The European Commission’s science and knowledge service
Joint Research Centre

European Quality Assurance Scheme for Breast Cancer Services

Robert Mansel, chair QASDG
ECIBC Plenary, Varese 24.11.2016
A QA scheme covering all processes
A modular QA scheme
The European QA scheme framework

Relation between NAB, CB and BCS (incl. testing and examination)

NAB=National Accreditation Body
CB= Certification Body
BCS=Breast Cancer Service
European QA scheme public call for feedback*

* Available soon online

- **What:** Scope of the *European Quality Assurance scheme for breast cancer*
- **When:** from 17 February 2016 to 8 March 2016
- **Who:**
  - Organisations
    - National accreditation bodies
    - ECIBC National contacts
    - Healthcare organisations
    - Professional societies or organisations
  - Individuals (*e.g.* Professionals, Citizens)
- **How:** EU survey
Results - 1

Number of valid responses: 63
Organisations: 48 (76%)
Individuals: 15 (24%)

Countries' distribution (23/ 28 EU countries)
Q: Is the modular approach applicable in the health care system in your country

<table>
<thead>
<tr>
<th>Country</th>
<th>Response</th>
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<tbody>
<tr>
<td>Austria</td>
<td>Yes</td>
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<td>Belgium</td>
<td>Yes</td>
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<td>Bulgaria</td>
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<td>Croatia</td>
<td>NA</td>
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<td>Czech Republic</td>
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<td>Estonia</td>
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<td>EU candidate country</td>
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<td>Finland</td>
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<td>France</td>
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<td>Germany</td>
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<td>Greece</td>
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<td>Hungary</td>
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<td>Montenegro</td>
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<td>Sweden</td>
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<tr>
<td>UK</td>
<td>Yes/No</td>
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</table>
Q: Is the breast cancer treatment pathway applicable in your healthcare system?
Q: Do you agree with the use standard ISO17065:2012 for the accreditation of certification bodies?
Q: Do you agree with the use of standard ISO15189:2012 for testing and examination activities?
Public call for feedback – results

• Respondents represented the main categories of stakeholders and expressed acceptance and positive consideration of the main features of the *European QA scheme*

• Two critical points:
  1. the applicability of ISO 15189:2012 as an accreditation standard for pathology laboratories in Germany
  2. a lack of detailed information on the methodology proposed for the selection of requirements and indicators

• Critical points addressed in the new version of the Scope (published soon) and in the Methodology document (website)
What else has happened so far?

In respect to developing
1. Certification of clinical processes
2. Accreditation of conformity assessment body
3. Accreditation of labs, imaging, pathology
4. Data assessment and reporting
1. Certification of clinical processes

Identify requirements/indicators for the quality of clinical care

1. Develop methodology
2. Train QASDG
3. Start identifying requirements/indicators
4. For surgery and organisational structure first
**Indicator examples**

Patients operated on in a defined time between Diagnosis and Surgery

- All patients undergoing surgery

Clinical node negative patients undergoing surgery having sentinel node biopsy

- All clinical node negative patients undergoing surgery
Define Scheme Owner (SO) requirements

- First draft of SO requirements under discussion with EA and Certification Processes subgroup
3. Accreditation of labs, imaging, pathology

Give details on the use of ISO 15189 or equivalent standards

1. List of tests performed by BCS falling under accreditation
2. Reference documents needed:
   • Reference documents for what
   • Criteria for acceptance of reference documents
4. Data assessment and reporting: Idea
What is next?

- Requirements/indicators by 2018
- List of tests performed by BCS falling under accreditation by mid-2018
- List of reference documents for imaging and pathology
- IT data management
- Piloting 2018
Thank you and keep in touch!

European Commission Initiative on Breast Cancer
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