonkologie

**Ziel:** In Deutschland wurde 2003 ein flächendeckendes, freiwilliges, externes wissenschaftliches Benchmarkingsystem zur Analyse und Verbesserung der Versorgungsqualität beim Mammakarzinom etabliert. Ziel der vorliegenden Untersuchung ist es, anhand der aktuellen Daten von 2009 zu zeigen, dass entsprechende Analysen auch für einzelne Querschnittsfächer wie die Radioonkologie möglich sind.

**Methodik:** Brustzentren wurden zur Teilnahme am Benchmarking eingeladen. Es wurden zunächst neun Qualitätsindikatoren (QI) aus leitlinienbasierten Qualitätszielen abgeleitet, die jährlich überprüft und durch Modifikation, Neueinführung oder Aufgabe von QI weiterentwickelt wurden. Die zeitlichen Veränderungen insbesondere der radioonkologisch relevanten QIs wurden deskriptiv ausgewertet.

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**Ergebnisse:** Im Untersuchungszeitraum 2003–2009 nahmen die Zahlen der am Benchmarking teilnehmenden Einrichtungen und der erfassten postoperativ gesicherten primären Brustkrebserkrankungen markant zu. Bis 2009 wurden, von neun Prozessindikatoren ausgehend, 15 QI als Surrogatindikatoren für die langfristige Ergebnisqualität entwickelt. Bei zwei der sieben radioonkologisch relevanten QI (Bestrahlungen nach brusterhaltender Therapie bzw. Mastektomie) ergaben sich von 2003–2009 erhebliche Steigerungen (von 20 auf 85 bzw. 8 auf 70 %). Drei weitere, bereits initial hohe QI erreichten praktisch die Vorgabewerte.

**Schlussfolgerung:** Mit den aktuellen Daten bestätigt sich der Proof-of-Concept für das etablierte Benchmarkingsystem, welches den Vergleich teilnehmender Einrichtungen sowie die Beobachtung zeitlicher Veränderungen in der Brustkrebsversorgungsqualität des gesamten Netzwerks erlaubt. Deutliche QI-Zuwächse weisen für 2003–2009 insgesamt auf Verbesserungen in der Brustkrebsversorgung in Deutschland hin. Erstmals sind Verbesserungen der Versorgungsqualität aber auch als Longitudinalverläufe für einzelne Brustzentren darstellbar. Anhand von Teilspektren relevanter QI lassen sich zudem Fortschritte, aber auch der weitere Verbesserungsbedarf für einzelne Querschnittsfächer nachweisen.

**Schlüsselwörter:** Mammakarzinom · Benchmarking · Versorgungsqualität · Qualitätssicherung · Radiotherapie

## Introduction

Over the past decade, specialist breast centers have been created in Germany to improve the care provided to breast cancer patients. The main objective in establishing such multidisciplinary centers was to ensure that care was based on clinical guidelines and continual quality assurance (QA) measures, and that quality management (QM) systems were introduced. In addition, it has become a legal requirement in Germany in recent years that all healthcare service providers introduce QA programs and maintain a QM system [4, 5, 8, 21].

Since 2003, a QM system and continual QA with comprehensive documentation of all treatments and external analysis of the QA data have also been prerequisites for certification to the Requirements of Breast Centers (*Fachliche Anforderungen für Brustzentren*; FAB) in Germany [4, 5, 8, 10]. The FAB were jointly developed by the German Cancer Society (*Deutsche Krebsgesellschaft*; DKG) and the German Society of Senology (*Deutsche Gesellschaft für Senologie*; DGS) largely on the basis of two evidence-based multidisciplinary level-3 guidelines [1, 16, 17, 22] and the EUSOMA (European Society of Breast Cancer Specialists) requirements for accreditation of breast units [2]. The FAB comprise the introduction of a QM system, on the one hand, and guideline-based requirements of health care delivery, on the other.

Based on specific data items from the 173, later 185, individual FAB items, the DGS, DKG, German Society of Obstetrics and Gynecology (DGGG), and the West German Breast Center/German Oncology Center (*Westdeutsches Brust-Centrum/Deutsches Onkologie Centrum*; WBC/DOC) jointly developed a set of uniformly calculated structural and process quality indicators (QIs) of breast cancer care as surrogates for long-term outcome QIs. The performance of QIs relative to specified DKG/DGS requirements was to serve as an objectifiable measure to assess and monitor compliance with the relevant guidelines. To this end, a nationwide, independently operated voluntary benchmarking program was developed and implemented. Proof of concept for the program was demonstrated by analyzing the data from the first 4-year and 5-year periods [6, 7, 27].

The analysis of the 7-year QI data reported here focuses particularly on the QIs relevant to radiation oncology as an important interdisciplinary field in cancer therapy and aims to show that the 2003–2009 data confirm the previously reported 4- and 5-year results.

## Methods

### Study Design and Objectives

The present study is the continuation of a previously reported prospective, interventional, multicenter proof-of-concept study which showed that the quality of BC care in Germany could be measured scientifically, and improved by implementing a nationwide benchmarking program based on QIs. These were derived from clinically relevant parameters which reflected key criteria of the two level-3 guidelines developed by the relevant scientific medical societies [1, 16, 17, 22]. Details of the study design and methodology have been reported previously [6, 7].

The objective of the present analysis was to demonstrate that it is also possible to consider the specific QIs individually and to analyze them by medical specialty, i.e., the interdisciplinary field of radiation oncology in the present case, and that nationwide collaborative benchmarking was associated with improvements in the guideline-concordant and appropriate radiation treatment of BC during 2003–2009.

### Participating Centers, Data Collection, and Data Analysis

Specialist breast centers were invited to participate voluntarily in an external, independent, scientific benchmarking program developed by the DKG and the DGS and operated by the West German Breast Center/German Oncology Center (WBC/DOC), Düsseldorf, Germany.

Data collection began individually for each breast center after its voluntary registration with the benchmarking program. For each patient, 173–185 parameters from the DKG/DGS Requirements of Breast Centers (*Fachliche Anforderungen an Brustzentren*; FAB [10]) were collected by staff members of the participating centers from 1 January, 2003 to 31 December, 2009. A FAB-derived, XML-based generic da-

taset was used for uniform data collection and external analysis. Anonymized, encrypted datasets were submitted to the WBC/DOC on CD-ROM twice a year for independent external overall and center-specific analyses [7]. Standard software was used (Access®, Excel®, and Word® from Microsoft Office 2002/2003 and Microsoft SQL Server 2005 (Microsoft Corporation, Redmond, WA, USA)). The query logic was written in SQL and, hence, compatible with other software.

### Quality Indicators

Based on selected clinically relevant FAB data items, QIs were calculated according to uniform algorithms and were designed to determine the degree to which predefined quality targets were met. Methodologically, QIs were rate-based indicators of, primarily, process quality designed to reflect treatment guideline compliance and methods of decision-making. At annual reviews, the program advisory board discussed existing QIs, recommended modifications if necessary, introduced new QIs and discontinued QIs that lacked discriminatory power or practicability. Process QIs (PQIs) served as short-term surrogate parameters of outcome quality, because the latter requires at least 5–10 years of data collection. Changes in QIs during the 2003–2009 period were analyzed using descriptive methods (tables and histograms) and reported annually [7, 28, 29].

### Plausibility Checks and Monitoring

Data plausibility was ensured by twice yearly WBC/DOC monitoring visits and data reviews at the annual participants' meetings. The monitoring visits were conducted primarily to ensure the correctness and completeness of the electronic documentation of patients' medical records and also provided opportunities for advice on the documentation process [7, 28, 29].

### Results
### Programme Participation

Figure 1 illustrates the marked, 3.86-fold increase in specialist breast centers participating in the voluntary benchmarking program from 2003–2009. This was also accompanied by a steady increase in postoperatively confirmed primary BC patients per participating institution from 101.59 in 2003 to 165.5 in 2009, reflecting an overall increase above the DKG/DGS requirement that breast centers should annually treat a minimum of 150 primary breast cancers. The overall number of primary BCs (as confirmed by postoperative histology) also increased 6.30-fold during the 7-year study period, as shown in Figure 2.

### Structural Changes in Quality Indicators

Starting from 9 FAB-based QIs (Nos. 1, 2, ex-3, 5, 6, 7.1b, 9, 10, and 11b in Table 1) in 2003, QIs were reviewed once a year and retained, modified, expanded, or discontinued as recommended by the program advisory board. Table 1 shows the 2009 set of 15 QIs (in bold type; QI 7.1 not counted, since it consists of 7.1a and 7.1b) and 5 subindicators (11a–e). For completeness, Table 1 also lists 9 QIs and sub-QIs (in italics) that were discontinued at the end of 2006 and 2007, thus, illustrating the discontinuation of QIs that lacked discriminatory power. Table 2 shows the addition, modification, or discontinuation of QIs, in particular the addition of new QIs during 2005–2009 (the latest addition being QI 7.2), the replacement of Nos. "ex-3" and "ex-4" by the new Nos. 3 and 4 in 2007, and the renaming of several QIs during the study period. The QIs identified for the benchmarking program cover a number of crucial aspects of the treatment process chain, ranging from preoperative (QI No. 1) and operative (Nos. 2–4) aspects to breast-conserving surgery (BCS) (No. 11), hormone receptor assessment (No. 5), and endocrine therapy (No. 6), neoadjuvant and adjuvant chemotherapy as standard regimens (Nos. 7.1a, 7.1b, and 7.2) and study regimens (No. 8), and radiothera-
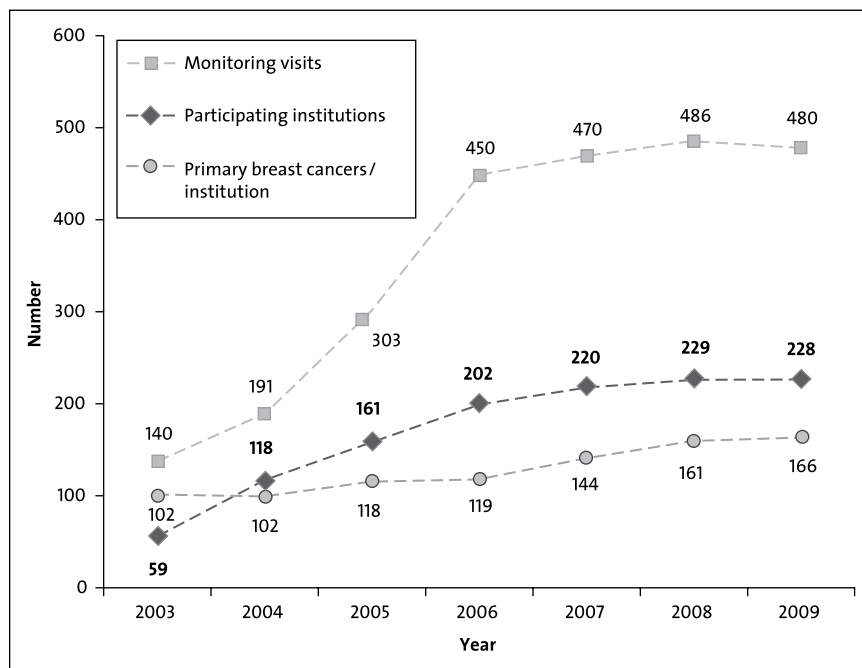


**Figure 1.** Breast center participation in the WBC/DOC program for voluntary benchmarking of the quality of breast cancer care in Germany during 2003–2009: numbers of participating institutions, monitoring visits, and number of postoperatively confirmed primary breast cancers per participating institution.

**Abbildung 1.** Teilnahme von Brustzentren am freiwilligen WBC/DOC-Benchmarking der Mammakarzinom-Versorgungsqualität im Zeitraum 2003–2009: Anzahl der teilnehmenden Einrichtungen, Monitorbesuche und postoperativ gesicherten primären Mammakarzinomen pro teilnehmender Einrichtung.
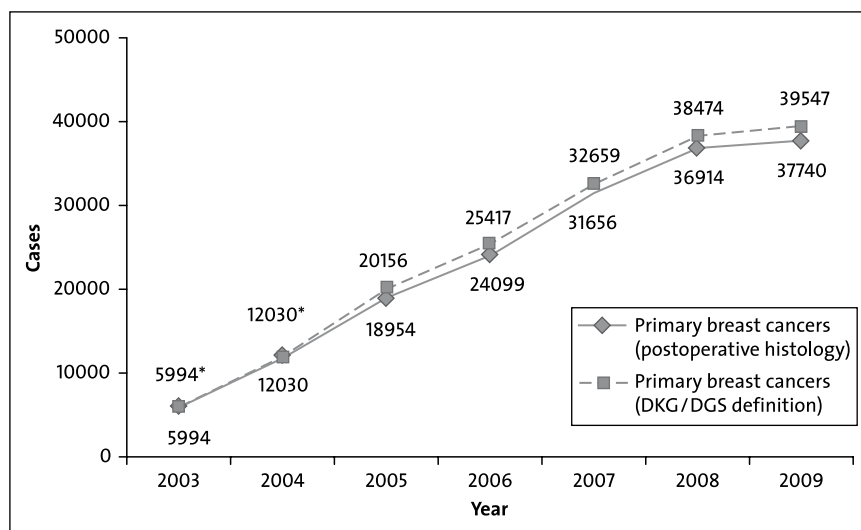
**Figure 2.** Patients with primary breast cancer according to the DKG/DGS definition (pre- or postoperatively histologically confirmed; including DCIS but excluding LCIS alone) and patients with postoperatively, histologically confirmed primary breast cancer as reported by the participating institutions during 2003–2009. *The data on postoperatively histologically confirmed cancers are given as estimates because the DKG/DGS definition was not introduced until 2005.

**Abbildung 2.** Anzahl Patientinnen mit primärem Mammakarzinom gemäß DKG/DGS-Definition (prä- oder postoperativ histologisch gesichert; einschließlich DCIS, aber ohne alleiniges LCIS) sowie Anzahl Patientinnen mit postoperativ gesichertem primärem Mammakarzinom, wie seitens der teilnehmenden Einrichtungen im Zeitraum 2003–2009 gemeldet. *Angaben zu postoperative histologisch bestätigten Karzinomdiagnosen sind Schätzwerte, da die DKG/DGS-Definition erst 2005 eingeführt wurde.

py after BCS (Nos. 9a and 9b (the latter for radiotherapy after BCS for DCIS)) or mastectomy (No. 10).

### Changes in Quality Indicators over Time

In the context of the present analysis, the DKG/DGS requirements served as target values. No DKG/DGS requirement applied to QIs 7.1b, 11a, and 11c–e, as these were not restricted to age ≤ 70 years. QIs Nos. ex-7.1b, ex-7.2a, ex-7.2b pertaining to the use of standard chemotherapy regimens were not directly derived from the relevant level-3 guidelines but introduced, and later discontinued, on the recommendation of the program advisory board.

Table 2 summarizes the results for all QIs evaluated in 2009 and shows how they developed during the study period. Among the 8 indicators tracked throughout 2003 to 2009, Nos. 1, 6, 7.1b, 9a, and 10 showed marked (>50%) increases, while the others exhibited little (>15%) change (Nos.5 and 11a) or practically no change (No. 2a). Among another 11 indicators tracked for at least 3 years during the study period, moderate increases were seen for Nos. ex-3, 4, 7.1a, ex-7.2d, and 8. Little or no change was noted for Nos. 3 and 11a–d, while No. 11e tended to decrease.

For those QIs representing parameters with FAB target values, performance levels were calculated relative to the

third-year DKG/DGS certification requirements. These were stricter than the first-year requirements in the cases of QIs Nos. 6, ex-7.1, 7.1a, 8, ex-8a, and 11b. Figure 3 shows the relative performance of QIs as a percentage of the third-year DKG/DGS requirement, where applicable, illustrating how these QIs developed during from 2003–2009.

### Quality Indicators Relevant to Guideline-Concordant Care in Radiation Oncology

Table 3 summarizes the QIs relevant to radiation oncology and how they developed over the study period. QIs Nos. 9a (radiotherapy after BCS) and 10 (radiotherapy after mastectomy) increased from very low levels (21% and 10%) to high (89% and 88%) levels relative to the respective DKG/DGS requirements. Based on the level-3 guideline, a new QI (No. 9b) for radiation treatment after breast-conserving surgery for DCIS was introduced in 2008 [16, 17]. From 2008 to 2009, the percentage of patients given radiation therapy for DCIS rose from 65% to 75%, thus, showing an increase in performance from 130% to 150% relative to the DKG/DGS requirement of 50%.

In addition to the above-mentioned QIs that directly reflect guideline-concordance of radiation therapy, a number of other QIs are important to making guideline-concordant decisions on radiation therapy. Therefore, high performance levels of these QIs are of paramount importance to the quality of care that patients receive. In particular, QIs No. ex-3 (complete tumor staging data), No. 3 (data on safety distance), and No. 4 (intraoperative specimen imaging) reflect information which is important to the multidisciplinary tumor board in order to make the correct decision about adjuvant therapy. No. ex-3 had a high initial performance level of 85% and further increased to around 100% of the DKG/DGS requirement. Nos. 3 and 4 (both introduced in 2007) increased from 91% to 98% and from 83% to 92%, respectively, during 2003–2009.

### Discussion

In line with European policies [12, 13], health policies in Germany have in recent years emphasized the increasing importance attributed to breast cancer. Efforts have been directed towards developing and implementing structured, multidisciplinary quality management programs designed to optimize breast cancer care and reduce both inappropriate care and the over- and underprovision of care. However, until the present

**Table 1.** Quality indicators (QIs) in the voluntary nationwide program for bench-marking breast cancer care, 2003–2009. n.d.: no details, DCIS: ductal carcinoma in situ, DKG: Deutsche Krebsgesellschaft (German Cancer Society), DGS: Deutsche Gesellschaft für Senologie (German Society of Senology), L3-GL/ED-BC (2003): level-3 guidelines for the early detection of breast cancer in Germany (2003) [22], L3-GL/DT-BC (2004): interdisciplinary S3 guidelines for the diagnosis and treatment of breast cancer in women (2004) [16], L3-GL/DT-BC (2008): interdisciplinary S3 guidelines for the diagnosis and treatment of breast cancer. 1st revision 2008 (2008) [17].

**Tabelle 1.** Qualitätsindikatoren (QIs) für das freiwillige flächendeckende Benchmarking der Mammakarzinom-Versorgungsqualität im Zeitraum 2003–2009.

| QI No. | Quality indicator (QI) | Intro-duced | Based on | Quality objective | DKG/DGS (FAB) requirement |
|---|---|---|---|---|---|
| 1[a] | Preoperative histological confirmation of diagnosis | 2003 | L3-GL/ED-BC (2003) | Frequently obtain preoperative histological confirmation of diagnosis in invasive breast cancer (BC) | >90% (palpable tumors), >70% (nonpalpable tumors) |
| 2a | Appropriate axillary dissection | 2003 | L3-GL/DT-BC (2004) | Always perform appropriate axillary dissection in invasive BC (axillary clearance) | >85% at initial certification; >95% after 3 years |
| 2b | Patients with sentinel lymph node biopsy (SLNB) | 2008 | L3-GL/DT-BC (2008) | Sentinel lymph node biopsy (SLNB) should, where possible, be performed in ≥75% of all patients with invasive BC to determine histological nodal status | ≥75% of patients with pT1 pN0 invasive BC undergoing SLNB only |
| *[ex-3]* [b] | *Complete tumor staging data* | 2003 | *L3-GL/DT-BC (2004)* | *Complete information on tumor stage (T-N-M-R-G) for all patients* | *>95% for pT and pN in invasive BC* |
| 3 | Safety distance between tumor and resection margin | 2007 | L3-GL/DT-BC (2004) | Always give details of safety distance | Pathologist's report must state the resection margin and minimum safety distance in 100% of cases (exceptions require justification) |
| *[ex-4]* | *HER-2/neu assessment* | *2005* | *Generally accepted criterion* | *Frequent assessment of HER-2/neu status* | *>95% in invasive BC* |
| 4 | Specimen imaging | 2007 | Generally accepted criterion | Always perform specimen radiography or sonography after preoperative wire localization | 2007: Postoperative specimen radiography in >95% of patients with microcalcifications after preoperative wire localization |
| | | | | | 2008: Intraoperative specimen radiography in >95% of patients after preoperative wire localization |
| | | | | | 2009: Intraoperative specimen radiography or sonography in >95% of patients after preoperative wire localization |
| 5 | Hormone receptor assessment | 2003 | L3-GL/DT-BC (2004) | Always determine hormone receptor status | >95% hormone receptor analysis in invasive BC (in principle always if the preconditions are met; exceptions require justification) |
| 6 | Guideline-concordant endocrine therapy in hormone receptor-positive patients | 2003 | L3-GL/DT-BC (2004) | Always use endocrine therapy to treat hormone receptor-positive BC | >70% at initial certification; >95% after 3 years |
| 7.1 | Guideline-concordant adjuvant and neoadjuvant chemotherapy | 2003 | L3-GL/DT-BC (2004) | Frequent use of appropriate adjuvant or neoadjuvant chemotherapy to treat hormone receptor-negative BC or BC with ≥4 affected lymph nodes, irrespective of receptor status | See 7.1a and 7.1b |
| *[ex-7.1a]* | *– during the previous analysis period; age ≤70 years* | *2005* | *L3-GL/DT-BC (2004)* | *See QI 7.1* | *>70% at initial certification; >80% after 3 years in patients ≤70 years* |
| *[ex-7.1b]* | *– during the previous analysis period; no age limit* | *2003* | *L3-GL/DT-BC (2004)* | *See QI 7.1* | *n.d.* |
| 7.1a | – during the current analysis period; age ≤70 years [2006: QI 7.1c] | 2005 | L3-GL/DT-BC (2004) | See QI 7.1 | >70% at initial certification; >80% after 3 years in patients ≤70 years |
| 7.1b | – during the current analysis period; no age limit [2006: QI 7.1d] | 2003 | L3-GL/DT-BC (2004) | See QI 7.1 | n.d. |

*(continued next page)*

**Table 1.** (continued)

**Tabelle 1.** (Fortsetzung)

| QI No | Quality indicator (QI) | Intro-duced | Based on | Quality objective | DKG/DGS (FAB) requirement |
|---|---|---|---|---|---|
| *[ex-7. 2]* | *Use of appropriate standard regimens in chemotherapy* | *2005* | *n.d.* | *Frequent use of appropriate standard regimens in chemotherapy* | *n.d.* |
| *[ex-7.2a]* | *– during the previous analysis period; age ≤70 years* | *2006* | *n.d.* | *See QI ex-7.2* | *n.d.* |
| *[ex-7.2b]* | *– during the previous analysis period; no age limit* | *2005* | *n.d.* | *See QI ex-7.2* | *n.d.* |
| *[ex-7.2c]* | *– during the current analysis period; age ≤70 years [2007: QI 7.2a]* | *2006* | *n.d.* | *See QI ex-7.2* | *n.d.* |
| *[ex-7.2d]* | *– during the current analysis period; no age limit [2007: QI 7.2b]* | *2005* | *n.d.* | *See QI ex-7.2* | *n.d.* |
| **7.2** | Adjuvant combination chemotherapy with anthracyclines and/or taxanes | 2008 | L3-GL/DT-BC (2008) | Adjuvant combination chemotherapy with anthracyclines and/or taxanes in ≥80% of all patients receiving adjuvant combination chemotherapy | Reference range: ≥80% |
| **8** | Percentage of patients in clinical trials | 2005 | L3-GL/DT-BC (2004) | Frequent inclusion of patients in clinical trials | ≥10% and ≥20% primary breast cancers at initial certification and after 3 years, respectively |
| *[ex-8]* | *– during the previous analysis period* | *2006* | *L3-GL/DT-BC (2004)* | *See QI 8* | *≥10% and ≥20% primary breast cancers at initial certification and after 3 years, respectively* |
| **9a** | Radiotherapy after breast-conserving surgery (BCS) | 2003 | L3-GL/DT-BC (2004) | Irradiation of the breast in all patients receiving BCS for invasive cancer. | >95% |
| **9b** | Radiotherapy after breast-conserving surgery (BCS) for DCIS | 2008 | L3-GL/DT-BC (2008) | Irradiation of the breast in all patients receiving BCS for DCIS | >50% |
| **10** | Radiotherapy after mastectomy | 2003 | L3-GL/DT-BC (2004) | Always give radiotherapy after mastectomy | >80% |
| **11** | Indication for breast-conserving surgery | 2003 | L3-GL/DT-BC (2004) | Indication for breast-conserving therapy | n.d. |
| 11a | – at any tumor stage | 2003 | L3-GL/DT-BC (2004) | See QI 11 | n.d. |
| 11b | – at T1 | 2005 | L3-GL/DT-BC (2004) | See QI 11 | BCS for pT1 tumors; >50% at initial certification, >70% after 3 years |
| 11c | – at T2 | 2006 | L3-GL/DT-BC (2004) | See QI 11 | n.d. |
| 11d | – at T3 | 2006 | L3-GL/DT-BC (2004) | See QI 11 | n.d. |
| 11e | – at T4 | 2006 | L3-GL/DT-BC (2004) | See QI 11 | n.d. |

[a]The set of QIs used in 2009 are printed in bold. [b] Square brackets and italics indicate QIs which were discontinued at the end of 2006 or 2007.

study was initiated in 2003, the necessary infrastructure for a benchmarking program with uniform data collection, external data analysis, and specific collaboration agreements did not exist in Germany or elsewhere [7].

Moreover, literature searches up to 2009 yielded no evidence that other countries had mandatory or voluntary supraregional interinstitutional benchmarking programs for assessing the quality of care provided to BC or other cancer patients. This shows the novelty of the approach that has been pursued in Germany since 2003 to create a nationwide benchmarking network of breast centers.

Guidelines of high methodological quality which are consistent with the principles of evidence-based medicine (EBM) aim to ensure and improve the quality of care for all patients, and cancer patients in particular. Although the necessity of guideline-concordant treatment had long since been recognized, the implementation and acceptance of guideline-concordant procedures along the entire process chain of breast

**Table 2.** Changes over time in the indicators used for benchmarking the quality of breast cancer care during 2003–2009. – : no specified requirement.

**Tabelle 2.** Zeitliche Entwicklung der Indikatoren für das Benchmarking der Mammakarzinom-Versorgungsqualität im Zeitraum 2003–2009.

| QI No. | Quality indicator (QI) | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 | DKG/DGS requirement 1st year | 3rd year |
|---|---|---|---|---|---|---|---|---|---|---|
| 1[a] | Preoperative histological confirmation of diagnosis | 58% | 71% | 78% | 84% | 88% | 93% | 95% | 90%[b] | 90%[b] |
| 2a | Appropriate axillary dissection | 85% | 85% | 80% | 83% | 88% | 90% | 90% | ≥85% | ≥95% |
| 2b | Patients with sentinel lymph node biopsy (SLNB) | | | | | | 69% | 74% | ≥75% | ≥75% |
| [ex-3][c] | *Complete tumor staging data* | *85%* | *96%* | *98%* | *95%* | | | | *>95%* | *>95%* |
| 3 | Data on safety distance between tumor and resection margin | | | | | 91% | 97% | 98% | 100% | 100% |
| [ex-4] | *HER-2/neu assessment* | | | | *94%* | *98%* | | | *>95%* | *>95%* |
| 4 | Specimen imaging (2007: preop. radiography in patients with microcalcifications; 2008: intraop. radiography; 2009: intraop. radiography or sonography) | | | | | 83% | 93% | 92% | >95% | >95% |
| 5 | Hormone receptor assessment | 92% | 96% | 96% | 97% | 98% | 99% | 99% | >95% | >95% |
| 6 | Guideline-concordant endocrine therapy in hormone receptor-positive patients | 27% | 82% | 92% | 94% | 93% | 96% | 97% | >70% | >95% |
| 7.1 | Guideline-concordant adjuvant and neoadjuvant chemotherapy | | | | | | | | | |
| [ex-7.1a] | *– during the previous analysis period; age ≤70 years* | | | *65%* | *76%* | | | | *>70%* | *>80%* |
| [ex-7.1b] | *– during the previous analysis period; no age limit* | *32%* | *45%* | *55%* | *65%* | | | | *–* | *–* |
| **7.1a** | – during the current analysis period; age ≤70 years [2006: QI 7.1c] | | | 65% | 75% | 81% | 79% | 81% | >70% | >80% |
| **7.1b** | – during the current analysis period; no age limit [2006: QI 7.1d] | 32% | 45% | 55% | 63% | 80% | 71% | 75% | – | – |
| [ex-7.2] | *Use of appropriate standard regimens in chemotherapy* | | | | | | | | | |
| [ex-7.2a] | *– during the previous analysis period; age ≤70 years* | | | | *60%* | | | | *–* | *–* |
| [ex-7.2b] | *– during the previous analysis period; no age limit* | | | *5%* | *55%* | | | | *–* | *–* |
| [ex-7.2c] | *– during the current analysis period; age ≤70 years [2007: QI 7.2a]* | | | | *65%* | *72%* | | | *–* | *–* |
| [ex-7.2d] | *– during the current analysis period; no age limit [2007: QI 7.2b]* | | | *57%* | *60%* | *69%* | | | *–* | *–* |
| 7.2 | Adjuvant combination chemotherapy with anthracyclines and/or taxanes | | | | | | 92% | 98% | ≥80% | ≥80% |
| 8 | Percentage of patients in clinical trials | | | 8% | 7% | 7% | 8% | 12% | ≥10% | ≥20% |
| [ex-8a] | *– during the previous analysis period* | | | | *6%* | | | | *≥10%* | *≥20%* |
| 9a | Radiotherapy after breast-conserving surgery | 20% | 46% | 60% | 70% | 79% | 80% | 85% | >95% | >95% |
| 9b | Radiotherapy after breast-conserving surgery for DCIS | | | | | | 65% | 75% | >50% | >50% |
| 10 | Radiotherapy after mastectomy | 8% | 26% | 35% | 47% | 65% | 65% | 70% | >80% | >80% |
| 11 | Indication for breast-conserving therapy | | | | | | | | | |
| 11a | – at any tumor stage | 64% | 66% | 64% | 68% | 70% | 71% | 70% | – | – |
| 11b | – at T1 | | | 79% | 83% | 85% | 85% | 85% | 50% | 70% |
| 11c | – at T2 | | | | 60% | 63% | 62% | 63% | – | – |
| 11d | – at T3 | | | | 15% | 13% | 14% | 16% | – | – |
| 11e | – at T4 | | | | 15% | 12% | 12% | 13% | – | – |

[a]The set of QIs used in 2009 are printed in bold. [b]Requirement for palpable tumors, 70% for nonpalpable tumors. [c]Square brackets and italics indicate QIs which were discontinued at the end of 2006 or 2007.

cancer care from diagnosis and treatment to follow-up was not studied on a large scale in Germany until 2003 [6, 7]. The creation of site-specific and comprehensive cancer centers, the implementation of a structured, intersectoral quality management (QM) system for the standardization and optimization of all procedures, and the comprehensive documentation of treatment procedures are considered key elements of quality assurance and high-quality care [4, 8]. To date, however, little basic scientific research has been done on the effects and impact of centralization and certification.
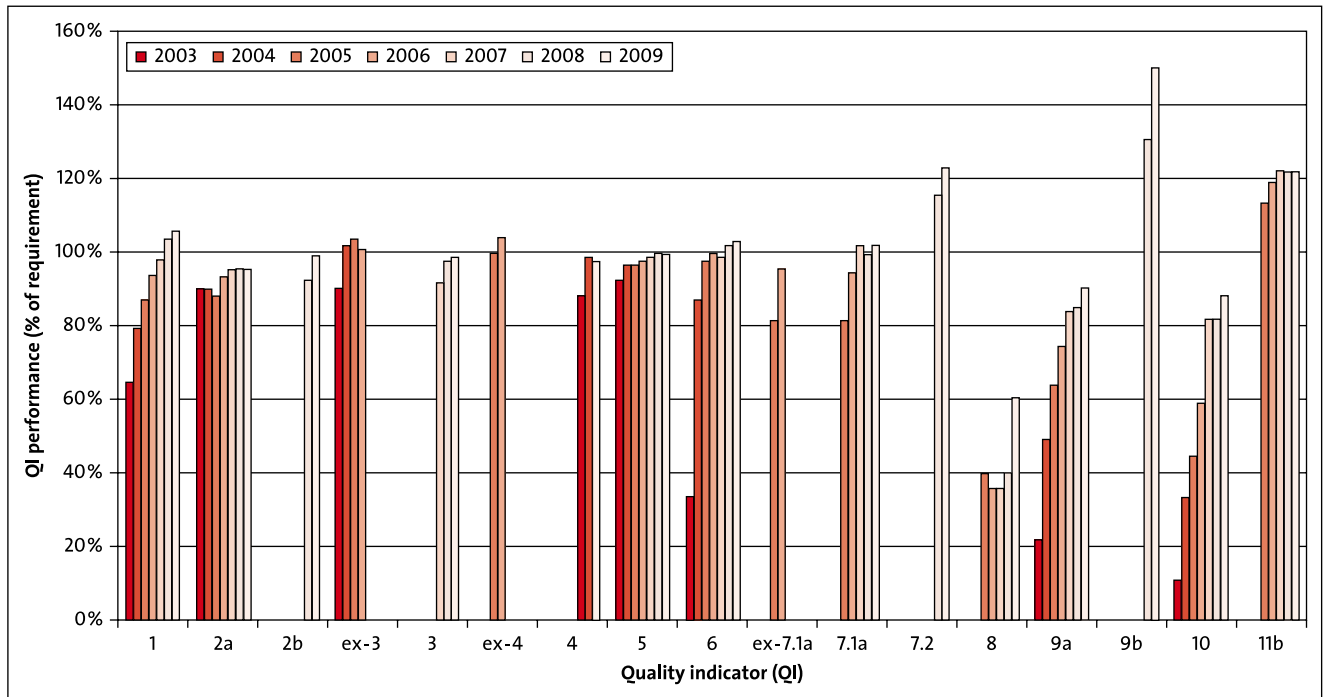
**Figure 3.** Performance of quality indicators (QIs) during the 2003–2009 period as a percentage of the respective third-year DKG/DGS Requirements of Breast Centers (FAB). QI No. 1 (Preoperative histological confirmation of diagnosis) was compared against the stricter DKG/DGS requirement of 90% (for palpable tumors as opposed to 70% for nonpalpable tumors) as the benchmark. The benchmarking program does not currently distinguish between palpable and nonpalpable tumors. QIs labeled "ex-3" (Complete tumor staging data) and "ex-4" (HER 2/neu assessment) were discontinued at the end of 2006 and replaced by QIs "3" (Data on safety distance between tumor and resection margin) and "4" (Specimen imaging) in 2007. Relative performance was not defined for QIs ex-7.1b, 7.1b, ex-7.2a–d, 11a and 11c–e in the absence of relevant DKG/DGS requirements. 1: preoperative histological confirmation of diagnosis, 2a: appropriate axillary dissection, 2b: patients with SLNB, ex-3: complete tumor staging data, 3: data on safety distance between tumor and resection margin, ex-4: HER-2/neu assessment, 4: specimen imaging, 5: hormone receptor assessment, 6: guideline-concordant endocrine therapy in hormone receptor-positive patients, ex-7.1a: guideline-concordant adjuvant and neoadjuvant chemotherapy during the previous analysis period (age ≤ 70 years), 7.1a: guideline-concordant adjuvant and neoadjuvant chemotherapy during the current analysis period (age ≤ 70 years), 7.2: adjuvant combination chemotherapy with anthracyclines and/or taxanes, 8: percentage of patients in clinical trials, 9a: radiotherapy after breast-conserving surgery, 9b: radiotherapy after breast-conserving surgery for DCIS, 10: radiotherapy after mastectomy, 11b: indication for breast-conserving therapy at T1.

**Abbildung 3.** Relativer Erfüllungsgrad der Qualitätsindikatoren (QIs) im Zeitraum 2003–2009 als Prozentsatz der jeweiligen Vorgabe für das dritte Jahr der Zertifizierung gemäß den Fachlichen Anforderungen an Brustzentren (FAB). QI No. 1 (präoperativ histologisch gesicherte Diagnose verglichen mit den schärferen DKG/DGS-Kriterien von 90% für tastbare Tumoren bzw. 70% für nicht tastbare Tumoren. Das Benchmarking unterscheidet derzeit nicht zwischen tastbaren und nicht tastbaren. „ex-3" (Daten zum vollständigen Tumor Staging) und „ex-4" (HER 2/neu-Erfassung) wurden Ende 2006 aufgegeben und 2007 durch QIs „3"n (Angaben zum Sicherheitsabstand zwischen Tumor und Resektionsrand) und „4" ersetzt (Specimen Imaging). „Relative Performance" war für QIs ex-7.1b, 7.1b, ex-7.2a–d, 11a und 11c–e nicht definiert, da relevante DKG/DGS-Kriterien fehlten. 1: präoperative histologische Diagnosesicherung; 2a: ausreichende „Axillary Dissection"; 2b: Patienten mit Wächterlymphknoten-Biopsie; ex-3: vollständiges Tumor-Staging; 3: Sicherheitsabstand zwischen Tumor und Resektionsrand; ex-4: HER-2/neu-Status; 4: „Specimen Imaging"; 5: Hormonrezeptor-Status, 6: leitliniengerechte endokrinologische Therapie Hormonrezeptor-positiver Patientinnen; ex-7.1a: leitliniengerechte adjuvante und neoadjuvante Chemotherapie im vorherigen Untersuchungszeitraum (Alter ≤ 70 Jahre); 7.1a: leitliniengerechte adjuvante und neoadjuvante Chemotherapie im aktuellen Untersuchungszeitraum (Alter ≤ 70 Jahre); 7.2: adjuvante Kombinationschemotherapie mit Anthrazyklinen und/oder Taxanen; 8: Prozentsatz von Patientinnen in klinischen Studien; 9a: Strahlentherapie nach brusterhaltender OP; 9b: Strahlentherapie nach brusterhaltender OP eines DCIS; 10: Strahlentherapie nach Mastektomie; 11b: Indikation zur brusterhaltenden Therapie bei T1.

When the present nationwide, voluntary benchmarking program was implemented in Germany in 2003 as the first of its kind, it was unclear whether it would be possible to objectify quality of care and outcome quality. In the absence of long-term indicators of outcome quality in breast cancer care, e.g., morbidity and mortality rates, which require data covering at least 5–10 years, it was first necessary to define quality targets and use clinical measures based on the relevant level-3 guidelines [16, 17] to derive process QIs as surrogates for outcome quality. The performance of these process QIs over time has enabled us within a few years to objectify the extent of adherence to the process quality generally recognized as necessary for high-quality care.

The 7-year data reported here support the hypothesis that improvements in the quality of cancer care can be achieved and objectified by benchmarking and measuring the perfor-

**Table 3.** Quality indicators relevant to radiation oncology and the changes during 2003–2009 in their relative performance as a percentage of the DKG/DGS requirements.

**Tabelle 3.** Radioonkologisch relevante Qualitätsindikatoren und die Entwicklung ihres relativen Erfüllungsgrads als Prozentsatz der jeweiligen DKG/DGS-Vorgabe im Zeitraum 2003–2009.

| QI No. | Quality indicator (QI) | Tracked | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 | 3rd-year DKG/ DGS requirement |
|---|---|---|---|---|---|---|---|---|---|---|
| [ex-3][a] | *Complete tumor staging data* | *2003–2006* | *89%* | *101%* | *103%* | *100%* | | | | >95% |
| 3 | Data on safety distance between tumor and resection margin | 2007–2009 | | | | | 91% | 97% | 98% | 100% |
| 4 | Specimen radiography (2007: preoperative in patients with microcalcifications; 2008: intraoperative) | 2007–2009 | | | | | 87% | 98% | 97% | >95% |
| 8 | Percentage of patients in clinical trials | 2005–2009 | | | 40% | 35% | 35% | 40% | 60% | ≥20% |
| 9a | Radiotherapy after breast-conserving surgery | 2003–2009 | 21% | 48% | 63% | 74% | 83% | 84% | 89% | >95% |
| 9b | Radiotherapy after breast-conserving surgery for DCIS | 2008–2009 | | | | | | 130% | 150% | >50% |
| 10 | Radiotherapy after mastectomy | 2003–2009 | 10% | 33% | 44% | 59% | 81% | 81% | 88% | >80% |

[a]Square brackets and italics indicate QIs which were discontinued at the end of 2006 or 2007.

mance of QIs. Among the initially nine, currently 15 main QIs investigated in the present study, three (Nos. 9a, 9b, and 10) are directly related to breast cancer radiotherapy and another three (Nos. ex-3, 3, and 4) are also of interest to the radiation oncologist as they are relevant to radiotherapeutic decision-making. During 2003–2009, radiotherapy after breast-conserving surgery (QI 9a) increased from 20% to 85%, and radiotherapy after mastectomy (QI 10) increased from 8% to 70%. In view of the initial situation, these findings appear to indicate dramatic increases in the quality of radiotherapy over the study period. These improvements are likely due, on the one hand, to better documentation but may, on the other hand, also reflect a later increase in more guideline-concordant decision-making about adjuvant therapy. Moreover, it must be borne in mind that the program initially covered only the very limited number of 6,000 patients from as few as 59 breast centers, and this raises some doubt as to whether the early data actually provide a representative picture of the situation in radiation oncology care in Germany at that time. In fact it appears likely that initially patients receiving treatment were lost to documentation due to inadequacies in the documentation procedures, resulting in underestimation of treatment and, hence, overestimation of subsequent increases in the quality of radiation oncology care. Nonetheless, the QI increases observed later in the study can be assumed to reflect actual improvements in quality of care, not least because regular monitoring visits contributed substantially to eliminating the initial deficits in treatment documentation. The increase observed for QI 9b, on the other hand, appears far more credible than the dramatic increases in QIs 9a and 10 because QI 9b was introduced only recently, at a time when data collection and data administration were fully established. Furthermore, evidence-based guidelines were not available initially, and the indications for adjuvant radiotherapy, though they had been clearly formulated, were not yet

widely known [24]. This situation changed when the DKG and DGGG published evidence-based guidelines for the diagnosis, treatment, and follow-up care of breast cancer in 2004 [16], updating them in 2008 [17]. More recently, the German Society of Radiation Oncology (DEGRO) added supporting practical guidelines on breast-conserving therapy [19], postmastectomy radiotherapy, irradiation of regional lymphatics and treatment of locally advanced disease [20], and palliative radiotherapy of breast cancer-related brain metastases and leptomeningeal carcinomatosis [14] as well as bone metastases and metastatic spinal cord compression [23].

By 2009, the performance levels of QIs 9a and 10 had practically reached the respective DKG/DGS requirements. With QI No. 9b, which was newly introduced in 2008, the first- and second-year performance levels of 65% and 75% already exceeded the DKG/DGS requirement of 50% introduced in 2009. This likely reflects the increasing implementation of the DEGRO guidelines.

A meta-analysis published in 2005 investigating the effects of radiotherapy and of differences in the extent of surgery for early breast cancer on local recurrence and 15-year survival is also likely to have prepared the ground for the still growing acceptance of adjuvant radiotherapy in breast cancer [11]. It conveyed, also to the nonradiation oncologist, the evidence supporting the multiple benefits of radiation treatment in terms of both local and locoregional tumor control and patient survival if radiotherapy is systematically included as an integral part of a multimodal treatment plan. Several recent studies have also found radiotherapy to have beneficial effects on the survival of breast cancer patients [15, 25, 26].

As regards the QIs Nos. ex-3, 3, and 4 (complete tumor staging data, data on safety distance, and specimen imaging, respectively), the third-year DKG/DGS requirements were essentially met by 2006 (No. ex-3) or 2008 (Nos. 3 and 4).

Overall, the present 7-year data confirm the trends seen in the 4- and 5-year results previously reported and discussed in detail by Brucker et al. [6, 7]. The success of the German voluntary benchmarking program for quality in breast cancer care is evidenced by the 3.86-fold increase in participating centers from 59 to 228 and the 6.30-fold increase from 5,994 to 37,740 in patients with primary breast cancer (as confirmed by postoperative histology) from 2003 to 2009 and the remarkable cumulative number of more than 167,000 datasets collected by the end of 2009.

The numerous challenges encountered when designing, setting up, and funding such programs, even at the institutional and regional levels, have recently been reported e.g., for the United States, where the American Society of Clinical Oncology (ASCO) and the National Comprehensive Cancer Network (NCCN) have collaborated to identify quality-of-care measures for breast cancer and other malignancies with the ultimate aim of implementing performance metrics at the national level [3, 9, 18].

### Conclusion

The high incidence of breast cancer and the necessity for structured multidisciplinary care makes this cancer an ideal candidate to investigate whether a national scientific benchmarking program based on voluntary documentation of all treatment procedures and collection, centralized compilation, and external analysis of the data can be used to measure and evaluate of the quality of cancer care. The acceptance of the benchmarking concept and its postulates is evidenced by the increasing numbers of breast cancer patients treated at the participating breast centers in Germany – most of them now DKG/DGS certified – from 15% in 2003 to about 70% in 2009. Thus, the voluntary benchmarking program reported here has enabled the first direct, objective, and valid assessment of the reality of breast cancer care at specialist breast centers in Germany. It has proved a clinically orientated, practical, flexible, adaptable, and extensible tool for measuring and improving the quality of BC care. The course of the disease, and its treatment, can now be followed longitudinally for each individual breast center. Finally, in the age of the creation and certification of specialist breast centers, improvements in the primary treatment of breast cancer have been achieved by rapid increases in indication-appropriate radiotherapy and other cancer treatments between 2003 and 2009.

### Abbreviations

BC: breast cancer; BCS: breast-conserving surgery; BCT: breast-conserving therapy; DGGG: Deutsche Gesellschaft für Gynäkologie und Geburtshilfe (German Society of Obstetrics and Gynecology); DGS: Deutsche Gesellschaft für Senologie (German Society of Senology); DCIS: ductal carcinoma in situ; DEGRO: Deutsche Gesellschaft für Radioonkologie (German Society of Radiation Oncology); DKG: Deutsche Krebsgesellschaft (German Cancer Society); DOC: Deutsch-es Onkologie Centrum Holding GmbH (German Oncology Centre Ltd.); EUSOMA: European Society of Breast Cancer Specialists (formerly: of Mastology); FAB: Fachliche Anforderungen an Brustzentren (Requirements of Breast Centers); HER-2/neu: human epidermal growth factor receptor 2; PQI: process quality indicator; QA: quality assurance; QI: quality indicator; QM: quality management; SLNB: sentinel lymph node biopsy; SQL: structured query language; WBC: Westdeutsches Brust-Centrum (West German Breast Center); XML: extensible markup language.

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