European Commission Initiative on Breast Cancer (ECIBC): Summary of the development of the European quality assurance scheme for breast cancer services

This document reports on the QASDG’s first output and describes: a) the interventions and services covered by the European Breast QA scheme; b) the quality domains included; and c) how the scheme will be implemented in the European context.

This scheme defines a common set of quality and safety requirements for breast cancer services in Europe. It covers all the relevant areas of healthcare provision for breast cancer and all breast cancer care procedures. It defines its requirements by considering evidence-based recommendations arising from high-quality guidelines, where possible, best professional practices, and the relevant legislation. On completion, and before wider implementation, it will be piloted among participant services in Europe.

a) Services, interventions, diseases and care processes covered by the QA scheme

The European Breast QA scheme applies to breast cancer services, defined as ‘all healthcare services covering, in continuum, the full extent of breast cancer management, from screening to follow-up, and in some cases until the end-of-life care’.

This includes:

- Primary prevention when the intervention is specifically targeted at breast cancer (e.g. physical activity recommendations), although primary prevention interventions in general may be included as ‘service/process requirements’ in one or more of the breast cancer procedures (e.g. smoking cessation or alcohol reduction counselling in early diagnosis or treatment settings).
- Prevention (hormonal prevention or prophylactic mastectomy), surveillance, diagnosis (including genetic testing), treatment, rehabilitation and palliative
- Care of breast cancer in women at increased risk of breast cancer also fall within the scope of the scheme.
- Lesions pathologically defined as associated with ‘uncertain malignant potential’ (so-called B3 lesions) also come under the scope of the scheme.
- Other non-malignant breast diseases are covered by the scheme when implied in a differential diagnosis of cancer.

Male breast cancer and other male breast diseases, such as gynecomastia, do not fall under the scope of this scheme.
Breast cancer care pathway

To ensure that requirements follow a patient/person-centred approach, requirements are defined by taking into account the care pathway for breast cancer (and its related processes and subprocesses).

The care pathway describes the healthcare chain and interfaces across healthcare sectors by bundling and visualising the outcomes of the relevant healthcare processes involved and considering quality targets. In detail, the care pathway aims at:

- Presenting the intervention/processes for which quality should be assured in a structured way;
- Presenting the relevant healthcare sectors involved;
- Assigning the responsibilities of healthcare providers to healthcare processes;
- Identifying starting points for quality assurance;
- Identifying quality potential within the care pathway of breast cancer.

The care pathway visualises via a flow chart the pathway followed by a patient. This flow chart includes specific services, end points, quality targets and quality potentials relevant to the specific subject of the quality assurance scheme, considering the course of the disease as well as the various services involved (1).

While dealing with breast cancer, persons go through different processes of care. Thereby, a general care pathway can be identified that applies to ‘typical cases’ of breast cancer. These care pathways are meant to be interpreted as a guide for the definition of requirements, and are not an exhaustive definition of all the possible variations of a general pathway, due to different local organisational settings and practise, or specific individual cases of breast cancer that, for one reason or another, need to follow a different pathway. The simplified general care pathway proposed for the European QA scheme is represented in the Figure 1.

Figure 1: Breast cancer care pathway

Thus, the main stages of breast cancer care can be identified as follows:

- Screening
- Diagnosis
- Treatment
- Rehabilitation
- Follow-up and survivorship care
- Palliative care
Particular emphasis is given to requirements at the interface of the care processes, thereby addressing the quality dimension of continuity of care. One important example may be the availability of psychosocial support resources across all different processes, as considered appropriate for each case. The presence of a case manager (e.g. breast care nurse) throughout the entire continuum of procedures would facilitate the continuity of care.

b) Quality domains

In the European Breast QA scheme, requirements are classified according to the following domains:

- Clinical effectiveness
- Facilities, resources and workforce
- Personal empowerment and experience
- Safety

c) Implementation of the scheme: modular approach to the European context

In the investigation and treatment of the disease, the patient goes through various care processes and related sub-processes along the care pathway. These processes and sub-processes are provided by multiple professionals and services. The process of ‘treatment’ itself comprises various different sub-processes (e.g. surgery, radiation therapy, medical oncological treatment, psycho-oncology care, rehabilitation, palliative care), similarly to the primary treatment of breast cancer and the treatment of recurrent or metastatic disease. In this context, the concept of continuity of care becomes highly relevant. The person/patient must always be involved and empowered in all processes along the care pathway.

Continuity of care is defined as ‘the degree to which a series of discrete healthcare events is experienced as coherent and connected and consistent with the patient’s medical needs and personal context’.

The results of a survey on the organisation of breast cancer care in Europe, conducted by the JRC in 2012 (2), showed that only in four out of 25 countries (16%) a single entity takes responsibility for all breast cancer care processes. All the remaining countries reported a scenario in which different entities are responsible for different care processes. Frequently (40%), a public entity is responsible for the organised screening programme, while others (breast centres, public and/or private) are responsible for the subsequent care processes. Further regional and/or local organisation within the countries may also be expected, although this was not reported in the publication cited.

Two concepts can be used to describe the intervention of different entities and professional profiles in the breast cancer pathway: externalisation and modules.

**Externalisation (outsourcing)**

A process or sub-process is defined as externalised (outsourced) when an entity which is responsible for the coordination of care provides a certain process or sub-process via an agreement with a different entity or healthcare professional. The responsibility for the coordination of care remains with the first entity. In the case of breast centres, there may be:

- A unique geographical entity (single comprehensive approach) that takes the responsibility for the entire pattern of care and hosts all the services to be provided (the ‘physical’ breast unit), which is also connected to different levels of care.
• Services and specialists from more than one hospital or structure (multi-site network approach), within the same geographical area, enabling close multidisciplinary working, service networks and guaranteeing easy access to all the necessary services (6) (‘breast centre without walls’).

Examples of processes or sub-processes that may be outsourced for a breast centre through an agreement are: magnetic resonance imaging, interventional radiology, medical oncology, radiation therapy, clinical genetics, nuclear medicine, and rehabilitation.

Modules

A module is a distinct process or aggregation of processes (e.g. screening and diagnosis; treatment, follow-up and rehabilitation, etc.) which fall under the responsibility of a single entity. The difference between outsourcing services and the module approach is that in the first case the coordination of care remains the responsibility of the entity contracting the external services, whilst in the second case the responsibility is transferred from one entity responsible for the first module (which comes ‘before’ considering the care pathway, like the breast centre comes ‘after’ the population-based screening programme) to the entity responsible for the subsequent care (which comes ‘after’, e.g. like the end-of-life care comes ‘after’ the treatment in the breast centre).

Taking into account the results of the 2012 survey (2), separate certification may be possible for the following modules:

• Breast cancer screening programme (organised, population-based) – corresponding to the screening process, to include/not include the ‘diagnosis’ process after positive screening events;
• Breast centre – corresponding to the following processes: diagnosis, treatment, rehabilitation, follow-up and survivorship care, palliative care;

Diagnosis is a process common to both the screening programme (for asymptomatic persons) and the breast centre (for symptomatic persons). In the case where a screening module sends all positive cases at first reading to the breast centre, diagnosis will only be carried out at the breast centre imaging facility.

Bibliography
