THE ECIBC – OVERVIEW OF ISO STANDARDS AND QA SCHEMES IN EUROPE FOR BREAST CANCER CARE

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Disclaimer: The contents of this presentation are the views of the author and do not necessarily represent an official position of the European Commission.
To understand the wide picture of accreditation and conformity assessment in the field of breast cancer care across Europe

To include the experiences already built in the use of standards in setting-up of a European QA scheme

- ISO 15189:2012
- ISO/IEC 17020:2012
- ISO/IEC 17021:2011
- ISO/IEC 17025:2005
Report of a survey on accreditation and conformity assessment in the field of breast cancer in Europe - 2
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Conclusions:

- ISO standards are in place in healthcare
- Need for enhancement and unification of quality assurance in breast cancer care services throughout Europe
- ISO 15189:2012 and ISO/IEC 17021:2011 were the most used standards
- Diagnosis was most widely addressed

ISO STANDARDS PROPOSED FOR THE EUROPEAN QA SCHEME:
- ISO 15189:2012 for testing
- ISO 17065:2012 for service certification
Review and analysis of external quality assessment of breast cancer services in Europe - METHODOLOGY

Sources

Pubmed, Google, JRC 2012 Survey, JRC 2013 Workshops, bilaterals, conferences, ISQua website, previous reviews on the topic

Inclusion criteria for breast cancer schemes

• fully implemented

• with evidence of current activity

• with at least one centre in Europe currently holding the certificate awarded by that organisation

• foreseeing a third-party audit / on-site survey

• [with at least basic information, such as name of the programme, name of the organisation and scope, available in one of languages mastered by the reviewers at B2 level or more (i.e. English, Italian, Spanish, French, Greek, Romanian, Turkish)]
CONCEPTUAL MODEL OF BREAST CANCER QUALITY ASSESSMENT
List of entities providing quality schemes in Europe

**Unregulated, voluntary schemes**

- **Generic; N= 22**
- **Cancer-specific; N= 6**
- **Breast cancer-specific; N= 17** – meeting the Report's eligibility criteria N= 9

**Supervisory organisations and regulatory bodies**

*E.g.* Institute for Quality and Accreditation in Healthcare (DK), French National Authority for Health (FR), Netherlands Institute for Accreditation in Health Care (NL), etc.
Europe's map of quality schemes
<table>
<thead>
<tr>
<th>PROGRAMME NAME</th>
<th>ENTITY</th>
<th>COUNTRIES</th>
<th>NR OF CENTRES AWARDED</th>
<th>TYPE</th>
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<tbody>
<tr>
<td>International Accreditation Program for Breast Centres/Units</td>
<td>Senologic International Society / International School of Senology</td>
<td>FR, PL, LT</td>
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<tr>
<td>Breast Centres Certification Label de qualité</td>
<td>Anticancer Swiss League / Senology Swiss Society</td>
<td>CH</td>
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<td>Private</td>
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<td>Mammography screening certification Zertifizierung nach § 22 Krebsfrüherkennungs-Richtlinie</td>
<td>Kooperationsgemeinschaft Mammographie GbR</td>
<td>DE</td>
<td>94</td>
<td>Public</td>
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<td>Certification system for breast cancer centers from the German Cancer Society and German Society for Breast Diseases</td>
<td>German Cancer Society / German Society for Breast Diseases</td>
<td>DE, CH, IT, AT</td>
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<td>Private</td>
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<td>Breast Centres Certification</td>
<td>European Cancer Care Certification / European Society of Breast Cancer Specialists</td>
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<td>Senology and Breast Pathology Spanish Society</td>
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<td>Quality Assurance in National Health Service Breast Screening Programme</td>
<td>National Health Service National Breast Screening Programme</td>
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<td>Private</td>
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<tr>
<td>National Cancer Peer Review Programme</td>
<td>National Cancer Action Team</td>
<td>UK</td>
<td>152 peer reviewed in 2012-2013</td>
<td>Public</td>
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Breast cancer quality schemes - topics
Conclusions: implications for ECIBC and the European QA scheme

- Several schemes already running in Europe → hundreds of requirements and technical documents used and potentially relevant for the European QA scheme

- Lack of harmonisation and likelihood of inconsistent practices in place

- Several ISO standards already in use, especially for diagnostics

- Potential for the European QA scheme to get to a uniform level of service provision for breast cancer care through a healthcare-targeted use of ISO 15189 and ISO 17065