The story of prosperity in certification of Breast Centres: a model of comprehensive Cancer and Organ Centres

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Rationale

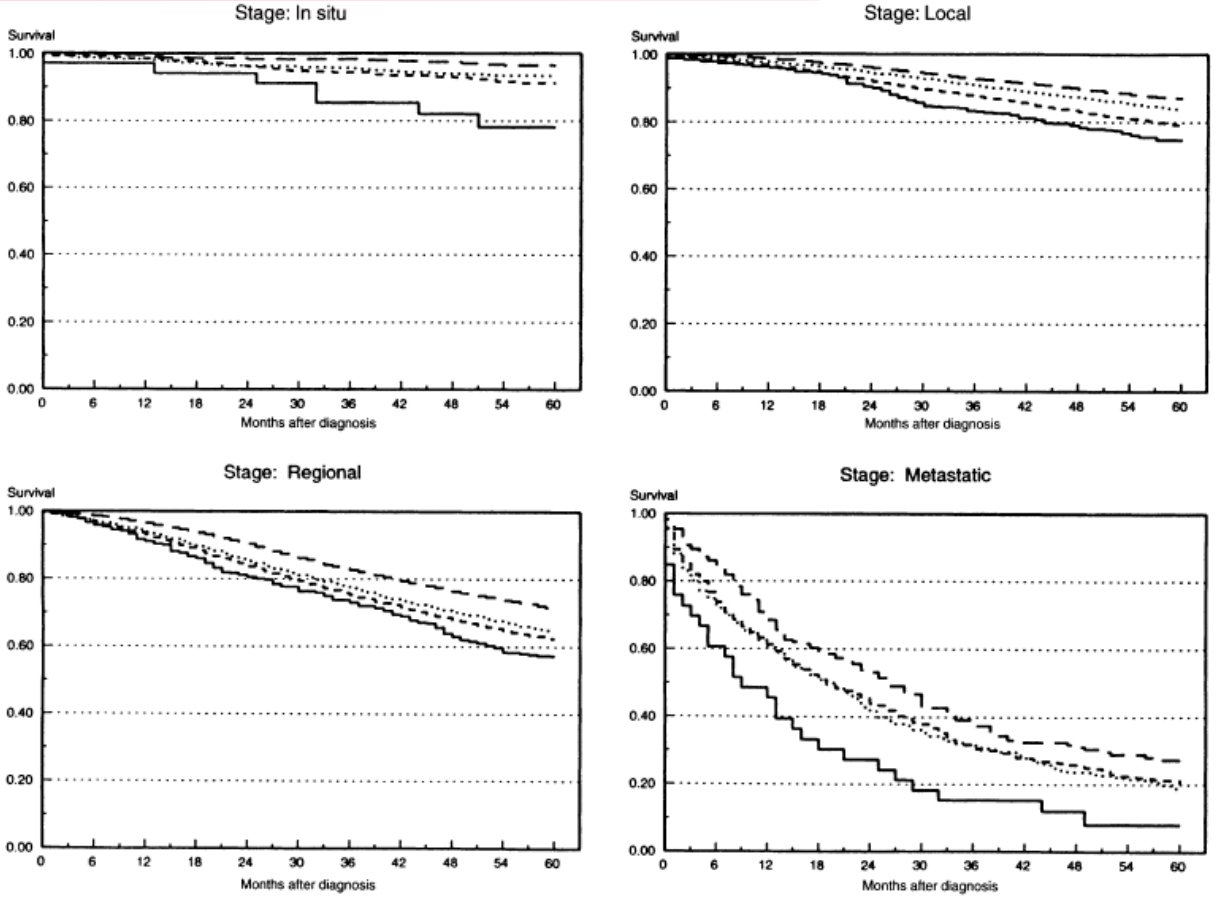
- Centralization
- Specialization
- Multidisciplinarity

Centralization

Hospital Volume Differences and Five-Year Survival from Breast Cancer

Patrick J. Roohan, MS, Nina A. Bickell, MD, MPH, Mark S. Baptiste, PhD, Gene D. Therriault, MSPH, Elysa P. Ferrara, MPA, and Albert L. Siu, MD, MSI

Results:
At 5 years, patients
from very low-volume
hospitals
had a 60% greater risk of all-cause mortality than patients from highvolume hospitals.



Note. Hospital volume was defined as number of breast cancer surgeries per year:
Very low (<10) per year ———
Low (11–50) per year - - - - - - -
Moderate (51–150) per year — - - — - -
High (151+) per year – —— — —

FIGURE 1—Breast cancer survival, by cancer stage and hospital volume: patients hospitalized in New York State between 1984 and 1989.

American Journal of Public Health March 1998, Vol. 88, No. 3

Specialization

Survival outcome of care by specialist surgeons in breast cancer: a study of 3786 patients in the west of Scotland

Charles R Gillis, David J Hole

Key messages
• Patients with breast cancer have 9% better survival at five years and 8% better survival at 10 years when cared for by specialist surgeons • This finding is not a consequence of case mix or selective referral • The maximum survival benefit for patients was seen in those aged 50-64 years and applied across all socioeconomic groups • The findings could have implications for policies in cancer treatment and for purchasing cancer services

BMJ 1996;312:148-53

Multidisciplinarty

Annals of Oncology **9**: 365–374, 1998.

Review

Do specialists do it better? The impact of specialization on the processes and outcomes of care for cancer patients

R. Grilli,[1] S. Minozzi,[1] A. Tinazzi,[2] R. Labianca,[3] T. A. Sheldon[4] & A. Liberati[5]

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18% reduction in mortality!

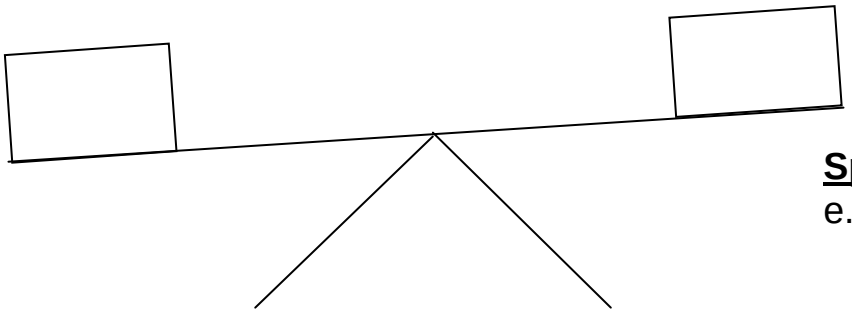
Certified Multidisciplinary Breast Centres

Centralization (Case Load/Center): OAS ↑↑ **[> 150 OP/a]** *Roohan, 1998*

Specialization (Case Load/Surgeon): OAS ↑ (10%) **[> 30 OP/a]** *Gillis, 1996*

Multidisciplinarity („process chain") OAS ↑↑ (18%) [LL] *Grilli, 1998*

Multidisciplinarity
e.g. Breast Cancer



Specialisation
e.g. Colon or Ovarian Cancer

Onkologe 2005, Brucker, Kreienberg, Jonat, Bamberg, Wallwiener et al.

A nationwide network of breast centres

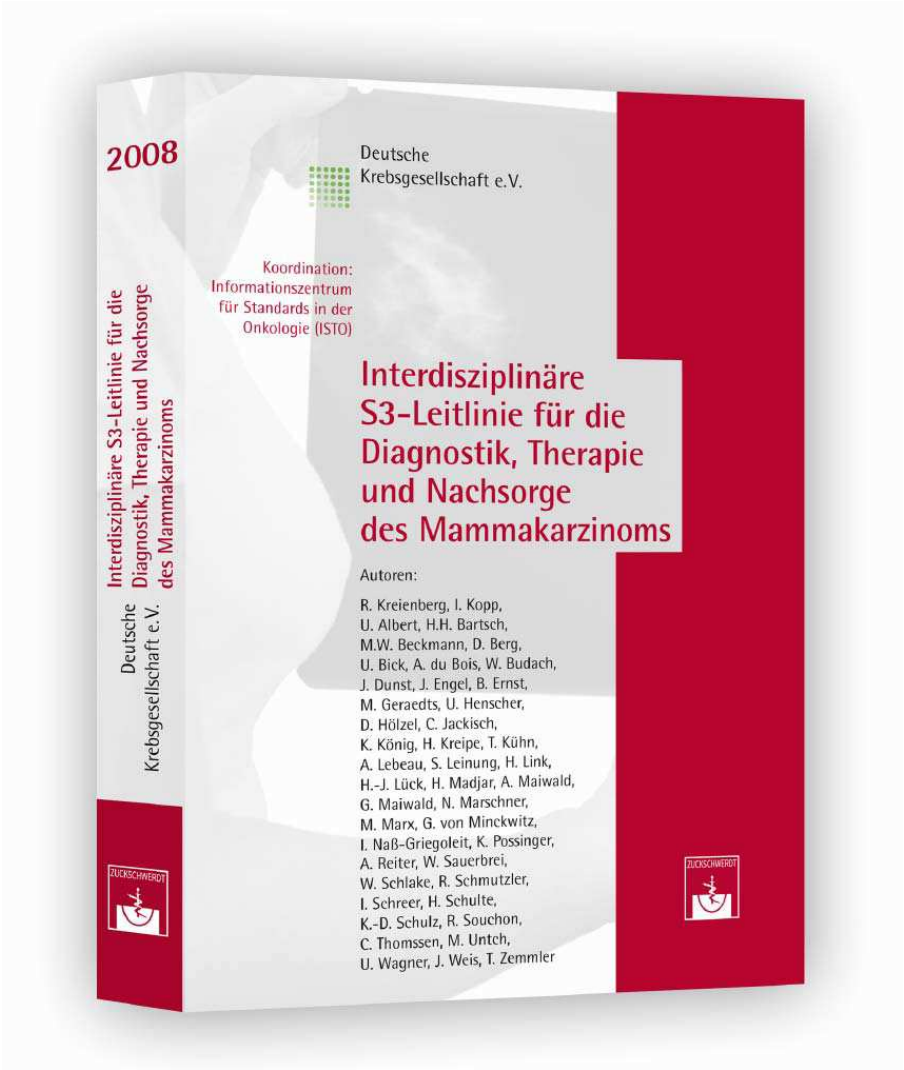
What had to be done?

The 3 basic steps

1. Guidelines
2. Certification
3. Benchmarking

(+ Screening Program)

S3-Guidline


2008
Deutsche Krebsgesellschaft e.V.
Koordination: Informationszentrum für Standards in der Onkologie (ISTO)
Interdisziplinäre S3-Leitlinie für die Diagnostik, Therapie und Nachsorge des Mammakarzinoms
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Certification

Requirements for Certification (185 items)

Table 1: The DKG/DGS Requirements of Breast Centres (FAB): structure and general overview

1	**General information on the breast centre** Structure of the network; tumour board/treatment planning; collaboration with doctors in private practice; access to support groups; psychosocial and psycho-oncological care; aftercare and follow-up; patient involvement; scientific research activities
2	**Information on radiology services** Mammography equipment; stereotactic biopsy requirements; magnetic resonance imaging; breast ultrasound; radiography assistants; specialist radiologists (min. 2 names); basic and continuing medical education; quality circles (≥ 4 minuted meetings per year); number of mammograms read (> 2000/year (per breast)); specimen radiography; percutaneous biopsies (number); image-guided localisations (number); ductography (galactography) (images/year); description of techniques and procedures used; guidelines (fulfilment of requirements)
3	**Information on nuclear medicine services** Medical laboratory assistant (min. 2 names); specialist doctors (min. 2 names); continuing education for medical and paramedical staff; quality circles (≥ 4 minuted meetings per year); number of bone scintigrams (1st/3rd year requirement: > 200/> 400); sentinel node biopsies (SNBs, (1st/3rd year requirement: > 20/> 30); SNB detection rate (1st/3rd year requirement: > 80%/> 90% (gamma probe guided)), (1st/3rd year requirement: > 80%/> 90% (scintigraphy; optional)); quality control testing of equipment; fulfilment of relevant level-3 guideline requirements
4	**Information on surgical treatment – surgery – gynaecology – specialist breast services** Inpatient care; description; sufficient time for patients to consider treatment choices between core biopsy results and surgery (max. 14 days); operating theatre (OT) for breast surgery (min. 1 OT); continuing education of nursing staff; nursing staff (min. 2 full-time nurses/100 primary cases); specialist cancer nurse (min. 1); basic and continuing education for medical and paramedical staff; specialist doctors for the breast centre (min. 2 names); breast surgeons (min. 2 with specialist qualifications); details of breast surgeons' qualifications; quality circles (≥ 4 minuted meetings per year); number of primary breast cancers per surgeon: > 50 per year; total number of surgical procedures (axillary dissections (1st/3rd year requirement: > 85%/> 95%), revision procedures (< 5%), postoperative wound infections (2.5-max. 5%)); number of operations for breast tumours (benign, precancerous, primary, recurrences), primary carcinomas per centre per year (1st/3rd year requirement: > 100/> 150); number of pTis (1st/3rd year requirements: > 10%/> 15%); number of benign/malignant open biopsy findings; postoperative specimen radiography of microcalcifications after preoperative marker placement > 95%; rate of breast-conserving surgery (1st/3rd year requirement for pT1: > 50%/> 70%); mastectomy rate (1st/3rd year requirement for pT1: < 50%/< 30%); primary surgical treatment involving 1, 2, 3 or > 3 procedures, and rate of R1 resections; mean number of removed lymph nodes > 10 (in accordance with the guideline); breast reconstruction (responsibilities, details of collaboration if performed elsewhere, type of reconstruction procedure, surgeon's qualifications, general reconstructive surgery requirements); patient information and discussion of treatment options; breast clinics at least once weekly for early detection, treatment planning, advice to outpatients considering reconstruction, advice on benign breast disease, inflammation and impaired development (waiting times for clinic appointments/consultation < 2 weeks/1 hour); biopsies for histology (results after < 6 days); histological confirmation of tumour status (by core biopsy) in 90% of palpable and 70% of nonpalpable tumours; communication of tumour status diagnosis within < 1 week; documentation of the number of patient who refuse treatment; side-effects of treatment; knowledge and implementation of level-3 guideline.

Requirements for Certification

5 Information on radiotherapy services

High energy radiotherapy equipment (minimum specifications, other requirements); description of radiotherapy techniques (guideline-concordant dose regimen); radiography assistants (min. 2); continuing education for medical and paramedical staff; quality circles (≥ 4 minuted meetings per year); specialist radio-oncologists (min. 2); aftercare and follow-up; documentation/tumour assessments, reactions to radiotherapy (acute, subacute, late); compliance with level-3 guideline for treatment; written patient information during and after radiotherapy; applicable level-3 radiotherapy guidelines

6 Information on pathology services

Specialist pathologists (min. 2 names); qualifications: details of expertise in breast histology and cytology; continuing education for medical and paramedical staff; external quality assurance; quality circles (≥ 4 minuted meetings per year); specialist experience: examination of 200 routine histological specimens from breast disease patients and 3000 histological specimens; rapid frozen sectioning (infrastructure, cryostat); number of rapid frozen sections performed per year; time to result; lymph node examination; specimen storage time: paraffin blocks ≥ 10 years, wet specimens ≥ 4; weeks; gross, microscopic and immunohistochemical examination and diagnosis; standardised processing for gross examination according to level-3 guideline; pathologist's report on breast specimens (except diagnostic core biopsies) must contain guideline-specified details for the gross pathology report microscopic examination; resection/safety margins; pT and pN status for > 95% of invasive tumours; measurable receptors (hormone receptors (> 95%), HER2/neu (> 95%), FISH analysis if necessary)

7 Information on oncology services (gynaecology, medical oncology, inpatient/outpatient services)

Specialist oncologist (internist or gynaecologist, experienced in chemotherapy (≥ 800 treatment cycles) and endocrine, immunological, adjuvant, palliative and supportive therapy and treatment of side effects); quality circles (≥ 4 minuted meetings per year); continuing education for medical and paramedical staff; ≥ 50 breast cancer chemotherapies/year per treatment unit or partner, or ≥ 200 chemotherapies/year for various cancers; provision of inpatient and outpatient chemotherapy; appropriate infrastructure; min. 2 chemotherapy rooms; description of facilities for supportive/palliative care; description of treatment phases during chemotherapy (initiation to termination); provision of information to patients and dialogue with patients; compliance with relevant level-3 guideline requirements

8 Tumour documentation/outcome quality

Details of tumour documentation system (TDS), which must contain complete patient and treatment details for ≥ 3 months prior to initial certification, details of treatment stage, data for cancer registries; guideline-compliant data sets; data collection by calendar year and certification period; responsible documentation manager; 50% position/breast centre for data collection-related tasks; data selection options must include by year, patient's name, diagnosis, type of treatment, date of recurrence/metastasis, survival data; outcome quality indicators: disease-free survival (DFS), overall survival (OAS), date and proportion of recurrence per stage and type of surgery (breast-conserving surgery (BCS) vs. mastectomy); date and location of metastasis; quality of life; Kaplan-Meier curves (local recurrence-free survival and OAS, by relevant prognostic groups, survival from progression); comparisons with other breast centres; multivariate analyses; appraisal of achievement of TDS objectives (transparency); DFS and OAS must be available at recertification every 3 years; 10-year recurrence rates for mastectomy/BCS: < 10%/< 15%; completed questionnaire and relevant process descriptions must be available at initial certification; documented data must be accessible; uses for TDS data: at least once-yearly in-house analysis of the data, centre-specific and comparative analyses, analysis-based improvements; archiving of results (data analysis, appraisal, actions); discussion of results with the main collaborating partners and the breast centre network as a whole; compliance of data with guideline requirements; responsible physicians' awareness of their data compared with other centres and the literature (quality of data, quality of care); appraisal of flexibility of documentation

The FAB of 2006 encompass 185 items from eight main areas. Applicant breast centres need to (1) describe existing facilities, resources and procedures and (2) meet specified requirements in order to attain initial or full certification and recertification.

Certificationprocess

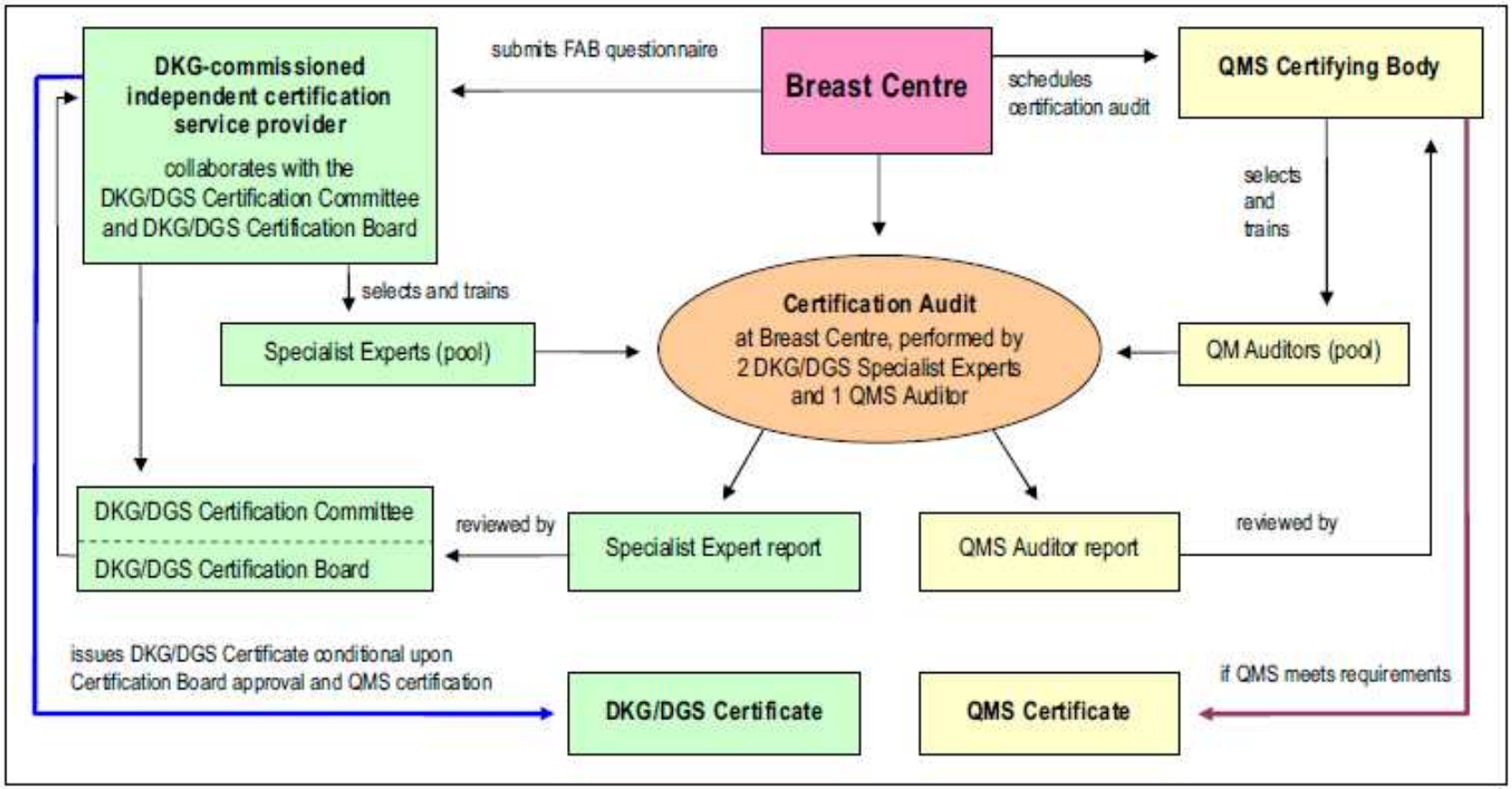

Figure 1
Dual certification of breast centres to the DKG/DGS Requirements (FAB) and an accepted QMS standard. Adapted from [23] and [11]. DKG = German Cancer Society; DGS = German Society of Senology; QM(S) = quality management (system).

Certified centres

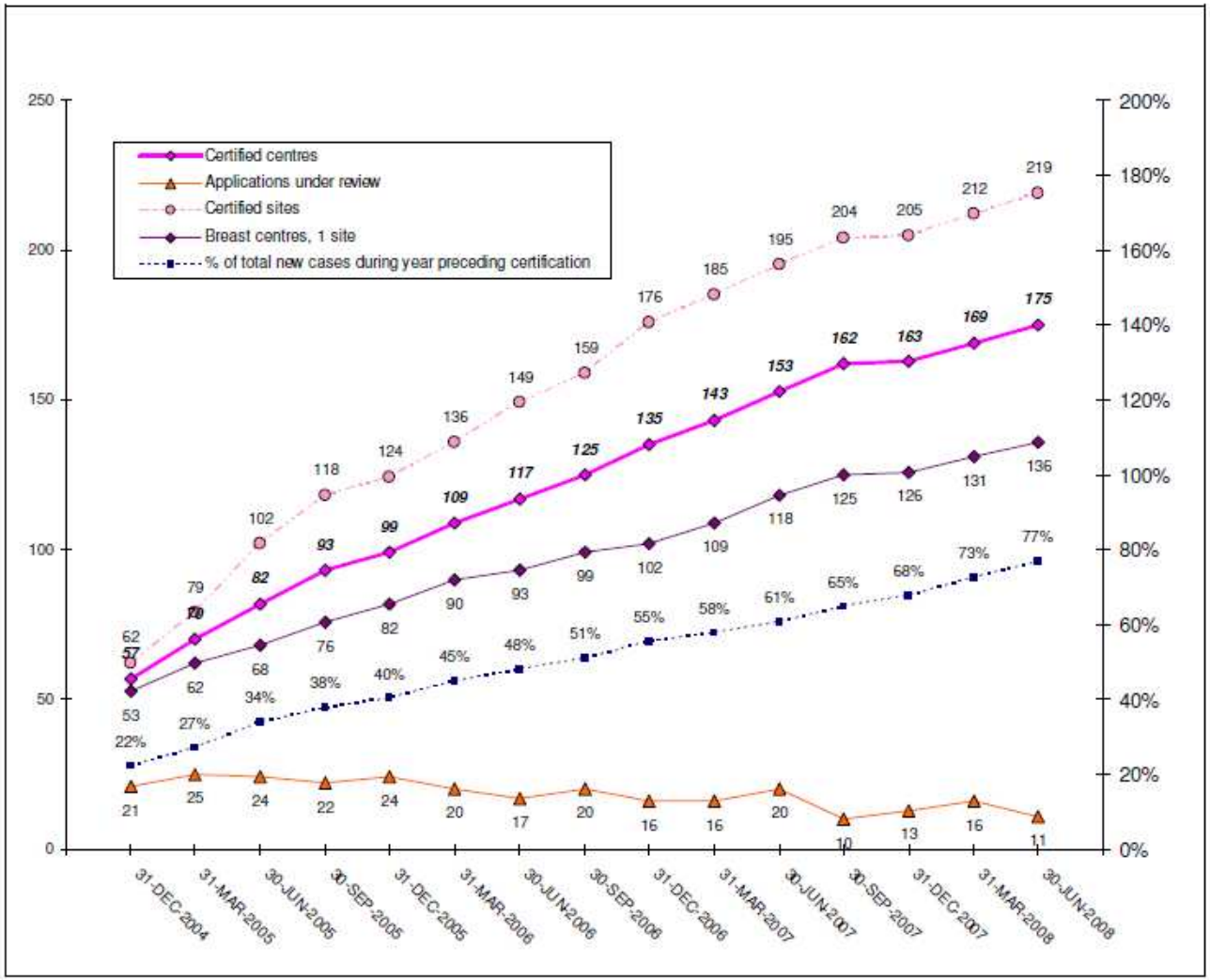

Figure 2
DKG/DGS-certified breast centres: applications, certified centres and sites, and primary cases/year treated at certified centres.

Certification

BMC Cancer

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Research article

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Certification of breast centres in Germany: proof of concept for a prototypical example of quality assurance in multidisciplinary cancer care

Sara Y Brucker[†1], Michael Bamberg[†2], Walter Jonat[3], Matthias W Beckmann[4,5], Andreas Kämmerle[6], Rolf Kreienberg[†7,8] and Diethelm Wallwiener*[†1]

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Benchmarking – Quality Indicators

Benchmarking

Table 1: Quality indicators (QIs) used in the new, nationwide system for benchmarking breast cancer care in 2007

QI No.	Quality indicator (QI)	Introduced	Based on	Quality target	DKG/DGS (FAB) requirement
1	**Preoperative histological confirmation of diagnosis**	2003	L3-GL/ED-BC (2003)	Frequent preoperative histological confirmation of diagnosis in invasive breast cancer	> 90% (palpable tumours), > 70% (nonpalpable tumours)
2	**Appropriate axillary dissection**	2003	L3-GL/DT-BC (2004)	Appropriate axillary dissection in all patients with invasive breast cancer (axillary clearance)	> 85% at initial certification; > 95% after 3 years
[ex-3][a]	***Complete tumour staging data***	*2003*	*L3-GL/DT-BC (2004)*	*Complete information on tumour stage (T-N-M-R-G) for all patients*	*> 95% for pT and pN in invasive BC*
3	**Data on safety distance between tumour and resection margin**	2007	L3-GL/DT-BC (2004)	Data on safety distance for all patients	Pathologist's report must state the resection margin and minimum safety distance in 100% of cases (exceptions require justification)
[ex-4][a]	***HER-2/neu assessment***	*2005*	*Generally accepted criterion*	*Frequent assessment of HER-2/neu status*	*> 95% in invasive BC*
4	**Specimen radiography**	2007	Generally accepted criterion	Specimen radiography after preoperative wire localisation	Postoperative specimen radiography of microcalcifications following preoperative wire localisation in > 95% of cases
5	**Hormone receptor assessment**	2003	L3-GL/DT-BC (2004)	Assessment of hormone receptor status in all patients	100% (except in justified cases)
6	**Appropriate endocrine therapy in hormone receptor-positive patients**	2003	L3-GL/DT-BC (2004)	Endocrine therapy in all hormone receptor-positive patients	> 70% at initial certification; > 95% after 3 years

Benchmarking

7.1	**Appropriate adjuvant and neoadjuvant chemotherapy**	2003	L3-GL/DT-BC (2004)	Frequent appropriate adjuvant or neoadjuvant chemotherapy in breast cancer patients with negative hormone receptor status, or with ≥ 4 affected lymph nodes irrespective of receptor status	See 7.1a and 7.1b
7.1a	during the current 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
7.1b	during the current analysis period; no age limit	2003	L3-GL/DT-BC (2004)	See QI 7.1	n. d.
7.2	**Use of appropriate standard regimens in chemotherapy**	2005	n. d.	Frequent use of appropriate standard regimens in chemotherapy	n. d.
7.2a	during the current analysis period; age ≤70 years	2006	n. d.	See QI 7.2	n. d.
7.2b	during the current analysis period; no age limit	2005	n. d.	See QI 7.2	n. d.
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

Benchmarking

9	**Appropriate radiotherapy after breast-conserving therapy**	2003	L3-GL/DT-BC (2004)	Appropriate radiotherapy for all patients receiving breast-conserving therapy	Complete record of the number of radiation treatments; exceptions require justification
10	**Appropriate radiotherapy after mastectomy**	2003	L3-GL/DT-BC (2004)	Appropriate radiotherapy for all mastectomy patients	Complete record of the number of radiation treatments; exceptions require justification
11	**Indication for breast-conserving therapy**	2003	L3-GL/DT-BC (2004)	Appropriate indication for breast-conserving therapy in all patients	Breast-conserving surgery for pT1 tumours; > 50% at initial certification, > 70% after 3 years
11a	at any tumour stage	2003	L3-GL/DT-BC (2004)	See QI 11	n. d.
11b	at T1	2005	L3-GL/DT-BC (2004)	See QI 11	Breast-conserving surgery for pT1 tumours; > 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.

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)
L3-GL/DT-BC (2004) = Interdisciplinary S3 guidelines for the diagnosis and treatment of breast cancer in women (2004)
[a] *Square brackets and italics indicate QIs which were discontinued at the end of 2006*; n. d. = no details.
Numbering and names of current QIs and their year of introduction, rationale, quality target and DKG/DGS requirements for years 1 and 3 of DKG/DGS certification.

Benchmarking

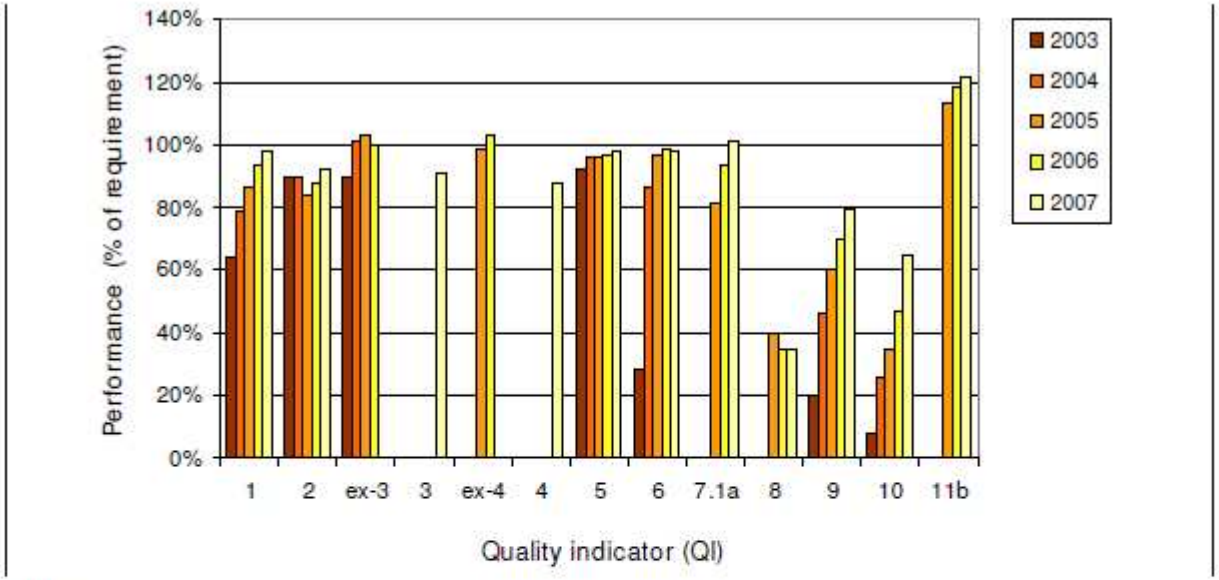

Figure 3
Performance of quality indicators (QIs) compared to the respective DKG/DGS Requirements of Breast Centres (FAB) during the 2003–2007 period. QIs Nos.: 1 = Preoperative histological confirmation of diagnosis; 2 = Appropriate axillary dissection; [ex-3] = Complete tumour staging data; 3 = Data on safety distance between tumour and resection margin; [ex-4] = HER-2/neu assessment; 4 = Specimen radiography; 5 = Hormone receptor assessment; 6 = Appropriate endocrine therapy in hormone receptor-positive patients; 7.1a = Appropriate adjuvant and neoadjuvant chemotherapy during the analysis period, age ≤70 years; 8 = Percentage of patients in clinical trials; 9 = Appropriate radiotherapy after breast-conserving therapy; 10 = Appropriate radiotherapy after mastectomy; 11b = Indication for breast-conserving therapy at T1. QI No. 1 *(Preoperative histological confirmation of diagnosis)* was compared against the stricter DKG/DGS requirement of 90% (for palpable tumours as opposed to 70% for nonpalpable tumours) as the benchmark. The benchmarking system does not currently distinguish between palpable and nonpalpable tumours. QIs labelled "ex-3" *(Complete tumour 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 tumour and resection margin)* and "4" *(Specimen radiography)* in 2007. Relative performance was not defined for QIs 7.1b, 7.2a, 7.2b, 11a and 11.c-e in the absence of relevant DKG/DGS requirements.

Benchmarking

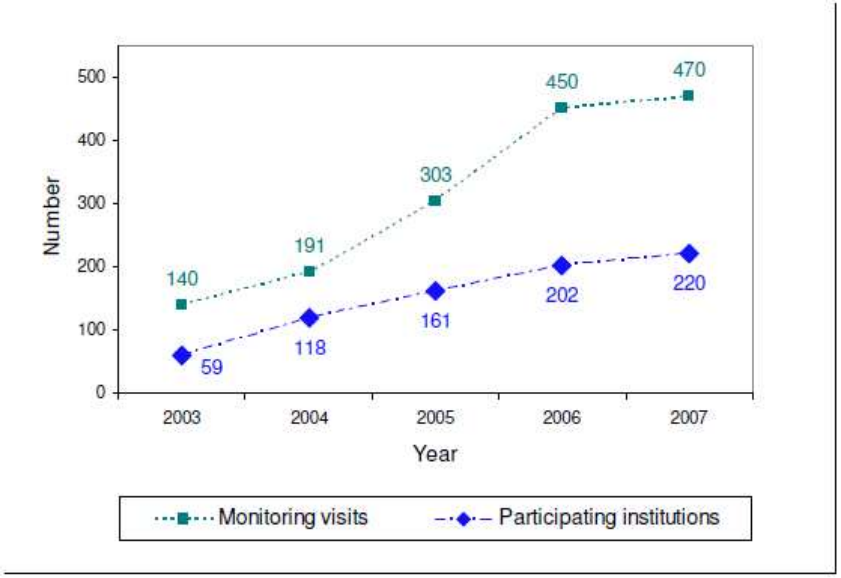

Figure 1
Number of breast centres participating in the benchmarking of breast cancer care and number of monitoring visits during 2003–2007.

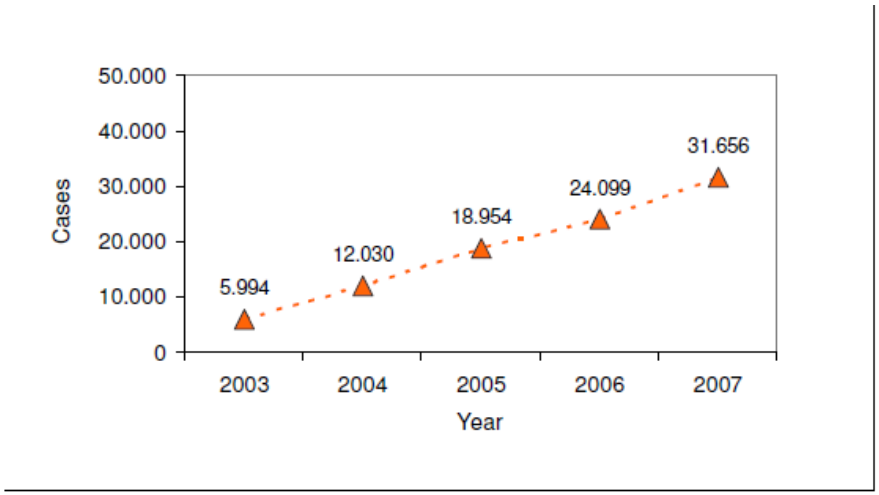

Figure 2
Histologically confirmed primary breast cancers reported by the participating institutions during 2003–2007.

Benchmarking

BMC Cancer

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Research article

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Benchmarking the quality of breast cancer care in a nationwide voluntary system: the first five-year results (2003–2007) from Germany as a proof of concept

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Breast Centres

Do we really do better?

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Does guideline-adherent therapy improve the outcome for early-onset breast cancer patients?

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Abstract

BACKGROUND AND OBJECTIVE: Guidelines for the treatment of early-onset breast cancer have been proposed in several countries, but to date, their impact on outcomes is unverified. The objective of this study was **to evaluate the association between guideline-adherent versus nonadherent treatment and recurrence-free survival (RFS) and overall survival (OAS) in early-onset breast cancer patients.**

METHODS: A total of 1,778 patients were included in the study, of whom 111 were 35 years or younger and 1,667 were between 36 and 55 years. RFS and OAS were compared between the two groups, with respect to multiple parameters. All survival data were adjusted for tumor characteristics and analyzed with respect to guideline adherence according to the German Step 3 guidelines.

RESULTS: Statistically significant differences between the two groups (<35 years, 36-55 years) were observed with regard to breast surgery (p = 0.002) and hormone therapy (p = 0.006). Both groups were treated identically in terms of guideline adherence concerning axillary dissection (p = 0.9), radiation therapy (p = 0.7) and chemotherapy (p = 0.556). Young breast cancer patients whose treatment adhered to guideline recommendations had increased RFS and OAS [RFS: p = 0.030, hazard ratio (HR) 2.95, 95% confidence interval (CI) 1.11-7.83; OAS: p < or = 0.001, HR 2.92, 95% CI 2.01-4.23].

CONCLUSION: **Guideline-adherent treatment for early-onset breast cancer patients significantly improves OAS and RFS and should therefore be demanded for all patients.**

Thank you!


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