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Position Paper

Quality indicators in breast cancer care

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ABSTRACT

To define a set of quality indicators that should be routinely measured and evaluated to confirm that the clinical outcome reaches the requested standards, Eusoma has organised a workshop during which twenty four experts from different disciplines have reviewed the international literature and selected the main process and outcome indicators available for quality assurance of breast cancer care. A review of the literature for evidence-based recommendations have been performed by the steering committee.

The experts have identified the quality indicators also taking into account the usability and feasibility. For each of them it has been reported: definition, minimum and target standard, motivation for selection and level of evidence (graded according to AHRO). In overall 17 main quality indicators have been identified, respectively, 7 on diagnosis, 4 on surgery

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and loco-regional treatment, 2 on systemic treatment and 4 on staging, counselling, follow-up and rehabilitation. Breast Units in Europe are invited to comply with these indicators and monitor them during their periodic audit meetings.

Introduction

Since 1990, in United States and many European countries, breast cancer mortality is decreasing by 1–2% per year, thanks to early detection and improved treatment.

Breast cancer care is complex, onerous and expensive, therefore quality measurements are essential to monitor effectiveness and to guide improvements in healthcare.

It has been reported that in Europe there were stillwide differences in treatment offered to patients with breast cancer in terms of mastectomy and radiotherapy rates and use of adjuvant chemotherapy and hormone therapy.

It has also been shown that the specialised breast cancer care was associated with a significant reduction in mortality.

The European Parliament Resolution on Breast Cancer (B6/0528/2006) calls on Member States to 'Ensure nationwide provision of interdisciplinary breast units in accordance with the EU guidelines by 2016 since treatment in an interdisciplinary breast unit has been proved to raise chances of survival and to improve the quality of life, and calls on the Commission to deliver a progress report on this every two years'.

In accordance with this resolution, the European Society of breast cancer specialists – EUSOMA has started a voluntary certification process to assess the clinical performance in breast cancer care in dedicated Europeans units. So far, 32 breast units have been recognised to comply with the requirements requested by EUSOMA and other EU Guidelines on the basis of information collected by a questionnaire and by a site visit carried out by an independent team of breast cancer care experts.

It is therefore necessary to define a set of quality indicators that should be routinely measured and evaluated in order to confirm that the clinical outcome reaches the requested standards.

With this aim, a workshop was organised in Milan from 23rd–24th June 2008 during which 24 experts from different disciplines have reviewed the international literature and selected the main process and outcome indicators available for quality assurance of breast cancer care (Table 1).

Methods

In order to identify appropriate indicators for breast cancer healthcare quality assurance, according to national and international guidelines, a review of the literature for evidence-based recommendations has been performed by the steering committee. Twenty-eight selected papers and documents were sent, well before the Eusoma workshop, to the experts invited to prepare this consensus paper. Experts met in June 2008, with an initial and a final plenary discussion of about 3 hours each and with a separated discussion in four panel groups (diagnosis, surgery and loco-regional treatment, systemic treatment and staging).

Each expert panel selected and defined a core set of indicators, taking into account the evidence-based effect on outcome of the items they are related to.

As stated in the Agency for Healthcare Research and Quality (AHRQ) Evidence Report, nO. 105 04-E030-2, 2004, the key properties of a quality measure taken into consideration were reliability, meaning that the observation is highly consistent whenever measured, by the same observer at different points or by different observers, and validity, which means that the indicator is really measuring what it is intended to do.

Two additional properties were of concern for selecting the most appropriate quality indicators: usability, that means the observations generated by the measured application are easily interpretable in order to prompt actions concerning healthcare delivery, and feasibility, that requires easy data collections during routine clinical activities with limited related costs.

Expert panels were requested, whenever possible, to select both process and outcome measures, simply and clearly defined. Considering the certification process setting, quality indicators were restricted to a minimum, reflecting the whole diagnostic and therapeutic process and requiring readily available and systematically collected variables to be calculated.

For each indicator was reported:

(1) The definition
(2) The minimum and target standard
(3) The motivation for selection
(4) The level of evidence

The level of evidence is defined as the probability that the quality indicator is based on sound evidence (well designed and conducted studies). The level of evidence has been graded according to the short version of the *US Agency for Healthcare Research and Quality* (AHRQ, www.ahrq.org)[1] classification, as follows:

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. This implies the absence of good quality clinical studies on the relevant matter

Quality indicators on diagnosis

1. *Title: Completeness of clinical and imaging diagnostic work-up*

Definition: Proportion of women with breast cancer who pre-operatively underwent:

- Mammography
- Physical examination
- Ultrasound

Minimum standard: >90%
Target: >95%
Motivation: To allow a proper triple diagnostic approach and to identify size, site and possible multifocal and/or contralateral disease. Axillary ultrasound (possibly separately recorded) and contralateral breast examination (mammography and physical) are included.
Level of evidence: III Several studies have shown an increase of accuracy by the combination of different diagnostic tests.

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

Definition: Ratio of benign to malignant diagnoses is based on definitive pathology report (surgery only, non-operative biopsies excluded).
Minimum standard: 1:2
Target: 1:4
Motivation: To minimise unnecessary operations for benign conditions
Level of evidence: III according to NA and NHS guidelines based on the literature evidence on the follow-up of non-operated lesions, which are not at risk of developing cancer.

3. *Title: Pre-operative diagnosis*

Definition: The proportion of women with breast cancer (invasive or in situ) who had a pre-operative definitive diagnosis (B5 or C5).
Minimum standard: 80%
Target: 90%
Motivation: To reduce the number of unnecessary operations, to plan complete assessment and treatment, and for patient counselling
Level of evidence: III

4. *Title: Completeness of prognostic/predictive characterisation*

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

- Histological type
- Grading (according to EU Guidelines)
- ER & PgR
- HER 2

Minimum standard: >90%
Target: >95%
Motivation: Histological type and grade have not only been a prognostic influence but also a predictive value for multifocality and metastatic pattern and are part of the core data set on breast cancers.

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. Some units may choose not to include PR testing (Ref. NICE Guidelines UK and latest EBCTCG data). ER testing is however recommended as a mandatory item. Units offering ER testing should participate in quality control of the test.

Her-2 testing by immunohistochemistry or CISH/SISH/FISH as a primary test should also be performed and borderline cases should be verified by repeated or alternate testing (ISH for immunohistochemistry and immunohistochemistry for primary FISH). Laboratory-based quality control is also essential here.
Level of evidence: II
4b Definition: The proportion of invasive cancer cases with primary surgery, for which the following prognostic/predictive parameters have been recorded:

- Histological type
- Grading (according to EU Guidelines)
- ER & PgR
- HER 2
- Pathological stage (T and N)
- Size in mm for the invasive component
- peritumoral vascular invasion
- Distance to nearest radial margin

Minimum standard: >95%
Target: >98%
Motivation: Adjuvant therapy and treatment planning.
Level of evidence: II
4c Definition: The proportion of non-invasive cancer cases for which the following prognostic/predictive parameters have been recorded:

- Dominant histologic pattern
- Size in mm (best pathology or radiology estimate if 2 stage pathology)
- Grading (according to EU Guidelines)
- Distance to nearest radial margin

Minimum standard: >95%.
Target: >98%.
Motivation: Treatment planning. In the framework of BCT, the tumour-free margin should ideally be measured in all directions. For BCT in DCIS, margins play probably an even more important role (together with age) as a risk factor for LR, compared to invasive cancer.
Level of evidence: II.

5. *Title: Waiting time*

Definition: Time between the date of first diagnostic examination within the breast unit and the date of surgery or start of other treatment within 6 weeks

Minimum standard: >75%.

Target: >90%.

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

Level of evidence: IV.

6. *Title: MRI availability*

Definition: The proportion of cancer cases examined pre-operatively by MRI.

Minimum standard: suggested 5%.

Target: not applicable.

Motivation: To allow proper diagnostic assessment and to identify size, site and possible multifocal and/or contralateral disease.

Level of evidence: IV.

7. *Title: Genetic counselling availability (this standard should be collected but is considered non-mandatory)*

Definition: The proportion of cancer cases referred for genetic counselling.

Minimum standard: suggested 5%.

Target: not applicable.

Motivation: To allow counselling.

Level of evidence: IV.

Quality Indicators on surgery and loco-regional treatment

– Surgery and local control

8. *Title: Multidisciplinary discussion*

Definition: The proportion of cancer patients to be discussed by a multidisciplinary team.

Minimum standard: 90%.

Target: 99%.

Motivation: To select optimal treatment based on guidelines + 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 BC); to document proposed treatment (medico-legal issues); to select patients for clinical trials. Pre-operative discussion seems preferable but not obligatory. The consensus is that there should be multidisciplinary discussion without specifying the time point.

Level of evidence: IV (with consensus opinion)

9. *Title: Appropriate surgical approach*

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

Minimum standard: 80%.

Target: 90%.

Motivation: this also encompasses optimal pre-operative imaging; optimal pre-operative handling and optimal pathological examination, all concordant with guidelines.

Level of evidence: III consensus based on compromise with regard to the discussion in the literature on the importance of margins; e.g. Dutch guidelines require no re-excision in case of focally involved margins whilst German guidelines require re-excision.

9b Definition: The proportion of patients (DCIS only) who received just one operation.

Minimum standard: 70%.

Target: 90%.

Motivation: this also encompasses optimal pre-operative imaging; optimal preoperative handling and optimal pathological examination.

Level of evidence: II.

9c Definition: The proportion of patients with invasive cancer and a clinically negative axilla (+US ± FNA/CNB) who had sentinel lymph node biopsy.

Minimum standard: 90%.

Target: 95%.

Motivation: LN status is important for prognosis and treatment planning and sentinel node biopsy is an accepted means of surgical and pathological staging of the axilla in patients with no clinical (including ultrasound and/or cytological) evidence of lymph node involvement.

Level of evidence: II.

9d Definition: The proportion of patients with invasive cancer and axillary clearance performed, who had at least 10 lymph nodes examined.

Minimum standard: 95%

Target: 98%.

Motivation: if 10 nodes from level 1 are negative, there is a 90% probability of no involvement at any level. A high average lymph node yield reflects both good surgery and pathological examination.

Level of evidence: III.

– Radiotherapy and local control

10. *Title: Post-operative RT*

10a Definition: The proportion of patients with invasive breast cancer (M0) who received post-operative radiotherapy after surgical resection of the primary tumour and appropriate axillary staging/surgery in the framework of BCT.

Minimum standard: 90%.

Target: 95%.

Motivation: Post-operative radiotherapy decreases the local recurrence risk and increases long-term survival. Depending on patient- and tumour-related prognostic factors, the absolute gain varies so that for selected patients (short life-expectancy based on poor WHO ± age and low-risk BC), follow-up alone might be selected. DCIS is kept out because of the ongoing controversy and the variance in the guidelines.

Level of evidence: I.

10b Definition: The proportion of patients with involvement of axillary lymph nodes (⩾ pN2a) who received post-mastectomy radiotherapy.

Minimum standard: 90%.

Target: 95%.

Motivation: ⩾ pN2a is a general accepted criterion; the debate is ongoing for pN1a patients.

Level of evidence: I (EBCTCG meta-analysis from ⩾ pN1a on).

– Surgery and quality of life

11. *Title: Avoidance of overtreatment*

11a Definition: Proportion of patients with invasive breast cancer not greater than 3 cm (total size, including DCIS component) who underwent BCT.

Minimum standard: 70%.

Target: 80%.

Motivation: to conserve the organ with related effects; fewer 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 radiotherapy.

Level of evidence: level I evidence of the equivalence of MRM and BCT for early BC.

11b Definition: The proportion of patients with non-invasive breast cancer not greater than 2 cm who underwent BCT

Minimum standard: 70%.

Target: 80%.

Motivation: To conserve the organ with related effects; fewer 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 radiotherapy.

Level of evidence: level II* evidence of the equivalence in terms of overall survival but a higher local recurrence rate after BCT as compared to MRM.

*Randomised trials comparing BCT with mastectomy in patients with DCIS do not exist. We have however numerous prospective trials evaluating the role of BCT. Therefore: Level II of evidence.

11c Definition: The proportion of patients with DCIS who do not undergo axillary clearance.

Minimum standard: 95%.

Target: 98%.

Motivation: the rate of axillary involvement is about 1–2% and depends on grade and diameter (related to occult invasive cancer); axillary surgery increases morbidity.

Level of evidence: IV, no randomised trials but consensus in all guidelines based on a lot of clinical data.

11d Definition: The proportion of invasive breast cancer patients with pN0 who do not undergo axillary clearance.

Minimum standard: 80%.

Target: 90%.

Motivation: morbidity is dependent on the extent of surgery (SNB < AC). The number of contraindications to performing SNB is continuously decreasing.

Level of evidence: II. A lot of evidence supports the use of SNB for all patients in the framework of their primary treatment for BC, unless LN involvement was confirmed preoperatively.

Quality indicators on systemic treatment

12. *Title: Appropriate hormonotherapy*

12a Definition: The proportion of patients with endocrine sensitive invasive carcinoma who received hormonotherapy, out of the total number of patients with this diagnosis.

Minimum standard: 80%.

Target: >90%.

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

In the last St. Gallen consensus paper, it is pointed out that ER– PgR+ tumours are probably artefactual. Despite this there is no clear evidence that ER– /PgR+ patients do not benefit from adjuvant endocrine therapy.

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 11.8% and 9.2% absolute benefit in terms of 15-years relapse-free survival (RFS) and overall survival (OS), respectively. 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-years RFS and OS, respectively.

Data from more recent trials show that the introduction of an aromatase inhibitor in postmenopausal patients with ER-positive early breast cancer further reduce the risk of tumour relapse over single agent tamoxifen without improving survival.

12b Definition: The proportion of patients with ER– and PgR– carcinoma who did not receive adjuvant hormonotherapy, out of the total number of patients with the same diagnosis.

Minimum standard: 98%.

Target: 100%.

Motivation: Endocrine therapy should not be offered to patients with ER- and PgR-negative invasive breast cancer.

Level of evidence: I. Data from the EBCTCG show no benefit from endocrine therapy in patients with ER-poor breast cancer.

13. *Title: Appropriate chemotherapy and other medical therapy*

13a Definition: The proportion of patients with ER– (T > 1 cm or Node+) invasive carcinoma who received adjuvant chemotherapy, out of the total number of patients with the same diagnosis.

Minimum standard: 80%.

Target: >90%.

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.

13b Definition: The proportion of patients with N+ or N– T > 1 cm HER2+ (IHC 3+ or in situ hybridisation positive FISH +) invasive carcinoma treated with chemotherapy and who had adjuvant trastuzumab, out of the total number of patients with the same diagnosis.

Minimum standard: 80%.

Target: >90%.

It is recommended to follow the ASCO guidelines for HER2 testing.

Motivation: Trastuzumab should be offered to patients with HER2-positive (IHC 3+ or FISH+) invasive breast cancer N+ or N– T > 1 cm if they receive adjuvant chemotherapy.

Level of evidence: I. Clinical trials have shown that adjuvant trastuzumab improves RFS and OS in patients with node positive or node-negative T > 1 cm HER2+ early breast cancer above chemotherapy alone.

13c Definition: The proportion of patients with HER2 negative invasive carcinoma who did not have adjuvant trastuzumab, out of the total number of patients with the same diagnosis.

Minimum standard: 98%.

Target: 100%.

Motivation: Trastuzumab should not be offered to patients with HER2 negative invasive breast cancer.

Level of evidence: II. A Study conducted in the metastatic setting showed no advantage from a trastuzumab based treatment in patients with HER2negative breast cancer.

13d Definition: The proportion of patients with HER2+ invasive carcinoma who had adjuvant chemotherapy, out of the total number of patients with the same diagnosis who had adjuvant trastuzumab.

Minimum standard: 95%.

Target: 100%.

Motivation: Chemotherapy should be offered to patients with HER2 positive (IHC 3+ or FISH+) invasive breast cancer who are candidates to receive trastuzumab.

Level of evidence: IV – All the studies investigating the role of trastuzumab in the adjuvant setting incorporated chemotherapy in the treatment plan (sequential or concomitant strategy). No data are available on the role of single agent trastuzumab (or in combination with only an endocrine treatment) in the adjuvant setting.

13e Definition: The proportion of patients with inflammatory breast cancer (IBC) or locally advanced non-resectable ER carcinoma who had neo-adjuvant chemotherapy over the total of patients with the same diagnosis.

Minimum standard: 90%.

Target: >95%.

Motivation: IBC requires sequential multidisciplinary treatment with primary or neo-adjuvant chemotherapy representing the mainstay of treatment. Tumour downstaging is mandatory to reconvert initially non-resectable locally advanced breast cancer to a resectable stage.

Level of evidence: II Several trials have shown that chemotherapy allows tumour shrinkage in patients with inflammatory BC and locally advanced non-resectable breast cancer.

Quality indicators on staging, counselling, follow-up and rehabilitation

14. *Title: Appropriate staging procedure*

14a Definition: The proportion of women with stage I breast cancer who do not undergo baseline staging tests (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 society's recommendations the percentage of patients with asymptomatic metastases detected with these tests is irrelevant to the management of stage I breast cancer.

Level of evidence: III.

14b Definition: The 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: CT scan, bone radiographs, MRI-, PET-scan should be used only when indicated by symptoms, in the framework of clinical trials and/or to clarify an abnormal outcome of the mandatory diagnostic procedures.

Level of evidence: III.

15. *Title: Perform appropriate follow-up*

Definition: The proportion of asymptomatic patients who undergo routine annual mammographic screening and clinical evaluation every 6 months in the first 5 years after the operation.

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.

Level of evidence: I.

16. *Title: Avoid inappropriately intensive follow-up*

Definition: The proportion of asymptomatic patients who do not undergo a follow-up protocol more intensive than local examination (mammography, US and clinical evaluation every 6/12 months in the first 5 years after the operation).

Minimum standard: 95%.

Target: 99%.

Motivation: two randomised trials showed no survival benefit from intensive screening for asymptomatic metastatic disease.

Level of evidence: I.

17. *Title: Availability of nurse counselling*

17a Definition: The proportion of patient referred for nurse counselling at the time of primary treatment.

Minimum standard: 85%.

Target: 95%.

Motivation: Oncology nurses can give assessment and psychological support to women undergoing breast cancer treatment. Adequate information can help women in finding more balance and sense of control with respect to the disease.

Level of evidence: IV.

17b Definition: All women with a diagnosis of breast cancer should have direct access to a breast care nurse specialist for information and support with treatment-related symptoms and toxicity during the treatment and follow-up and rehabilitation after initial treatment.

Table 1 – Summary table of quality indicators in breast cancer care.

	Indicator	Level of evidence	Mandatory/ Recommended	Minimum standard	Target
Diagnosis					
1.	Completeness of clinical and imaging diagnostic work-up (Proportion of women with breast cancer who pre-operatively underwent mammography, ultrasound and physical examination)	III	M	90%	95%
2	Specificity of diagnostic procedures (B/M ratio)	III	M	1:2	1:4
3.	Proportion of women with breast cancer (invasive or in situ) who had a pre-operative definitive diagnosis (B5 or C5)	III	M	80%	90%
4.	*Completeness of prognostic/predictive characterization*				
4a	Proportion of invasive cancer cases for which the following prognostic/ predictive parameters have been recorded: histological type, grading, ER&PgR, HER 2	II	M	90%	95%
4b	Proportion of invasive cancer cases with primary surgery, for which the following prognostic/predictive parameters have been recorded: histological type, grading, ER & PR, HER 2, pathological stage (T and N), size in mm for the invasive component, peritumoral vascular invasion, distance to nearest radial margin	II	M	95%	98%
4c	Proportion of non-invasive cancer cases for which the following prognostic/predictive parameters have been recorded: Dominant histologic pattern, Size in mm (best pathology or radiology estimate if 2 stage pathology), Grading, distance to nearest radial margin	II	M	95%	98%
5.	Waiting time (Time between the date of first diagnostic examination within the unit and the date of surgery or start of treatment within 6 weeks)	IV	R	75%	90%
6.	MRI availability (at least 5% of cancers preoperatively examined)	IV	R	5%	NA
7.	Genetic counselling availability (proportion of cancer cases referred)	IV	R	5%	NA
Surgery and loco-regional treatment					
8.	Multidisciplinary discussion (proportion of cancer patients to be dicussed)	IV	M	90%	99%
9.	*Appropriate surgical approach*				
9. a	Proportion of patients (invasive cancers) who received a single (breast) operation for the primary tumour (excluding reconstruction)	III	M	80%	90%
9. b	Proportion of patients (DCIS only) who received just one operation	II	M	70%	90%
9. c	Proportion of patients (invasive cancers) and a clinically negative axilla (+US ±FNA/CNB) who had sentinel lymph-node biopsy	II	M	90%	95%
9d	Proportion of patients with invasive cancer and axillary clearance performed with at least 10 lymph nodes examined	III	M	95%	98%
10	*Appropriate post-operative RT*				
10. a	Proportion of patients (invasive cancer M0) who received postoperative radiotherapy 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 radiotherapy	I	M	90%	95%
11.	*Avoidance of overtreatment*				
11a	Proportion of patients with invasive breast cancer not greater than 3 cm (total size, including DCIS component) who underwent BCT.	I	M	70%	80%
11b	Proportion of patients with non-invasive breast cancer not greater than 2 cm who underwent BCT	II	M	70%	80%
11c	Proportion of patients with DCIS who do not undergo axillary clearance	IV	M	95%	98%
11d	Proportion of invasive breast cancer patients with pN0 who do not undergo axillary clearance	II	M	80%	90%
	Systemic treatment				
12.	*Appropriate hormonotherapy*				
12a	Proportion of patients with endocrine sensitive invasive carcinoma who received hormonotherapy, out of the total number of patients with this diagnosis	I	M	80%	90%
12b	Proportion of patients with ER– and PgR– carcinoma who did not receive adjuvant hormonotherapy out of the total number of patients with the same diagnosis	I	M	98%	100%

(*continued on next page*)

Table 1 – (continued)

Indicator		Level of evidence	Mandatory/ Recommended	Minimum standard	Target
13. *Appropriate chemotherapy and other medical therapy*					
13a	Proportion of patients with ER– (T > 1 cm or Node+) invasive carcinoma who received adjuvant chemotherapy, out of the total number of patients with the same diagnosis	I	M	80%	90%
13b	Proportion of patients with N+ or N– T > 1 cm HER2+ (IHC 3+ or in situ hybridisation positive FISH +) invasive carcinoma treated with chemotherapy and who had adjuvant trastuzumab, out of the total number of patients with the same diagnosis.	I	M	80%	90%
13c	Proportion of patients with HER2 negative invasive carcinoma who did not have adjuvant trastuzumab, out of the total number of patients with the same diagnosis.	II	M	98%	100%
13d	Proportion of patients with HER2+ invasive carcinoma who had adjuvant chemotherapy, out of the total number of patients with the same diagnosis who had adjuvant trastuzumab	IV	M	95%	100%
13e	Proportion of patients with inflammatory breast cancer (IBC) or locally advanced non-respectable ER carcinoma who had neoadjuvant chemotherapy over the total of patients with the same diagnosis	II	M	90%	95%
Staging, counselling, follow-up and rehabilitation					
14. *Appropriate staging procedure*					
14a	Proportion of women with stage I breast cancer who do not undergo baseline staging tests (US of liver, chest X-ray and bone scan).	III	M	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	M	95%	99%
15	*Perform appropriate follow up*				
15.	Proportion of asymptomatic patients who undergo routine annual mammographic screening and clinical evaluation every 6 months in the first 5 years after the operation.	I	M	95%	99%
16. *Avoid inappropriately intensive follow up*					
16.	Proportion of asymptomatic patients who do not undergo a follow up protocol more intensive than routine annual mammographic screening and clinical evaluation every 6 months in the first 5 years after the operation.	1	R	95%	99%
17. *Availability of nurse counselling*					
17a	Proportion of patient referred for nurse counselling at the time of primary treatment	IV	R	85%	95%
17b	All women with a diagnosis of breast cancer should have direct access to a breast care nurse specialist for information and support with treatment related symptoms and toxicity during follow up and rehabilitation after initial treatment	IV	R	95%	99%

Motivation: All these symptoms should be recognised and treated if indicated.

Minimum standard: 95%.

Target: 99%.

Level of evidence: evidence-based recommendations of the major scientific societies.

Conflict of interest statement

None declared.

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Introduction

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