The ECIBC: a useful example on how Guidelines, QA schemes and, potentially, standardisation can work together

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Quality assurance

Epidemiology

Public health

Cancer registries

IT, web hub development

Systematic reviews

Evidence-based guidelines

Quality indicators

Healthcare Quality

Cancer screening

Health Technology Assessment

Radiology

Oncology
The ECIBC
Why ECIBC?

Breast cancer: relevant problem in the EU

The European Commission supports

- the development of European Guidelines for breast cancer services
- the development & pilot a voluntary quality assurance scheme for breast cancer services

DG SANTE allocated to JRC the coordination of the ECIBC (Dec 2012)

JRC is a suitable institution to coordinate this initiative:

- Sustainable structure in the long-term
- Neutral platform for the involvement of stakeholders
What is ECIBC, what are expected outcomes?

- A pilot and voluntary European quality assurance (QA) scheme for breast cancer services based on guidelines
- New European Guidelines for breast cancer screening and diagnosis
- A platform of guidelines for other stages of BC
- A long-term web hub hosting all the outcomes

After the successful implementation of the ECIBC, its outcomes and results could be of value for other areas of healthcare
The JRC needs the support of experts and stakeholders

Guideline Development Group (GDG)

Quality Assurance Scheme Development Group (QASDG)

Kick-offs: from 7 to 11 September 2015
First outcomes starting from 2016

34 ECIBC National Contacts

European/international entities and projects
Updates from the kick-offs

GDG: 7-9 September 2015
Rules, structure and scope approved
Literature review service

QASDG: 9–11 September 2015
Rules, structure and scope approved
Accreditation service (EA)

Guidelines based on evidence (PICO structure)

QA scheme based on evidence and on accreditation regulation

GLs provide evidence to QA scheme

Guidelines & QA scheme go hand in hand

QA scheme supports GLs implementation
Breast Cancer Services Report: 2012-2013 survey

Prevalence of (mainly) public health systems

Many organisational models for BCSs

Many (co-existing) QA schemes
ECIBC: a common benchmarking, the voluntary QA scheme

Underpinned by Regulation (EC) No 765/2008 and including:

1 - Specific requirements from Guidelines and from searches
(plus trackability between stages and information to patients on what they can expect at next stages)

2 - General context (inputs from Directive 2011/24/EU & Council Recommendation of 2009, inputs from relevant projects and Joint Actions)

And:

Quality Management Systems, Testing activities accreditation, Data collection requirements (KPIs, possible cancer registries indicators)
Accreditation & standardisation
## HEALTHCARE

<table>
<thead>
<tr>
<th>Accreditation</th>
<th>Legal framework</th>
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**Voluntary program, sponsored by a non-governmental agency (NGO),** in which trained external peer reviewers evaluate a health care organization’s compliance with pre-established performance standards. […]

*Rooney AL, van Ostenberg PR.*

**An attestation by a national accreditation body that a conformity assessment body** meets the requirements set by harmonised standards and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity (testing activity is included)

*Regulation (EC) No 765/2008*
ACCREDITATION for ECIBC


- The choice of ISO 17065 for framing the European QA scheme ensures the necessary flexibility for a 'sectoral' scheme to adapt to all countries organisational settings and to include scheme owner (e.g. audit modalities, audit team composition) and specific requirements (based on best available evidence and on experts' inputs).
STANDARDS

• In the healthcare accreditation field, a **standard is a desired and achievable level of performance** against which actual performance is measured.

• In the ISO context, a standard is a document that **provides requirements, specifications, guidelines** or characteristics that can be used consistently **to ensure that** materials, products, processes and services **are fit for their purpose**.

**Implementation of standards is voluntary**

**Which 'standards' are being used for ECIBC?**
ISO 17065, 15189/17025. + e.g. testing methods, performance requirements
Guidelines
Validated protocols and methods
Best practices
Requirements already in use
Common sense?

3.2.23. *Healthcare services*²⁷

Patients require safe, high quality services in order to have confidence in healthcare systems throughout Europe. To develop European Standards, clinicians and representatives of regulatory authorities, research and development as well as accreditation and standardisation organisations should bring together their knowledge and experience. In order to manage complex healthcare systems in a consistent manner, specific horizontal aspects could be subject to standardisation requests to CEN in line with relevant Union legislation and policies on healthcare.
# What do you think of standards? (ISO 17065 as an example)

## DO STANDARDS IMPLY IMPROVEMENT?

**In its use for ECIBC:** 'The Certification Body shall ensure that:....any opportunities for improvement are identified.'

**In its development process:** Issued in 2012 and within ISO/CASCO no updating planned yet

## ARE STAKEHOLDERS INVOLVED?

**In its use for ECIBC:** YES (feed-back on the European QA scheme) – lists published

**In its development process:** Declared on ISO/CASCO webpage

## ARE THEY BASED ON EVIDENCE?

**In its use for ECIBC:** Specific requirements (clinical) based on evidence when appropriate

**In its development process:** Based on best practices? Is evidence applicable?

## CAN THEY PROVIDE ADDDED VALUE?

**In its use for ECIBC:** YES. Flexible and modular approach. SO requirements

**In its development process:** Clarifications and tools available for users
Flexible approaches

CEN Workshop Agreement (CWA) (tested within EPAAC)

List of participants, business plan available
ECIBC again...
Forthcoming event

ECIBC Plenary 2015

'Improving breast cancer screening, diagnosis and care in Europe'
Lago Maggiore District, Italy, 9-11 December 2015

For more information on ECIBC

Institutional JRC Website


(the ECIBC dedicated web hub is planned to be developed during 2015-2016)

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Thank you for your attention