Quality Assurance in Treatment Essential
Monitoring and Evaluation

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Cardiff University (United Kingdom)
ECIBC
the EUROPEAN COMMISSION INITIATIVE
on BREAST CANCER

Prof ROBERT MANSEL
Chair QASDG
3 sections to this talk

• Benefits of multidisciplinary working

• The Eusoma system – an example of an accreditation scheme

• The ECIBC scheme – the pan European project
Position Paper

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

L. Cataliotti,1 A. Costa,2 P. A. Daly,3 L. Fallowfield,4 G. Freilich,5 L. Holmberg,6 M. Piccart,7 C.J.H. van de Velde8 and U. Varonesi3

1President, EUSOMA, Università degli Studi di Firenze, Istituto di Clinica Chirurgica Generale e Terapia Chirurgica, Florence; 2European Institute of Oncology, Via Ripamonti 435, 20141 Milan, Italy; 3St James’s Hospital, Department of Clinical Haematology/Oncology, Dublin, Ireland; 4University College London, Medical School, CRC Psychosocial Oncology Group, London; 5President, Europa Donut, The Cancerkin Centre, Royal Free Hospital, London, UK; 6University Hospital Uppsala, Department of Surgery, Uppsala, Sweden; 7Institute Jules Bordet, Department of Chemotherapy, Brussels, Belgium; and 8Chairman, EORTC—BCCG, University Hospital Leiden, Leiden, The Netherlands
STUDY ON SPECIALIST CARE (MDT)- Scotland

• 13,722 women with breast cancer
• 1 health Board with specialist care compared with general surgery care

• After introduction of MDT/specialist care in 1995 specific breast cancer mortality fell by 18%

Kesson et al BMJ May 2012
HOSPITAL VOLUME IN BELGIUM

• 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
The EUSOMA scheme
The requirements of a specialist Breast Centre

A.R.M. Wilson a, *, L. Marotti b, S. Bianchi c, L. Biganzoli d, S. Claassen e, T. Decker f, A. Frigerio g, A. Goldhirsch h, E.G. Gustafsson i, R.E. Mansel j, R. Orecchia k, A. Ponti l, P. Poortmans m, P. Reggiani m, M. Rosselli Del Turco n, E.J. Th. Rutgers o, C. van Asperen p, C.A. Wells q, Y. Wengström r, L. Cataliotti s

Quality indicators in breast cancer care

M. Rosselli Del Turco a, *, A. Ponti b, U. Bick c, L. Biganzoli d, G. Cserni e, B. Cutuli f, T. Decker g, M. Dietel h, O. Gentilini i, T. Kuehn k, M.P. Mano l, P. Mantellini m, L. Marotti n, P. Poortmans o, F. Rank p, H. Roe q, E. Scaffidi r, J.A. van der Hage s, G. Viale t, C. Wells u, M. Welnicka-Jaskiewicz v, Y. Wengström w, L. Cataliotti x
<table>
<thead>
<tr>
<th>Indicator</th>
<th>Level of evidence</th>
<th>Mandatory/Recomm.</th>
<th>Minimum standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Completeness of clinical and imaging diagnostic work-up (Proportion of women with breast cancer who pre-operatively underwent mammography, ultrasound and physical examination)</td>
<td>III</td>
<td>M</td>
<td>90% 95%</td>
</tr>
<tr>
<td>3. Proportion of women with breast cancer (invasive or in situ) who had a pre-operative definitive diagnosis (B5 or C5)</td>
<td>III</td>
<td>M</td>
<td>80% 90%</td>
</tr>
<tr>
<td>4b Proportion of invasive cancer cases with primary surgery, for which the following prognostic/predictive parameters have been recorded: histological type, grading, ER &amp; PR, HER 2, pathological stage (T and N), size in mm for the invasive component, peritumoral vascular invasion, distance to nearest radial margin</td>
<td>II</td>
<td>M</td>
<td>95% 98%</td>
</tr>
<tr>
<td>Surgery and loco-regional treatment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Multidisciplinary discussion (proportion of cancer patients to be discussed)</td>
<td>IV</td>
<td>M</td>
<td>90% 99%</td>
</tr>
<tr>
<td>9c Proportion of patients (invasive cancers) and a clinically negative axilla (+US ±FNA/CNB) who had sentinel lymph-node biopsy</td>
<td>II</td>
<td>M</td>
<td>90% 95%</td>
</tr>
<tr>
<td>9d Proportion of patients with invasive cancer and axillary clearance performed with at least 10 lymph nodes examined</td>
<td>III</td>
<td>M</td>
<td>95% 98%</td>
</tr>
</tbody>
</table>
Italcert in partnership with BCCCert has developed a certification scheme in compliance with EUSOMA requirements

www.breastcentrescertification.com
## EUSOMA Network web data system

**Quality indicators 2003-2012 in certified Units**

EUSOMA database – 48 units – 43256 invasive cancers

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>Count</th>
<th>Percentage</th>
<th>Missing (%)</th>
<th>Passed (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Cancers with a pre-operative diagnosis (BS or CS)</td>
<td>32438</td>
<td>83.2%</td>
<td>0</td>
<td>95.4%</td>
</tr>
<tr>
<td>2</td>
<td>Invasive ca with hist type, grading, ER/PR, stage &amp; size recorded</td>
<td>33085</td>
<td>92.4%</td>
<td>1,233</td>
<td>83.5%</td>
</tr>
<tr>
<td>3</td>
<td>Non-invasive ca with hist type, hist pattern &amp; grading recorded</td>
<td>3778</td>
<td>78.8%</td>
<td>0</td>
<td>99.9%</td>
</tr>
<tr>
<td>4</td>
<td>Invasive ca with axillary clearance with &gt;= 10 LNs examined</td>
<td>13119</td>
<td>87.9%</td>
<td>0</td>
<td>99.9%</td>
</tr>
<tr>
<td>5</td>
<td>M0 Invasive ca receiving postoperative RT after BCT</td>
<td>19009</td>
<td>94.6%</td>
<td>0</td>
<td>99.9%</td>
</tr>
<tr>
<td>6</td>
<td>Invasive ca &lt;= 3 cm (incl. DCIS component) treated with BCT</td>
<td>19612</td>
<td>80.0%</td>
<td>743</td>
<td>99.9%</td>
</tr>
<tr>
<td>7</td>
<td>Non-invasive ca &lt;= 2 cm treated with BCT</td>
<td>2245</td>
<td>84.1%</td>
<td>151</td>
<td>99.9%</td>
</tr>
<tr>
<td>8</td>
<td>DCIS with no axillary clearance</td>
<td>4030</td>
<td>93.5%</td>
<td>0</td>
<td>99.9%</td>
</tr>
<tr>
<td>9</td>
<td>Endocrine sensitive invasive ca receiving HT</td>
<td>22994</td>
<td>94.5%</td>
<td>0</td>
<td>99.9%</td>
</tr>
<tr>
<td>10</td>
<td>ER- (T &gt; 1 cm or N+) invasive ca receiving adjuvant CT</td>
<td>3679</td>
<td>91.1%</td>
<td>0</td>
<td>99.9%</td>
</tr>
<tr>
<td>11</td>
<td>Invasive ca receiving just 1 operation (excl. reconstruction)</td>
<td>28518</td>
<td>80.3%</td>
<td>55</td>
<td>99.9%</td>
</tr>
<tr>
<td>12</td>
<td>DCIS receiving just 1 operation (excl. reconstruction)</td>
<td>2775</td>
<td>62.3%</td>
<td>0</td>
<td>99.9%</td>
</tr>
<tr>
<td>13</td>
<td>Invasive ca pN0 not receiving axillary clearance (SLN only)</td>
<td>16439</td>
<td>76.3%</td>
<td>0</td>
<td>99.9%</td>
</tr>
</tbody>
</table>
In the last 10 years, Breast centres Certification, certified almost 40 centres around Europe and recently we received requests from China and some other countries outside Europe.

BREAST CERTIFICATION COVERS EUROPE AND NOW EXTENDING TO CHINA AND INDIA
EUSOMA Network web data system
3 - DCIS with main histopathology parameters recorded

<table>
<thead>
<tr>
<th>Year</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>%</td>
<td>49%</td>
<td>55%</td>
<td>55%</td>
<td>59%</td>
<td>66%</td>
<td>66%</td>
<td>89%</td>
<td>90%</td>
<td>91%</td>
<td>94%</td>
</tr>
</tbody>
</table>

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

Target 90%
THE Z - 11 EFFECT

Proportion (%) of ALND in invasive pN+ cases

Year (N)

2006 (946)
2007 (1220)
2008 (1201)
2009 (1739)
2010 (1874)
2011 (1800)
2012 (1368)
2013 (1186)
2014 (1151)
2015 (972)

%
### Comparison of Eusoma indicators before vs after Certification 2006-2012

<table>
<thead>
<tr>
<th>Indicator</th>
<th>N</th>
<th>Before %</th>
<th>N</th>
<th>After %</th>
<th>Or</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancers with a pre-operative diagnosis (B5 or C5)</td>
<td>7571</td>
<td>85.5</td>
<td>22873</td>
<td>86.4</td>
<td>1.08</td>
<td>0.041</td>
</tr>
<tr>
<td>Invasive or MI ca with hist. type, grading, ER/PR, stage &amp; size recorded</td>
<td>6677</td>
<td>91.4</td>
<td>20207</td>
<td>94.8</td>
<td>1.69</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>M0 invasive ca receiving post operative RT after BCT</td>
<td>4376</td>
<td>93.9</td>
<td>13249</td>
<td>94.8</td>
<td>1.17</td>
<td>0.045</td>
</tr>
<tr>
<td>DCIS with no axillary clearance</td>
<td>811</td>
<td>93.1</td>
<td>2391</td>
<td>95.8</td>
<td>1.68</td>
<td>0.003</td>
</tr>
<tr>
<td>Invasive or MI ca pN0 staged by SLN only</td>
<td>3968</td>
<td>78.6</td>
<td>12222</td>
<td>83.5</td>
<td>1.38</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Van Dam P et al, EJSO 2015
ECIBC

the EUROPEAN COMMISSION INITIATIVE on BREAST CANCER
EUROPEAN ACTION BASED ON PARLIAMENTARY RESOLUTIONS

• European Commission via JRC (joint research centre based in Ispra, Italy - part of the public health division of the EC –DG Sante) has commissioned a 4yr programme to update European Breast Guidelines and produce an accreditation plan to be used across all European Breast Centres according to European Parliament resolutions

• Large investment of around 8 million Euros for the project

Nomination of GDG (guidelines) and QASDG (Accreditation) groups

The EC was in 2014 requested to create the working groups based on a public call for experts (open from 24 October to 11 December 2014) – nominations completed in July 2015 (validity, eligibility, competence, independence)

Quality Assurance Scheme Development Group (QASDG)

63 applications:
- Professionals
- Individuals
European Commission Initiative on Breast Cancer (ECIBC)
A modular approach for European breast cancer services
Working modality

- Agreed rules of procedure
- Physical meetings at JRC premises and online collaboration
- Explicit and transparent approach to define requirements for breast cancer services (Delphi rounds)
- GRADE approach and trustworthy guidelines for clinical recommendations
- Call for feedback on key documents (scope & PICOs)
Method: identifying requirements and Indicators
PATIENT EMPOWERMENT IN THE QASDG PROCESS

4 patients /advocates full members of the committee (all very experienced in the field of advocacy)

Full voting rights on all issues including clinical matters

Open debate with full participation of the patients/advocates

Transparency in all issues with all conflicts openly declared on each topic being debated

Delphi process to allow balancing of differing views

All subgroup work open to patients/advocates who choose which groups they wish to join.
ECIBC QUALITY INDICATORS (1)

<table>
<thead>
<tr>
<th>GEN13_MDT</th>
<th>The breast center must hold at least weekly a multidisciplinary case management meeting to discuss all patients prior to treatment (including patients with metastatic disease) and also post-operatively and at change of treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rationale</td>
<td>Multidisciplinary teams are assumed to optimize decision making in diagnosis, treatment and support of patients. All women with breast cancer visiting the breast center should be discussed in the multidisciplinary team.</td>
</tr>
<tr>
<td>Numerator</td>
<td>Number of women with breast cancer discussed by the multidisciplinary team prior to treatment (including patients with metastatic disease), post-operatively and at change of treatment</td>
</tr>
<tr>
<td>Denominator</td>
<td>Total number of women with breast cancer treated in the breast center</td>
</tr>
<tr>
<td>Inclusion</td>
<td>All women with breast cancer visiting the breast center</td>
</tr>
<tr>
<td>Exclusion</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Norm</td>
<td>≥90% (to be decided by QASDG)</td>
</tr>
</tbody>
</table>
| Reference to norm | • ≥90% of all breast cancer cases should be discussed pre- and/or post treatment in multidisciplinary team (NABON 2016)  
• ≥95% of patients discussed at the multidisciplinary team before definitive treatment (NHS Scotland 2016) |
| Evidence for recommendation | Recommendation : Conditional/provisional  
Evidence : Low to very low quality (Risk of bias and imprecision) |
| Data source | Protocols, agendas and minutes of multidisciplinary meeting are available. Breast center provides document explaining what strategies have been implemented to assure that each patient is discussed at the appropriate time. To be checked in audit. |
| Guideline recommendations | IberoAmerican Cochrane Centre (Martinez 2016)  
We suggest that women with breast cancer are discussed in multidisciplinary meetings (provisional and conditional recommendation)  
Five observational studies. Significant effects reported in favor of MDT for 5 year breast cancer mortality (RR 0.82, 95%CI 0.73 to 0.91), 5 year mortality (HR 0.83, 95%CI 0.78 to 0.89) and breast cancer specific 5 year survival (RR 1.04, 95%CI 1.02 to 1.07). Significantly more women satisfied with MDT than in the non-MDT group (RR 1.28,
**Indicator examples**

Patients operated on in a defined time between Diagnosis and Surgery

- All patients undergoing surgery

Addresses patient concerns about timeliness

Clinical node negative patients undergoing surgery having sentinel node biopsy

- All clinical node negative patients undergoing surgery

Addresses overtreatment
Implementation of the accreditation programme

EC has no mandate for implementation of health policies—these are sole remit of each member country, but DG Sante (the European Commission Health Department) is able to recommend health improvement and equality of healthcare but cannot enforce any changes.

The ECIBC plan is due to be launched in 2019 and the implementation is the responsibility of each country and is a voluntary process.

Using a common set of quality indicators and process monitoring should allow identification of problems in breast units and allow for the introduction of improvement plans.

Current problematic areas are the added costs of implementing accreditation and the issue of “ownership” and the legal basis of accreditation.
PROBLEMS OF ACCREDITATION

“Healthcare systems based on reimbursement find the effective implementation of MDM more challenging

MDM structure has enormous potential to harmonise and improve cancer care through better documentation, staging, audit of outcomes and clinical research.”

(Gina Brown BMJ Editorial 2012;344:e2780)

Currently the 2 biggest problems will be correct MDT working and accuracy of databases.
Timeline for QASDG requirement development

- **2016**
  - Surgery & general Relevance
  - Surgery & general Feasibility

- **2017**
  - Surgery & general Relevance
  - Surgery & general Feasibility

- **2018**
  - All other requirements/indicators Relevance
  - All other requirements/indicators Feasibility
  - Leftovers & review the outcome
  - Results from country consultation

Working on:
- GDG S+D recommendations & Q-indicators relevant for screening programmes

Pilot
CONCLUSIONS

Large input from patients/advocates in the ECIBC process

This balances the effects of the “expert” opinion

These inputs should increase the acceptability of the accreditation programme for users and stakeholders.

Quality indicators relevant and feasible

The key is multidisciplinary working (but it is not cheap!)
Thank you and keep in touch!

ecibc.jrc.ec.europa.eu