GISMa VIRTUALE DICEMBRE 2021

ECIBC:

CERTIFICAZIONE EUROPEA PER PROGRAMMI DI SCREENING E CENTRI DI SENOLOGIA

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EUSOMA

What is ECIBC?

✓ **The European Commission Initiative on Breast Cancer (ECIBC) has been mandated by the EU Council (2008) and is coordinated by the Joint Research Centre (JRC) to improve and harmonize breast cancer care in Europe.**

✓ **ECIBC has developed up-to-date evidence-based recommendations on screening and diagnosis**

✓ **These served as a basis for developing a quality assurance scheme applicable by breast cancer services.**

ECIBC

the EUROPEAN COMMISSION INITIATIVE on BREAST CANCER

The European Guidelines

The Quality Assurance Scheme

ECIBC

the EUROPEAN COMMISSION INITIATIVE on BREAST CANCER

The European Guidelines

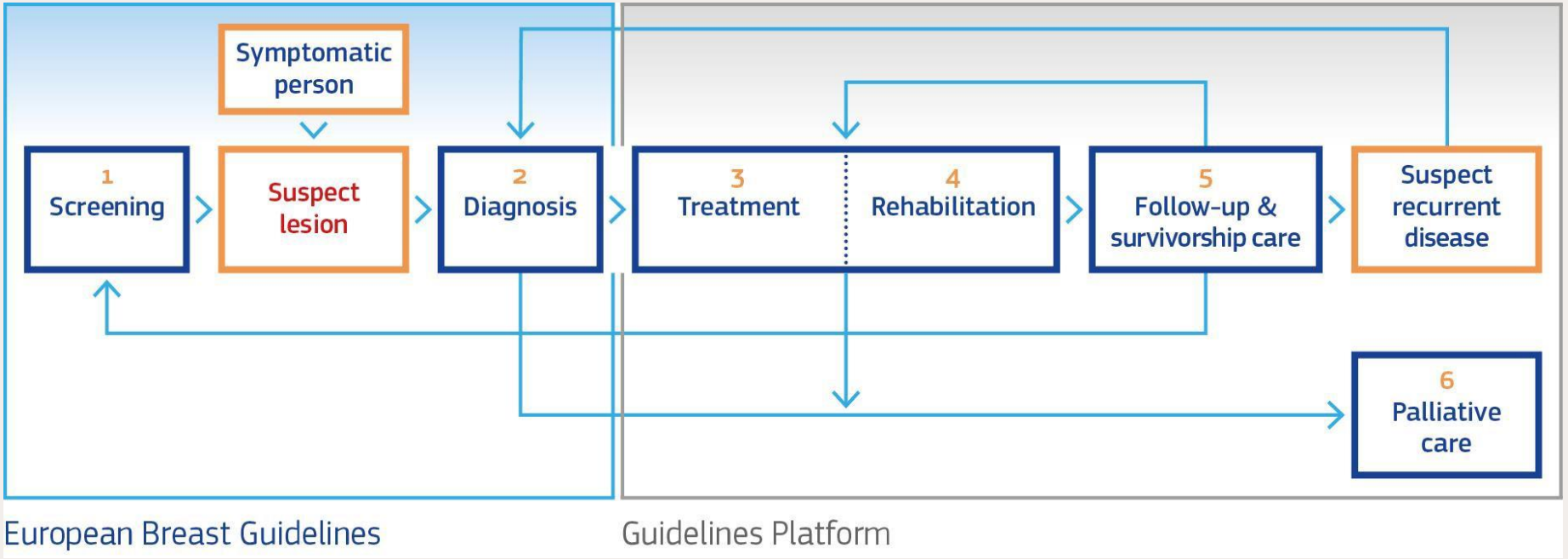
The Quality Assurance Scheme

The ***European QA scheme*** is a collection of requirements and indicators.

The application of the *European QA scheme* is not mandatory by law.

It covers the full extent of breast cancer management: from screening to treatment to palliative care.

Services, interventions, diseases, and care processes covered (continuity of care)



Important terms

Continuity of care

The degree to which a series of discrete health care events in BCS is experienced as coherent, connected and consistent with the patient’s medical needs and her personal context

Important terms

Breast cancer services (BCS)

Comprises all healthcare services covering the full extent of breast cancer care

Scope of certification

The BCS can be certified for the European QA scheme requirements for modules:

a. **Entire breast cancer care pathway**: all breast-care processes, including outsourced services (screening, diagnosis, treatment, rehabilitation, follow-up and survivorship care, and palliative care).
b. **Screening programme, including outsourced services** (and, where applicable, diagnosis for referrals following screening).
c. **Breast cancer care pathway without screening, including outsourced services**: breast centre, including diagnosis (including symptomatic women and referrals following screening), treatment, rehabilitation, follow-up and survivorship care, and palliative care.

Manuals produced (Spring 2021):

- Scheme Owner Manual

- Manual for Breast Cancer Services

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Scheme Owner Manual

European Quality Assurance Scheme for Breast Cancer Services

Important terms

QA scheme

A set of essential requirements.

Important terms

Scheme owner

The party responsible for designing, validating and mantaining the QA scheme, its normative documents and its related criteria

Important terms

Certification bodies (CAB)

A third-party body that performs conformity assessment activities including testing, certification and inspection. Must have registered with, be accredited and have entered into an agreement with a National Accreditation Body.

Important terms

Certification

Process by which accredited certification bodies (CAB), based on Audit, provide assurance that BCS activities conform to standards of the QA scheme.

Eligibility includes:

- Having a database capable of collecting performance data and to transfer the data to its CAB in the agreed format at least yearly

Important terms

National accreditation body (NAB)

Authoritative body that accredites CABs

Important terms

Audit

Systematic, independent, documented process for obtaining evidence to determine the extent to which Scheme requirements are fulfilled. The purpose of audit is to verify the compliance of the BCS to the European QA scheme

Composition of audit team

The composition of the overall audit team (including both on- and off-site auditors), and the required competences, will largely be determined by the scope of activities for which the BCS entity is seeking certification. In all cases, a lead auditor will be appointed to coordinate the audit process.

The following competences will be required within the overall audit team for each of the breast cancer care processes.

Screening

Knowledge, understanding and experience of:

- providing a breast cancer screening programme;
- screening performance evaluation;
- imaging modalities used to assess suspicious findings in first-level screening mammography (additional mammographic views or tomosynthesis, ultrasound, etc.);
- percutaneous breast biopsy;
- patient safety;
- the patient experience of breast cancer screening;
- the European QA scheme requirements;
- the relationships between screening and other breast cancer care processes.

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Manual for Breast Cancer Services

European Quality Assurance Scheme for Breast Cancer Services

REQUIREMENTS AND QUALITY INDICATORS

Requirements and quality indicators (QIs), including both structural and process/outcome indicators, are an important tool to assist BCSs in measuring, monitoring and improving their performance. These have been developed by the Quality Assurance Scheme Development Group using a rigorous and extensive process, which is described fully in the *Manual of the European QA Scheme for Breast Cancer Services*. As part of the certification process, compliance with European QA scheme requirements will be verified using these QIs, alongside other audit techniques (see section 5, under 'Audit techniques').

Important terms

Indicators (1)

The European Breast QA scheme assesses whether requirements are being met by using qualitative and quantitative indicators.

Important terms

Indicators (2)

-Concentrate where significant variation exists (quality potential)

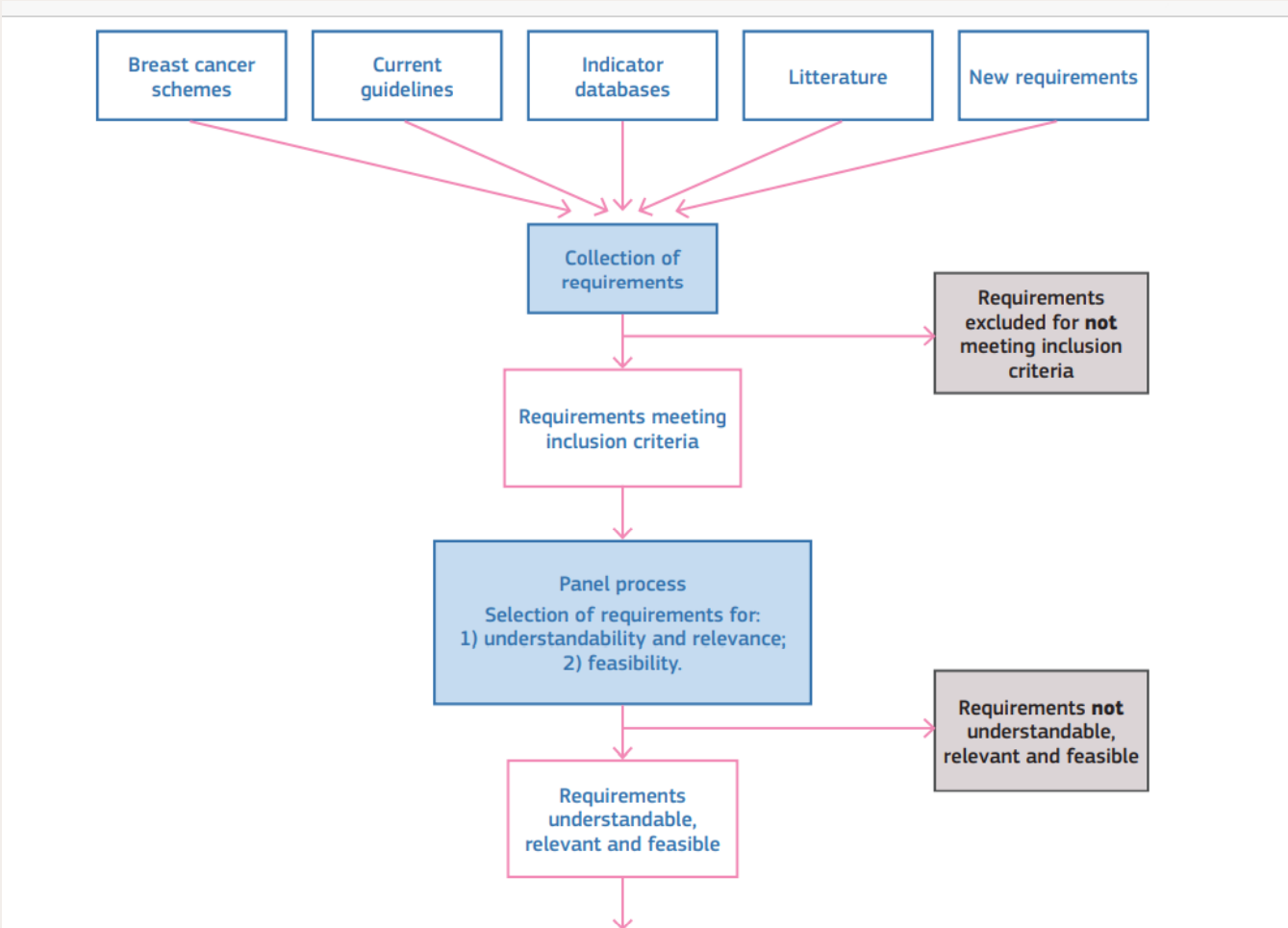
-Measurable

-Actionable

Important terms

Indicators (3)

Obtained by Delphi rounds on:
-Understandability
-Relevance
-Feasibility


Breast cancer schemes
Current guidelines
Indicator databases
Litterature
New requirements
Collection of requirements
Requirements excluded for **not** meeting inclusion criteria
Requirements meeting inclusion criteria
Panel process
Selection of requirements for:
1) understandability and relevance;
2) feasibility.
Requirements **not** understandable, relevant and feasible
Requirements understandable, relevant and feasible

GENERAL REQUIREMENTS		
CODE	**NAME**	**STATEMENT**
GEN-1	**Disciplines**	The BCS must have a clinical director and the following professionals: radiologists, radiographers, oncoplastic breast surgeons (or both a breast surgeon and a plastic surgeon), pathologists, medical oncologists, radiation oncologists, breast care nurses, data managers, psycho-oncologists, clinical geneticists, clinical psychologists, nuclear medicine specialists, medical technical assistants, physiotherapists, nutrition specialists and lymphoedema specialists. Professionals can be in the same hospital or associated through a written agreement/contract.
GEN-2	**Guidelines**	The BCS must have adopted evidence-based protocols for the full pathway and all processes of care for patients with breast cancer, at all stages.
GEN-3	**Quality improvement policy**	The BCS must have a written quality improvement policy, including a quality management system, a patient safety system, and a clinical information system for monitoring the quality of breast cancer care.
GEN-4	**Data management**	The BCS must have a written policy defining the governance of data management.
GEN-5	**Patient-reported outcome measures (PROMs) policy**	The BCS must have a policy for routine measurement of patient-reported outcomes to monitor the well-being of women with breast cancer throughout the care pathway.

GEN-11: LEAD TIME BETWEEN PATHOLOGY REPORT WITH DIAGNOSIS AND FIRST TREATMENT

Statement

The lead time between the pathology report with a diagnosis of cancer and the start of treatment must be no longer than 4 weeks.

Rationale

Limiting the lead time between first consultation and primary treatment is considered important for high-quality services. This is relevant from a medical perspective and from the patient's perspective in terms of patient-centredness. The lead time between the consultation to discuss the pathology report with a diagnosis of cancer and primary treatment should not be longer than 4 weeks.

Quality domain: Clinical effectiveness; Personal empowerment and experience; Safety.

Breast cancer process: Treatment.

Measurement: This requirement is measured by 1 indicator.

- **Indicator to be monitored (GEN-11.1):** Proportion of women diagnosed in the BCS with lead time between pathology report with diagnosis of cancer and start of treatment no longer than 4 weeks.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT GEN-11	
GEN-11.1 indicator	Number of women with breast cancer diagnosed in the BCS who have no longer than 4 weeks' lead time between the pathology report with a diagnosis of breast cancer and primary treatment _____ x 100 Total number of women with breast cancer

The distribution of requirements and measurement elements (criteria and indicators), according to the different care pathway processes, is shown in this table:

PATHWAY PROCESS	NUMBER OF REQUIREMENTS
General	20
Screening	10
Diagnosis	25
Treatment	25
Rehabilitation	2
Follow-up	3
Palliative care	1
Total	**86**

Example of dichotomous indicators

✓ **The Breast Cancer screening Centre must have a written policy for counseling about nutrition and physical activity for women attending screening**

✓ **The Breast Centre must have a written policy for counseling about nutrition and physical activity for breast cancer survivors**

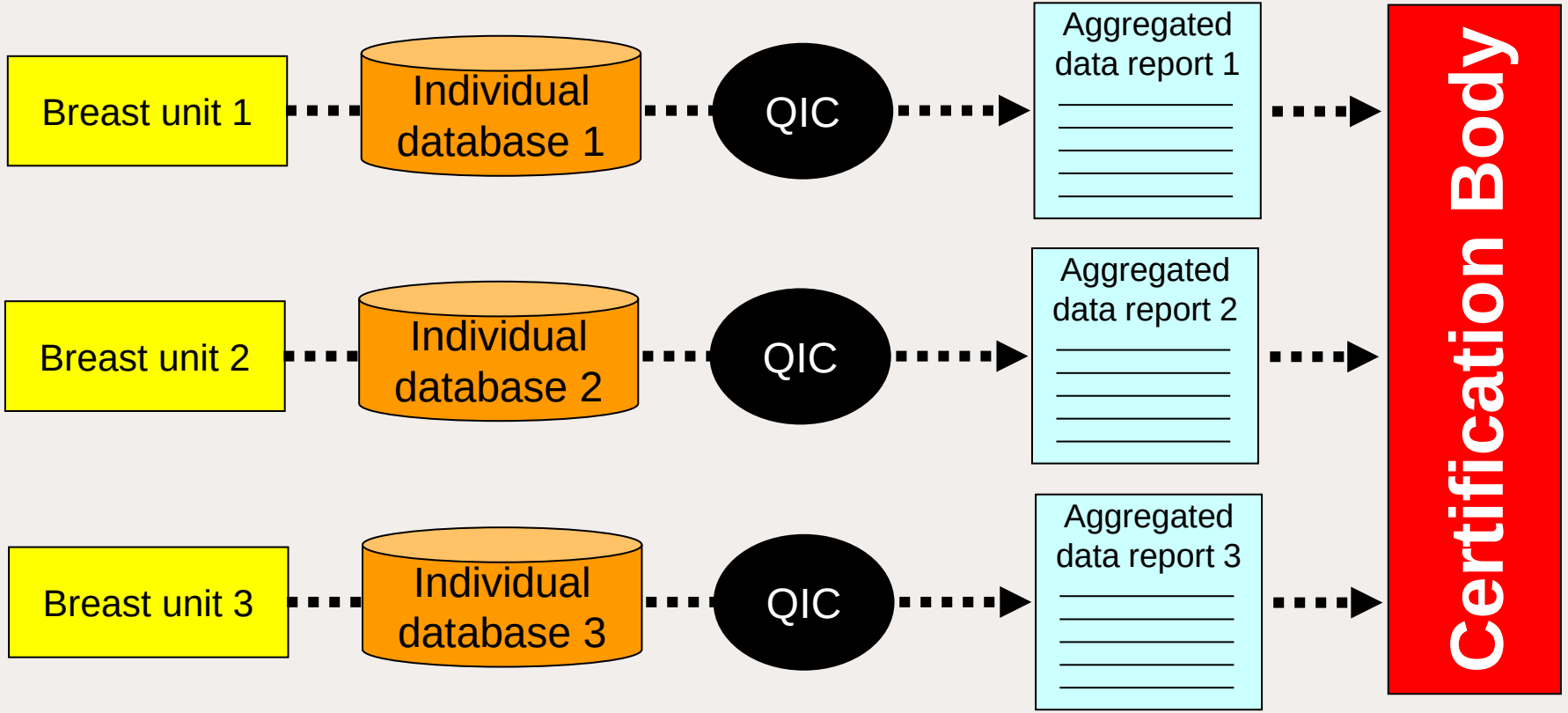
3 macro-indicators

50. Screening_Program_1b (16 indicators)
Participation rate
Invasive breast cancer detection rate
Screening coverage
Interval cancer rate
Episode sensitivity
Recall rate
Breast cancer detection rate
DR Cancer ≤10 mm
DR Cancer > 20 mm
Lymph node negative rate
Time interval between screening mammogram and treatment
Benign open surgical biopsy rate
Advanced cancer (T2+), review errors
Interval cancer, review errors
Proportion of women undergoing a technical repeat examination
Time between screening mammogram and issuing of results
51. Screening_Center_Mammography_1a (3 indicators)
Recall rate
Breast cancers detection rate
Invasive cancers ≤10 mm rate
52. Screening_50_69 (Invitation coverage 50-69)
Proportion of asymptomatic women aged 50 to 69 invited for screening within a screening program.

Quality Indicators Calculator (QIC): Algorithms for computation

An algorithm for computation of each indicator is provided, including also how the missing values are managed when calculating indicators

In the JRC system, breast units will use the European QIC to produce aggregated data reports. Aggregated data is sent to the CB



QIC = Quality Indicators Calculator

QIC: Data quality checks

Internal consistency of the data variables in each record;

checks for duplications of records in the data file;

checks for completeness of information for all data record variables.

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Self-assessment Tool User Manual

European Quality Assurance Scheme for Breast Cancer Services

- Definire obiettivi comuni tra centri di screening e di senologia finalizzati a comuni raccomandazioni e protocolli, a base di popolazione, con una nuova capacità di offrire appropriati strumenti per la riduzione del rischio alle donne.

- Necessità di investimenti di Ricerca&Pratica clinica per la progettazione e realizzazione di nuovi interventi organizzati e progetti valutazione EBM e di impatto da parte istituzionale e degli stakeholders.

Eugenio Paci, GISMa 2018, Roma

L’auspicio di Paci viene raccolto, giudicando i risultati del lavoro del ECIBC?

Sì e No…

Centri di senologia e screening

Continuity of care……

…..Tuttavia a parte questo statement in ECIBC non si va molto più in là nel motivare e valorizzare le relazioni tra screening e BU.

Centri di senologia e screening

Una certa confusione nella ‘classificazione’ degli indicatori di screening

Nel sottogruppo pochi potevano dirsi ‘esperti’ di qualità e certificazione o tanto meno professionisti in questo ambito

PERO’…..forse per la prima volta la qualità è stata declinata non solo in termini di ‘ISO’ ma in modo più vicino alla valutazione clinica ed epidemiologica

….E tutto ciò senza confini in Europa!

GRAZIE A:

The JRC Team (Ispra)

Lorenza Marotti (BCC)

Mariano Tomatis (Torino)

Questa presentazione è dedicata a Karen Benn