European Quality Assurance Scheme for Breast Cancer Services
Scheme owner view and future pilot run

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Overview

- Introduction
- Development of the scheme
- Implementation and pilot run

Introduction

European Quality Assurance (QA) scheme

- A collection of **requirements and indicators**
- Covers the **whole care pathway**
- **Voluntary** implementation, **modular and adaptable** to national/local contexts
- **Experts** (including patients) supporting the development
- **Accreditation** legal framework
  - Accredited (ISO 17065) certification for services
  - EA MLA agreement

Development of the QA scheme

- Scope of the QA scheme
- Development of the care pathway
- Service/process requirements
  - Collection of requirements / indicators fulfilling defined criteria
    - Classification and creation of worksheets
      - Statement, Rationale, Criteria, Evidence, Reference documents, Information for auditing
    - Delphi rounds for understandability, relevance and feasibility
- Certification process requirements

Requirements

- 'Service/process requirements‘: clinical and organisational requirements including quality indicators for all the processes covered by the scheme. Services will need to demonstrate that they fulfil these requirements in the provision of their services.
- 'Certification process requirements’ for certification bodies: audit and surveillance requirements, i.e. surveillance functions and activities; audit plans; selection of auditors and assignment criteria; decision-making mechanisms.

Scope of the QA scheme

- Describes
  - Services, interventions, and care processes covered
    - (e.g. Lesions associated with ‘uncertain malignant potential’ (B3 lesions), Other non-malignant breast diseases when implied in a differential diagnosis of cancer)
  - Quality dimensions included
    - Clinical effectiveness
    - Facilities, resources and workforce
    - Personal empowerment and experience
    - Safety
  - How the scheme can be implemented

Care pathway

- Care pathway: the way that a typical cancer patient /person attending screening is taken through health services.
- Along the care pathway there are:
  - **Quality targets** (refer to patient) related outcomes and appropriate breast cancer care (e.g. quality of life, survival)
  - **Quality potentials*** correspond to known or anticipated deficits in the quality of care. They are relevant for attaining quality targets. (E.g. Time: communication of the positive finding - diagnostic workup)

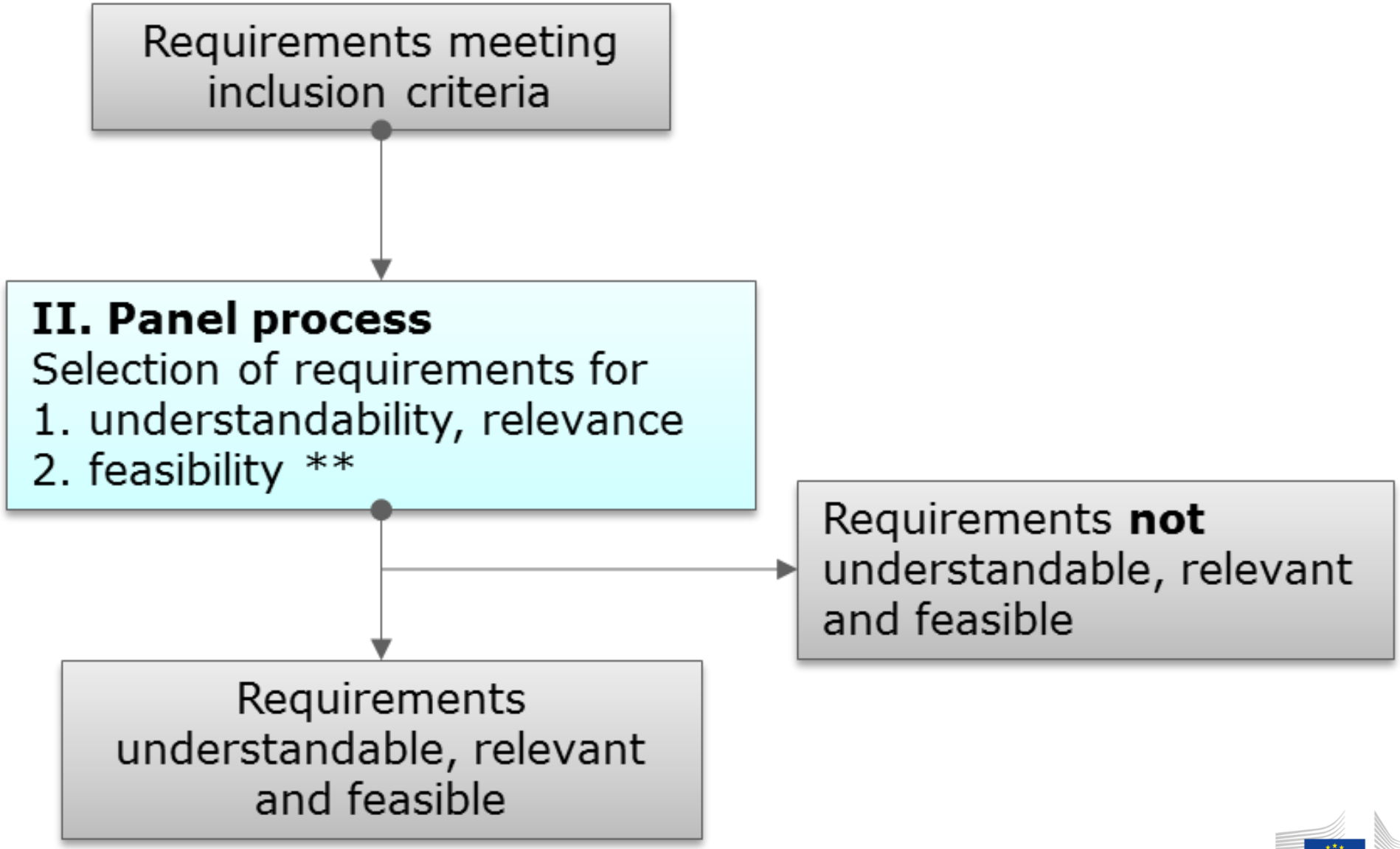
*from AQUA Institute *Methodenpapier*

Development of the requirements for services

Requirements & indicators

- **Requirement:**
  - The level of performance required with respect to a certain aspect meaningful for breast cancer care and diagnosis.
  - It is composed of a **statement**, associated with the corresponding supporting evidence and references, which is explained in a number of criteria.
- **Indicator:**
  - Describes the fulfilment of a requirement by a clearly defined numerator and denominator.
  - Indicators are always linked to a requirement, but not every requirement will have as a result a quantitative indicator to be measured.

II. Panel Process



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Panel round I: Understandability

- It is clearly stated what the requirement measures
- Description does not leave room for interpretation, it is unambiguous, and can be reproduced
- The statement is understandable across countries, health systems and healthcare providers.

Panel round I: Relevance for quality of care

- Relationship between what the requirement measures and the desired health care clinical outcome.
- Capability to distinguish between good and bad healthcare performance.
- Relevance for individuals and populations.
- Benefits outweigh possible negative effects.
- Service can influence the performance related to the requirement.
- Stimulates for improvement in health care performance.

Panel Round II: Feasibility

- The assessment methodology and data sources proposed are adequate
- The time and efforts needed to assess the requirement is adequate for all centres
- It is possible to adequately check the plausibility of data, to control for false data.

European QA scheme

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

Examples of requirements

- **Example 1:** Requirement for the screening programme
  - **Requirement:** Women aged 50-69 years must be invited for mammography screening within a screening program.
  - **Indicator to be monitored:** Proportion of asymptomatic women aged 50–69 who were invited for screening within the screening programme.

Development of the requirements for certification

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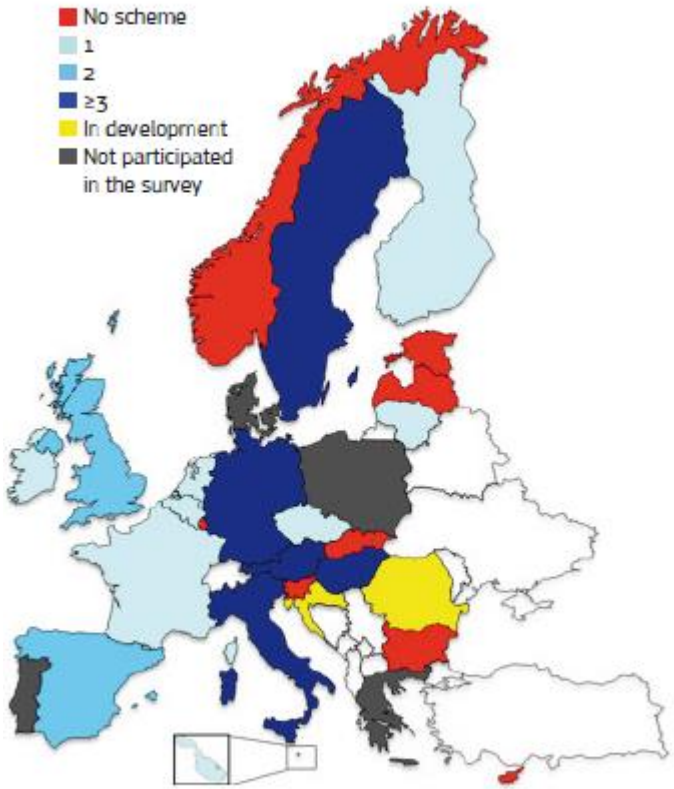
Certification process requirements

- Determination of certifiable `blocks' (modules) of the scheme.
- How the European QA scheme is organised, managed and maintained.
- European QA scheme owner's requirements for services and certification bodies participating in the scheme.

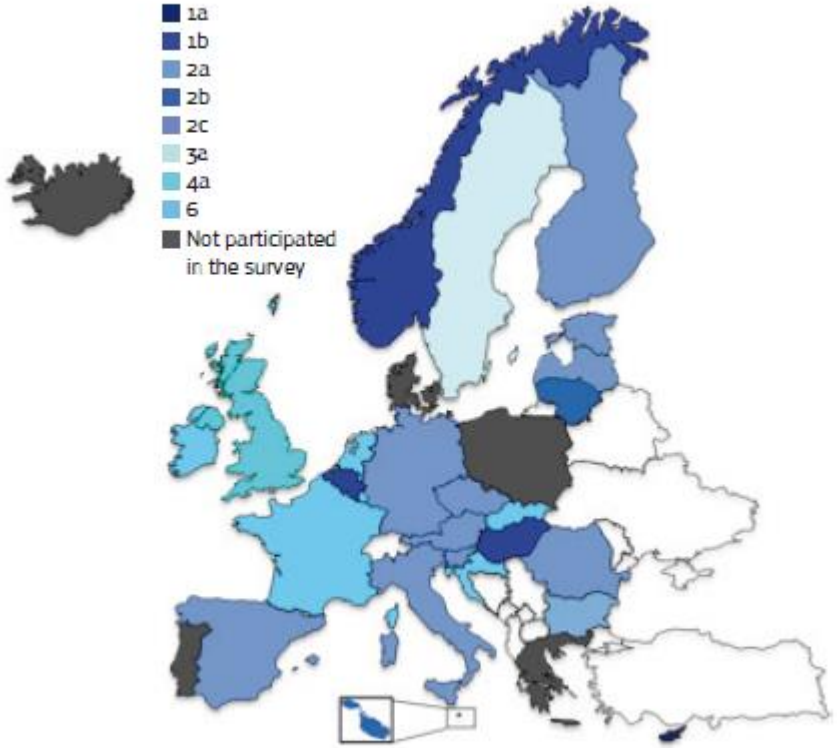
Diversity of organisational settings for breast cancer care

Figure 24. *Number of quality schemes*



UK* data refer to England only.
The magnified area corresponds to Malta.

Figure 20b. *Organisation of breast cancer care services (per country)*



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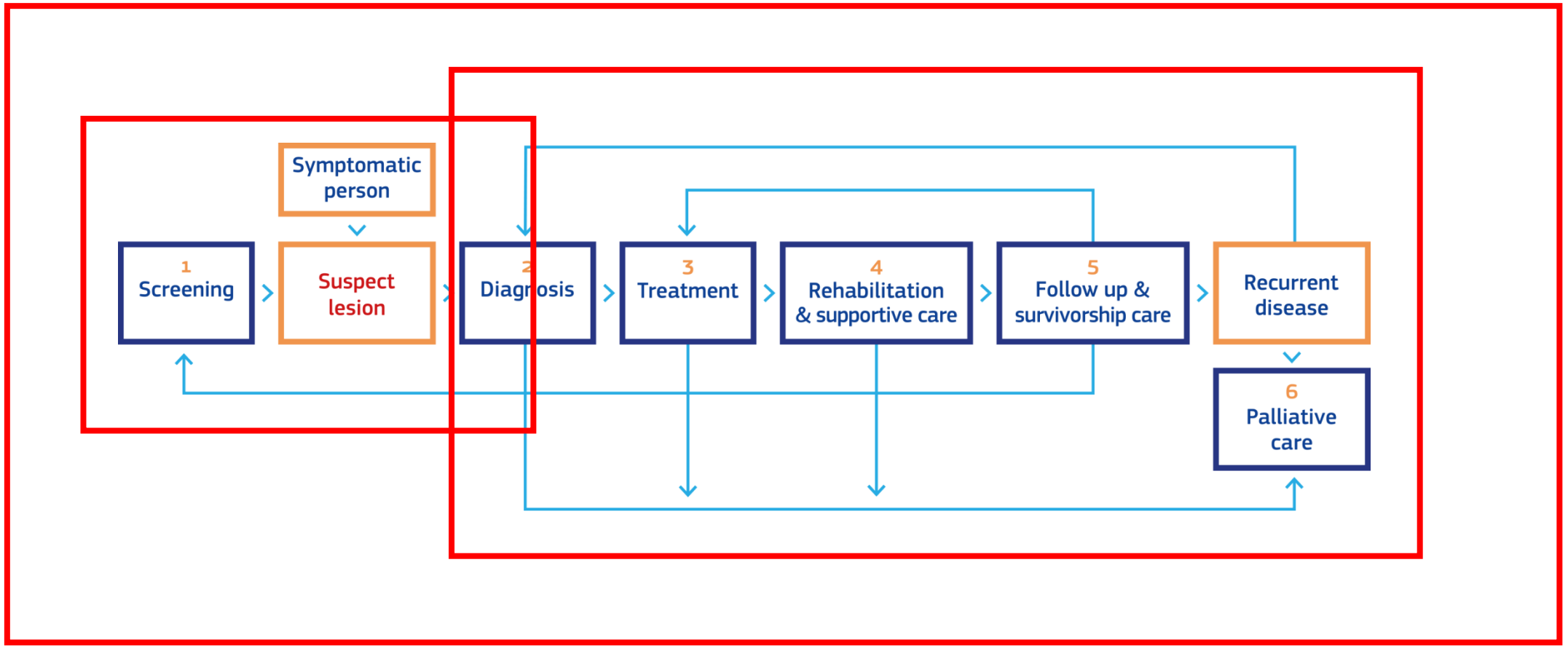
Modular approach and continuity of care



Example - certification

- CBs are required to manage the competence of personnel involved in the certification process in accordance with the requirements of ISO 17065, clause 6.1.
- Composition of audit team: Diagnosis
  - Knowledge, understanding and experience of:
    - diagnostic imaging;
    - percutaneous breast biopsy;
    - cytology and histopathology of breast lesions;
    - patient safety;
    - breast cancer nursing care;
    - the patient experience of breast cancer diagnosis;
    - the European QA scheme requirements;
    - the relationships between diagnosis and other breast cancer care processes.

Implementation: tools to support the services

Download the manuals

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Implementation and pilot run

Feasibility testing – breast cancer services

- Check the feasibility of the requirements for breast cancer services (BCS), including continuity of care aspects
- Involve several breast cancer services on a voluntary basis covering some specific settings – 12 in 10 EU countries
- Process:
  - Agreements with the BCS
  - Training
  - Self-assessment & calculation of the indicators
  - Feedback regarding the requirements and the tools

Pilot run

- Aim: to test the auditing and certification part of the scheme
- Timeline:
  - preparation of BCSs and CBs from April 2022
  - pilot July – December 2022

Pilot run

- With the support of European Accreditation
- CBs from Italy and Spain
- European (Breast) Cancer certification schemes
- BCSs from Germany, Italy, Latvia, Poland, Portugal, Romania, Slovenia, Spain covering all certification modules

Next steps

- Analyse the results of the feasibility exercise, amend the requirements and indicators if needed
- Based on the results of the pilot run, improve the certification module
- Update of the clinical requirements based on new evidence
- Update all the tools

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Thank you

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