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**Health in Society**

# **European Commission Initiative on Breast Cancer (ECIBC): Methods of the voluntary European Quality Assurance scheme for Breast Cancer Services Selection of requirements and indicators**

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## Introduction

The European Breast Quality Assurance Scheme for Breast Cancer Services (*European Breast QA scheme*) defines a set of requirements with which breast cancer services (BCSs), providing services from screening to follow-up, and in some cases until end-of-life care, will have to comply in order to be certified under the scheme.

This document addresses the methodology used for the selection of requirements.

## Definitions

**Require (requirement)** 'express need essential to the fulfilment of something'

(source: *ISO 9000 Introduction and support package: Guidance on some of the frequently used words found in the ISO 9000 family of standards*).

The operational definition used within the ECIBC (European Commission Initiative on Breast Cancer) encompasses the meaning of a 'standard' in the healthcare field: it is the level of performance required by a quality assessment scheme with respect to a certain aspect meaningful for breast cancer screening, diagnosis and treatment.

In the *European Breast QA scheme*, each requirement will comprise a **statement**, associated with the corresponding supporting evidence and references, which is explained in a number of **criteria**.

- The statement represents the overarching requirement and its general intent or principle;
- The criteria present measurable points by which achievement of the goal of the statement may be objectively assessed. Criteria should also be selected on grounds of clarity, simplicity and measurability, as well as relevance to objectives.

In this document, a requirement refers to the statement, criteria and supporting evidence attached.

The *European Breast QA scheme* will assess whether requirements are met by means of several tools (on-site visit, review of medical records, interview with staff, etc.), including quantitative **indicators**. Indicators in the *European Breast QA scheme* describe the fulfilment of a requirement by a clearly defined numerator and denominator. Therefore, indicators are always linked to a requirement, but not every requirement will have a quantitative indicator to be measured.

**Quality potentials** correspond to known or anticipated deficits in the quality of care for a specific disease, indication or intervention. They correspond to processes in the care pathway for which under-, over- or inadequate treatment has been reported, meaning that the required quality of care is not being provided. Thus, quality potentials are the starting point for measures to improve the quality of care. Aligning quality assurance with quality potentials is contributing to the effort/benefit balance.

## Selection of requirements

The selection of requirements/indicators is proposed according to a series of steps, which are also described in Figure 1, oriented towards methods such as RAND/UCLA (1). This implies that an expert panel will select requirements and indicators in Delphi-like rounds, by rating them for relevance and feasibility and by considering the evidence that they are based on.

## I. Collection of requirements

### Step1: Define the care pathway and quality potentials for breast cancer

By using a flow chart, the care pathway visualises the path followed by a patient through the breast cancer care processes. This chart includes specific services, end points, quality targets and quality potentials relevant to a specific subject in the quality assurance scheme. Furthermore, it takes into account the course of the disease as well as the various services involved.

The identification of quality potentials is followed by the question as to whether it is possible to reliably **measure health service performance** against these quality potentials in a systematic way that enables a comparison to be made between the services. It must be acknowledged that data may not be assessed for every relevant quality potential identified, since it may not be possible to retrieve the necessary information through the data sources available to the quality assurance scheme (1). The aim of the care pathway is to keep the discussion on requirements patient-centred and focused. Consequently, the care pathway is continuously under development throughout the whole process.

The care pathway for breast cancer is included in the scope of the *European Breast QA scheme*.

### Step2: Search for requirements/indicators already developed

Since several schemes (2) and an even higher number of sets of indicators for breast cancer are already available, the following sources were investigated:

- Schemes relevant to the topic (for cancer and breast cancer in particular)
- Literature
- Guidelines
- Indicator databases.

In addition to this search, for quality potentials that have not been addressed by pre-existing requirements/indicators new ones will be developed.

### Step 3: Classify requirements/indicators retrieved

For each requirement/indicator retrieved, the following is documented:

1. The quality potential addressed by the requirement/indicator, according to the list developed by the Quality Assurance Scheme Development Group (QASDG) at step 1.
2. The quality domain (e.g. effectiveness, safety, etc.) that is addressed by the requirement/indicator, according to the final list included in the scope of the *European Breast QA scheme*.
3. The breast cancer care processes addressed by the requirement/indicator (screening, diagnosis, treatment, rehabilitation, follow-up and survivorship, palliative care).
4. The content of the requirement/indicator (what is actually measured).

5. The evidence upon which the requirement/indicator is based, including its publication date and the strength of the evidence according to defined evaluation criteria.
6. The methodology/data by which the requirement/indicator is usually measured (3) (e.g. as regards measurement of an indicator, the possible indicators and the source of data; as regards requirements not linked to an indicator, the evidence that should be checked during the audit and the source: interview, review of records, etc.).

#### **Step 4: Exclude requirements/indicators**

Requirements/indicators that do not pass the first three steps will be excluded.

#### **Step 5: Summarise the requirements/indicators selected**

Requirements/indicators selected will be summarised in worksheets, including:

- An identification number;
- A clear title for the requirement/indicator;
- A statement of what the requirement/indicator is actually measuring and what it is targeting (e.g. xy % of women receive radiotherapy after breast-conserving surgery);
- A rationale as to why it is important to measure or assess it (e.g. 'there is evidence that transfer time to surgery is usually inadequate, i.e. either too short or too long' or 'there is evidence that psychosocial distress is a frequent problem in cancer and impacts quality of life', etc.);
- A possible method for measuring the requirement, such as
  - continuous indicator (e.g. percentage of women receiving radiotherapy);
  - dichotomous indicator (e.g. presence of the breast nurse in the team: yes/no);
  - onsite assessment of an implemented and consistent recommended practice (e.g. procedure for monitoring patients for psychosocial distress, and evidence in medical records that such monitoring is done consistently);
- Inclusion and exclusion criteria (e.g. 'all women over 50 with breast cancer diagnosis', 'all physicians engaging in breast surgery', etc.);
- Reference to the underlining evidence, including a grading for the quality of evidence;
- Classification of the requirement/indicator in terms of quality;
- A proposal for how the data could be collected or the requirement audited during the on-site visit;
- Comments, such as the need for risk adjustment for the indicators, or others.

## **II. Panel process**

#### **Step 6: Assessing the requirements using the Delphi methodology**

The approach presented more or less follows that described by the AQUA Institute for developing quality assurance for the German statutory health system (<https://www.aqua-institut.de/en/home/index.html>). The Institute's methodology for selecting indicators has been inspired by, among others, the appropriate RAND/UCLA method (1, 4). Therefore, requirements/indicators that were identified in steps 1 to 5 above are assessed for their understandability, relevance, and feasibility in a Delphi-like procedure. This assessment will be carried out by a multi-disciplinary expert panel which also includes patients. The QASDG will constitute this expert panel.

The Delphi-like process will comprise two rating rounds for each requirement. Each round consists of a remote rating which is followed by an on-site panel meeting with discussions and a second rating. In the first round, requirements will be rated for their understandability and relevance. Those requirements rated as understandable and relevant in the first round will be judged for their feasibility in the second round. During this process, requirements can be adjusted and sharpened according to the needs of the quality assurance scheme.

**Understandability** of a requirement is defined as:

- It is clearly stated what the requirement measures (nominator/denominator or measurable clinical or organisational practice);
- The description of the requirement does not leave room for interpretation, it is unambiguous, and can be reproduced;
- The wording is understandable across countries, health systems and healthcare providers.

Understandability will be rated as 'yes' or 'no'. The panel must revise the wording of requirements/indicators until they are understandable.

**Relevance** of a requirement is defined by:

- The strength of the relationship between what the requirement measures and the desired healthcare goal/clinical outcome.
- The ability of a requirement to distinguish between good and bad healthcare performance.
- The relevance of the requirement to patients.
- The relevance of the requirement to the target population (epidemiological outcome).
- The benefits of meeting the requirement outweigh any possible negative effects (perverse incentives).
- The healthcare provider can actually influence the performance related to the requirement (accountability).
- The requirement stimulates performance improvement.

Relevance is rated on a 9-point scale ranging from 1 (not relevant at all) to 9 (extremely relevant). Only those requirements rated by at least 75 % of the voting panel members with 7 to 9 points will be considered relevant.

Those requirements rated as both understandable and relevant will also be assessed for their feasibility.

**Feasibility** relates to the possibility that the measurement of this requirement can actually be implemented. Feasibility will be assessed using three consecutive methods:

1. By the expert panel in a second Delphi-like round. It will provide a theoretical assessment of whether the implementation of the requirement/indicator is feasible, particularly from the clinical point of view;
2. By consulting with countries, once the final set of requirements has been identified. Countries will provide a theoretical estimate as to whether the implementation of the requirement/indicator is feasible, in particular from the organisational and policy-making point of view (see step 8);

- By pilot testing, involving a range of health systems and different types of breast cancer services (see step 9).

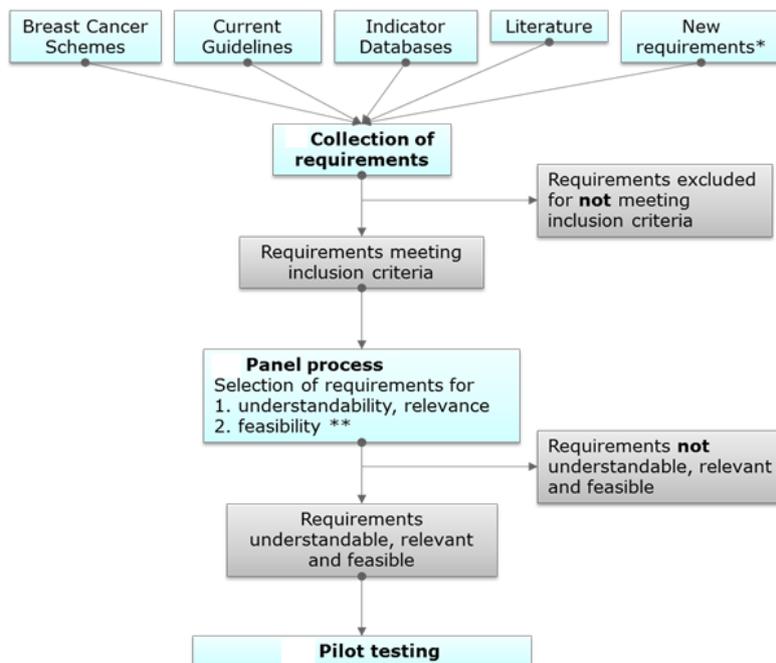
**Feasibility** of a requirement is defined by:

- The assessment methodology (e.g. indicator, or standard to be checked) and data sources proposed are adequate, i.e. the least demanding but most accurate methodology is proposed;
- The time and effort needed to assess the requirement is adequate for all breast cancer services;
- It is possible to adequately check the plausibility of data and to check for false data.

Feasibility is rated by the panel again, initially remotely and then in an on-site meeting on a 9-point scale ranging from 1 (not feasible at all) to 9 (extremely feasible). Only those requirements rated by at least 75 % of the voting panel members with 7 to 9 points will be considered feasible.

By carrying out the panel procedure, only those indicators that are rated by at least 75 % of the voting panel members as both relevant and feasible will be considered for inclusion in the *European Breast QA scheme*.

**Figure 1: Procedure of requirement/indicators development**



\* For quality potentials where no pre-existing requirements are available, new requirements will be developed.

\*\* For evaluating feasibility, the requirements will be presented to the panel including options on how to measure them, and presentation of the indicators related to those requirements.

### Step 7: Summarise the selected indicators/requirements in a report

This report will summarise the selection process for the requirement and the reasons for excluding specific requirements. It presents the selected requirements according to the requirement

statement, their rationale, criteria for measuring them, evidence base and assessment methodology proposed, including required data source.

### **III. Pilot testing**

#### **Step 8: Test *European Breast QA scheme* in a number of breast cancer services**

The requirements/indicators will be tested in a pilot run. Thus, the *European Breast QA scheme* will be implemented in a number of breast cancer services that are volunteering to participate in the pilot and have been chosen according to different variables that may influence their implementation. Such variables include the health system, type of breast cancer service (screening, treatment), service structure, whether it is a network or a comprehensive service, the structure of the catchment area, and others. They are amended according to the experiences gathered during the pilot run and then implemented within the *European Breast QA scheme*.

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