EUROPEAN COMMISSION
DIRECTORATE GENERAL
JOINT RESEARCH CENTRE
Directorate F – Health, Consumers and Reference Materials
Unit F1 Health in Society

ECIBC Reference Documents

Explanatory note

1. ECIBC glossary

European Commission Initiative on Breast Cancer: ECIBC

European Guidelines for breast cancer screening and diagnosis: *European Breast Guidelines*

European Quality Assurance scheme for breast cancer services: *European Breast QA scheme*

WHAT SHOULD BE/NOT BE PROVIDED: defined by evidence-based Guidelines (in ECIBC = Recommendations)

HOW SHOULD IT BE DELIVERED: defined by best practices, SOPs, etc. (in ECIBC = Reference documents)

HOW TO CHECK WHETHER IT IS DELIVERED: licencing, audits, patients' records (in ECIBC = QA schemes)

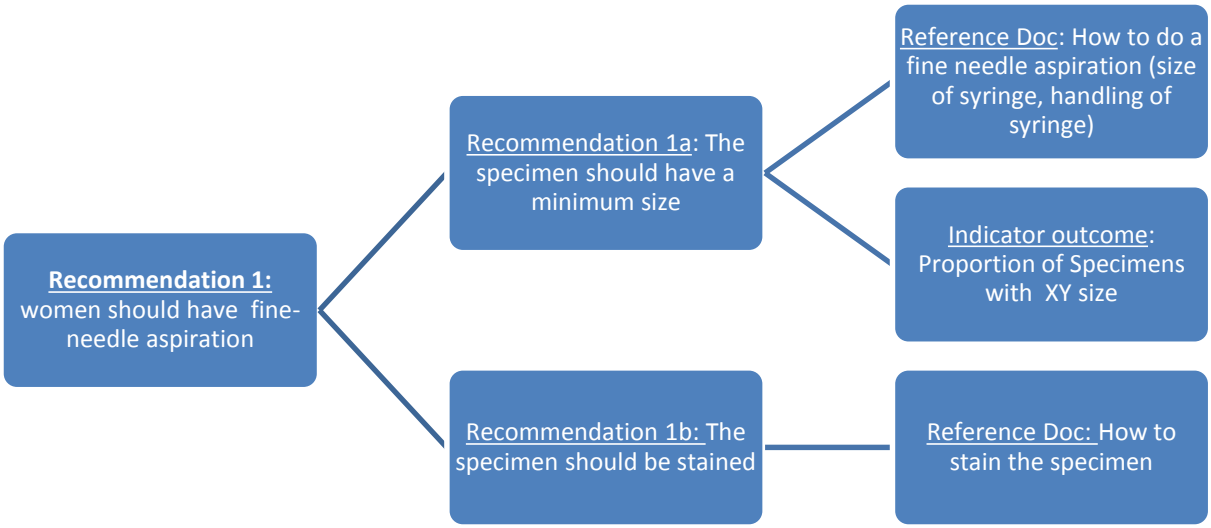
2. INTRODUCTION

This document reports how reference documents are foreseen to support ECIBC, within its remit, in particular for enhanced implementation of both *European Breast Guidelines* and the *European Breast QA scheme*, how they will be selected, and how they will be associated to the inherent parts of ECIBC.

'Reference documents' is the terminology adopted by ECIBC to indicate documents describing in detail how a certain recommendation and/or requirement should be implemented. They may include e.g. best practices, lists of indicators, standard operating procedures, methods for testing activities, testing protocols, templates for invitations and satisfaction questionnaires, training standard curricula, competence requirements, legal frameworks, etc.

3. BACKGROUND

The on-going ECIBC aims to have an impact on the quality of breast cancer care via evidence-based recommendations (*European Breast Guidelines*) and a voluntary quality assurance scheme (*European Breast QA scheme*). The *European Breast QA scheme* will include requirements for breast cancer services (BCSs), based on evidence-based recommendations. Recommendations will cover only screening and diagnosis; requirements will cover all processes of care. Neither will address technical details related to fulfilment of the respective requirement. Therefore, Reference documents need to be collected in order to provide the necessary details, as shown in the following example:



4. COLLECTION OF REFERENCE DOCUMENTS

To avoid duplication with entities already developing reference documents, ECIBC in principle will not develop new ones but rather search for existing ones along two main criteria:

1. TOPIC: given that ECIBC resources are not unlimited, a prioritisation exercise among all the possible topics needing reference documents according to GDG and QASDG opinion, is necessary. Topics not included in positive recommendations and/or requirements will not be included.

2. ELIGIBILITY CRITERIA: requirements to be applied for selecting all types of reference documents are set and published. In addition, for each typology of reference document, ECIBC will agree and make publicly available relevant additional specific criteria.

Special reference documents are:

a. the Guidelines Platform that is subject to another set of rules (see the methodology and report) and is not within the scope of this document;
b. the training template for screening radiologists and radiographers that is under development under JRC coordination;
c. the validated instrument for measuring the satisfaction of women attending screening programmes, whose selection is under development by the JRC.

All other Reference documents will be identified via (systematic) search, open calls for documents or else, as most appropriate. They will be available as they become ready at: http://ecibc.jrc.ec.europa.eu/reference-documents.

Topics needing Reference documents and Reference documents can be proposed by GDG and QASDG members, associate members and external experts who have the knowledge on what is the appropriate technical guidance necessary to fulfil a certain recommendation/requirement.

Other topics most likely covered by ECIBC reference documents will be:

Technical quality and clinical quality for imaging tests recommended in the European Breast Guidelines (e.g. mammography)

Technical quality for pathology examinations

Skills and training needs for staff involved in breast cancer screening, diagnosis and care (the list of staff included will be defined at a later stage).

5. CRITERIA FOR PRIORITISATION OF REFERENCE DOCUMENTS

The list of topics for which Reference documents can facilitate ECIBC implementation is potentially very long, so it was decided to limit the topics according to the following criteria:

- Activity **covered by requirements of the *European Breast QA scheme***
- Activity **recommended by the *European Breast Guidelines*** (priority given to strong recommendation → weak recommendation → recommendation for research)
- Reference document **cited in the legislation** of one or more involved countries (see at http://ecibc.jrc.ec.europa.eu/national-contacts)
- **Key processes** highlighted by the subgroups (possibly providing evidence for its selection, e.g. data on errors, incident reports, etc.)
- Other aspects of cancer screening delivery explicitly mentioned in the Council Recommendation of 2 December 2003 on cancer screening (2003/878/EC), for example:
  - registration and management of screening data (2003/878/EC – point 2)
  - monitoring (2003/878/EC – point 3)
  - training (2003/878/EC – point 4, only partly covered by the Special reference document b.)
- Other aspects regarding patient safety and patients' rights in cross-border healthcare

For very detailed procedures, no detailed reference documents are needed. However, as the interpretation phase can be accredited, reference documents and/or performance requirements should cover interpretation.

6. WHERE REFERENCE DOCUMENTS WILL BE MADE AVAILABLE?

Reference documents will be associated to relevant recommendations and requirements. E.g. for Guidelines, they may be incorporated through an additional tab with respect to those already available for the users' profiles (see figure 2 below).

In case Reference documents are publicly available and/or (pre-acquired) intellectual property rights released to the JRC, the documents will be directly made available, otherwise a link will be provided.

For many topics more than one Reference document may be provided; stakeholders willing to implement ECIBC may select from more than one reference documents the one closer to their context (organisational setting, machine brand, laboratory instrumentation, service user typology, etc.).