Breast Cancer Services in Germany

COUNTRY DELEGATES WORKSHOP
Ispra (VA) - 13 and 14 March 2013

Karen Budewig, Federal Ministry of Health, Germany
Vanessa Kääb-Sanyal, Mammography-Screening-Program, Germany
Simone Wesselmann, German Cancer Society, Germany
Breast cancer services in Germany

Breast Cancer Centers

Evidence based guideline for Breast Cancer

Mammography Screening

Cancer registries
Breast cancer services in Germany

Breast Cancer Centers

Evidence based guideline for Breast Cancer

Cancer registries

Mammography Screening
Relevant Legislation:

National guidelines for the screening-program but higher ranking legislation on regional (mainly state) level, regarding:

- Data protection (privacy)
- Registration of address
- Cancer registration
- Public health care provision
- Radiation Control Regulations


Germany is made up of 16 Länder (federated states)
Mammography Screening

Federal level (KoopG + 5 RC)

Supraregional
(5 RC each with 15-23 SE)

Reference Centres (RC)
Evaluation, Training, Quality Assurance

Kooperationsgemeinschaft (KoopG)
Evaluation, Organization, Coordination

State level

Invitation Centres
Written invitation

Population Registries

Ep. Cancer Registry

Association of SHI Physicians

Statutory Health Insurance

Regional level
(94 SU each with ~120 thousand eligible women)

Screening Unit (SU)
Organisation, Controlling, QM

Pathology Breast Cancer Centres

Mammography Unit (MU)

Assessment Unit (AU)
Non-invasive & minimal invasive (Biopsy)
Mammography-Screening-Program in Germany:

• Population based: all women from 50 to 69 (>10 million)
• 24-month interval
• Personal written invitation with appointment (time & place) based on population registries
• Service only within special certified units with trained personnel (radiographer & physicians)
• Extensive quality control and management system
• Continuous evaluation of process and performance indicators (including linkage with cancer registries)
Mammography Screening

**Invitation**
Written invitation with time and place

- **Participation**
  - ~54%

**Mammography Exam**
4 Mammograms: each side in two projections (cc & mlo)

- **Double Reading**
  - blinded double reading, if needed consensus meeting
  - 100%

- **Non-invasive Assessment**
  - Clinical assessment, additional mammography, ultrasound
  - positive ~5%

- **Minimal-invasive Assessment (Biopsy)**
  - Tissue sample with histological diagnoses
  - positive ~1.5%

**Pre-surgical multi disciplinary meeting**
Radiologist, pathologist, surgeon

- **Surgery/Therapy**
  - Breast Cancer Centre
  - positive ~7.6‰

**Post-surgical multi disciplinary meeting**
Radiologist, pathologist, surgeon
Quality Assurance and Management

Basic Specifications
- Premises and technical equipment
- Confirmation of qualification
  - Special trainings
  - Hospitations
  - Reading test
  - Minimal number of cases
  - Supervision (starters)
- Development of qualification
  - Special trainings
  - Reading test
  - Sampling inspections
  - Minimal number of cases
- Extensive physical technical quality assurance & management

Process monitoring
- Double Reading
- Multi disciplinary meetings
  - Consensus meeting
  - Pre- and post-surgical meeting
- Internal quality management, methods for self-testing including expert consultation with RC
  - Diagnostic image quality
  - Reading quality
  - Biopsy quality
  - Histopathological QM
  - Assessment QM
  - Selected set of performance indicators to monitor the entire screening process

Auditing of Results
- Regular certification (with respect to structure, process and results in performance and surrogate indicators) every 30 months
- Linkage with cancer registries to identify interval cancers
- Regular monitoring and public report of the Quality assurance measurements by KoopG
- Regular evaluation of and report on outcome of screening program (performance and surrogate indicators) by KoopG
Mammography Screening

Surrogate and Performance Indicators

- Eligible population
- Invitation rate
- Participation rate
- Recall rate
- Breast cancer detection rate
- Proportion of in-situ screen-detected cancers (DCIS)
- Proportion of invasive screen-detected cancers
- Proportion of invasive cancer ≤ 10 mm
- Proportion of invasive cancer < 15 mm
- Proportion of invasive node-negativ cancers
- Proportion of invasive cancers of stage II+
- Positive predictive values
- Proportion of repeated screening examination
- Proportion of women attending assessment
- Early recall rate
- Proportion of women referred to biopsy
- Benign to malignant biopsy ratio
- Biopsies with insufficient results
- Pre-surgical histological confirmations
- Time between screening exam and notification on result
- Time between notification on result and offered assessment
- Time between assessment and notification on result
- Breast cancer incidence in target population
- Breast cancer mortality in the target population
- Interval cancer rate 1st and 2nd year & classification of interval cancers
Breast cancer services in Germany

Breast Cancer Centers

Mammography Screening

Cancer registries
Definition:

A network of qualified and jointly certified multidisciplinary and cross-sectoral [...] facilities, that [...] represent the entire supply chain for patients [...].

National Cancer Plan, Germany
Obligatory facilities within the network:

gynecology, radiotherapy, pathology, radiology, medical oncology, nursing, general practitioners, mammography screening, genetic counseling, psycho-oncology, social services, physiotherapy, palliative care, pain management, rehabilitation, cancer registries and self-help group
Breast Cancer Centers

State 31.12.2012:

• 212 certified Breast Cancer Centers nationwide

• In these Centers were 50.329 patients with the initial diagnosis of breast cancer treated in 2012 ( = 87.9% of incident breast cancer patients in Germany)
Certification of Breast Cancer Centers

- **Catalog of requirements** based on:
  - Requirements + Quality Indicators for the interdisciplinary, multi-professional and trans-sectoral cooperation
  - Requirements + Quality Indicators for evidence-based treatment of patients transferred from the: [German Guideline Program in Oncology (GGPO)](http://www.ggp-lin.de)

- **Audit** 1/year
- **Auditors**: Clinically active oncology specialists with training for certification
- **Accredited certification institute**: OnkoZert
- **Certificate** of the German Cancer society
Evidence-based guideline for Breast Cancer

German Guideline Program in Oncology (GGPO)

2 evidence-based guidelines for breast cancer in Germany:

- Early detection
  Last Update: 2008

- Diagnostic, therapy and follow-up
  Last update: 2012
Certification of Breast Cancer Centers

- **Catalog of requirements** based on:
  - Requirements + Quality Indicators for the interdisciplinary, multi-professional and trans-sectoral cooperation
  - Requirements + Quality Indicators for evidence-based treatment of patients transferred from the: **German Guideline Program in Oncology (GGPO)**

- **Audit** 1/year
- **Auditors**: Clinically active oncology specialists with training for certification
- **Accredited certification institute**: OnkoZert
- **Certificate** of the German Cancer society
Quality Indicators for Breast Cancer Centers:
No. 1: Postoperative tumor conference
No. 2: Pretherapeutic tumor conference
No. 3: Tumor conference at local recurrence / metastasis
No. 4.1/2: Recommended/Performed Radiation therapy after breast-conserving therapy
No. 5.1/2: Recommended/Performed Radiation therapy after breast-conserving therapy for carcinoma in situ
No. 6.1/2: Recommended/Performed Radiation therapy after mastectomy
No. 7.1/2: Recommended/Performed chemotherapy in receptor negative findings
No. 8.1/2: Recommended/Performed chemotherapy in receptor pos. and node-pos. findings
No. 9.1/2: Recommended/Performed endocrine therapy in receptor positive findings
No. 10.1/2: Recommended/Performed antibody therapy in HER2 pos. findings
No. 11: Psycho-oncological care
No. 12: Social services counseling
No. 13: Proportion study patients
No. 14: Preoperative histological confirmation
No. 15: Primary breast cancer cases
No. 16: Breast-conserving surgery for pT1
No. 17: Number of mastectomies
No. 18: DCIS at primary surgery (pTIS)
No. 19: Determining nodal status at invasive breast cancer
No. 20: Exclusive sentinel lymph node removal (SLNE) at pT1 and pN0
No. 21: Intraoperative sample radiography/sonography
No. 22: Revision surgery
No. 23: Postoperative wound infection
No. 24: Breast Reconstruction
No. 25: Indication of resection margin and safe distance
Quality Indicators for Breast Cancer Centers:

No. 1: Postoperative tumor conference
No. 2: Pretherapeutic tumor conference
No. 3: Tumor conference at local recurrence / metastasis

No. 4.1/2: Recommended/Performed Radiation therapy after breast-conserving therapy
No. 5.1/2: Recommended/Performed Radiation therapy after breast-conserving therapy for carcinoma in situ
No. 6.1/2: Recommended/Performed Radiation therapy after mastectomy
No. 7.1/2: Recommended/Performed chemotherapy in receptor negative findings
No. 8.1/2: Recommended/Performed chemotherapy in receptor pos. and node pos. findings
No. 9.1/2: Recommended/Performed endocrine therapy in receptor positive findings
No. 10.1/2: Recommended/Performed antibody therapy in HER2 positive findings

No. 11: Psycho-oncological care
No. 12: Social services counseling
No. 13: Proportion study patients

No. 14: Preoperative histological confirmation
No. 15: Primary breast cancer cases
No. 16: Breast-conserving surgery for pT1
No. 17: Number of mastectomies
No. 18: DCIS at primary surgery (pTIS)
No. 19: Determining nodal status at invasive breast cancer
No. 20: Exclusive sentinel lymph node removal (SLNE) at pT1 and pN0
No. 21: Intraoperative sample radiography/ sonography
No. 22: Revision surgery
No. 23: Postoperative wound infection
No. 24: Breast Reconstruction
No. 25: Indication of resection margin and safe distance

Quality Indicators for the interdisciplinary, multi-professional cooperation
Quality Indicators for Breast Cancer Centers:

No. 1: Postoperative tumor conference
No. 2: Pretherapeutic tumor conference
No. 3: Tumor conference at local recurrence / metastasis

No. 4.1/2: Recommended/Performed Radiation therapy after breast-conserving therapy
No. 5.1/2: Recommended/Performed Radiation therapy after breast-conserving therapy for carcinoma in situ
No. 6.1/2: Recommended/Performed Radiation therapy after mastectomy
No. 7.1/2: Recommended/Performed chemotherapy in receptor negative findings
No. 8.1/2: Recommended/Performed chemotherapy in receptor pos. and node-pos. findings
No. 9.1/2: Recommended/Performed endocrine therapy in receptor positive findings
No. 10.1/2: Recommended/Performed antibody therapy in HER2 pos. findings

No. 11: Psycho-oncological care
No. 12: Social services counseling
No. 13: Proportion study patients

No. 14: Preoperative histological confirmation

No. 15: Primary breast cancer cases
No. 16: Breast-conserving surgery for pT1
No. 17: Number of mastectomies
No. 18: DCIS at primary surgery (pTIS)

No. 19: Determining nodal status at invasive breast cancer
No. 20: Exclusive sentinel lymph node removal (SLNE) at pT1 and pN0
No. 21: Intraoperative sample radiography/sonography

No. 22: Revision surgery
No. 23: Postoperative wound infection
No. 24: Breast Reconstruction

No. 25: Indication of resection margin and safe distance
Quality Indicators for Breast Cancer Centers:

No. 1: Postoperative tumor conference
No. 2: Pretherapeutic tumor conference
No. 3: Tumor conference at local recurrence / metastasis
No. 4.1/2: Recommended/Performed Radiation therapy after breast-conserving therapy
No. 5.1/2: Recommended/Performed Radiation therapy after breast-conserving therapy for carcinoma in situ
No. 6.1/2: Recommended/Performed Radiation therapy after mastectomy
No. 7.1/2: Recommended/Performed chemotherapy in receptor negative findings
No. 8.1/2: Recommended/Performed chemotherapy in receptor pos. and node-pos. findings
No. 9.1/2: Recommended/Performed endocrine therapy in receptor positive findings
No. 10.1/2: Recommended/Performed antibody therapy in HER2 pos. findings
No. 11: Psycho-oncological care
No. 12: Social services counseling
No. 13: Proportion study patients
No. 14: Preoperative histological confirmation
No. 15: Primary breast cancer cases
No. 16: Breast-conserving surgery for pT1
No. 17: Number of mastectomies
No. 18: DCIS at primary surgery (pTIS)
No. 19: Determining nodal status at invasive breast cancer
No. 20: Exclusive sentinel lymph node removal (SLNE) at pT1 and pN0
No. 21: Intraoperative sample radiography/sonography
No. 22: Revision surgery
No. 23: Postoperative wound infection
No. 24: Breast Reconstruction
No. 25: Indication of resection margin and safe distance
• Annual evaluations of the quality indicators for all centers
• Personalized reports for the centers
• Reports download: [Download Jahresbericht 2012](#)
Report 2012 with the results of:

- 206 Centers
- 49,332 Patients with the initial diagnosis of breast cancer
Breast Cancer Centers
Breast cancer services in Germany

Breast Cancer Centers

Mammography Screening

Cancer registries
The epidemiological and clinical cancer registries are obligate partners in the breast cancer centers:
• Data for quality indicators
• Outcome data (overall survival, relapse-free survival)

• Epidemiological cancer registries in every federal state (population based)
• Clinical cancer registries (52, not regular population based until now)
The epidemiological and clinical cancer registries are obligate partners in the breast cancer centers:

- Data for quality indicators
- Outcome data (overall survival, relapse-free survival)

- Epidemiological cancer registries in every federal state (population based)
- Clinical cancer registries (52, not regular population based until now)
(One) Result of the National Cancer Plan:

In January and March 2013 the German Parliament (Bundestag) and the Chamber of the Federal Laender (Bundesrat) have passed the law on "the further development of the early detection of cancer and quality assurance through clinical cancer registries"
Breast cancer services in Germany

Breast Cancer Centers

Evidence based guideline for Breast Cancer

Mammography Screening

Cancer registries
Thank you !