

Case Numbers and Process Quality in Breast Surgery in Germany

**Plenary of the European Commission Initiative on Breast Cancer (ECIBC):
"Improving breast cancer screening, diagnosis and care in Europe"
Lago Maggiore District, Italy, 10 December 2015**

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Agenda

- **Introduction**
 - Volume-Outcome-Relationships
 - Minimum Provider Volumes in Germany
 - Quality Assurance in Breast Surgery

Breast Cancer Centers in Germany
- **Case Numbers and Process Quality in Breast Surgery in Germany**
- **A look in the future / possible solutions**
 - a) mandatory quality assurance
 - b) hospital planning using quality indicators
 - c) minimum provider volumes
 - d) oncologic (breast cancer) centers
 - e) EU-Projects; EU-Guidelines

Introduction

- In recent decades, numerous studies have addressed outcome relationships in medical care provision
- Positive association between case numbers (per hospital; operation per surgeon) and the quality of medical care

Introduction

Explanations for volume-outcome-relationships

- Greater experience and routine
- Better placed to provide the necessary multidisciplinary treatment and / or
- Better infrastructure
- In Germany, a minimum number of more than 100 primary cases per year is required for certified breast cancer centers at first certification
- Alternative explanation:
High-Risk-Patients may increasingly attend smaller hospitals (which may be underestimated by risk adjustment methods)

Introduction

- In Germany federal laws postulated the introduction of “minimum provider volumes” for selected medical procedures (areas of medical care provision) by the joint federal committee (G-BA)

Regelungen



**des Gemeinsamen Bundesausschusses
gemäß § 137 Abs. 3 Satz 1 Nr. 2 SGB V für
nach § 108 SGB V zugelassene Krankenhäuser**

(Mindestmengenregelungen, Mm-R)

in der Fassung vom 20. Dezember 2005
veröffentlicht im Bundesanzeiger 2006 (S. 1373)
in Kraft getreten am 20. Dezember 2005

in der 1. Neufassung vom 21. März 2006
veröffentlicht im Bundesanzeiger 2006 (S. 5389)
in Kraft getreten am 21. März 2006

zuletzt geändert am 18. Juni 2015
veröffentlicht im Bundesanzeiger (BAnz AT 27.07.2015 B1)
in Kraft getreten am 28. Juli 2015

Introduction

- Minimum provider volumes” for which medical procedures (areas of medical care provision)?
 - Liver Transplantation 20 / Year and Hospital
 - Kidney Transplantation 25 / Year and Hospital
 - Esophagus Surgery 10 / Year and Hospital
 - Stem Cell Transplantation 25 / Year and Hospital
 - Knee Joint Prosthesis 50 / Year and Unit
 - VLBW (Level 1; < 1250g BW) 14 / Year and Hospital

Introduction

In Volume Outcome Analyses

- Mortality (Survival) => severe complication is frequently chosen as outcome measure
- High risk and low volume procedures of rare diseases are often analyzed

Introduction

Breast Surgery following Breast Cancer

- High Volume in EU

Estimated incidence and mortality from breast cancer, 2012

Country	Incidence		Mortality	
	Number	Rate	Number	Rate
Europe	458337	92.8	131259	23.1
European Union (27)	358967	106.6	90665	22.4

International Agency for Research on Cancer



World Health Organization

EUCAN

<http://eco.iarc.fr/eucan>

<http://eu-cancer.iarc.fr/eucan/CancerOne.aspx?Cancer=46&Gender=2>

- Low risk (short term outcome)
- Effect of recent health care quality may be difficult to describe

Objective/Aim

- To assess volume effects on the quality of health care provision in breast surgery, in Germany
- Using current data (up to date information)
- Entire health care setting

Not only in specialized units or selective samples of patients but comprehensive perspective

=> Recent and Population based data

Patients and Methods

Quality Assessment Programme (§ 137 Social Code, Book V)

- Compulsory for inpatients with breast surgery, since 2002
- Assessing Process Quality Indicators (adherence to guidelines)
- 2001-2009  Bundesgeschäftsstelle Qualitätssicherung
- 2010-2015  Institute for Applied Quality Improvement and Research in Health Care GmbH
- From 2016  Federal Institute for Quality Assurance and Transparency in Healthcare

Patients and Methods

Further information referring to the mandatory quality assessment programme (§ 137 Social Code, Book V) => www.sqg.de

SQG Cross-sectoral quality in health care

SEARCH

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TOPICS

AQUA Institute Project information


Cross-sectoral quality in Healthcare

SQG brings the quality assurance of the inpatient and outpatient sectors in Germany together, which have, up to now, been separate. Our goal is to meaningfully coordinate the quality requirements of both of these sectors in order to reach a better and more efficient quality of care in Germany.

Patients and Methods

Quality Survey (79 Items)

MUSTER - Nicht zur Dokumentation verwenden



Datensatz Mammachirurgie
18/1 (Spezifikation 2014 V06)

BASIS		Präoperative Diagnostik und Therapie	
Genau ein Bogen muss ausgefüllt werden			
14 Basisdokumentation		10	
1 Institutionskennzeichen <small>repro:instkenn</small>	□□□□□□□□	Einstufung nach ASA-Klassifikation <input type="checkbox"/>	
2 Entlassender Standort <small>repro</small>	□□	<ul style="list-style-type: none"> 1 = normaler, ansonsten gesunder Patient 2 = Patient mit leichter Allgemeinanästhesie und Lokalanästhesie 3 = Patient mit schwerer Allgemeinanästhesie und Lokalanästhesie 4 = Patient mit hohem/variabler Allgemeinanästhesie, mäßige Lebensbedrohung 5 = moribunder Patient 	
3 Betriebsstätten-Nummer	□□		
4 Fachabteilung <small>repro:instkenn repro:instkenn</small>	□□□□		
Schlüssel 1			
5 Identifikationsnummer der Patientin <small>repro:instkenn</small>	□□□□□□□□□□□□□□		
6 Geburtsdatum <small>repro:instkenn</small>	□□.□□.□□□□		
7 Geschlecht	<input type="checkbox"/>		
<ul style="list-style-type: none"> 1 = männlich 2 = weiblich 			
8 Aufnahme datum Krankenhaus <small>repro:instkenn</small>	□□.□□.□□□□		
9 Aufnahme diagnose(n) <small>repro:instkenn</small>			

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Patients and Methods

Study Population

- Fully inpatients
- Admitted 2013/14, Discharged before 31.Jan. 2015
- First surgical procedure for a primary tumor
- Histology:
„invasive breast cancer”
“ductal carcinoma in situ (DCIS)”

Data basis				
	2012	2013		
	Reported	Reported	Expected	Case completeness
Records	114,400	115,640	115,758	99.9 %
Hospitals	910	904	913	99.0 %

Patients and Methods

hospital volume (categories)

Defining case number categories on the basis of quintiles		
Category (quintile)	Number of patients	Number of hospitals
≤ 105	30 121	650
106–162	31 347	117
163–227	31 795	82
228–326	30 969	58
≥ 327	29 243	32
Total	153 475	939

Defining case number categories on the basis of case number groups defined beforehand		
Category (case number groups)	Number of patients	Number of hospitals
<50	11 223	525
50–99	17 052	116
100–149	24 172	97
≥ 150	101 028	201
Total	153 475	939

Patients and Methods

QI 1 Pretherapeutic histological confirmation of diagnosis

The indicator “Pretherapeutic histological diagnosis verification” (QI-ID 51846) was newly introduced as a modification of one indicator of the S3 guideline “Diagnosis, therapy and after-care of breast cancer”. As a result, a joint indicator for palpable and non-palpable findings was used for the first time with a reference range of $\geq 90.0\%$. The previous indicator group “Pretherapeutic diagnosis verification” has been omitted.

Patients and Methods

- QI 2: Intraoperative specimen radiography with sonographic wire marking: as large a number of interventions as possible with intraoperative specimen radiography after wire marking using sonography.
- QI 3: Primary axillary dissection in DCIS: as small a number of patients as possible with primary axillary dissection in DCIS and completed primary surgical treatment.
- QI 4: Lymph node removal in DCIS and breast conserving treatment: as small a number of patients as possible having axillary lymph nodes dissected in DCIS and breast conserving treatment after completed primary surgical therapy.
- QI 5: Indication for sentinel lymph node biopsy: as large a number of patients as possible having sentinel lymph node biopsy (SLNB) and without axillary dissection after completed primary surgical therapy and in lymph node–negative (pN0) invasive breast cancer.

Patients and Methods

- QI 6: A time interval of less than 7 days between diagnosis and operation: as small a number of patients as possible with a time interval of less than 7 days between pre-therapeutic histological diagnosis and date of surgery at first open procedure for primary invasive breast cancer or DCIS.
- QI 7 Time interval of more than 21 days between diagnosis and operation: as few patients as possible with a time interval of more than 21 days between pretherapeutic histological diagnosis and date of surgery in first open procedure for primary invasive breast cancer or DCIS.

Patients and Methods

- Process Indicators => no risk adjustment necessary
- Subgroup analyses (1)

Patients younger than 65 years

ASA1 or ASA2

pN0 node status

pT0 or pT1, according to the TNM classification

Quality Indicators 1, 2, 5-7

Patients and Methods

- Subgroup analyses (2)

Patients younger than 65 years

ASA1 or ASA2

(pN0 node status

pT0 or pT1)

Tumor size smaller than 5 cm

Indicators 3,4 (DCIS)

Patients and Methods

Statistical Methods

- Means per Volume Category (95% Confidence Intervals)
- Scatter Plots and Lowess Regression (Cleveland 1979)
(Rogowski et al.: JAMA 2004)

Results

Means of the quality indicators by the different categories, differentiated by case number categories

Category (quintile)	Number of patients	Mean (95% CI)	Category (case number groups)	Number of patients	Mean (95% CI)
QI 1 Pretherapeutic histological confirmation of diagnosis					
≤ 105	28 985	93.7 (93.4–93.9)	<50	10 740	90.8 (90.3–91.4)
106–162	30 185	96.7 (96.4–96.8)	50–99	16 457	95.3 (95.0–95.6)
163–227	30 957	97.0 (96.8–97.2)	100–149	23 318	96.6 (96.3–96.8)
228–326	30 069	96.8 (96.6–97.0)	≥ 150	98 347	96.8 (96.7–97.0)
≥ 327	28 666	96.8 (96.5–97.0)			

Subgroup analysis for quality indicators, differentiated by case number categories*

Category (quintile)	Number of patients	Mean (95% CI)	Category (case number groups)	Number of patients	Mean (95% CI)
QI 1 Pretherapeutic histological confirmation of diagnosis					
≤ 105	4160	97.7 (97.2 to 98.1)	<50	1223	96.7 (95.6 to 97.6)
106 to 162	5294	98.5 (98.1 to 98.8)	50 to 99	2607	98.0 (97.4 to 98.5)
163 to 227	5924	98.4 (98.1 to 98.7)	100 to 149	4115	98.6 (98.2 to 98.9)
228 to 326	5669	98.6 (98.3 to 98.9)	≥ 150	19 043	98.6 (98.4 to 98.8)
≥ 327	5941	98.9 (98.6 to 99.1)			

Results

Means of the quality indicators by the different categories, differentiated by case number categories

QI 2 Intraoperative specimen radiography with sonographic wire marking					
≤ 105	6450	94.4 (93.8–95.0)	<50	1877	89.0 (87.5–90.3)
106–162	8015	98.0 (97.7–98.3)	50–99	4298	97.0 (96.4–97.4)
163–227	9158	96.5 (96.1–96.9)	100–149	5924	97.8 (97.4–98.2)
228–326	9411	98.6 (98.4–98.9)	≥ 150	31 977	97.3 (97.1–97.4)
≥ 327	11 042	96.6 (96.2–96.9)			

Subgroup analysis for quality indicators, differentiated by case number categories*

QI 2 Intraoperative specimen radiography with sonographic wire marking					
≤ 105	949	96.4 (95.0 to 97.4)	<50	234	91.0 (86.7 to 94.1)
106 to 162	1437	98.7 (98.0 to 99.2)	50 to 99	674	98.5 (97.3 to 99.2)
163 to 227	1778	96.6 (95.7 to 97.4)	100 to 149	1046	98.5 (97.5 to 99.1)
228 to 326	1718	99.0 (98.3 to 99.3)	≥ 150	6219	97.9 (97.5 to 98.2)
≥ 327	2291	97.9 (97.3 to 98.5)			

Results

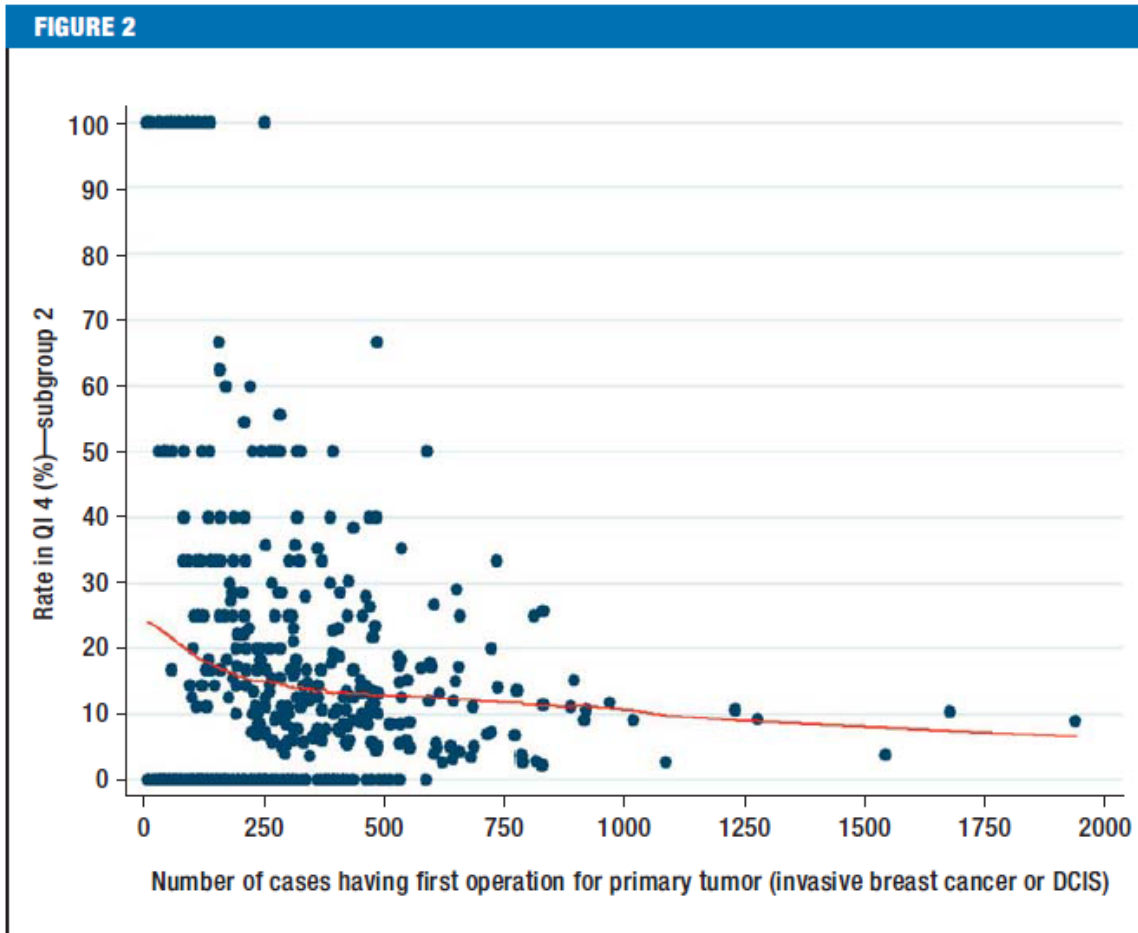
Means of the quality indicators by the different categories, differentiated by case number categories

QI 3 Primary axillary dissection in DCIS					
≤ 105	1976	1.0 (0.7–1.6)	<50	564	2.5 (1.5–4.1)
106–162	2808	0.4 (0.2–0.7)	50–99	1265	0.4 (0.2–0.9)
163–227	3125	0.3 (0.2–0.5)	100–149	2146	0.5 (0.3–0.9)
228–326	3192	0.4 (0.2–0.7)	≥ 150	10 118	0.3 (0.2–0.5)
≥ 327	2992	0.3 (0.2–0.6)			

Subgroup analysis for quality indicators, differentiated by case number categories*

QI 3 Primary axillary dissection in DCIS					
≤ 105	932	0.2 (0.1 to 0.8)	<50	233	0.4 (0.1 to 2.4)
106 to 162	1479	0.3 (0.1 to 0.7)	50 to 99	623	0.2 (0.0 to 0.9)
163 to 227	1727	0.3 (0.2 to 0.8)	100 to 149	1134	0.2 (0.0 to 0.6)
228 to 326	1748	0.1 (0.0 to 0.4)	≥ 150	5531	0.2 (0.1 to 0.4)
≥ 327	1635	0.1 (0.0 to 0.3)			

Results



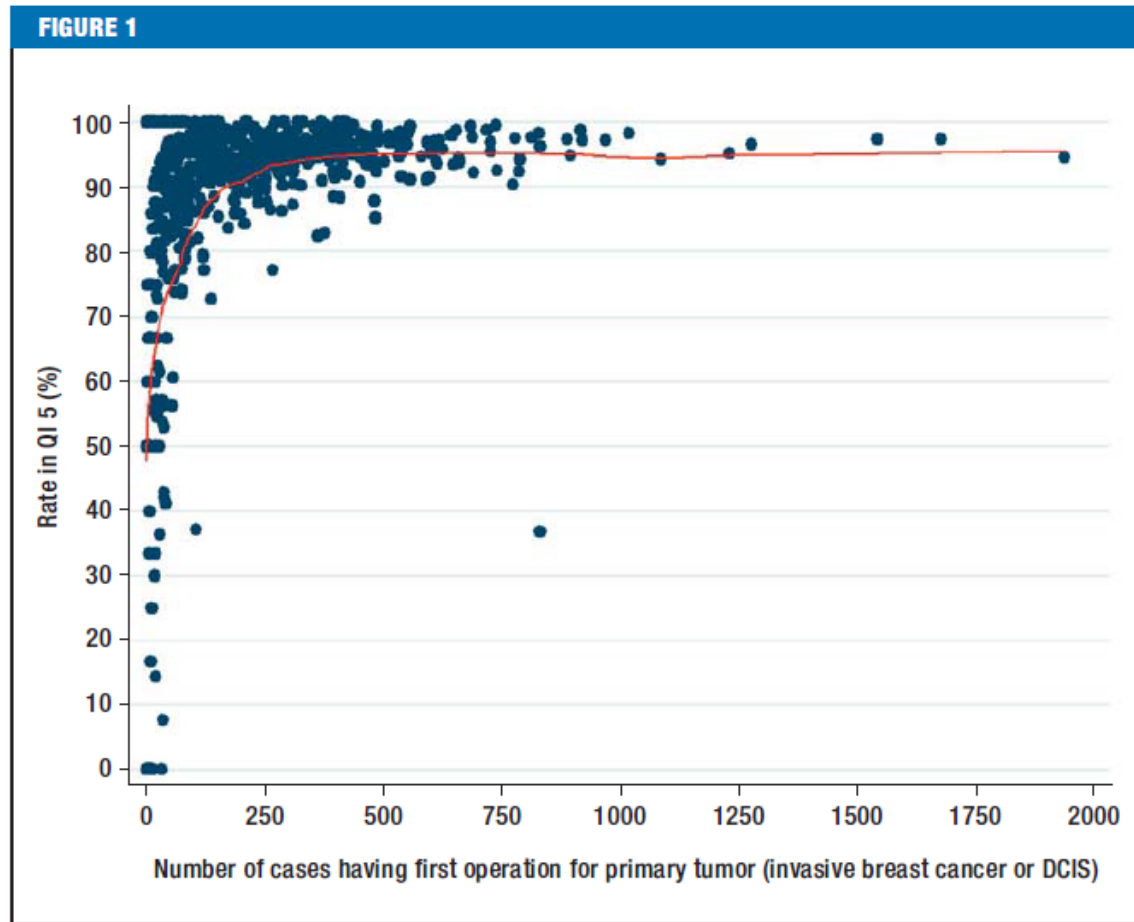
Q1 4 “Lymph node biopsy in ductal carcinoma in situ (DCIS) and breast conserving therapy”

The indicator was calculated on the basis of subgroup 2, which includes patients younger than 65 years with ASA1 or ASA2 and a total tumor size <5 cm. The result for the indicator is shown as a scatter plot. Each hospital is visualized as a blue dot. The red curve represents a non-parametric regression, which can show up non-linear associations and is based on locally weighted smoothing algorithms (Lowess regression; [30]). The x axis shows the number of inpatient cases and the y axis shows the indicator result.
DCIS, ductal carcinoma in situ

Results

QI 5 “Indication for sentinel lymph node biopsy (SLNB)”

The quality indicator 5 was calculated on the basis of the patient population without restrictions. The result for the indicator is shown as a scatter plot. Each hospital is visualized as a blue dot. The red curve represents a non-parametric regression, which can show up non-linear associations and is based on locally weighted smoothing algorithms (Lowess regression; [30]). The x axis shows the number of inpatient cases and the y axis the indicator result. DCIS, ductal carcinoma in situ



Results

Means of the quality indicators by the different categories, differentiated by case number categories

QI 6 Time interval of less than 7 days between diagnosis and operation					
≤ 105	24 072	15.6 (15.1–16.0)	<50	8785	21.0 (20.2–21.9)
106–162	25 544	10.9 (10.5–11.3)	50–99	13 817	12.7 (12.2–13.3)
163–227	26 062	8.4 (8.0–8.7)	100–149	19 734	11.9 (11.4–12.3)
228–326	24 784	8.0 (7.7–8.4)	≥ 150	81 002	7.3 (7.2–7.5)
≥ 327	22 876	5.2 (4.9–5.5)			
QI 7 Time interval of more than 21 days between diagnosis and operation					
≤ 105	24 072	22.0 (21.5–22.6)	<50	8785	18.1 (17.3–18.9)
106–162	25 544	25.8 (25.3–26.3)	50–99	13 817	24.0 (23.3–24.7)
163–227	26 062	29.4 (28.8–29.9)	100–149	19 734	25.3 (24.7–25.9)
228–326	24 784	30.2 (29.6–30.8)	≥ 150	81 002	31.7 (31.4–32.0)
≥ 327	22 876	37.4 (36.8–38.0)			

Discussion

- Better quality of care in hospitals with larger numbers
 - Not consistently steady
 - Worst results in lowest case number category
 - Subgroup analyses
 - => results can not be explained with sicker patients in smaller hospitals
 - Longer intervals to operations
 - => histological confirmation
 - => treatment capacities in large centers exhausted
 - => more patients from mammographic screening programs
- However, no optimal interval between treatment and surgery is defined according to guidelines

Discussion

- Our results show considerable variation of process quality within Germany in recent years
- Smaller (more remote) units perform worse than larger units (breast cancer centers) ...

Possible Solutions:

- mandatory quality assurance
- minimum provider volumes
- quality-orientated hospital planning
- restriction of treatment to breast cancer centers
- EU-Projects; EU-Guidelines

ORIGINAL ARTICLE

Case Numbers and Process Quality in Breast Surgery in Germany

A Retrospective Analysis of Over 150 000 Patients From 2013 to 2014

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Thank You for your attention!

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