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Position Paper

Quality indicators in breast cancer care: An update from the EUSOMA working group

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Abstract In 2010, EUSOMA published a position paper, describing a set of benchmark quality indicators (QIs) that could be adopted by breast centres to allow standardised auditing and quality assurance and to establish an agreed minimum standard of care. Towards the end of 2014, EUSOMA decided to update the paper on QIs to consider and incorporate new scientific knowledge in the field. Several new QIs have been included to address the need for improved follow-up care of patients following primary treatments. With regard to the management of elderly patients, considering the complexity, the expert group decided that, for some specific quality indicators, if centres fail to meet the minimum standard, older patients will be excluded from analysis, provided that reasons for non-adherence to the QI are specified in the clinical chart and are identified at the review of the clinical records. In this way, high standards are promoted, but centres are able to identify and account for the effect of non-

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standard treatment in the elderly. In the paper, there is no QI for outcome measurements, such as relapse rate or overall survival. However, it is hoped that this will be developed in time as the databases mature and user experience increases. All breast centres are required to record outcome data as accurately and comprehensively as possible to allow this to occur. In the paper, different initiatives undertaken at international and national level to audit quality of care through a set of QIs have been mentioned.

Introduction

The management of early breast cancer is complex and is best performed within the context of a specialist multidisciplinary breast centre to ensure optimal outcomes in terms of patient survival and quality of life. In recognition of this fact, European Union (EU) member states are expected to ensure nationwide access to such centres for all patients with breast cancer, and the European Society of Breast Cancer Specialists (EUSOMA) provides requirements of a specialists breast centre and fosters the voluntary European certification process to facilitate compliance with recognised guidelines.

In 2010, EUSOMA published a position paper, in which were described a set of benchmark quality indicators (QIs) that could be adopted by breast centres to allow standardised auditing and quality assurance, and to establish an agreed minimum standard of care. They are now listed in the National Quality Measures Clearing House (NQMC). Importantly, these QIs provide a set of metrics to allow centres to follow patients over time in a standardised manner, and easily recognise when attention is required to improve particular areas of healthcare delivery.

A recent assessment of 22 EUSOMA-certified breast centres has shown that standards according to these QIs improved after certification, and that the minimum standard of care was met in 12/13 QIs. These findings support the claim that this framework for quality assurance is manageable for centres and provide meaningful data to allow assessment of performance and identification of areas needing improvement.

Towards the end of 2014, EUSOMA decided to update the paper on Quality Indicators. This was felt to be important for several reasons: (1) to consider and incorporate new scientific knowledge in the field; (2) to evaluate the experience acquired in more than 80,000 primary cases treated in European Breast Centres undergoing certification procedures, included in the database; (3) to examine user experience with the database; and (4) to encourage ongoing improvement in the level of care by upgrading minimum standards.

As in the first version, a number of QIs are considered mandatory requirements while others are recommended. Several new QIs have been included to address the need for improved follow-up care of patients following primary treatments (see Table 1). QIs related to the use of targeted therapy (endocrine or anti-HER2) in cancers not expressing the relevant receptor were removed, as these reflect prescribing indications rather than 'best practice'. Similarly, the QI related to ensuring that patients receiving trastuzumab also receive chemotherapy was removed, as no trials or guidelines support the use of trastuzumab alone as sole adjuvant therapy, and possible exceptions would be linked to patient's refusal or presence of comorbidities.

The management of elderly patients with breast cancer is complex, and the best way to structure the QIs to allow appropriate treatment tailoring, yet still encourage the highest standards, required careful consideration. In particular, it was felt that the current QIs 9d, 10, 12 and 13 should allow for flexibility when treating such patients, in order to provide the best benefit to harm ratio. Options included lowering the minimum standard for certain QIs, introducing an age upper limit or considering patients on a case-by-case basis. It was noted that, on review of the certification process, the minimum standard was not met for some QIs specifically because of a different approach in older patients. In its deliberations, the working group took several factors into consideration: with an ageing population, the number of elderly patients presenting with breast cancer is increasing, thus QIs must be ready for a changing demographic; there is strong evidence that a more conservative approach to primary surgery and postoperative radiation therapy may be adopted in older patients without affecting longer term outcomes, and this should not be a reason for failing to achieve a minimum standard; similarly, in unfit older patients, standard chemotherapy regimens may not be appropriate, and Centres should not be penalised for altering treatment in such cases.

However, EUSOMA is also keen to emphasise that undertreatment in the elderly is associated with worse outcomes, and age in itself is not a contraindication to treatment. Centres should be encouraged to consider all patients for standard treatment, regardless of age. Thus an upper age limit for inclusion in QI measuring was seen to go against this approach. Furthermore, case-by-case discussion was deemed counterproductive to the purpose and nature of QIs as a tool for assessing

Table 1
Summary table of Quality Indicators in breast cancer care.

Indicator	Level of evidence	Mandatory Recommended	Minimum standard	Target
Diagnosis				
Completeness of clinical and imaging diagnostic work-up				
1. Proportion of women with breast cancer who preoperatively underwent mammography, physical examination and ultrasound of both breasts and axillae	III	M	>90%	>95%
Specificity of diagnostic procedures (B/M ratio)				
2. Ratio of benign to malignant diagnoses based on definitive pathology report (surgery only, non-operative biopsies excluded)	III	M	1:4	1:5
Preoperative diagnosis				
3a. Proportion of patients with invasive cancer who underwent image-guided axillary staging (by US ± FNA/CNB)	III	R	85%	95%
3b. Proportion of women with breast cancer (invasive or in situ) who had a preoperative histologically or cytologically confirmed malignant diagnosis (B5 or C5)	III	M	85%	90%
Completeness of prognostic/predictive characterisation				
4a. Proportion of invasive cancer cases for which the following prognostic/predictive parameters have been recorded: histological type (according to WHO Classification of Tumours of the Breast), grading (according to WHO and EU Guidelines: Elston and Ellis modified Bloom and Richardson-Grading system Elston, CWet al. 1991), ER, PgR*, HER-2/neu, Proliferation index (Ki67)* *This marker is recommended but not mandatory, and does not need to be included in the calculation for compliance with the QI For patients receiving primary systemic treatment (PST), characterisation on core biopsy prior to therapy is mandatory.	II	M	>95%	>98%
For patients receiving primary surgery, characterisation may be performed on the surgical specimen only. In addition to the above parameters, the following parameters must be recorded after surgery: Pathological stage (pT and pN, or ypT and ypN in case of PST), Size in mm for the invasive component, Peritumoral vascular invasion (L,V), Distance to nearest radial margin	II	M	>95%	>98%
4b. Proportion of non-invasive cancer cases for which the following prognostic/predictive parameters have been recorded: Grading (according to WHO Classification of Tumours of the Breast), dominant histological pattern, size in mm (best pathology or radiology estimate if two- stage pathology), distance to nearest radial margin, ER.	II	M	>95%	>98%
Waiting time				
5. Time interval of ≤6 weeks, from the date of first diagnostic examination within the breast centre to the date of surgery or start of other treatment.	IV	R	80%	90%
MRI availability				
6a. Proportion of cancer cases examined preoperatively by MRI (excluding patients treated with PST)	IV	R	10%	NA
6b. Proportion of patients treated with PST undergoing MRI (pre, during, post PST)	III	R	60%	90%
Genetic counselling availability				
7. Proportion of cancer cases referred for genetic counselling	IV	R	10%	NA
Surgery and loco-regional treatment				
Multidisciplinary discussion				
8. Proportion of cancer patients to be discussed pre and postoperatively by a multidisciplinary team	III	M	90%	99%
Appropriate surgical approach				
9a. Proportion of patients (invasive cancer only) who received a single (breast) operation for the primary tumour (excluding reconstruction)	II	M	80%	90%
9b. Proportion of patients (DCIS only) who received just one operation (excluding reconstruction)	II	M	70%	90%
9c. Proportion of patients receiving immediate reconstruction at the same time of mastectomy	III	R	40%	NA
Radiation therapy (RT) and local control				
Post-operative RT				
10a. Proportion of patients with invasive breast cancer (M0) who received postoperative radiation therapy (RT) after surgical resection of the primary tumour and appropriate axillary staging/surgery in the framework of BCT	I	M	90%	95%
10b. Proportion of patients with involvement of axillary lymph nodes (≥pN2a) who received post-mastectomy radiation therapy to the chest wall and all (non-resected) regional lymph-nodes	I	M	90%	95%

(*continued on next page*)

Table 1 (*continued*)

Indicator	Level of evidence	Mandatory Recommended	Minimum standard	Target
10c. Proportion of patients with involvement of up to three axillary lymph nodes (pN1) who received post-mastectomy radiation therapy to the chest wall and non-resected axillary lymph-nodes, including level IV (supraclavicular), and in medially located tumours, the internal mammary lymph-nodes	I	M	70%	85%
Surgery and quality of life				
Avoidance of overtreatment				
11a. Proportion of patients with invasive cancer and clinically negative axilla who underwent sentinel lymph-node biopsy (SLNB) only (excluding patients who received PST)	I	M	90%	95%
11b. Proportion of patients with invasive cancer who underwent sentinel lymph-node biopsy with no more than 5 nodes excised	I	R	90%	95%
11c. Proportion of patients (BRCA1 and BRCA2 patients excluded) with invasive breast cancer not greater than 3 cm (total size, including DCIS component) who underwent BCT as primary treatment.	I	M	70%	85%
11d. Proportion of patients with non-invasive breast cancer not greater than 2 cm who underwent BCT	II	M	80%	90%
11e. Proportion of patients with DCIS only who do not undergo axillary clearance	II	M	97%	99%
Systemic treatment				
Appropriate endocrine therapy				
12. Proportion of patients with endocrine sensitive invasive cancer who received endocrine therapy	I	M	85%	90%
Appropriate chemotherapy and HER2-targeted therapy				
13a. Proportion of patients with ER− (T > 1 cm or Node+) invasive carcinoma who received adjuvant chemotherapy	I	M	85%	95%
13b. Proportion of patients with HER2 positive (IHC 3+ or *in situ* hybridisation positive FISH-positive) invasive carcinoma (T > 1 cm or N+) treated with chemotherapy who received adjuvant trastuzumab	I	M	85%	95%
13c. Proportion of patients with HER2-positive invasive carcinoma treated with neo-adjuvant chemotherapy who received neo-adjuvant trastuzumab	I	M	90%	95%
13d. Proportion of patients with inflammatory breast cancer (IBC) or locally advanced non-resectable ER-carcinoma who received neo-adjuvant chemotherapy	II	M	90%	>95%
Staging, counselling, follow-up and rehabilitation				
Appropriate staging procedure				
14a. Proportion of women with stage I or primary operable stage II, breast cancer who do not undergo baseline-staging tests (e.g. US of liver, chest X-ray and bone scan)	III	R	95%	99%
14b. Proportion of women with stage III breast cancer who undergo baseline staging tests (US of liver, chest X-ray and bone scan)	III	R	95%	99%
Perform appropriate follow-up				
15a. Proportion of asymptomatic patients who undergo routine annual mammographic screening and 6/12 months clinical evaluation in the first 5 years after primary surgery.	I	M	95%	99%
15b. Proportion of treated patients for which the breast centre collects data on life status and recurrence rate (for at least 5years)	III	R	80%	90%
Availability of nurse counselling				
16a. Proportion of patients referred for nurse counselling at the time of primary treatment	IV	R	85%	95%
16b. Proportion of women with a diagnosis of breast cancer who have direct access to a breast care nurse specialist for information and support with treatment-related symptoms and toxicity during the treatment, follow-up and rehabilitation after initial treatment.	IV	R	95%	99%
The availability of data manager				
17. The breast centre must have a data manager responsible for the breast centre data	IV	M	NA	NA

overall performance. Lowering the minimum standard would be the simplest way to allow flexibility, but this too could be seen as failing to promote overall improvement in breast cancer care. Finally, it was decided that in cases where centres fail to meet a minimum standard for QIs, 10, 12 and 13, older patients (arbitrary defined by a chronological age $\geq$ 70 years) will be excluded from the analysis, provided that reasons for non-adherence to the QI (i.e. comorbidities, patient's refusal, barrier to treatment, reference to clinical trials specifically conducted in the older population, etc) are specified in the clinical chart and are identified at the review of the clinical records. In this way high standards are promoted, but centres are able to identify and account for the effect of non-standard treatment in the elderly.

Currently there is no QI for outcome measurements, such as relapse rate or overall survival. However it is

hoped that this will be developed in time as the databases mature and user experience increases. All breast centres are required to record outcome data as accurately and comprehensively as possible to allow this to occur.

Although this position paper focusses on optimal care for early and locally advanced breast cancer, Breast Centres should also be directly involved in the management of patients with advanced/metastatic disease. EUSOMA will produce a paper on QIs applicable to care of this patient population.

Methods

A literature review was performed through PubMed, to identify relevant studies that had been published in the 6 years since the first workshop, which retrieved 203 articles, which are listed by topic in the references. A working group of European experts in the different disciplines met to up-date the original articles. Each QI was reevaluated in the context of the literature and of the results achieved by Breast Centres included in the EUSOMA certification process.

As in the initial review, for each indicator the panel reported the definition, the minimum and target standard, the motivation for selection, and the level of evidence. Level of evidence is graded according to the short version of the United States Agency for Healthcare Research and Quality (AHRQ, www.ahrq.org) classification:

Level of evidence

(I) Requires at least a randomised clinical trial (RCT) as part of the body of the literature – overall of good quality and consistency – which supports the clinical recommendation (quality indicator)
(II) Requires well-designed quasi-experimental clinical studies, but not RCT
(III) Requires well designed descriptive studies
(IV) Expert judgment. Its use implies the absence of good quality clinical studies on the relevant matter

Quality indicators on diagnosis

1 Completeness of clinical and imaging diagnostic work-up

Definition: Proportion of women with breast cancer who preoperatively underwent:

- Mammography
- Physical examination
- Ultrasound (US) of both breasts and axillae

Minimum standard: >90%
Target: >95%
Motivation: to allow a proper diagnostic approach and to identify size, site and possible multifocal and/or contralateral disease. Axillary US (separately recorded) and contralateral breast examination (mammography and physical) are included.
Level of evidence: III.

Several studies have shown improved accuracy using a combination of different diagnostic tests.

In most cases these basic examinations are performed by a dedicated breast radiologist, who should also perform and register physical examination, axillary US and classification of the level of suspicion by Breast imaging-Reporting and Data Systems (Bi-Rads) or European classification. This is preliminary to a proper triple assessment including Fine Needle Aspiration Cytology (FNAC) or percutaneous biopsy (CNB).

2 Specificity of diagnostic procedures (B/M ratio)

Definition: Ratio of benign to malignant diagnoses (B/M ratio), based on definitive pathology report (surgery only, non-operative biopsies excluded).
Minimum standard: 1 benign to 4 malignant diagnoses.
Target: 1 benign to 5 malignant diagnoses.
Motivation: to minimise unnecessary operations for benign conditions.
Level of evidence: III.

This is in accordance with North America and UK National Health System (NHS) guidelines, based on evidence in the literature regarding follow-up of non-operated lesions, which demonstrate that benign lesions are not at risk of developing into cancer.

Triple assessment, including FNAC and CNB, is accurate in the diagnosis of breast cancer. Magnetic Resonance and Vacuum-assisted Biopsy (VAB) may further contribute to study some equivocal cases, such as B3 lesions.

In summary, cases with lesions which do not have a final preoperative diagnosis and need open surgery for a final diagnosis are very few. Surgery for benign lesions should be limited to large lesions and on request of the patient, after informed consent that includes the patient understanding that benign lesions normally do not progress to cancer. Pathological examinations of tissue removed for inflammatory disease, for cosmetic reasons or prophylactic surgery should not be included in the calculation of this indicator.

3 Preoperative diagnosis

3a *Definition:* Proportion of patients with invasive cancer who underwent image-guided axillary staging (by US ± FNA/CNB).
Minimum standard: 85%
Target: 95%
Motivation: Preoperative identification of nodal metastasis may decrease the need for second surgeries

and identify candidates for primary systemic treatment.

Level of evidence: III.

Axillary US is a non-invasive means of predicting disease burden preoperatively and as such is a powerful tool to individualise treatment plans – Lymph-nodes suspicious at US can easily be examined by FNAC or CNB with a high Positive Predictive Value. Obviously, a negative axillary US does not exclude the need for further assessment by means of sentinel lymph node biopsy.

3b *Definition:* Proportion of women with breast cancer (invasive or *in situ*) who had a preoperative, histologically or cytologically confirmed malignant diagnosis (B5 or C5).

Minimum standard: 85%

Target: 90%

Motivation: To reduce the number of unnecessary operations, to plan complete assessment and treatment, and for patient counselling.

Level of evidence: III.

A definitive preoperative diagnosis is essential to allow discussion at the multidisciplinary meeting regarding the need further assessment and the most appropriate surgical or medical treatment. Preoperative diagnosis is also very important to inform the patient, to discuss with her the most appropriate treatment and to prepare her to accept the adverse effects of treatment.

4 Completeness of prognostic/predictive characterisation

4a *Definition*: Proportion of invasive cancer cases for which the following prognostic/predictive parameters have been recorded:

- Histological type (according to WHO Classification of Tumours of the Breast)
- Grading (according to WHO and EU Guidelines: Elston and Ellis modified Bloom and Richardson-Grading system Elston, CW *et al.*, 1991)
- ER
- PgR*
- HER-2/neu
- Proliferation index (Ki-67)*

*This marker is recommended but not mandatory, and does not need to be included in the calculation for compliance with the QI.

For patients receiving primary systemic treatment (PST), characterisation on core biopsy prior to therapy is mandatory.

For patients receiving primary surgery, characterisation may be performed on the surgical specimen only.

In addition to the above parameters, the following parameters must be recorded after surgery:

- Pathological stage (pT and pN, or ypT and ypN in case of PST)
- Size in mm for the invasive component
- Peritumoral vascular invasion (L,V)
- Distance to nearest radial margin

Minimum standard: >95%

Target: >98%

Level of evidence: II.

Motivation: PST or Adjuvant therapy and treatment planning require complete tumour characterisation.

Histological type and grade have not only been prognostically useful but also show a predictive value for multifocality and metastatic pattern, and are part of the core data set on breast cancers.

Patient management also relies on approximations of molecular subtypes by immunohistochemical staining of oestrogen receptor (ER), progesterone receptor (PgR), human epidermal growth factor receptor-2 (HER-2) and Ki-67.

ER testing by immunohistochemistry is also essential in the proper delivery of tailored anti-oestrogen therapy and should be measured by a standard immunohistochemical technique using validated methods. Although some centres may choose not to include PgR testing (Ref. National Institute for Clinical Excellence (NICE) Guidelines UK and Early Breast Cancer Trialists' Collaborative Group (EBCTCG) data), ER testing is recommended as a mandatory item.

HER-2 testing by immunohistochemistry (IHC) or *in situ* hybridisation (ISH) techniques (such as chromogenic *in situ* hybridisation (CISH)/ silver-enhanced *in situ* hybridisation (SISH)/ fluorescence *in situ* hybridisation (FISH)) as a primary test must be performed, and equivocal cases must be verified by alternate testing (ISH for immunohistochemistry and immunohistochemistry for primary ISH). Although no consensus about best cut off values and relatively low interobserver agreement for the Ki-67 proliferation index exist, at least very low and very high proliferating tumours can be distinguished with this marker.

Centres offering ER, PgR, Ki-67 and HER-2 testing should regularly participate in external quality control schemes for these tests.

4b *Definition:* Proportion of non-invasive cancer cases for which the following prognostic/predictive parameters have been recorded:

- Grading (according to WHO Classification of Tumours of the Breast)
- Dominant histological pattern
- Size in mm (best pathology or radiology estimate if two-stage pathology)
- Distance to nearest radial margin
- ER

Minimum standard: >95%

Target: >98%

Level of evidence: II.

Motivation: Treatment planning. Young age, high nuclear grade, comedo necrosis, larger lesion size, and positive margin status have been associated with an increased risk of local recurrence and/or progression to invasive cancer. In the framework of breast conserving therapy (BCT), the tumour-free margin should ideally be measured in all directions.

Currently, ER is the only biomarker validated for routine clinical practice in ductal carcinoma in situ (DCIS).

5 Waiting time

Definition: Time interval of ≤6 weeks, from the date of first diagnostic examination within the breast centre to the date of surgery or start of other treatment.

Minimum standard: 80%

Target: 90%

Motivation: to maximise benefit of early detection and to reduce anxiety of the patient and her family.

Level of evidence: IV.

The waiting time from the first diagnostic examination to the date of surgery or other primary treatment should be based on two issues: On one hand sufficient time is required to adequately advise the patient and allow shared decision making. On the other hand, the primary treatment should start as soon as the treatment plan has been defined in order to reduce anxiety.

6 MRI availability

6a *Definition:* Proportion of cancer cases examined preoperatively by magnetic resonance imaging (MRI) (excluding patients treated with PST.

Minimum standard: suggested 10%

Target: not applicable.

Motivation: To allow proper diagnostic assessment and to identify size, site and possible multifocal and/or contralateral disease in a selected subgroup, while avoiding 'over-diagnosis'.

Level of evidence: IV.

MRI is more accurate than conventional imaging in defining the extension of disease, the presence of multifocality and/or contralateral disease. Conversely there is a risk of over-diagnosis and false positives. For this reason, we recommend the availability of MRI for use in selected patient according to EUSOMA recommendations.

6b *Definition*: Proportion of patients treated with PST undergoing MRI (pre, during, post PST.

Minimum standard: suggested 60%

Target: 90%

Motivation: to allow proper evaluation of response to the PST.

Considering the increasing indication and use of PST in clinical setting, especially for triple negative and HER2+ cancer, it is important that Breast centre monitor the appropriate use of MRI in this setting.

7 Genetic counselling availability

Definition: Proportion of cancer cases referred for genetic counselling.

Minimum standard: suggested 10%

Target: not applicable.

Motivation: to allow counselling.

Level of evidence: IV.

Approximately 10–20% of all breast cancer cases have an underlying genetic cause. Women with BReast CAncer gene1 or gene2 (BRCA1 or BRCA2) mutations have a lifetime risk of developing breast cancer of 60% (range 44–75%) and 55% (range 41–70%) respectively, and a lifetime risk of developing ovarian cancer of 59% (43–76%) and 16.5% (7.5–34%), 16.5% (7.5–34%) respectively. The cumulative risk for developing a contralateral secondary cancer is 27% for BRCA 1 and 19% for BRCA 2 carriers.

Patients with a family history of breast cancer should have access to genetic counselling. Risk factors include young age and number of family members affected with breast or ovarian cancer.

In case of a *BRCA 1* or *BRCA 2* mutation, the option of intensified surveillance including annual MRI should be discussed with the patient. Alternatively, bilateral prophylactic mastectomy (with primary reconstruction) should be offered. Retrospective data from a large retrospective cohort study have shown a survival benefit for patients, who underwent bilateral mastectomy (88% versus 66% after 20 years). In another prospective cohort, the mortality was 9.6% in the group of patients who underwent prophylactic mastectomy compared to 21.6% in women who did not undergo preventive surgery (related to 1000 person-years of observation. Prophylactic surgery did not affect long-term quality of life.

Prophylactic adenectomy should be recommended for patients older than 40 years, after ensuring that they completed family planning.

Quality indicators on surgery and loco-regional treatment

Surgery and local control

8 Multidisciplinary discussion

Definition: Proportion of cancer patients to be discussed pre- and postoperatively by a multidisciplinary team.

Minimum standard: 90%

Target: 99%

Motivation: to select optimal treatment based on guidelines and clinical criteria; to select patients for non-standard treatment based on individual patient needs and tumour-related factors (e.g. old patients with low-

risk breast cancer); to select patients for clinical trials; to document proposed treatment.

Level of evidence: III.

The UK department of Health defines the multidisciplinary team as a group of people of different health care disciplines, which meets together at a given time to discuss a given patient and who are each able to contribute independently to the diagnostic and treatment decisions about the patients. The multidisciplinary meeting (MDM) represents the key opportunity for multidisciplinary coordination of a Breast Centre, and is a vital step. The benefits of MDMs in terms of shared decision on treatment options and contributing to improved survival have been demonstrated in the published literature.

MDMs also provide a teaching element for the training of young specialists.

Multidisciplinary teams are perceived to lead to better clinical decisions, evidence-based practice and improved quality of treatment.

9 Appropriate surgical approach

9a *Definition:* Proportion of patients (invasive cancer only) who received a single (breast) operation for the primary tumour (excluding reconstruction.

Minimum standard: 80%

Target: 90%

Motivation: To reduce the rate of multiple surgeries where a single operation may be sufficient; this also encompasses optimal preoperative imaging, optimal preoperative and intraoperative handling, use of oncoplastic techniques and optimal pathological examination, all concordant with guidelines.

Level of evidence: II.

Multiple recent reports have documented significant variability of care for reoperation after initial wide excision for breast cancer. Rates of reoperation vary from less than 10% to more than 50%. Reoperations after breast conserving surgery adversely affect cosmetic outcome and have the potential for additional stress for patients and families. Local control is a function not only of disease burden, but of tumour biology and the availability of effective systemic therapy. A toolbox of recommendations to reduce the proven variability of reoperation and the suspected variability of cosmetic outcome after initial wide excision for breast cancer has been developed by the American Society of Breast Surgeons (ASBrS) in a multidisciplinary consensus conference entitled 'Collaborative Attempt to Lower Lumpectomy Reoperation Rates' (CALLER). The consensus was based on a meta-analysis which included 28,162 patients in 33 studies examining the relationship between margin width and local control. The goal of the conference, recommended by two-thirds of the participants, is to have an average reoperation rate of less than 20% by the year 2020. The compliance with the Society of Surgical Oncology–American Society for Radiation Oncology (SSO–ASTRO) margin guideline not to perform routine reoperation for close margins with no tumour on ink in patients with invasive cancer received a strong-moderate recommendation during the CALLER Conference, a multidisciplinary meeting organised by the ASBrS, with a 2A level of evidence (according to National Comprehensive Cancer Network (NCCN) guidelines). The consensus indicates that the routine use of re-excision to obtain some arbitrary clear margin width is not supported by data for any patient subset with invasive carcinoma.

9b *Definition*: Proportion of patients (DCIS only) who received just one operation (excluding reconstruction).

Minimum standard: 70%

Target: 90%

Motivation: To reduce the rate of multiple surgeries where a single operation may be sufficient; this also encompasses optimal preoperative imaging, optimal preoperative and intraoperative handling, use of oncoplastic techniques and optimal pathological examination, all concordant with guidelines.

Level of evidence: II.

Approximately 30% of patients attempting wide excision for DCIS undergo a re-excision which compromises cosmetic outcome, may increase surgical complications and health care costs, and causes additional distress for patients and families. Moreover, re-excision contributes to the decision for bilateral mastectomy. There is a lack of consensus on what represents adequate margins in DCIS treated with breast conserving surgery and whole breast irradiation, and the use of adjuvant endocrine therapy reduces rates of ipsilateral breast tumour recurrence. A meta-analysis of margin width and ipsilateral breast tumour recurrence from a systematic review of 20 studies including 7883 DCIS patients and other published literature was performed by the Society of Surgical Oncology (SSO), the American Society for Radiation Oncology (ASTRO) and the American Society of Clinical Oncology (ASCO) as the evidence base for consensus. The conclusions are that a 2 mm margin should be the standard for an adequate margin and that re-excision could be selectively used for margins smaller than 2 mm.

9c *Definition*: Proportion of patients receiving immediate reconstruction at the same time of mastectomy.

Minimum standard: 40%

Target: not applicable.

Motivation: cosmetic satisfaction and quality of life.

Level of evidence: III.

The Women's Health and Cancer Rights Act in the United States in 1998 sought to improve access to postmastectomy reconstruction. In a study on 20,560 United States patients undergoing reconstruction within 2 years of breast cancer treatment, from 1998 to 2007, reconstruction use increased from 46% to 63% ($p < 0.001$),

with increased use of implants and decreased use of autologous techniques over time ($p < 0.001$). Delayed reconstruction was performed in 21% of patients who underwent reconstruction. In this study rates of reconstruction varied dramatically by geographic region in association with plastic surgeon density and were correlated with other treatments. A New York State law passed in 2010 mandates that surgeons discuss the availability of breast reconstruction with patients before breast cancer treatment. The 2003 European Parliament Resolution on breast cancer calls on the member states to protect the psychological well-being and physical integrity of women by ensuring that, wherever possible, breast reconstruction operations are performed using the patient's own tissue and within the shortest possible.

This procedure largely reflects patient demand and should be a key consideration in the multidisciplinary management of breast cancer.

Radiation therapy (RT) and local control

10 Post operative RT

10a *Definition:* Proportion of patients with invasive breast cancer (M0) who received postoperative radiation therapy (RT) after surgical resection of the primary tumour and appropriate axillary staging/surgery in the framework of BCT.

Motivation: Overall, postoperative RT decreases the local recurrence risk and increases long-term survival. Older patients (age >70) with small tumours who do receive adjuvant endocrine therapy may be treated without RT without a subsequent reduction in OS. Before extending this to a broad group of patients, an update with a longer follow-up of the published studies should be performed and a comparison between the respective benefits and side-effects of postoperative RT and adjuvant endocrine therapy are warranted. Anyway, depending on patient and tumour-related prognostic factors as well as on the prescription of endocrine therapy, the absolute benefit of RT varies. For selected patients with a low-risk breast cancer and/or a short life expectancy (based on factors including performance status, comorbidity and age), who are committed to take adjuvant endocrine therapy, postoperative radiation therapy might be withheld with follow-up for early detection of local recurrences.

Minimum standard: 90%

Target: 95%

Level of evidence: I.

Several prospective randomised trials and an Early Breast Cancer Trialists' Collaborative Group (EBCTCG) meta-analysis demonstrated a clear benefit from postoperative RT in the framework of breast-conserving therapy. A number of studies showed that low-risk patients, mainly elderly, who do receive adjuvant endocrine therapy, have limited benefit from RT in terms of local control, and no benefit for overall survival. However, the results for these patients are similar if they receive adjuvant endocrine therapy or postoperative RT, making the choice between these treatments part of the shared decision-making process.

10b *Definition:* Proportion of patients with involvement of axillary lymph nodes (≥pN2a) who received post-mastectomy radiation therapy to the chest wall and all (non-resected) regional lymph-nodes.

Minimum standard: 90%

Target: 95%

Motivation: ≥pN2a is a generally accepted criterion for postoperative loco-regional RT. It reduces all types of recurrences and improves overall survival.

Level of evidence: I.

Several prospective randomised trials and EBCTCG meta-analyses demonstrated a clear benefit from post-mastectomy RT in the case of involved axillary lymph nodes. The 2014 update of the EBCTCG meta-analysis reinforced the data published in 2005, showing that this effect was similar irrespective of the number of involved lymph nodes and of the administration of adjuvant systemic therapy. The effect was less pronounced if only regional RT was given, without treatment of the chest wall. More recently, the benefits for elective irradiation of the internal mammary lymph nodes was demonstrated by two prospective randomised and one prospective population-based study.

10c *Definition:* Proportion of patients with involvement of up to 3 axillary lymph nodes (pN1) who received post-mastectomy radiation therapy to the chest wall and non-resected axillary lymph-nodes, including level IV (supraclavicular) and, in medially located tumours, the internal mammary lymph-nodes.

Minimum standard: 70%

Target: 85%

Motivation: the benefit for pN1 patients is similar to that for ≥ pN2a patients, therefore, it should be advised especially for those pN1 patient subgroups that have a higher risk of nodal involvement based on the site of the tumour within the breast (medial/central) and the prognostic characteristics of the tumour.

Level of evidence: I.

Several prospective randomised trials and the EBCTCG meta-analyses demonstrated a clear benefit from post-mastectomy RT in the case of involved axillary lymph nodes (see 10b), including N1 disease. We have to recognise that, notwithstanding this evidence, there exists no generally supported consensus about loco-regional treatment in pN1 disease. Therefore, it is often 'advised taking also into account factors like patient's age, tumour location and other risk factors'.

Surgery and quality of life

11 Avoidance of overtreatment

11a *Definition*: Proportion of patients with invasive cancer and clinically negative axilla who underwent sentinel lymph-node biopsy (SLNB) only (excluding patients who received PST).

Minimum standard: 90%

Target: 95%

Motivation: To ensure adequate staging and avoid unnecessary axillary dissection.

LN status is important for prognosis and treatment planning and sentinel node biopsy is an accepted and sufficient means of surgical and pathological staging of the axilla in patients with no clinical evidence of lymph node involvement. The risk associated morbidity is related to the number of nodes excised.

Level of evidence: I.

The axillary nodal status is the strongest prognostic factor in breast cancer that tailors many loco-regional and systemic treatment decisions. The determination of the pN-status is important for all breast cancer patients in whom adjuvant treatment decisions are based on prognosis. Several randomised trials compared SLNB with full axillary dissection (AD) in patients with clinically negative lymph nodes. No difference was identified with regard to disease-free survival (DFS) and overall survival (OS), Morbidity and quality of life of life were significantly better in patients who underwent SLNB alone. SLNB is therefore regarded as the gold standard to assess the axillary lymph node status in clinically node-negative patients.

11b *Definition*: Proportion of patients with invasive cancer who underwent sentinel lymph-node biopsy with no more than 5 nodes excised.

Motivation: To reduce excessive extent of SLNB. SLNB with no more than 5 nodes excised limits the risk of associated morbidity. Moreover it is well demonstrated that it is not necessary to remove additional sentinel nodes or non-sentinel nodes.

Minimum standard: 90%

Target: 95%

Level of evidence: I.

Shoulder/arm morbidity has the greatest impact on quality of life in long time survivors of breast cancer. Since the number of resected nodes is closely related to morbidity, the extent of SLNB should also be restricted. In most trials a median of two sentinel lymph nodes (SLNs) is resected and provides a false-negative rate (FNR) of less than 10%. In some patients, however, many more SLNs can be identified. The National Surgical Adjuvant Breast and Bowel Project trial B-32 (NSABP-B 32) study in Canada and USA showed a close relation between the number of dissected SLNs and the false negative rate (FNR). For patients with two or more removed SLNs, however, the FNR was reliably less than 10%. The extension of surgery did not significantly improve the FNR (6.9% for three SLNs, 5.5% for four SLNs and 1% for five or more SLNs).

11c *Definition*: Proportion of patients (BRCA1 and BRCA2 patients excluded) with invasive breast cancer not greater than 3 cm (total size, including DCIS component) who underwent BCT as primary treatment.

Minimum standard: 70%

Target: 85%

Motivation: to conserve the organ with related effects; to reduce the frequency of second operations such as delayed reconstruction. The rate is related to a large number of factors including (expected) cosmetic outcome, patient preference and access to radiation therapy.

Level of evidence: I.

Evidence of at least equivalence of BCT compared to modified radical mastectomy (MRM) for early breast cancer.

There is strong evidence from numerous randomised trials and a meta-analysis, that breast conserving surgery followed by whole breast irradiation is equivalent to mastectomy in terms of overall survival. The preservation of the breast has an important impact on life quality. Furthermore, breast reconstruction (primary or secondary, implant or autologous) is associated with additional risks and costs. Oncoplastic techniques or primary systemic treatment are important tools to achieve breast conservation, even in patients with an unfavourable breast/tumour relation or tumour site, and thus improve the rate of BCT. There is evidence from meta-analyses that 'no ink on tumour' can be accepted as sufficient margin width in invasive disease.

11d *Definition*: Proportion of patients with non-invasive breast cancer not greater than 2 cm who underwent BCT.

Minimum standard: 80%

Target: 90%

Motivation: to conserve the organ with related effects; to reduce the frequency of second operations such as delayed reconstruction. The rate is difficult to fix firmly, however, as it is related to a large number of factors including (expected) cosmetic outcome, patient preference and access to radiation therapy.

Level of evidence: II.

*Evidence of the equivalence of MRM and BCT for non-invasive breast cancer.

There are no randomised trials that compare BCT and MRM with regard to DFS or OS in patients with DCIS. As DCIS is not an invasive disease, the mortality rate is low. A recently published observational study including 108,196 patients from the Surveillance, Epidemiology and End Results (SEER) program database (a premier source of cancer information and statistics in the United States implemented by the National Cancer Institute) observed, however, a breast cancer-specific mortality rate of 3.3% for patients with DCIS which is slightly higher (1.8-fold) compared to the US population (1.8). Although certain risk factors (age at diagnosis, invasive recurrence, ethnicity) were identified that affected the risk

of dying from breast cancer, the extent of local treatment (BCT versus MRM, BCT with or without radiation therapy) had no impact on survival. According to a meta-analysis of retrospective studies on patients who were treated with BCT and whole breast irradiation, a margin width of 2 mm was identified as minimum requirement for the surgical treatment of patients with DCIS. In view of the very good prognosis of DCIS in terms of overall survival issues of life quality should be assigned a high priority. For most patients with small lesions up to 2 cm breast conserving surgery should be feasible, especially when oncoplastic techniques are employed in cases of a critical relation between the surgical target volume and the breast size.

11e *Definition*: Proportion of patients with DCIS only who do not undergo axillary clearance.

Minimum standard: 97%

Target: 99%

Motivation: To avoid unnecessary axillary surgery. The rate of axillary involvement is about 1–2% in this setting (DCIS by definition does not metastasise) and depends on grade and diameter (i.e. risk of occult invasive cancer); axillary surgery increases morbidity.

Level of evidence: II.

No randomised trials but consensus in all guidelines based on substantial clinical data.

DCIS is a non-invasive disease and tumour cells cannot spread to the lymph nodes in cases of pure DCIS. Therefore, in general, axillary staging is not required. In some patients (1–2%) the histological assessment of the surgical specimen reveals unexpected invasive disease. A secondary SLNB is feasible and reliable after BCT and should be recommended in these patients. When mastectomy is performed, a secondary SLNB is technically not feasible because the efferent lymphatic vessels are destroyed by the primary surgery. Upfront SLNB is therefore recommended in patients who are scheduled for mastectomy.

SLNB has replaced axillary clearance as a staging procedure in clinically node-negative patients. Axillary dissection is therefore not indicated as a staging procedure in patients with DCIS and incidentally detected invasive disease. The therapeutic role of full axillary dissection has been questioned recently for patients with a positive SLN who undergo BCT and whole breast irradiation. Among the few patients with incidentally detected invasive breast cancer and a positive SLNB, axillary clearance is only indicated in patients who undergo mastectomy.

Systemic treatment

12 Appropriate endocrine therapy

Definition: Proportion of patients with endocrine-sensitive invasive cancer who received endocrine therapy.

Minimum standard: 85%

Target: 90%

Motivation: endocrine therapy should be offered to patients with endocrine-sensitive invasive breast cancer.

Level of evidence: I.

Data from the EBCTCG show that 5 years of tamoxifen in women with ER-positive early breast cancer results in an absolute benefit in terms of 15-years relapse-free survival (RFS) and breast cancer-specific survival (BCS) of 13.2% and 9.2%, respectively. The benefit is independent of progesterone receptor status (PgR). ER-negative PgR-positive tumours might be artefactual. There is no evidence that ER-negative/PgR-positive patients do benefit from adjuvant endocrine therapy.

A meta-analysis of individual data on 31,920 post-menopausal women with ER-positive early breast cancer entered in randomised trials evaluating the role of aromatase inhibitors (AIs) show that AIs reduce recurrence rates by about 30% (proportionately) compared with tamoxifen when treatments differ, but not thereafter. Five years of an aromatase inhibitor reduces 10-year breast cancer mortality rates by about 15% compared with 5 years of tamoxifen. In the comparison of 5 years of aromatase inhibitor versus 2–3 years of tamoxifen then aromatase inhibitor to year 5, breast cancer mortality reduction is not significant. Adjuvant therapy with tamoxifen remains an option in selected postmenopausal patients.

In premenopausal women with ER-positive early breast cancer, ovarian suppression/ablation results in a 4.3% and 3.2% absolute benefit in terms of 15-year RFS and OS, respectively. Recent data from the SOFT trial show that the addition of ovarian suppression to tamoxifen might be beneficial for women who are at sufficient risk of recurrence to warrant adjuvant chemotherapy and who remain premenopausal after the cytotoxic treatment. Compared with tamoxifen plus ovarian suppression, adjuvant treatment with exemestane plus ovarian suppression significantly reduces recurrence.

Omission of endocrine therapy is an option for older patients with a very low-risk tumour (pT1aN0) with favourable biology or life-threatening comorbidities.

13 Appropriate chemotherapy and HER2-targeted therapy

13a *Definition*: Proportion of patients with ER− (T > 1 cm or Node+) invasive carcinoma who received adjuvant chemotherapy.

Minimum standard: 85%.

Target: 95%.

Motivation: Chemotherapy should be offered to patients with ER-negative invasive breast cancer (T > 1 cm or Node +).

Level of evidence: I.

Data from the EBCTCG and from several clinical trials offer evidence of benefit from chemotherapy versus no treatment in terms of RFS and OS in patients with ER-negative tumours.

In patients with invasive breast cancer T < 1 cm N0/N1mi that is hormone receptor-negative, different guidelines suggest considering chemotherapy. This treatment is suggested rather than formally recommended because this population is poorly represented in prospective randomised trails. The prognosis of patients with T1a and T1b tumours who are node negative is uncertain even when ER is negative The decision to use chemotherapy in these patients must balance the known toxicities of the treatment against the uncertain absolute benefits that may exist with treatment. As it is not possible to quantify the applicability in clinical practice of such suggestions, this population is not included in this quality indicator.

There are limited data to make chemotherapy recommendations in elderly patients (i.e. >70 years old). Treatment should be individualised with consideration of comorbid conditions.

13b *Definition*: Proportion of patients with HER2 positive (IHC3-positive or *in situ* hybridisation positive FISH-positive) invasive carcinoma (T > 1 cm or N+) treated with chemotherapy who received adjuvant trastuzumab.

Minimum standard: 85%.

Target: 95%.

It is recommended to follow the American Society of Clinical Oncology/College of American Pathologists (ASCO/CAP) guidelines for HER2 testing.

Motivation: Trastuzumab should be offered to patients with HER2-positive invasive breast cancer if they are to receive adjuvant chemotherapy.

Level of evidence: I.

Clinical trials have shown that adjuvant trastuzumab plus chemotherapy improves RFS and OS in patients with node positive or node-negative T > 1 cm HER2+ early breast cancer, compared to chemotherapy alone.

In patients with invasive breast cancer T < 1 cm N0/N1mi that is HER2-positive, different guidelines suggest considering chemotherapy plus trastuzumab. This treatment is suggested rather than formally recommended because this population is poorly represented in prospective randomised trails. The prognosis of patients with T1a and T1b tumours who are node negative is uncertain even when HER2 is over-expressed or amplified. The decision to use chemotherapy plus trastuzumab in these patients must balance the known toxicities of the treatment against the uncertain absolute benefits that may exist with treatment. As it is not possible to quantify the applicability in clinical practice of such suggestions, this population is not included in this quality indicator.

There are limited data to make chemotherapy and HER2-targeted therapy recommendations in elderly patients (i.e. >70 years old). Treatment should be individualised with consideration of comorbid conditions.

13c *Definition*: Proportion of patients with HER2-positive invasive carcinoma treated with neoadjuvant chemotherapy who received neo-adjuvant trastuzumab.

Minimum standard: 90%

Target: 95%.

Motivation: Standard PST for HER2-positive breast cancer includes chemotherapy and trastuzumab.

The addition of trastuzumab to primary chemotherapy significantly improves the pathological complete response (pCR) rate in HER2-positive breast cancer.

Level of evidence: I.

In the randomised phase 3 NeOAdjuvant Herceptin (NOAH) trial conducted in women with HER2-positive locally advanced or inflammatory breast cancer, neoadjuvant trastuzumab significantly improved pCR rate and event-free survival. Event-free survival (EFS) was strongly associated with pCR in patients given trastuzumab. Hazard ratios for EFS obtained from unadjusted Cox model for patients assigned to trastuzumab compared with those assigned to no trastuzumab were 0· 87 (95% CI 0· 43–1· 74) for ER and/or PgR-positive tumours and 0· 46 (95% CI 0· 27–0· 80) for ER and PgR-negative cases.

A pooled analysis of 12 clinical trials of neoadjuvant treatment of breast cancer conducted by the Collaborative Trials in Neoadjuvant Breast Cancer (CTNeoBC) has shown that patients who attain pathological complete response have improved survival. The association between pCR and long-term outcomes differed in the different cancer subtypes and was strongest in patients with triple-negative breast cancer and in those with HER2-positive, hormone-receptor negative tumours who received trastuzumab.

Patients older than 70 years may not be treated with chemotherapy or HER2-targeted due to comorbidity or concomitant diseases.

13d *Definition*: Proportion of patients with inflammatory breast cancer (IBC) or locally advanced non-resectable ER-carcinoma who received neo-adjuvant chemotherapy.

Minimum standard: 90%.

Target: >95%.

Motivation: IBC requires sequential multidisciplinary treatment, with primary or neo-adjuvant chemotherapy representing the mainstay of treatment. Tumour down-staging is mandatory to convert initially un-resectable locally advanced breast cancer to a resectable stage.

Level of evidence: II.

Due to its rarity, there are no large RCTs examining neoadjuvant therapy in IBC, but rather several smaller or retrospective studies, as well as extrapolation from studies of all locally advanced breast cancer, that support this approach. The addition of taxane to anthracycline based therapy was associated with higher pCR

rates in a series from MD Anderson. HER2-positive disease should also receive trastuzumab, as this too increases the chance of downstaging and pCR, as seen in the NOAH trial.

Staging, counselling, follow-up and rehabilitation

14 Appropriate staging procedure

14a *Definition*: Proportion of women with stage I or primary operable stage II, breast cancer who do not undergo baseline-staging tests (e.g. US of liver, chest X-ray and bone scan).

Minimum standard: 95%.

Target: 99%.

Motivation: As demonstrated by clinical studies and indicated in the various societies' recommendations, the percentage of patients with asymptomatic metastases detected with these tests is so low as to be irrelevant to the management of stage I or primary operable stage II breast cancer.

Level of evidence: III.

Several prospective, retrospective, and systemic review papers have been published on the value of staging in newly diagnosed stage I/II breast cancer since the previous publication of the EUSOMA Quality Indicator Guidelines. The reported incidences of distant metastasis (DM) after staging in stage I/II breast cancer patients varies between 0.3 and 1.2% which is consistent with the result of older studies. Therefore, staging for DM should not be a routine procedure in patients diagnosed with early stage breast cancer.

14b *Definition*: Proportion of women with stage III breast cancer who undergo baseline staging tests (US of liver, chest X-ray and bone scan).

Minimum standard: 95%.

Target: 99%.

Motivation: Stage III disease is associated with a sufficiently high risk of clinically asymptomatic metastases to warrant screening. These additional findings will have an impact on treatment strategy in the individual patient. Therefore, additional staging in high risk, i.e. stage III breast cancer, patients is highly recommended.

Computed tomography (CT) scan, bone radiographs, MRI or positron emission tomography (PET) scan can be used as an alternative, particularly in the setting of symptoms and/or to clarify any abnormal outcome of the mandatory diagnostic procedures, or in the framework of clinical trials.

Level of evidence: III.

In contrast to newly diagnosed stage I/II patients, stage III breast cancer patients harbour a higher risk of having synchronous DM. The published incidence rates vary from 5 to 50% and seem to increase in more advanced disease. Concerning the use of PET/CT scanning versus conventional staging modalities, a systemic review by Brennan *et al.* suggested that [18F]-fluorodeoxyglucose positron emission tomography (FDG-PET) or [18F]-fluorodeoxyglucose positron emission tomography /computed tomography (FDG-PET/CT) had a higher sensitivity (median sensitivity 98.7%, range 78–100%) than conventional imaging (median sensitivity 70%, range 37.5–85.9%), but specificity was more variable.

15 Perform appropriate follow-up

15a *Definition*: Proportion of asymptomatic patients who undergo routine annual mammographic screening and 6/12 months clinical evaluation in the first 5 years after primary surgery.

Minimum standard: 95%.

Target: 99%.

Motivation: At least three sets of evidence-based guidelines recommend periodic history taking, physical examination and yearly mammography. No consensus exists on the frequency and duration of physical examination. Two randomised trials showed no survival benefit from intensive screening for asymptomatic metastatic disease.

Level of evidence: I.

Although the incidence of breast cancer has increased, breast cancer mortality has decreased, likely as a result of both breast cancer screening and improved treatment. For breast cancer survivors, appropriate surveillance continues to be a subject of controversy. Only performance of yearly screening mammography is supported by evidence. Although advanced imaging technologies and sophisticated circulating tumour biomarker studies are exquisitely sensitive for the detection of recurrent breast cancer, there is no proof that earlier detection of metastases will improve outcome. A lack of specificity may lead to more tests and patient anxiety.

Two prospective trials were initiated in Italy in the 1980s in which women with a prior history of breast cancer and who were asymptomatic and free of disease were randomly assigned to either routine follow-up without any special testing or periodic evaluation for occult metastases using standard techniques available at the time. Neither of these two trials demonstrated a benefit from intensive follow up. Indeed, in one of these trials serial quality-of-life analysis suggested that the anxiety and false-positive findings associated with surveillance were worse in the screened patients.

Neither of these trials encompassed what would be considered modern diagnostic techniques. In a more recent Finnish trial however, conducted in the 1990s, patients were randomly assigned to blood counts, sedimentation rate, liver enzymes, and CA15-3 every 3 or 6 months after primary treatment, or to routine use of diagnostic examinations, or use based on

clinical grounds only if concerning clinical findings were identified. This trial also failed to detect any difference in outcome among any of the arms. A 2005 Cochrane meta-analysis of these trials concurred that there was no apparent benefit from intensive surveillance of patients who were asymptomatic following primary and adjuvant systemic therapy for breast cancer.

15b *Definition*: Proportion of treated patients for which the breast centre collects data on life status and recurrence rate (for at least 5 years.

Minimum standard: 80%.

Target: 90%.

Motivation: the availability of outcome information strengthens quality assurance and facilitates participation in clinical trials.

Level of evidence: III.

Appropriate arrangements, in the respect of privacy regulations, should be taken between the breast centre and cancer registries or other appropriate sources in order to be able to periodically (ideally yearly) update outcome information on treated patients. In addition, information on patient outcomes should be collected during clinical follow up or by means of direct calls to patients who are lost to follow up.

16 Availability of nurse counselling

16a *Definition*: Proportion of patients referred for nurse counselling at the time of primary treatment.

Minimum standard: 85%.

Target: 95%.

Motivation: Oncology nurses can support patients throughout the course of breast cancer treatment though assessment and psychological support. Adequate information can help women to find greater balance and sense of control with respect to the disease.

There is limited evidence that patient support programmes improve the outcomes of quality of life and reduce distress. However, there is good evidence that patient support programmes improve patients' satisfaction. Therefore it is recommended that support programmes are used for adult cancer to improve patients' satisfaction. Nurse-led follow-up can potentially result in better continuity of care and the availability of more time to provide psychosocial support and address patients' information needs.

Level of evidence: IV.

Breast care nurses (BCNs) are an important part of the multidisciplinary team, and provide a range of interventions including support, information, and patient advocacy while acting as a liaison between other the members of the multiprofessional team surrounding the patient. Supportive care in this setting has been defined in various ways and is often interpreted as an umbrella term that can include anything from evidence-based interventions to bedside conversations. In relation to the BCN role, supportive care interventions are aimed at improving quality of life for women with breast cancer. The supportive role focusses on the identification of the multiple physical, psychological, social, sexual, cultural and spiritual needs of the breast cancer patient. This includes the identification of these needs at all stages of the illness, implementation of evidence-based interventions and psychosocial support in conjunction with anti-cancer treatment.

16b *Definition:* Proportion of women with a diagnosis of breast cancer who have direct access to a breast care nurse specialist for information and support with treatment-related symptoms and toxicity during the treatment, follow-up and rehabilitation after initial treatment.

Motivation: Nurse-led follow-up can potentially result in better continuity of care and the availability of more time to provide psychosocial support and address patients' information needs.

Minimum standard: 95%

Target: 99%

Level of evidence: IV.

17 The availability of data manager

Definition: The Breast Centre must have a data manager responsible for the breast centre data.

Minimum standard: not applicable.

Target: not applicable.

Motivation: Data collection is essential in a Breast Centre to ensure audit and monitoring of data, for Quality Assurance.

Level of evidence: IV.

The data manager of a Breast Centre has responsibility for ensuring that all relevant and required data are collected, recorded and analysed.

The data manager facilitates the organisation of the audit meeting and the participation of the Breast Centre in external benchmarking activities.

Conclusion

The worldwide relevance of monitoring Breast Centre's performance through a set of Quality Indicators is demonstrated by the various initiatives undertaken at international and national level.

The EUSOMA Quality Indicators are an essential part of the voluntary European certification process based on the EUSOMA document on 'The requirements of a specialist Breast Centre'.

The Certification procedure consists of: a questionnaire to be filled in by the Breast Centre, a peer to peer audit visit and a EUSOMA report on the outcomes on Quality Indicators, based on an annual data transfer to the EUSOMA data warehouse. During the site visit, each member of the Audit Team collects all the necessary information to express his/her evaluation on the conformity

to the EUSOMA Requirements through: inspection of the documents prepared by the Breast Centre for each single discipline/issue, interview with the Breast Centre team members, evaluation of daily activity and the results of quality indicators relative to the year previous to the site visit summarised in the EUSOMA data report.

The European Commission has launched the ECIBC project (European Commission Initiative on Breast Cancer) made up by two working groups. The Guidelines Developing Group responsible for up-dating the European guidelines for quality assurance in breast cancer screening and diagnosis and the Quality Assurance Scheme Development Group responsible for the development of a set of common quality requirements for breast cancer centres in Europe. Similarly, to EUSOMA, the Quality Indicators set by ECIBC have a defined minimum standard and a target to comply with.

At National level there are some interesting initiatives which deserve mentioning.

One of the first European Countries recognising the role of Breast Centre and monitoring of quality indicators has been UK. Nowadays the National Health Service (NHS) system operates the National Cancer Peer Review (currently renamed as Quality Surveillance Programme QSP), a quality assurance programme for NHS services, including breast cancer. It foresees both self-assessment by cancer Centre's teams and external reviews conducted by professional peers, against national agreed quality measures. The Quality surveillance team will issue yearly a quality surveillance report, highlighting those services which require further monitoring and/or would benefit from a review visit.

The Netherlands runs a systemic audit of breast cancer services, the NABON Breast Cancer Audit. NABON collects data from all Dutch hospitals with the aims of nationwide evaluation of quality parameters, evaluation of guidelines adherence and weekly feedback to participating institutions.

In Germany, the vast majority of hospitals treating Breast Cancer have joined the certification system developed by the Breast Cancer Society and the German Society for Breast Disease. This system includes requirements and quality indicators collected during the certification process. Annually, anonymised results are reported to the public for all breast cancer centres through benchmarking reports.

Overseas, the ICHOM (The International Consortium for Health Outcomes Measurement) Initiative assembled a multidisciplinary international working group, to develop a standard set of value-based patient-centered outcomes for breast cancer. The standard set encompasses survival and cancer control, and disutility of care outcomes, to be collected through patients' reports and administrative and/or clinical records.

In all the cited initiatives, as well as in the one by EUSOMA, the important point is that the set of quality indicators is not only defined using a sound methodology, but is also used in structured quality assurance schemes. In this way, quality indicators are challenged against practice and can evolve and change and be periodically updated in order to be instrumental in producing better care.

Conflict of interest statement

None declared.

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Introduction

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1: Completeness of clinical and imaging diagnostic workup

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2: Specificity of diagnostic procedures (B/M ratio)

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3: Preoperative diagnosis

3a–3b

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4: Completeness of prognostic/predictive characterisation

4a

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