EUSOMA GUIDELINES

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President Elect EUSOMA
Cardiff University
• No disclosures to reveal
Position Paper

Florence Statement on Breast Cancer, 1998 Forging the Way Ahead for More Research on and Better Care in Breast Cancer

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Position Paper

The requirements of a specialist breast unit

EUSOMA

EUSOMA Secretariat, Viale B. d’Este 37, 20122 Milan, Italy
Received 24 February 2000; accepted 25 May 2000
CRITERIA

- A single integrated Unit
- Sufficient cases to allow effective working and continuing expertise
- Care by breast specialists in all the required disciplines
- Working in multidisciplinary fashion in all areas
- Providing all the services necessary – from genetics and prevention, through the treatment of the primary tumour, to care of advanced disease and palliation.
- Patient support
- Data collection and Audit
Patient
Radiologist
Surgeon
Pathologist
Medical Oncologist
RT
Breast Care Nurse
Technician
Data Manager
Geneticist
Psychoncologist
Physiotherapist
Advocacy
WHAT IS THE EVIDENCE FOR MDT?

- No RCT evidence in breast
- Population comparisons in Scotland
- Hospital volume in Belgium
RECENT STUDY ON SPECIALIST CARE

- 13,722 women with breast cancer
- 1 health Board with specialist care compared with general hospital care
- After introduction of specialist care and MDT in 1995 specific breast cancer mortality fell by 18%
- This study used contemporaneous controls not historical comparisons

Kesson et al BMJ May 2012
Cancer registry study using 11 process quality indicators
25,000 BC pts between 2004-6
Hospitals graded v.low (<50), low (50-99), med (100-149) and high (≥150)
5 year survivals were 75%, 79%, 80%, 83%
Hazard Ratio for death was 1.42 in very low.

Vrijens et al Breast 2012, 21:261
Quality Indicators

L. Cataliotti
<table>
<thead>
<tr>
<th>Indicator</th>
<th>Level of evidence</th>
<th>Mandatory/ Recomm.</th>
<th>Minimum standard</th>
<th>Target standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Completeness of clinical and imaging diagnostic work-up (Proportion</td>
<td>III</td>
<td>M</td>
<td>90%</td>
<td>95%</td>
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<td>of women with breast cancer who pre-operatively underwent mammography,</td>
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<td>ultrasound and physical examination)</td>
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<td>3. Proportion of women with breast cancer (invasive or in situ) who had</td>
<td>III</td>
<td>M</td>
<td>80%</td>
<td>90%</td>
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<td>a pre-operative definitive diagnosis (B5 or C5)</td>
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<td>4b Proportion of invasive cancer cases with primary surgery, for which</td>
<td>II</td>
<td>M</td>
<td>95%</td>
<td>98%</td>
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<tr>
<td>the following prognostic/predictive parameters have been recorded:</td>
<td></td>
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<tr>
<td>histological type, grading, ER &amp; PR, HER 2, pathological stage (T and N),</td>
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<td>size in mm for the invasive component, peritumoral vascular invasion,</td>
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<td>distance to nearest radial margin</td>
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<td>Surgery and loco-regional treatment</td>
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<tr>
<td>8. Multidisciplinary discussion (proportion of cancer patients to be</td>
<td>IV</td>
<td>M</td>
<td>90%</td>
<td>99%</td>
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<tr>
<td>discussed)</td>
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<tr>
<td>9d Proportion of patients with invasive cancer and axillary clearance</td>
<td>III</td>
<td>M</td>
<td>95%</td>
<td>98%</td>
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<tr>
<td>performed with at least 10 lymph nodes examined</td>
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<tr>
<td>Indicator</td>
<td>Level of evidence</td>
<td>Mandatory/ Recomm.</td>
<td>Minimum standard</td>
<td>Target</td>
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<td>-------------------------------------------------------------------------</td>
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<tr>
<td>Proportion of patients with DCIS who do not undergo axillary clearance</td>
<td>IV</td>
<td>M</td>
<td>95%</td>
<td>98%</td>
</tr>
<tr>
<td>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</td>
<td>I</td>
<td>M</td>
<td>98%</td>
<td>100%</td>
</tr>
<tr>
<td>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.</td>
<td>II</td>
<td>M</td>
<td>98%</td>
<td>100%</td>
</tr>
<tr>
<td>Proportion of women with stage I breast cancer who do not undergo baseline staging tests (US of liver, chest X-ray and bone scan).</td>
<td>III</td>
<td>M</td>
<td>95%</td>
<td>99%</td>
</tr>
<tr>
<td>Perform appropriate follow up</td>
<td>I</td>
<td>M</td>
<td>95%</td>
<td>99%</td>
</tr>
<tr>
<td>Proportion of asymptomatic patients who undergo routine annual mammographic screening and clinical evaluation every 6 months in the first 5 years after the operation.</td>
<td>I</td>
<td>M</td>
<td>95%</td>
<td>99%</td>
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</tbody>
</table>
“Procedure through which a third party gives written certification, that a product, process or service is in compliance with the specified requirements”

UNI CEI EN 45020:1996
Breast Unit requirements

Quality Indicators: The Unit must achieve or take the necessary measures to achieve the minimum standard for quality indicators indicated by EUSOMA.

Multidisciplinary Case Management Meetings: MDMs must be held at least weekly and must be minuted. The Unit must discuss 90% of cases. All members of the core team (radiologist, pathologist, surgeon, reconstructive surgeon, radiation oncologist, medical oncologist, breast care nurse) should attend the MDM.
EUSOMA QA VISITS

- Questionnaire for the Eusoma Accreditation of a Breast Unit
- The requirements of a specialist Breast Unit
- R W Blamey & L Cataliotti on behalf of EUSOMA
- This is a revised version of the original EUSOMA Position paper published in 2000 (European Journal of Cancer 2000;36:2288-2293).
1. How many clinics per week are held for the diagnosis of newly referred or self-referred patients?

- 2 - 3 days/week

Mandatory: Evidence to be checked on the samples of weekly lists available onsite

- Visitor:
  - Confirmed
  - Not Confirmed

- Write here your comments

1. How many patients are seen in each clinic?

- 10 - 15

1. Are new patient clinics staffed by a surgeon or a radiologist from the Breast Unit?

Mandatory: To be checked on the samples of weekly clinical chart available on site

- Visitor:
  - Confirmed
  - Not Confirmed

- Write here your comments
2. GENERAL REQUIREMENTS

2.1

1. What is the referring population (total population, male and female) covered by your unit?

500,000

Visitor:
- Confirmed
- Not Confirmed

Write here your comments

2.2

1. How many newly diagnosed breast cancers (all ages and stages) are diagnosed as new breast cancer patients by the unit - cite the calendar year prior to that of audit:

272

Visitor:
- Confirmed
- Not Confirmed

Write here your comments
Welcome in European Cancer Care Certification website.

European Cancer Care has been appointed by Eusoma to develop the voluntary certification process of Breast Unit following the Eusoma guidelines "The requirements of a specialist Breast Unit".
For more information on the procedure and application: info@cancercarecert.biostatistica.net

Please enter your username and password to access the section of the database you are entitled to use.

Unit Code or Username:

Password:

Enter
CANCER CARE CERT DATABASE
Currently contains data on ~40,000 pts

You will be provided with a personal user and password to enter the database and view the info on the Unit assigned to you.
<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>Value 1</th>
<th>Value 2</th>
<th>Value 3</th>
<th>Value 4</th>
<th>Value 5</th>
<th>Value 6</th>
<th>Value 7</th>
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<th>Value 9</th>
<th>Value 10</th>
<th>Value 11</th>
<th>Value 12</th>
<th>Value 13</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Cancers with a pre-operative diagnosis (B5 or C5)</td>
<td>32438</td>
<td>38989</td>
<td>83.2%</td>
<td>0</td>
<td>1523</td>
<td>6551</td>
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<td>2</td>
<td>Invasive ca with hist.type, grading, ER/PR, stage &amp; size recorded</td>
<td>33085</td>
<td>35794</td>
<td>92.4%</td>
<td>0</td>
<td>2709</td>
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<tr>
<td>3</td>
<td>Non-invasive ca with size, hist.pattern &amp; grading recorded</td>
<td>3778</td>
<td>4794</td>
<td>78.8%</td>
<td>0</td>
<td>1016</td>
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<td>4</td>
<td>Invasive ca with axillary clearance with &gt;= 10 LNs examined</td>
<td>13119</td>
<td>14922</td>
<td>87.9%</td>
<td>613</td>
<td>1803</td>
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<tr>
<td>5</td>
<td>M0 invasive ca receiving postoperative RT after BCT</td>
<td>19609</td>
<td>20721</td>
<td>94.6%</td>
<td>2612</td>
<td>1112</td>
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<td>6</td>
<td>Invasive ca &lt;= 3 cm (incl. DCIS component) treated with BCT</td>
<td>19612</td>
<td>24502</td>
<td>80%</td>
<td>743</td>
<td>4890</td>
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<tr>
<td>7</td>
<td>Non-invasive ca &lt;= 2 cm treated with BCT</td>
<td>2245</td>
<td>2668</td>
<td>84.1%</td>
<td>151</td>
<td>423</td>
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<tr>
<td>8</td>
<td>DCIS with no axillary clearance</td>
<td>4030</td>
<td>4308</td>
<td>93.5%</td>
<td>27</td>
<td>278</td>
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<tr>
<td>9</td>
<td>Endocrine sensitive invasive ca receiving HT</td>
<td>22994</td>
<td>24324</td>
<td>94.5%</td>
<td>6481</td>
<td>1330</td>
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<tr>
<td>10</td>
<td>ER- (T &gt; 1 cm or N+) invasive ca receiving adjuvant CT</td>
<td>3670</td>
<td>4035</td>
<td>91%</td>
<td>500</td>
<td>365</td>
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<tr>
<td>11</td>
<td>Invasive ca receiving just 1 operation (excl. reconstruction)</td>
<td>28518</td>
<td>35521</td>
<td>80.3%</td>
<td>55</td>
<td>7003</td>
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<tr>
<td>12</td>
<td>DCIS receiving just 1 operation (excl. reconstruction)</td>
<td>2775</td>
<td>4455</td>
<td>62.3%</td>
<td>3</td>
<td>1680</td>
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<tr>
<td>13</td>
<td>Invasive ca pN0 not receiving axillary clearance (SLN only)</td>
<td>16439</td>
<td>21549</td>
<td>76.3%</td>
<td>7</td>
<td>5110</td>
<td></td>
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</tbody>
</table>
EUSOMA Network web data system
1 - Cancers with a pre-operative diagnosis (B5 or C5)


Target 90%
EUSOMA Network web data system
3 – DCIS with main histopathology parameters recorded


Target 98%
EUSOMA Network web data system
4 – Axillary clearance with >= 10 LN examined


Target 98%
EUSOMA Network web data system
6 - Invasive ca <= 3 cm (incl. DCIS comp.) with BCS


Target 80%
EUSOMA Network web data system
8 – DCIS with no axillary clearance

Target 98%
EUSOMA Network web data system
13 - SLN only in pN0

Target 90%
EUSOMA database – 48 units – 43256 invasive cancers

% SLNB & ALND trend across years
• 15,369 cancers 2003-10
• Significant decline in mastectomy rate
• Factors associated with MX were:
  young and elderly
  DCIS/G2&3/multifocal
  Pos ax nodes
MX rate lower than in US

Garcia-Etienne Eur J Cancer 2012
THE EUROPEAN AGENDA

- 2008 passed resolution to harmonise breast care across Europe
- The Europe Commission has tasked the JRC to produce quality indicators and revise the European guidelines.
- This work has progressed in 2012/3 and new European QA Guidelines will be produced with consensus from all EU countries.
EUROPEAN CANCER CARE CERTIFICATION
REFERRING STANDARD

“Document issued following a consensus and approved by a recognized body, which gives, for common and repeated uses, rules, guidelines or characteristics related to specific activities or its results, to obtain the best organisation in a specific context”

UNI CEI EN 45020:1996
By 2016 only certified breast units will be able to be reimbursed for treatment of breast cancer patients

Smaller units (low volume or non-MDT) will have to merge/partner with larger accredited units
Conclusions

- Certified units have a high level of performance (voluntary self selected units)
- The database suggests that compliance with clinical guidelines is generally correct
- The real need is to audit and certify the remaining units as per European Parliament intentions.