European Commission

JRC SCIENCE AND POLICY REPORT

Review and analysis of external **quality assessment** of **breast cancer services** in Europe

Supporting information for the development of a European Quality Assurance scheme for Breast Cancer Services

Silvia Deandrea, Donata Lerda, Jesús López Alcalde, Luciana Neamtiu, Zuleika Saz-Parkinson, Aslı Ulutürk

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List of abbreviations

ACI	Accreditation Canada International
ACSA	National Accreditatíon Programme in Health (PT: Programa Nacional de Acreditação em Saúde)
AGREE	Appraisal of Guidelines for Research & Evaluation
AZUS	Agency for Accreditation of Healthcare Institutions of Serbia
BCC	Breast Centres Certification
BCS	Breast Cancer Service
CEN	FR: Comité Européen de Normalisation
CMJ	Quality Monitoring Centre (PL: Centrum Monitorowania Jakości)
CPA	Clinical Pathology Accreditation
CQC	Care Quality Commission
DDKM	Danish Healthcare Quality Programme
DGS	German Society for Breast Diseases
DG SANTE	Directorate-General for Health and Food Safety
DKG	German Cancer Society
DKH	German Cancer Aid
DNV	DE: Det Norske Veritas
DUQuE	Deepening our understanding of quality improvement in Europe

EA	European co-operation for Accreditation
EBMT	European Group for Blood and Marrow Transplantation
EC	European Commission
ECIBC	European Commission Initiative on Breast Cancer
EFQM	European Foundation for Quality Management
EFTA	European Free Trade Area
ENCR	European Network of Cancer Registries
EPSO	European Partnership of Supervising Organisations in Healthcare
ERN	European Reference Network
ESMO	European Society for Medical Oncology
EUR	Euratom, a number of JRC cataloguing, a series unique for JRC (JRC was formerly called Euratom)
EUREF	European Reference Organisation for Quality Assured Breast Screening and Diagnostic Services
EUSOMA	European Society of Breast Cancer Specialists (formerly European Society of Mastology)
EXPH	Expert Panel on Effective Ways on Investing in Health
GDG	Guidelines Development Group
HAI	Hospital-acquired infections
HAS	FR: Haute Autorité de Santé
HQIP	Healthcare Quality Improvement Partnership

HTA	Health Technology Assessment
IARC	International Agency for Research on Cancer
IAP	International Accreditation Programme
IKAS	Institute for Quality and Accreditation in Healthcare (DK: Institut for Kvalitet og Akkreditering i Sundhedsvæsenet)
ISAS	Imaging Services Accreditation Scheme
ISCT	International Society for Cellular Therapy
ISO	International Organization for Standardization
ISQua	International Society for Quality in Health Care
ISS	International School of Senology
JACIE	Joint Accreditation Committee of European Society for Blood and Marrow Transplantation and International Society for Cellular Therapy
JCI	Joint Commission International
JRC	Joint Research Centre
JRC-IHCP	Joint Research Centre - Institute for Health and Consumer Protection
KM	Mammography Cooperative (DE: Kooperationsgemeinschaft Mammographie)
MARQuIS	Methods of Assessing Response to Quality Improvement Strategies
MS	Member State
NAB	National Accreditation Body
NCAPOP	National Clinical Audit and Patient Outcomes Programme

NCPR	National Cancer Peer Review Programme
NHSBSP	National Health Service Breast Screening Programme
NICE	The National Institute for Health and Care Excellence
PaSQ	Patient Safety and Quality of Care
PHPS	Public Health Policy Support
QA	Quality Assurance
QASDG	Quality Assurance Scheme Development Group
QMSI	Quality Management System Index
SANITAS	Self-Assessment Network Initial Testing and Standards
SEP	Excellent Healthcare Programme (ES: Programa Sanidad Excelente Privada)
SESPM	Senology and Breast Pathology Spanish Society
SHQS	Social and Health Quality Service
SIS	Senologic International Society
SSS	Senology Swiss Society
TC	Technical Committee
TJC	The Joint Commission
UKAS	The United Kingdom Accreditation Service
WG	Working Group
WHO	World Health Organization

ISO codes of countries

Country Name	ISO Code	Country Name	ISO Code
Albania	AL	Liechtenstein	LI
Austria	AT	Lithuania	LT
Bosnia and Herzegovina	BA	Luxembourg	LU
Belgium	BE	Latvia	LV
Bulgaria	BG	Montenegro	ME
Switzerland	CH	The former Yugoslav Republic of Macedonia	MK
Cyprus	CY	Malta	MT
Czech Republic	CZ	Netherland	NL
Germany	DE	Norway	NO
Denmark	DK	Poland	PL
Estonia	EE	Portugal	PT
Spain	ES	Romania	RO
Finland	FI	Serbia	RS
France	FR	Sweden	SE
Greece	GR	Slovenia	SI
Croatia	HR	Slovakia	SK
Hungary	HU	Turkey	TR
Ireland	IE	United Kingdom	UK
Iceland	IS	Kosovo	XK
Italy	IT	-	-

International Organisation of Standardisation (ISO) 3166 standard.

Foreword

by **Krzysztof Maruszewski**
Director, *JRC Institute for Health and Consumer Protection*

Developing a single European quality assurance scheme, as foreseen by the European Commission Initiative on Breast Cancer (ECIBC) steered and coordinated by Joint Research Centre (JRC), is highly complex. In order to encompass different healthcare systems' settings and the related quality assessment systems within each country, a series of three reports was launched.

The first report was based on a survey conducted on 25 Member States in 2012-2013 and the results are presented in the *Report of a European survey on the organisation of breast cancer care services*.[1]

The second, *Report of a survey on accreditation, conformity assessment and quality assurance in the field of breast cancer care in Europe* (referred to as *Conformity Assessment Report*) concerns International Organization of Standardization (ISO) accreditation, certification and conformity assessment of breast cancer services under National Accreditation Bodies' (NABs) governance [https://ec.europa.eu/jrc/en/research-topic/healthcare-quality].

1. http://bookshop.europa.eu/en/report-of-a-european-survey-on-the-organisation-of-breast-cancer-care-services-pbLBNA26593/?CatalogCategoryID=l1QKABstlLsAAAEjCpEY4e5L.

And now this third report focuses on peer reviewing and healthcare accreditation of Breast Cancer Services (BCS) in Europe and it includes an extensive analysis of the already existing quality schemes. It is based on information collected through various available sources, namely scientific papers, reports published by other entities, institutional websites and the aforementioned survey conducted in 2012-2013.

The combination of these three reports provides a much clearer map of BCSs in Europe. This now facilitates a more thorough evaluation of the differences in reported information at country level and provides a basis for understanding the diverse interpretation of the accreditation domain in healthcare services compared to the accreditation legal framework.

I highly appreciate the role of the JRC Institute for Health and Consumer Protection (JRC-IHCP) in coordinating the ECIBC which provides essential support to countries and stakeholders for improving healthcare quality, starting with breast cancer care. The report will serve as a primary reference for subsequent stages of the ECIBC and is openly available for other projects in the field.

I warmly invite all stakeholders to provide feed-back on the impact and potential use of this information and any suggestions for future surveys and reports under the ECIBC are very welcome.

Executive summary

The JRC, the European Commission's (EC) in-house science service, was assigned in December 2012 with the tasks of (i) developing a new version of the *European guidelines for breast cancer screening and diagnosis* (in the following mentioned as the *European Guidelines*) and of (ii) developing a voluntary European Quality Assurance scheme for BCS (in the following mentioned as *European QA scheme*) based on the European legal framework on accreditation (defined in Regulation (EC) No 765/2008[2] and its implementation acts, henceforth mentioned as the *European legal framework*). These tasks, among others, are part of the ECIBC.

The *European QA scheme* has the goal of ensuring the implementation of evidence-based practices throughout the entire breast cancer pathway, including screening and diagnosis. Keeping in mind that the EC's objective is to develop a pan-European programme across borders, the *European legal framework*, which is the legal reference allowing a consistent and publicly controlled implementation of the *European QA scheme* in the different Member States (MSs) and associated countries, is used in order to achieve a harmonised approach to quality assurance in breast cancer care.

Therefore, both with the scope of building up the knowledge base for the ECIBC, and in view of designing a flexible quality assurance scheme adaptable to different organisational settings, a search of external quality assessment schemes for breast cancer care already in place in Europe was carried out using different strategies in: MEDLINE, website of relevant scientific societies, and EC Reports. Only schemes fully implemented, with evidence of current activity, with at least one centre in Europe currently holding the certificate awarded by that organisation and foreseeing a third-party audit/on-site survey were considered. A general analysis of schemes not including breast cancer specific requirements, but including general organisational recommendations impacting on breast cancer pathways was performed. For breast cancer specific schemes, on the other hand, information was collected and reported in two ways: (i) descriptive and (ii) comparative by applying three objective references: one on the accreditation-healthcare side (International Society for Quality in Healthcare – ISQua standards assessment and International Accreditation Programme – IAP), one on the ISO side (ISO 15189:2012) and the last one with a hospital management profile (Quality Management System Index – QMSI). For this analysis, however, only schemes where the information was available in English, French and Spanish were considered.

2. *OJ L* 218, 13.8.2008, p. 30.

Globally, the results can be summarised as follows:

- At least one external quality assessment scheme is present, including non-breast-specific ones, in 25 European countries.
- Seventeen schemes specifically addressing breast cancer were identified, but only eight were fully analysable due to fact that the requirements and procedures of the remaining nine were not available in a language known by the JRC-IHCP Healthcare Quality team.
- Globally, 13 countries have at least one breast cancer-specific scheme in place.

The analysis of the eight schemes analysed yielded the following results:

- The total number of BCSs in Europe awarded by such schemes is 664; considering each scheme, the number of BCSs goes from three to 277 with a median of 23.
- In some countries more than one scheme is present, with a maximum of four in CH. Six schemes are managed by private entities and three by public organisations.
- All the schemes cover more than one stage of breast cancer care, and four schemes cover the whole breast cancer pathway. One scheme focuses on screening and diagnosis only, whilst the other ones cover treatment as well. Requirements for diagnosis are included in all the schemes, and requirements for screening are available in all the schemes but one. Most schemes also include requirements for follow-up, palliative care, rehabilitation, research and training.
- Regarding the requirements, their number is highly variable, as well as their format, wording and organisation; all of them require a list of quantitative indicators for monitoring, and in some cases a centralised database for benchmarking is in place.
- Comparing the schemes to ISO 15189:2012, the requirements most covered by the reviewed schemes are those related to organisation and management (*e.g.* definition of organisation and responsibilities of the service), ethics (*e.g.* informed consent, counselling), advisory services (*e.g.* multidisciplinary meeting), preventive actions and continuous improvement (*e.g.* indicators and continuous monitoring), and examination procedures (*e.g.* reference to clinical guidelines). Only in a few cases the schemes provide requirements for document control (*e.g.* procedure for the management of documents, records, *etc.*), external services and supplies (*e.g.* establishing purchasing procedures), accommodation and environmental conditions (*e.g.* procedures for environmental safety), information systems (*e.g.* requirement for hardware and software).
- The comparison with the ISQua reference confirms the strengths and weaknesses observed using the ISO reference, highlighting also the scarce presence in

the schemes of requirements related to the cultural and spiritual sensitivity of users (*e.g.* providing access to spiritual care, and training staff on the cultural beliefs and needs of different groups served) and the widespread paucity of risk management and patient safety requirements.

- The comparison using QMSI highlighted that all the schemes comply with the item 'Medical/clinical audit (various disciplines work together to assess and improve the results of care delivery)', strongly linked to multidisciplinary meetings, and with 'Development of care pathways/process redesign', that is one of the core issues in specialty external quality assessment schemes. As was also reported for the ISQua comparison, patient safety requirements were among the items less present in the schemes examined.

- All the schemes but one define a minimum number of procedures that must be performed by a BCS in order to be eligible for certification; the European Society of Breast Cancer Specialists (Eusoma) threshold of 150 primary cases per year is proposed by two schemes, the other ones requiring other thresholds as 100 cases per year, 125 cases per year, and 50 cases per year for the surgeon. Minimal volumes are usually defined also for other procedures like diagnostics, chemotherapy, and radiotherapy.

- The radiologist and the surgeon appear to be the profiles for which the schemes consistently provide specific recommendations, including minimum workload. Few schemes include requirements for: genetist, physiotherapist, data manager and psychoncologist.

- For all the schemes a temporal sequence of preparation/site visit/follow-up is present. The preparation step includes always the compilation of a questionnaire by the applying centre. The site visit is usually one-day long with a variable number of auditors, from two to seven, and it foresees: interviews with the personnel, revision of medical records and other relevant documents, inspection of facilities, assessment of multidisciplinary meetings. As a conclusion of the audit, a written report is always released; the follow-up is managed in different ways according to the scheme.

- The period between two full site visits is usually three or five years.

Several examples of schemes, general and cancer-specific, sharing characteristics in between the organisational healthcare accreditation, the clinical assessment and the ISO context might suggest a convergence across different models. This would be essential for the *European QA scheme*, where a clinical assessment scheme which focuses on breast cancer will have to also guarantee the respect of relevant organisational issues (*e.g.* patient safety that is also object of a Council Recommendation[3]) and comply with the *European legal framework*.

3. *OJ C* 151, 3.7.2009, p. 1.

Glossary

ACCREDITATION

As the term 'accreditation' can mean different things according to the context, *e.g.* professional bodies, consortia of clinician and managers, and ISO [1] as applied also within the *European legal framework*, thereinafter this word will be spelled in a different way, in order to be consistent with the respective field terminology without creating confusion.

With specific regard to clinical services, accreditation is 'a self-assessment and external peer assessment process used by [clinical services] to accurately assess their level of performance in relation to established standards and to implement ways to continuously improve'. [3]

On the other hand, the definition of the term accreditation-ISO in the ISO context is: 'an attestation by a national accreditation-ISO body that a conformity assessment body meets the requirements set by harmonised standards and, where applicable, any additional requirement including those set out in relevant sectoral schemes [*the European QA scheme* will be developed as sectorial scheme], to carry out a specific conformity assessment activity' (*European legal framework*).

Table 1. *Definition of 'accreditation'.*

Used by	Intended meaning	Since	In this document
Professional bodies	Recognition of specialty training	19th Century	Not used
Consortia of clinicians and managers	Recognition of service delivery	about 1920	Accreditation
International Organisation of Standardisation (ISO)	Recognition of agency competent to certificate healthcare providers	1946	Accreditation-ISO

Adapted by Shaw *et al.*, 2000.

In the healthcare field, 'Accreditation is usually a voluntary programme, sponsored by a non-governmental agency, in which trained external peer reviewers evaluate a healthcare organisation's compliance with pre-established performance standards. Accreditation addresses organisational, rather than individual practitioner, capability or performance. Unlike licensing, accreditation focuses on continuous improvement strategies and achievement of optimal quality standards, rather than adherence to minimal standards intended to assure public safety'. [2]

For this and the following definitions, when contemplated by the *European legal framework*, please refer also to the *Conformity Assessment Report*.

ASSESSMENT

Process by which the characteristics and needs of clients, groups or situations are evaluated or determined so that they can be addressed. The assessment forms the basis of a plan for services or action.[4]

AUDIT

An audit is a systematic evidence gathering process. Audits must be independent and evidence must be evaluated objectively to determine how well audit criteria are being met (*European legal framework*).

Internal audits, sometimes called first-party audits, are conducted by, or on behalf of, the organisation itself for management review and other internal purposes, and may form the basis for an organisation's self-declaration of conformity. In many cases, particularly in smaller organisations, independence can be demonstrated by the freedom from responsibility for the activity being audited (*European legal framework*).

BREAST CANCER CARE

Any kind of healthcare intervention aimed at preventing, diagnosing or treating breast cancer, including the follow-up of any other condition caused by the disease or the treatment itself. It may include primary prevention when the intervention is specifically targeted to breast cancer (*e.g.* dietary recommendations for high-risk women).

BREAST CANCER SERVICES

Comprises all healthcare services covering, in continuum, the full extent of breast cancer management, from screening to follow-up, and in some cases end-of-life care. These services may provide primary care as well as a range of high specialty services including, but not limited to, screening, diagnostic imaging, pathology, surgery, radiation and medical oncology.

BREAST CANCER STAGE (of care)

A cancer stage is a step in the pathway of cancer care which a patient goes through. In ECIBC, the pathway of breast cancer care is divided into five stages:

- Screening
- Diagnosis
- Treatment
- Rehabilitation
- Follow-up

These stages should be distinguished from **clinical** stages of breast cancer defining the extent of disease which are usually expressed in numbers 0 through 4.

CENTREDNESS (patient-centredness or patient responsiveness)

Consideration of individual patients' and society's preferences and values. [5]

CERTIFICATION

It is the process of provision of a certificate by an independent body that the product, service or system in question meets specific requirements (*European legal framework*).

4. http://www.iso.org/iso/casco_building-trust.pdf.

CLINICAL AUDIT

Clinical audit is a quality improvement cycle that involves measurement of the effectiveness of healthcare against agreed and proven standards for high quality, and taking action to bring practice in line with these standards so as to improve the quality of care and health outcomes.[5]

CLINICAL SERVICE

The term clinical service describes a group of health and, when relevant, social care staff and facilities and the processes that link them; both with each other and with other components of the wider healthcare system. [3]

CLINICAL SERVICE ACCREDITATION

The focus of this type of accreditation is a facility, a clinical team or a specific group of patients as opposed to a whole organisation. Although accreditation standards might include those that relate to broader organisational processes, such as training, recruitment and finance management, in clinical service accreditation the focus of these organisational standards will be on the impact that these processes have on the quality of clinical and social care. [3]

CONFORMITY ASSESSMENT

The process demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled (*European legal framework*).

Therefore, conformity assessment can be applied to a product, a process (such as surgery, psychosocial care or survivorship support offered to cancer patients), a system, a body and includes activities such as testing, inspection and certification of management systems, products or services and persons.

EVIDENCE-BASED

Evidence-based medicine is the integration of best research evidence with clinical expertise and patient values. [6]

INSPECTION

According to ISO 17020:2012, inspection is the 'examination of a product, service, process or installation or their design and determination of their conformity with specific requirements or, on the basis of professional judgement, general requirements'. For example some diagnostic equipment needs to be inspected regularly to ensure their efficacy and safety (*European legal framework*).

ORGANISATION

Comprises all sites/ locations under the governance of, and accountable to, the governing body/owner(s). [4]

PATIENT SAFETY

Patient safety refers to freedom from accidental or preventable injuries produced by medical care. Thus, practices or interventions that improve patient safety are those that reduce the occurrence of preventable adverse events.[6]

5. New Principles of Best Practice in Clinical Audit (*HQIP*, January 2011).

6. http://psnet.ahrq.gov/glossary.aspx#P AHRQ PSNet Patient Safety Network.

PEER ASSESSMENT

A process whereby the performance of an organisation, individuals or groups are evaluated by members of similar organisations or the same profession or discipline and status as those delivering the service. [4]

QUALITY ASSESSMENT

Planned and systematic collection and analysis of data about a service, usually focused on service content, delivery specifications, and client outcomes. [4]

QUALITY ASSURANCE

Quality assurance is the part of quality management which is directed at the creation of trust that quality requirements are satisfied.[7]

QUALITY CONTROL

The monitoring of an output to check if it conforms to specifications or requirements, and the action taken to rectify the output. It ensures safety, transfer of accurate information, accuracy of procedures and reproducibility. [4]

QUALITY IMPROVEMENT

Ongoing response to quality assessment data about a service in ways that improve the processes by which services are provided to clients. [4]

REQUIREMENT

A general word used in this document that encompasses the meaning of given standard in the healthcare field (see STANDARD); it is the level of performance required by a certain quality assessment scheme with respect to a certain aspect meaningful for breast cancer care and diagnosis.

SCREENING

It is defined by the World Health Organization (WHO) as the the systematic application of a screening test in a presumably asymptomatic population. In cancer screening, it aims to identify individuals with an abnormality suggestive of a specific cancer. These individuals require further investigation.[8]

Cancer screening programmes can be implemented in the following ways:[9]

Table 2. *Cancer screening programmes implementation.*

Non-programme screening (commonly referred also as opportunistic screening)	Examinations for early detection of breast cancer performed in a diagnostic or clinical setting, independent from the public screening policy (if existing)
Programme screening	Examinations financed by public sources performed in the context of a public screening policy documented in a law, or an official regulation, decision, directive or recommendation, and where the policy defines, at minimum: the screening test, the examination intervals, group of persons eligible to be screened
Organised screening	Programme screening where other procedures (*e.g.* standard operating procedures) are specified and where a team at national or regional level is responsible for implementing the policy, *i.e.* for coordinating the delivery of screening services, quality requirements, reporting on performances and results
Population-based screening	Programme screening where in each round of the screening the persons in the eligible target area served by the programme are individually identified and personally invited

7. Quality management systems – Fundamentals and vocabulary (EN ISO 9000:2005).

8. *Cancer control: Early detection. WHO guide for effective programmes.* WHO, 2007.

9. Von Karsa, L., Anttila, A., Ronco, G., *Cancer Screening in the European Union. Report on the Implementation of the Council Recommendation on Cancer Screening. First Report.* Luxembourg: European Commission, Office for Official Publications of the European Communities, 2008, cited in [7].

STANDARD

As for accreditation and accreditation-ISO, the word standard has different meanings according to the context.

In the healthcare accreditation field, standard is a desired and achievable level of performance against which actual performance is measured.[10]

In the ISO context, a standard (henceforth mentioned as standard-ISO) is a document that provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose.[11]

SURVEY

External peer assessment which measures the performance of the organisation against an agreed set of standards. [4]

10. International Society for Quality in Health Care: Glossary of Terms. 2006.

11. http://www.iso.org/iso/home/standards.htm.

1. Introduction to the European Commission Initiative on Breast Cancer

1.1. Background of the initiative

According to WHO 2012 estimates,[12] each year there are 2.6 million new cases of cancer in Europe (excluding non-melanoma skin cancers). Breast cancer is the most frequent one with 364 000 new cases. This represents 13.8 % of all new cancer cases detected, followed by prostate (360 000), colorectal (342 000), and lung (310 000) cancer. It is estimated that breast cancer causes 91 000 deaths each year in Europe. This represents the third most common cause of death from cancer in the overall population (7.2 % of the total deaths by cancer), after lung cancer (20.9 %) and colorectal cancer (11.9 %). Among women, breast cancer is the first cause of death from cancer, accounting for 16.3 % of all cancer deaths.

There are substantial differences in breast cancer incidence, mortality, prevalence and survival within and among countries in Europe. For example, the estimated age-standardised mortality rate in EU-27 was 22.4 in 2012, ranging from 15 to 29 across the countries, implying that age-standardised mortality in countries ranking the worst doubled those ranking the best. Although the higher mortality rates in some countries may reflect the higher incidence of breast cancer, in others they can be due to the lower survival of women with breast cancer. These differences suggest the presence of health inequalities among countries.

Due to the relevant burden of breast cancer on European women and the severe impact on morbidity, mortality and quality of life, European institutions have been actively issuing recommendations and supporting initiatives for more than 20 years. On 2 December 2003, the Council adopted the ***Recommendation (2003/878/EC) on cancer screening***.[13] Recognising that the overall benefits should outweigh any harm that may result from screening, the Council recommended population-based screening for breast, cervical and colorectal cancers on the basis of the available evidence, subject to implementation of appropriate quality assurance systems. Therefore, in 2006, the EC oversaw the production of the 4th edition of the *European Guidelines* in cooperation with: the International Agency for Research on Cancer (IARC), the European Reference Organisation for Quality Assured Breast Screening and Diagnostic Services (EUREF); the European Breast Cancer Network; and Eusoma. Those guidelines include a physical and technical protocol setting the quality control requirements for mammography equipment and its proper functioning as well as for radiology, radiography, pathology, surgery (when applied for diagnosis) and training. A certification protocol

12. http://eco.iarc.fr/.

13. *OJ L 327*, 16.12.2003, p. 34.

is as well included, establishing minimum requirements for diagnostic and screening units. A set of supplements to those guidelines was published by the EC in 2013.[14] The ***European Parliament resolution of 25 October 2006 on breast cancer in the enlarged European Union*** called for a number of actions related to breast cancer. Among others, the Parliament called on the MSs 'to ensure nationwide provision of interdisciplinary breast centres in accordance with EU guidelines by 2016'. The ***European Parliament Resolution of 10 April 2008*** acknowledged '…the startling and unacceptable differences (between MSs) in the quality of cancer treatment facilities, screening programmes and evidence-based best-practice guidelines…' and called on the EC 'to support the development of European accreditation/certification programmes in cancer screening, diagnosis and treatment based on European quality-assurance guidelines, which could also serve as an example for other areas of healthcare'. Later that year, the ***Council Conclusions of 10 June 2008 on reducing the burden of cancer***[15] invited the EC to 'explore the potential for the development of voluntary European accreditation schemes for cancer screening and appropriate follow-up of lesions detected by screening, such as a European pilot accreditation scheme for breast cancer screening and follow-up based on the *European guidelines for quality assurance in breast cancer screening and diagnosis*'. The Council also invited the EC to facilitate the development, publication, and update of web-based quality assurance and evidence-based guidelines on cancer (breast, cervical and colorectal) in the official languages of the EU.

In 2011, the Directorate-General for Health and Food Safety (DG SANTE) included those tasks in the Health Programme and allocated a budget to JRC,[16] in consideration of its independence and experience in carrying out large scientific projects with a strong cooperative dimension. This planning was formally translated into an Administrative Arrangement in December 2012 that can be considered the official starting point of the ECIBC project.

The following goals were defined:

a. To develop a new version of the *European Guidelines* based on new knowledge and evidence;

b. To develop the *European QA scheme* based on the *European legal framework*.

The new *European Guidelines* will collect the evidence to underpin the *European QA scheme*. With regard to guidelines covering stages other than screening and diagnosis (*i.e.* treatment, rehabilitation, follow-up and surveillance, pain management, psychological support and palliative care – which are essential for a patient-centred concept of quality), a web platform for breast cancer guidelines is envisaged to host existing evidence-based, high-quality

14. http://bookshop.europa.eu/en/european-guidelines-for-quality-assurance-in-breast-cancer-screening-and-diagnosis-pbND0213386/.

15. Council of the European Union: Council Conclusions on Reducing the Burden of Cancer. 2876th Employment, Social Policy, Health and Consumer Affairs Council Meeting. Luxemburg: 10 June 2008.

16. *OJ C* 358, 1.12.2011, p. 28.

guidelines/recommendations. In addition, the project foresees also the development of a Digital Mammography training guide and the deployment of a web-hub hosting all information, deliverables and tools related to ECIBC.

For tasks a. and b., working groups (WGs) are being set up, based on a Call for Expression of Interest for the Guidelines Development Group (GDG) and the Quality Assurance Scheme Development Group (QASDG)[17] organised by DG SANTE, published in October 2014. The selection process is based on specific qualification criteria and adheres to the principles of transparency implemented as a rule in the establishment of scientific and consultative groups in the EC. These principles safeguard against any potential conflict of interest. Owing to the inter-dependence of the work of the two tasks, close coordination and collaboration between the two WGs is essential for the success of the initiative. More details can be found at the JRC webpage for the project.

The JRC has been collecting and sharing background knowledge for ECIBC through different activities: bilateral meetings, workshops, training, and a series of past, on-going and future surveys and studies. The reports already published or forthcoming are listed in *Table 3*.

Table 3. *Overview of EUR Reports related to ECIBC.*

Title	Year	Scope	Link
A voluntary accreditation scheme for breast cancer services & the further development of European breast cancer guidelines - Project workshops report	2013	It includes the narration of the two workshops organised in 2013 in order to inform and involve stakeholders about the ECIBC, the conclusions derived and their impact on the planning of activities for meeting the requirements of the two tasks	http://bookshop.europa.eu/en/a-voluntary-accreditation-scheme-for-breast-cancer-services-the-further-development-of-european-breast-cancer-guidelines-pbLBNA26032/
European Commission initiative on breast cancer – ECIBC. Organisation of project guiding and support meetings: meetings 2011-2013	2014	A summary of the meetings JRC embarked with a wide range of stakeholders, experts and concerned authorities at the national level	http://bookshop.europa.eu/en/european-commission-initiative-on-breast-cancer-ecibc-pbLBNA26591/
Report of a European survey on the organisation of breast cancer care services	2014	To collect information from the countries involved in the ECIBC on the organisation of BCSs and to map out the organisation of breast cancer care and screening across Europe	http://bookshop.europa.eu/en/report-of-a-european-survey-on-the-organisation-of-breast-cancer-care-services-pbLBNA26593/
GRADE workshop – Grading the quality of evidence and strength of recommendations	2014	It presents the workshop on evidence-based guidelines development with GRADE ('Grading of Recommendations Assessment, Development and Evaluation') organised by the JRC	http://bookshop.europa.eu/en/grade-workshop-pbLBNA26958/

17. http://ec.europa.eu/health/major_chronic_diseases/diseases/cancer/call_ecibc_en.htm.

Table 3. *(cont.)*

Title	Year	Scope	Link
European Commission Initiative on Breast Cancer – ECIBC. Organisation of project guiding and support meetings: meetings 2014	2015	A similar report for 2014, including the ECIBC networking map	http://bookshop.europa.eu/en/european-commission-initiative-on-breast-cancer-ecibc-pbLBNA27172/
Report of a survey on accreditation and conformity assessment in the field of breast cancer care in Europe	2015	To understand the wide picture of accreditation-ISO and certification-ISO of breast cancer care pathway across Europe	In publication
Review and analysis of external quality assessment of breast cancer services in Europe – **this Report**	*2015*	To describe current external quality assessment schemes in place in Europe that are affecting the breast cancer pathway	-
Report of a survey on breast units: state-of-art in European countries	*2015*	*Following-up the Resolution of the European Parliament of 2006, it provides the state-of-art of breast units implementation in Europe*	-
State-of-play regarding individual level data collection on breast cancer patients in Europe	*2016*	*To give an overview on the current data collection practices for the breast cancer patients in Europe in order to provide support information on data availability and related processes to the workgroups of the ECIBC*	-

Forthcoming reports are in italics and the titles shall be considered as provisional.

2. International context and principles

2.1. Overview on dimensions and values of 'quality' in healthcare

Despite the huge debate on the topic and the relevance of the issue on the political and scientific agenda, there is no consensus on the definition of quality in the healthcare context. Its multidisciplinary and diverse nature and the lack of a consistent conceptual framework has led to a variety of national and international organisations addressing the issue and to the co-existence of various models and paradigms. Even if a broader examination of the quality concepts goes beyond the scope of the present document, it is worth mentioning the most influential definitions so far:

- 'Quality of care is the kind of care which is expected to maximise an inclusive measure of patient welfare, after one has taken account of the balance of expected gains and losses that attend the process of care in all its parts' [8] – Donabedian, 1980.

- 'Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge' [9] – Institute of Medicine, 1990.

- 'Quality of care is the degree to which the treatment dispensed increases the patient's chances of achieving the desired results and diminishes the chances of undesirable results, having regard to the current state of knowledge'[18] – Council of Europe, 1998.

Other relevant definitions were provided by Maxwell [10], UK Department of Health [11], Joint Commission on the Accreditation of Healthcare Organizations [12], and WHO [13].

If we consider the evolution across time of the different definitions and concepts of quality management [14] and how different terms are used in different healthcare services, we can recognise a shift from concepts more linked to the verification of the fulfilment of expected measures/standards ('quality control' / 'quality assessment') towards terms suggesting a dynamic organisation's process, that moves from its weaknesses towards a higher level of quality and better outcomes ('quality development' / 'quality improvement'). However, 'quality assurance' is the term most consistently used for identifying quality management activities in breast cancer screening programmes (see *Breast cancer-specific schemes* paragraph) and is also officially referenced by

18. Council of Europe. Committee of Ministers (1998). The development and implementation of quality improvement systems (QIS) in healthcare: Recommendation No. R(97)17 adopted by the Committee of Ministers of the Council of Europe on 30 September 1997 and explanatory memorandum. Council of Europe Publ.

the European institutions' recommendations on breast cancer (see *Background of the initiative* paragraph). The importance of technical accuracy of equipment and systems, beside clinical decision-making, patient experience and outcomes, might have had an influence on the prevalence of 'quality assurance' over other terms.

It is acknowledged that both the definition of quality of care [9] and the choice of dimensions to measure it [5] will determine the method of reviewing and assuring quality and the healthcare policies adopted. A document published by WHO in 2008 [5] reports that the set of dimensions most frequently included in the abovementioned definitions are (in descending order): effectiveness, efficiency, access, safety, equity, appropriateness, timeliness, acceptability, patient-centredness, satisfaction, health improvement and continuity of care. The topic of the definition of quality in healthcare has been included in the EU agenda since 2010, as one of the objectives of the Reflection Paper *Quality of Health care: policy actions at EU level* addressed to the Council Working Party on Public Health at Senior Level, was 'to agree on a definition of health care quality and on dimensions of health care quality that should be addressed at MS and EU levels. The proposed common understanding is that quality should take into account the following dimensions: safety, clinical outcomes and patient involvement'.[19]

19. http://register.consilium.europa.eu/doc/srv?l=EN&f=ST%209366%202010%20REV%201.

In addition to those dimensions, an additional classification for quality according to the level of policy development [15] [5] reports:

- Health systems (macro level): it includes legislation and policies on quality of care and patient safety; approval of pharmaceuticals and medical devices; registration and licensing of organisations and professionals; training of professionals; health technology assessment.

- Organisational (meso level): it covers the evaluation of organisations providing care.

- Clinical (micro level): it usually covers guidelines, quality indicators, quality circles, medical specialty peer reviews, and others systems mostly focused on the quality of professional practice.

Even if the macro level can impact on the quality of breast cancer care at different stages, from the approval and commercialisation of new drugs and medical devices to the training of medical doctors and other healthcare professionals, as the current document is focused on the comparison of breast cancer external quality assessment schemes, the following paragraph will describe the organisational and clinical quality assessment systems only (meso and micro levels).

2.2. External assessment in healthcare

There are a variety of methods for organisational quality assessment, which can differ with respect to several characteristics, *e.g.*

voluntary vs. compulsory, collegial (driven by professionals) vs. regulatory (driven by governments) [16]. Another important difference is between assessment systems of organisational aspects and other ones with a focus on clinical aspects or specialty services. In the following paragraphs the models more frequently used in Europe are summarised [1].

2.2.1. *External assessment systems – organisational standards*

2.2.1.1. The ISO for certification and accreditation-ISO

ISO is an independent, non-governmental membership organisation that develops voluntary international standards-ISO, covering almost every industrial / service area, from technology, to food safety, agriculture and healthcare.[20] As an example, ISO 9000 series of standards-ISO for quality management systems are now applied to assess quality systems in specific aspects of health services, and in whole hospitals and clinics. Hospitals, or parts of them, are assessed by independent auditors under NABs governance, according to the *European legal framework*. Certification is widely available and is recognised across national borders [17]. A new healthcare-based standards-ISO *EN 15224 Health care services – Quality management systems – Requirements based on EN ISO 9001:2008* was approved by the Comité Européen de Normalisation (CEN) in 2012.

In addition, other standards-ISO are used to accredit-ISO testing activities (*e.g.* medical laboratories) via specialty-based service standards (*e.g.* ISO 15189:2012). The most important feature is that ISO standards are used within a peer-reviewed system. A network of NABs is coordinated at European level by European co-operation for Accreditation (EA) in order to grant common standards-ISO for mutual recognition at national and international level [18]. Further details on the ISO models are given in the *Conformity Assessment Report*.

2.2.1.2. Healthcare accreditation

Healthcare accreditation recognises competent healthcare providers according to explicit standards which are specific to healthcare, such as hospitals, primary care or clinical services. Whilst for ISO standards there is a separated responsibility between standards development (ISO, CEN) from compliance assessment (EA, NABs), for healthcare accreditation often the entity developing the standard is also running the assessment. Since 1999, ISQua has assessed external healthcare assessment organisations against published standards [19]. Twenty-seven organisations (five Europe-based), and 56 sets of standards (10 Europe-based and among them four specialty-based ones) were accredited in March 2015.[21]

20. http://www.iso.org/iso/home/about.htm.

21. http://www.isqua.org/accreditation/accredited-organisations-standards.

2.2.1.3. European Foundation for Quality Management (EFQM)

The EFQM model is a framework for self-assessment, used by facilities applying for external review in order to achieve the European Quality Award or other national awards. The EFQM follows the Donabedian structure–process–outcome principle [8] and underlines organisational development through self-assessment. The model has had considerable influence, as it has also been adapted in some countries to form the basis of national awards [1]. Although the model is not widely used in the health sector, significant European experiences in this field come from BE, FI ,HU, IT, and LU [5] .

2.2.1.4. Registration and licensing

Registration and licensing include statutory programmes ensuring that professional staff or provider organisations achieve minimum standards of competence (*e.g.* training, registration, certification and revalidation); there are also function-specific inspectorates for public health and safety (*e.g.* fire, radiation and infection) in many countries. Supervision of healthcare institutions is a common element of regulatory systems at municipal, regional or national level. A list of current European organisations can be retrieved on the European Partnership for Supervisory Organisations in Health Services and Social Care (EPSO) website.[22]

22. http://www.epsonet.eu/.

2.2.2. *External assessment systems – clinical standards*

Quality assessment which focuses on professional practice usually relies on the development and implementation of clinical guidelines, measurement of significant indicators, peer review or visitation, although also specialty-based accreditation programmes may have overlapping clinical and organisational assessment. As the *European QA scheme* concept shares several characteristics with the clinical assessment, in this paragraph a list of relevant projects in areas other than breast cancer are given. Some of the features derived by external assessment systems based on clinical standards may also be useful for another EU policy, the European reference networks (ERNs) for rare diseases.[23]

A European country that has developed this kind of approach is UK, in particular with projects undertaken in the context of the Healthcare Quality Improvement Partnership (HQIP),[24] that includes the National and Local clinical audit programmes and the National Clinical Audit and Patient Outcomes Programme (NCAPOP). Principles that underpin this model are:

- Be inclusive of the range of interests in the clinical service that is the focus of accreditation.
- Have a patient-focus.

23. http://ec.europa.eu/health/rare_diseases/european_reference_networks/erf/index_en.htm.
24. http://www.hqip.org.uk.

- Have methodological rigour and draw on the evidence base in the development of standards and in the processes used to assess levels of performance.
- Exhibit excellence and show a commitment to quality improvement.
- Have sound governance.
- Be subject to evaluation and external quality assurance.
- Be aligned with the system that regulates and performance manages healthcare and be recognised as being part of that system. In particular, they should be based on National Institute for Health and Care Excellence (NICE) quality standards and contribute information to support registration by the Care Quality Commission (CQC).
- Demonstrate value for money.

Clinical service accreditation requires the engagement of clinicians in service evaluation, and peer review visit by clinicians that work in similar settings. A list of clinical service accreditation schemes meeting the definition above includes [3]:

- Clinical Pathology Accreditation[25] (CPA) and Imaging Services Accreditation Scheme[26] (ISAS) (see also paragraph *Accreditation-ISO and conformity assessment for breast cancer*).
- Accreditation for Inpatient Mental Health Services.[27]
- Quality Network for Community CAMHS.[28]
- Quality Network for Inpatient CAMHS.[29]
- Improving Quality in Physiological Services.[30]
- Anaesthesia Clinical Services Accreditation scheme.[31]
- Joint Advisory Group on GI Endoscopy.[32]

At European level there is also a well-established programme assessing and accrediting services that undertake haematopoietic stem cell transplantation, founded by the European Group for Blood and Marrow Transplantation (EBMT) and the International Society for Cellular Therapy (ISCT)[33] and managed by the Joint Accreditation Committee-ISCT & EBMT.

Outside Europe it is worth mentioning the existence of accreditation programmes for other specific conditions or services [20]:

25. http://www.cpa-uk.co.uk/.
26. http://www.isas-uk.org/default.shtml.
27. http://www.rcpsych.ac.uk/workinpsychiatry/qualityimprovement/ccqiprojects/psychiatricwards/aims.aspx.
28. http://www.rcpsych.ac.uk/quality/quality,accreditationaudit/communitycamhs.aspx.
29. http://www.rcpsych.ac.uk/quality/quality,accreditationaudit/qnic1.aspx.
30. https://www.iqips.org.uk/.
31. http://www.rcoa.ac.uk/acsa.
32. http://www.thejag.org.uk/.
33. http://www.jacie.org.

Society for Chest Pain accreditation,[34] Intersocietal Commission for Accreditation of Vascular Laboratories,[35] American Academy of Sleep Medicine accreditation,[36] American Association for Accreditation for Ambulatory Surgery Facilities.[37] The Joint Commission (TJC) programme for specific diseases (named Disease-Specific Care Certification in the US and Clinical Care Programme at international level)[38] is also addressing the implementation of clinical guidelines for specific diseases, in addition to the organisation and patient safety requirements.

Finally, a different model is represented by the peer review characterised as a reciprocal visiting driven by professionals. The UK experience with the National Peer Review Programme (see the *Results* paragraphs for the Cancer Peer Review Programme[39] in particular) is especially relevant, as it is a national quality assurance programme that has been in place since 2001 and reviews approximately 2000 National Health Service (NHS) clinical and service teams annually. This model has also been applied to service development, such as in the hospital specialties programme in NL (Dutch *visitatie*) [21].

34. http://www.scpcp.org/index.php/services/accreditation/chest-pain.
35. http://www.intersocietal.org/vascular/.
36. http://www.aasmnet.org/accreditation.aspx.
37. http://www.aaaasf.org/standards.html.
38. http://www.jointcommission.org/certification/diseasespecific_care.aspx.
39. http://www.nationalpeerreview.nhs.uk/.

3. Scope of the report

This report covers part of the research carried out so far by JRC for ECIBC (see *Table 3* at *page 21*) and includes all countries in the European area that belong to the following categories:

- MSs of the EU.
- Candidate countries.
- Potential candidates.
- European Free Trade Area (EFTA) members.

In this report, when the word 'Europe' is mentioned, it includes all and only the above-mentioned countries. With respect to the WHO Euro area, the following countries are not included: Andorra, Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Liechtenstein, Monaco, Republic of Moldova, Russian Federation, San Marino, Tajikistan, Turkmenistan, Ukraine, and Uzbekistan. The full list of countries is reported in the list of abbreviations at the beginning of this report (countries are coded according to the ISO 3166 standard available at: https://www.iso.org/obp/ui/#search).

The main objective of this document is to build up the knowledge needed in order to set up a *European QA scheme* that would make the best possible use of existing experiences with defining, assessing and improving standards for BCSs, while fulfilling the *European legal framework*. For this reason, the study whose results are presented here aims providing ECIBC WGs' members, and in particular the QASDG, a common understanding of existing systems (schemes) for the external assessment and improvement of BCSs, with particular reference to the development of validated standards/guidelines and reliable procedures for external audit/survey.

This report, therefore, will include the identification, description and mapping of scope of those schemes in Europe and their potential to complement a pan-European programme across borders, irrespective of their legal (*e.g.* public vs. private) or territorial (*e.g.* national vs. international) frame or whether or not they are falling under the *European legal framework*. Among them, the following will not constitute the core of the present document:

- Quality schemes which are not specific for breast cancer or which do not foresee a third-party audit (they will just be referenced and briefly described).
- Non-European quality schemes.
- The whole list of details of the ISO standards used for BCSs (they are covered by the JRC *Conformity Assessment Report*).

Therefore, this report focuses on accreditation in healthcare and/or specialty quality schemes for breast cancer; it aims to provide the entire European picture of external quality assessment in breast cancer care.

With regard to the information collected from the schemes, **this report exclusively relies on what is publicly available on their respective websites and publications at the moment of the latest search, March 2015**. As the information has not been checked with the schemes' owners, misinterpretation, omissions and missing updates may have occurred (see *Limitations and future developments of the research* paragraph for more details).

Some variables potentially relevant for understanding a given scheme and for designing the future *European QA scheme*, such as the costs of the different programmes, were not always retrievable and therefore they are not included in this report. In the *Limitations and future developments of the research* paragraph a possible strategy for addressing those gaps is described. Few data has been retrieved by direct contacts with stakeholders, in the context of institutional JRC activities, as reported in the two JRC Reports *European Commission initiative on breast cancer – ECIBC. Organisation of project guiding and support meetings* (2013 and 2014 editions). The list of people having provided data not publicly available is reported in the *Acknowledgments*.

Retrieval and description of quality schemes for other pathologies and clinical services, although potentially relevant for the ECIBC WGs' tasks, are not falling under the scope of this document and were, therefore, not covered. However, a non-exhaustive list of such schemes is reported under the *External assessment systems – clinical standards* paragraph.

4. Methods

4.1. Conceptual structure of the review

Due to the complexity of the issue of quality in healthcare, as described in *Chapter 2*, a compromise between the broad panorama of national and international quality schemes and a thorough analysis of breast cancer external quality assessment had to be made. In fact, although the list of quality schemes that may have an impact on the breast cancer pathway is potentially very large, going from national supervision standards to specific professional recommendations on single items (*e.g.* laboratory testing) to professional peer review (*e.g.* Dutch *visitatie*), those including requirements specifically on breast cancer are very few. Therefore, we followed an operational procedure with different search strategies, selection criteria and level of details according to the specific direct relevance of the scheme for breast cancer.

4.2. Search strategy

- Supervisory organisations and regulatory bodies: EPSO website,[40] accessed in January 2015. The search is limited to Europe.

- ISO standards used under NABs governance: as they fall under the scope of the *Conformity Assessment Report*, they were retrieved from that source. The search is limited to Europe.

- Unregulated, voluntary schemes (generic): previous reviews [1, 14, 17, 20, 22, 26]; ISQuA website of IAP,[41] accessed in March 2015. The search is limited to Europe.

- Unregulated, voluntary schemes (cancer and breast cancer):

- MEDLINE, from 01/01/1980 to 31/12/2014, with the following search string with expanded terms: (((accreditation) OR certification)) AND ((breast neoplasms) OR breast cancer).

- Google, using the same MEDLINE search string, searched on March 2015.

- ISQua website of IAP.

All the previous sources were complemented with information retrieved through the following JRC Reports:

- *Report on a European survey on breast cancer services.*

- *European Commission initiative on breast cancer – ECIBC. Organisation of project guiding and support meetings* (2013 and 2014 editions).

40. http://www.epsonet.eu.

41. http://www.isqua.org/accreditation/accreditation.

4.3. Inclusion criteria

Schemes that, as on 1st March 2015, complied with the following criteria were included in the analysis:

- Fully implemented (*i.e.* exclusion of schemes in piloting or testing phase).
- With evidence of current activity (*i.e.* exclusion of schemes active in the past and now closed or inactive).
- With at least one centre in Europe currently holding the certificate awarded by that organisation.
- Foreseeing a third-party audit/on-site survey in their accreditation or certification process (*i.e.* exclusion of the quality and safety tools if no evidence of on-site visit, such as: patient feedback tools, quality and safety indicators, generic methods for change planning [23]).
- With at least basic information, such as name of the programme, name of the organisation and scope, available in one of languages mastered by the reviewers of the JRC Healthcare Quality Team at B2 level or more (*i.e.* English, Italian, Spanish, French, Greek, Romanian, Turkish).

For those schemes included, the presence of breast cancer specific requirements was assessed. For 'breast cancer-specific' requirement it had to be intended as a statement, recommendation, criterion, or standard referring explicitly to an expectation related to the care to be provided for breast cancer (and not just generically to cancer patients, *e.g.* requirements for chemotherapy would not be considered sufficient).

4.4. Data extraction and analysis

Once the eligible schemes were identified, information relevant to the assessment of the presence of breast cancer requirements was looked for. This search relied mainly on the corresponding entity or programmes' website and included papers, books, manuals, presentations, abstracts, leaflets retrieved on the website. **All the mentioned material was accessed the last time on March 1, 2015**. Any information made available after that moment is not included in the present document. As already declared in the *Scope*, no specific inquiry in the form of a questionnaire or an interview was sent to the quality schemes owners. The little information that was collected in an informal way in the context of the institutional relations with stakeholders is acknowledged at the end of this document.

Information relevant for the description and analysis of external quality assessment schemes was derived from previous reviews [1, 2, 13, 17, 20, 22], from the ISQua Manual for International Principles for Healthcare Standards[42] and the CQC criteria for accreditation and peer review schemes.[43] Unfortunately, not all the relevant data could

42. http://www.isqua.org/docs/default-source/accreditation/international-principles-for-healthcare-standards---b.pdf?sfvrsn=0.
43. CQC-accreditation-information-source-criteria-and-application-form.doc.

be collected through the sole consultation of the publicly available information; therefore, the scope had to be limited to the variables defined in *Annex I*, that also reports the list of information collected according to the scheme's relevance for breast cancer. For the definitions related to the standards-ISO, the reference is the Methods section of the *Conformity Assessment Report*.

Information was recorded on a data extraction sheet developed with a pilot-tested procedure. A random double-check was performed in order to assess the correctness of data included. In addition, for breast cancer schemes we tried to give a broader overview of the contents, with respect to either a) standards/requirements (*i.e.* scope, services, disease stage, healthcare quality principles, key breast cancer process measures) and b) assessment (on-site compliance assessment/audit/survey, awarding system, selection of auditors/surveyors).

4.5. Analysis of breast cancer services requirements

As in the context of breast cancer quality schemes there is not a recognised or consistently used term for the definition of the quality expectations of the service, the generic word 'requirements' has been used for referencing the different standards and criteria assessed by the schemes.

We described the schemes according to:

- The services and disease stage covered by the requirements.[44]
- The healthcare quality topics addressed by the requirements.
- The way requirements are developed and scored (including indicators).
- The inclusion of specific requirements linked to peculiar quality issues in breast cancer.

With regard to healthcare quality topics, different classifications and tools were retrieved [4, 19, 24, 25], although none of them were used for the comparison of different clinical accreditation schemes addressing the same disease, as far as we know. Among the tools retrieved we adopted a standard-ISO from the ISO series, the ISQua principles, and the QMSI. A comparison table of those tools is reported in *Annex II*, which also includes the headings proposed by the SANITAS project.

That table was conceived with the sole purpose of guiding the reader to the concepts that are in common among the different systems and, therefore, they are evaluated in a similar way in this analysis. It does not, however, aim to bridge different systems, as these tools measure different things, and for different purposes. In particular:

- ISO 15189:2012 is the reference standard-ISO for laboratories and diagnostics. As the *European QA scheme* will have to com-

44. For definition of services and disease stage please refer to the *Glossary*.

ply with the *European legal framework* that foresees the application of standards, a comparison with the requirements of ISO 15189:2012 is of interest for the QASDG. The choice of ISO 15189:2012 instead of other standards in the ISO series, like the ISO 9000 family, is due to the fact that (i) this standard-ISO is the one reported by the *Conformity Assessment Report* as the most used for the diagnostic stage of care (which is the key part of the pattern of care determining, in cascade, the following decisions on care to be provided, and therefore tackled by all the eligible breast cancer-specific schemes – see *Results* for details); (ii) it is a technical standard directly applicable by NABs; and (iii) its structure reflects well the need to have requirements for each stage (the examination part) and across stages (the pre and post-examination parts). The paragraphs' names have been changed because the full standard-ISO is available only on purchase. Requirements were 'translated' to allow the comparison with the other two tools and to facilitate the qualitative analysis of schemes (see *Annex II*).

- ISQua standards assessment and IAP define the development and content of requirements for an accreditation programme. The current edition (2007) of the ISQua principles include standards for: quality improvement (designed to encourage healthcare organisations to improve quality and performance within their own organisations and the wider healthcare system), patient focus (designed with a focus on patients/service users and reflect the patient/service user continuum of care or service), organisational planning and performance (assessing the capacity and efficiency of healthcare organisations), safety (including measures to protect and improve the safety of patients/service users, staff and visitors to the organisation). Principles for standards development and measurement have not been used for the comparison of breast cancer schemes' requirements. In order to assess the schemes described in this report, we propose an operational declination of the ISQua standards in order to present a qualitative 'scoring' (*Annex II*). This declination of ISQua standards is not meant to be used for a purpose different from what is described in this Report.

- The QMSI [25] has been validated in the context of the Deepening our Understanding of Quality in Europe (DuQUE) project for assessing the strength of internal quality management systems in hospitals. It consists of nine dimensions: quality policy documents, quality monitoring by the board, training of professionals, formal protocols for infection control, formal protocols for medication and patient handling, analysing performance of care processes, analysing performance of care professionals, analysing feedback patient experiences and evaluating results. The validation of the instrument does not include assessment of external quality assessment schemes, as it has been developed in order to assess quality management systems already in place in hospitals. However, as most of the care

of breast cancer is offered in hospitals and QMSI is measuring significant aspects of quality in healthcare, it has been considered a suitable instrument for this exploratory comparison. Some requirements were considered applicable only to entire healthcare institutions or different medical specialties and were, therefore, not scored (*i.e.* balance score card, some of the infection control requirements).

- The SANITAS project [24] has developed organisational guidelines in line with the European Appraisal of Guidelines, Research and Evaluation in Europe project (AGREE)[45] process. This required discrete steps, including: definition of the subject; review of published evidence; drafting into a logical structure; consultation; field testing and evaluation. At the time this report was written, this project was not yet complete and therefore the tool was not applied. The self-assessment framework for safety in hospitals includes ten key headings: Mission & governance, Safety management systems; Patient orientation; Clinical practice and patient care; Workforce; Hospital facilities management; Medication; Hygiene and infection; Surgery, Interventional procedures & anaesthesia; Human tissue and transfusion; Records and communication.

ISO 15189:2012 (as example of accreditation-ISO criteria) and ISQua and QMSI (as examples of accreditation-healthcare criteria) were used for the comparative analysis. Details on the criteria applied for the evaluation are reported in *Annex II*.

A qualitative analysis of the terms most frequently detected in the scheme's chapter headings has been attempted through a word-cloud. **The outcome is reported in this Report's cover**.

Finally, we selected two breast cancer care requirements that were cited by the *European Parliament resolution of 25 October 2006 on breast cancer in the enlarged European Union*[46] in order to assess whether those recommendations were included in the external quality assessment schemes:

- Volumes of activity for a centre in order to be certified.

- Workload required for the different professional profiles (see *Annex I* for the definition).

Where possible, items derived from the ISQua principles and the CQC were collected in order to describe the processes related to self-assessment, the on-site visit, the follow-up and the awarding phase. As many data were not publicly retrievable and thus may be based too much on a subjective judgment by the reviewers, only basic information (as described in *Annex I*) was collected.

45. http://www.agreetrust.org/about-the-agree-enterprise/introduction-to-agree-ii/.

46. *G. 9.4.7 There has to be a minimum size for a Breast Unit from the point of view of numbers of specialist staff required, arrangement of frequent clinics, provision of equipment and cost-effectiveness. If two hospitals are close together it is more practical for only one of them to establish a functional breast unit serving both hospitals, i.e., the breast team works at both centres.*

5. Results

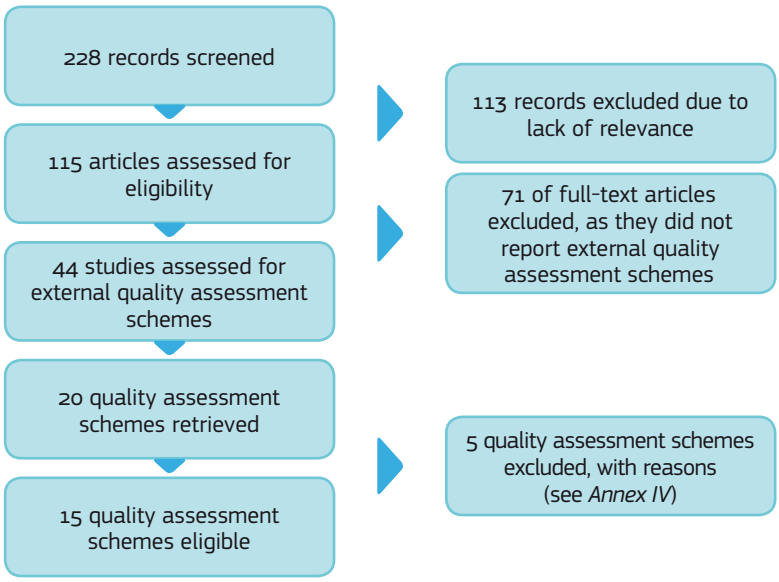
5.1. Results from the search strategy

Thirty-five eligible schemes were retrieved through the search strategies applied:

- Twenty-two 'general' schemes (*i.e.* with no specific requirements for cancer, unregulated and voluntary).
- Eight cancer-specific schemes (including two from 'general' ones, also covering a subset of cancer standards).
- Nine breast cancer-specific schemes (including two from cancer-specific ones, also covering a subset of breast cancer standards).

EPSO website was included in the search but yielded no relevant programmes.

Figure 1. *Flow chart of studies selected.*



The flow chart of studies selection from the MEDLINE search is reported in *Figure 1*. Two more schemes were retrieved from other sources. Most schemes were retrieved either from the literature or internet. The list of papers included is reported in *Annex III*. The list of excluded schemes is reported in *Annex IV*, and also includes schemes retrieved through other sources cited but that did not comply with the eligibility criteria.

5.2. General schemes and entities

5.2.1. *Accreditation-ISO and conformity assessment for breast cancer*

This paragraph includes a summary of the results from the *Conformity Assessment Report.*

A survey targeted at the NABs, which are full members of the EA, was launched by the JRC in 2013. The countries covered include MSs as well as CH, IS, ME, MK, NO, RS and TR. Contact persons for each NAB were identified with the support of EA.

Twenty-five of the 35 contacted countries responded to the survey, corresponding to a response rate of 71%. All the respondents were employed by the corresponding NABs. Nineteen of the 25 responding countries (76%) reported to have at least one healthcare organisation in the breast cancer care pathway which includes accredited-ISO conformity assessment activities or which is holding an

accredited-ISO conformity assessment certificate. Four ISO standards are in place for either accrediting-ISO the laboratories within the mentioned organisations or for accreditation-ISO of Conformity Assessment Bodies to assess these organisations: ISO 15189:2012 (14 countries), ISO/IEC 17020:2012, (two countries), ISO/IEC 17021:2011 (11 countries), and ISO/IEC 17025:2005 (four countries). Only UK reported using national standards besides ISO standards, which are mapped on ISO standards: CPA[47] and ISAS,[48] already mentioned in the paragraph on *External assessment systems – clinical standards*. Among the different stages of breast cancer care, the diagnosis stage was the most widely addressed. Laboratory tests, quality management and personal competence requirements were the items more frequently covered.

Details of all the ISO standards reported by the countries are in the *Conformity Assessment Report* and are summarised in *Table 4* in this report. In this table, the meaning of accreditation and standard is according to the *European legal framework* and therefore the suffix -ISO is omitted. It is worth noting that the ISAS Standard-ISO used for diagnostic imaging in the UK, although mapped on ISO 17020 and ISO 15189, is presented in the form of a 'manual' with requirements classified in domains and expressed as *standard statement*, *rationale* plus a number of *criteria*, in a way that is common to most of the accreditation schemes and some of the specialty-based certifications for breast cancer. In fact, CPA and ISAS are ISO-mapped but mentioned as clinical service accreditation standards by Lelliott *et al.* [3]

Table 4. *ISO standards used by the countries.*

Standard name	Field	Specifications	Short description	Use for breast cancer
ISO 15189:2012	Laboratory medicine in general; Quality management and quality assurance	Medical laboratories -- Requirements for quality and competence	It is used by the accreditation bodies to accredit medical laboratories and provides recognition of the medical laboratory's competence in both its management system and technical practice. It covers the requirements for medical laboratories to ensure the quality and competence of their services, and their consistency in delivering technically valid test results.	In 12 out of 14 countries the standard was reported as addressing the diagnosis phase. For each of the other stages there was at least one implementation of the standard. In the diagnosis phase, the aspiration of fluid and subsequent testing item was covered in 8 out of the 12 countries; biopsy and tissue histology item was covered in 9. Five countries declared that the standard was also used to address some molecular biology tests including HER2/neu tests.
ISO/IEC 17020:2012	Product and company certification. Conformity assessment	Conformity assessment -- Requirements for the operation of various types of bodies performing inspection	It is used to evaluate inspection bodies for the impartiality and consistency of their inspection activities. Inspection bodies provide information to their clients about the conformity of inspected items with regulations, standards, specifications, inspection schemes or contracts.	This standard was reported only by DE and FR. DE addressed the biopsy and tissue histology item of the diagnosis stage. FR reported addressing accreditation of inspection bodies for medical devices and external quality control by the standard.

47. http://www.ukas.com/services/CPA/Clinical_Pathology_Accreditation_CPA.asp.

48. http://www.isas-uk.org/default.shtml.

Table 4. (*Cont.*)

Standard name	Field (according to ICS*)	Specifications	Short description	Use for breast cancer
ISO/IEC 17021:2011	Product and company certification. Conformity assessment	Conformity assessment -- Requirements for bodies providing audit and certification of management systems	This standard is intended for use by accreditation bodies to assess certification bodies which provide audit and certification of management systems (e.g. using ISO 9001). The accredited bodies audit and, if they fulfill the standards, the will be enabled to certify their clients' management systems.	Eleven countries reported having this standard in place. Four of these countries noted they addressed the entire breast cancer pathway with the standard. For each of the screening, treatment and survivorship and follow-up stages there was at least one implementation of the standard. The items mostly covered were quality management (9 countries), mammography (8 countries), ultrasonography, information systems and personal competence requirements (7 countries each).
ISO/IEC 17025:2005	Product and company certification. Conformity assessment	General requirements for the competence of testing and calibration laboratories	This standard is applied to laboratories performing testing/ calibration activities to recognise their competence of testing and calibration. These also can include laboratories where testing and/ or calibration is part of inspection and product certification.	Four countries had this standard in place: ES, FE, GR and SE. It addresses the diagnosis stage in three countries, treatment stage and horizontal aspects in two, screening and survivorship and follow-up stages in only one.
ISO 9001:2008	Quality management and quality assurance	Quality management systems -- Requirements	ISO 9001:2008: specifies requirements for a quality management system where an organisation needs to demonstrate its consistency in providing product that meets the requirements and aims to provide effective application of the system. It is applicable to organisations of all type and size.	No specific information reported by respondents to the survey. It is a standard applied for the general management aspects. It does not directly cover technical / clinical aspects.
ISO/IEC 27001:2013	Character sets and information coding	Information technology -- Security techniques -- Information security management systems -- Requirements	It is an information security management system standard specifying the requirements within the context of the organisation. It also includes requirements for the assessment and treatment of information security risks tailored to the needs of the organisation.	No specific information reported by respondents to the survey.
ISO 13485:2003	Quality management and quality assurance; Medical equipment in general	Medical devices -- Quality management systems -- Requirements for regulatory purposes	It sets the requirements for a quality management system for an organisation providing medical devices and related services. It aims to facilitate harmonised medical device regulatory requirements for quality management systems.	No specific information reported by respondents to the survey.

Table 4. (*Cont.*)

Standard name	Field (according to ICS*)	Specifications	Short description	Use for breast cancer
ISO 14001:2004	Environmental management	Environmental management systems -- Requirements with guidance for use	It provides requirements for an environmental management system where an organisation demonstrates that their policy takes into account legal requirements and information about significant environmental aspects.	No specific information reported by respondents to the survey.
ISO/IEC TR 18001:2004	Character sets and information coding	Information technology -- Radio frequency identification for item management -- Application requirements profiles	It consists of the results of three surveys on the applications for radio frequency identification and provides classification of these applications and recommendations for areas of standardisation based on these surveys.	No specific information reported by respondents to the survey.
Clinical Pathology Accreditation standard (CPA)	-	-	This standard is a national one only reported by UK. It has been in use for accreditation of medical laboratories for over 20 years. The laboratories are now undergoing a transition from CPA standard to United Kingdom Accreditation Service (UKAS) accreditation to ISO 15189.	It applies to all breast cancer care stages that require laboratory testing.
Imaging Services Accreditation Scheme (ISAS)	-	-	This standard is a national one and only reported by UK. It has been mapped on ISO 17020 and ISO 15189, designed to be applied to all current imaging modalities and to interventional radiology services.	It applies to all breast cancer care stages that require image testing.

5.2.2. *Unregulated, voluntary, generic schemes*

Table 5a describes non-breast cancer specific schemes present in Europe, as reported in previously published reviews [1, 17, 22, 26] and complemented with new information provided by *ad hoc* searches, in particular through the ISQua database of accredited standards and organisations (see *Table 5b*); schemes reported in those previous reviews, but not retrievable on the web or through public sources in March 2015 were not included. General schemes for which there is evidence that they also include a cancer-specific set of standards and/or requirements are highlighted in *Table 5a* with an asterisk and are described also in the following paragraph *Unregulated, voluntary, cancer-specific schemes*.

Twenty-five European countries are covered by at least one scheme and schemes can

be classified according to different aspects and layers, according to the classifications already described in previous paragraphs. However, it has already been reported that the original voluntary, organisational self-regulation by peer review that characterises accreditation, in some cases, has developed into an institutional licencing model [22], thus making it difficult to provide clear classifications and place precise boundaries across schemes. First of all, we can classify the schemes into public (n=12) and private (n=10), though a large heterogeneity across different schemes and entities can be detected and some private entities collaborate with their respective national or regional supervising authorities. They all represent an organisational quality assessment, voluntary or compulsory, regulatory (mostly public ones) or collegial. Two entities seem to be active exclusively in the ISO area (Institute for Healthcare Quality Improvement and Hospital Engineering in HU and SanaCERT in CH), two exclusively in the accreditation area (JCI and Accreditation Canada International – ACI), and four entities are active both in the ISO and accreditation field: Social and Health Quality Service (SHQS), DNV-GL, Excellent Healthcare Programme (SEP), CHKS. ACI and CHKS also have cancer-specific requirements and are also reported in the paragraph *Unregulated, voluntary, cancer-specific schemes*. Health Information and Quality Authority (HIQA) used to run a programme on symptomatic breast cancer that is no longer available as is now managed in the context of the National Standards for Safer Better Healthcare.

Table 5a. *Basic characteristcs of unregulated, voluntary, generic schemes.*

Entity	Programme/ standards name(s)	Countries (Europe)	Website	General description
Agency for Quality and Accreditation in FBiH (AKAZ) *Agencija za kvalitet i akreditaciju u zdravstvu u Federaciji Bosne i Hercegovine*	**Accreditation programme for health institutions and family medicines teams**	BA	http://www.akaz.ba/	Legal basis: *Skužbene Gazette of BiH, no. 59/05, Article 6*. It is a voluntary accreditation process that is done at the request of medical institutions of primary and hospital care, and by private practice.
United Accreditation Commission *Spojená akreditační komise*	-	CZ	http://www.sakcr.cz	It accredits hospitals and other healthcare facilities according to a list of healthcare standards. The text of accreditation standards is linked to related legislation.
Quality and Accreditation in Healthcare (IKAS) *Institut for Kvalitet og Akkreditering i Sundhedsvæsenet* Institute for	**The Danish Healthcare Quality Programme (DDKM)**	DK	http://www.ikas.dk	It is a public accreditation system which operates with standards for hospitals, pharmacies, pre-hospital services and municipal healthcare facilities.
Social and Health Quality Service (SHQS)	**SHQS Quality Programme**	FI	http://www.qualification.fi	It provides ISO 9001:2008 certification, SHQS Quality Programme, clinical audit of imaging units, quality certificate in pathology and clinical researcher's individual certification.

Table 5a. *(Cont.)*

Entity	Programme/ standards name(s)	Countries (Europe)	Website	General description
French National Authority for Health (HAS) *Haute Autorité de Santé*	**Standards for Healthcare Organisations – V2010**	FR	http://www.has-sante.fr	HAS is an independent public body with financial autonomy. It acts as a supervising and accrediting/certifying authority in the field of: assessment of drugs, medical devices, and procedures to publication of guidelines for accreditation of healthcare organisations and certification of doctors.
Cooperation for Transparency and Quality in Healthcare (KTQ) *Kooperation für Transparenz und Qualität im Gesundheitswesen*	-	DE	http://www.ktq.de	It provides certification for the following: hospitals, clinics and medical centres, rehabilitation facilities, outpatient and inpatient care facilities, hospices, and alternative forms of housing and emergency services. It allows group and network certifications.
Institute for Healthcare Quality Improvement and Hospital Engineering *Gyógyszerészeti és Egészségügyi Minőség- és Szervezetfejlesztési Intézet*	-	HU	http://www.emki.hu	It is an entity focusing on the certification and conformity assessment of laboratories and medical devices according to the corresponding ISO standards.
Health Information and Quality Authority (HIQA)	**National Standards for Safer Better Healthcare** **National Standards for the Prevention and Control of Healthcare Associated Infections**	IE	http://www.hiqa.ie	It is an independent authority, responsible for driving improvements in the quality and safety of healthcare on behalf of patients. It develops standards, monitor compliance with standards and carry out investigations. Standards for social care and health information are available as well. The programme on symptomatic breast cancer is no longer available (see *Annex IV*) and it is now managed in the context of the National Standards for Safer Better Healthcare.
State Healthcare Accreditation Agency under the Ministry of Health *Valstybiné akreditavimo sveikatos priežurios veiklai tarnyba prie Sveikatos apsaugos ministerijos*	**Healthcare quality improvement in the implementation of health technology assessment and management systems and primary healthcare institutions accreditation**	LT	http://www.vaspvt.gov.lt	National accreditation for healthcare institutions (under improvement by the Ministry of Health).
Netherlands Institute for Accreditation in HealthCare (NIAZ) *Nederlands Instituut voor Accreditatie in de Zorg*	**NIAZ General Quality Standard for Health Care Organisations**	NL	http://www.niaz.nl	It develops quality standards and assesses whether healthcare organisations comply with these, on a voluntary basis. Long-term care and mental healthcare standards are available as well.

Table 5a. *(Cont.)*

Entity	Programme/standards name(s)	Countries (Europe)	Website	General description
DNV GL Business Assurance	**International Accreditation Standard for Hospitals, Version 3.0**	NO	http://www.dnvba.com	It is a certification body. The requirements of the DNV GL - International Healthcare Accreditation are based upon NIAHO® standards that have been approved by the US Government's Centers for Medicare and Medicaid. The International requirements have been adapted to be internationally applicable.
Quality Monitoring Centre – Ministry of Health (CMJ) *Centrum Monitorowania Jakości*	**Accreditation Programme** *Program Akredytacji*	PL	http://www.cmj.org.pl	Accreditation of hospitals is based upon TJC and ACI models and on the healthcare professional agreement. Hospital, primary care and addiction centres programmes are available. It is voluntary and approved by the Ministry of Health.[49]
Healthcare Quality Department – Healthcare Ministry *Departamento da Qualidade na Saúde – Ministério da Saúde*	**National Programme Healthcare Accreditation (ACSA)** *Programa Nacional de Acreditação em Saúde*	PT	http://www.dgs.pt	It is a voluntary accreditation programme managed by the Ministry of Health targeted at: healthcare facilities, professional skills, continuous medical education, and health-related websites.
Agency for Accreditation of Healthcare Institutions of Serbia (AZUS)	**Accreditation Programme**	RS	http://www.azus.gov.rs	It performs professional, regulatory and development activities in the process of accreditation of healthcare institutions.
Foundation for Accreditation of healthcare and Development (FADA-JCI) *Fundación para la Acreditación y el Desarrollo Asistencial*	**JCI Accreditation Programmes provided in partnership**	ES	http://acreditacionfada.org/	It is representative of the JCI in Spain. Through this exclusive agreement, both institutions offer accreditation of health services and health centres jointly in the country.
Aliad Knowledge and Service *Aliad Conocimiento y Servicio*	**Excellent Healthcare Programme (SEP)** *Programa Sanidad Excelente Privada*	ES	http://www.aliad.es	The SEP model is adapted to specific healthcare needs and includes the requirements of international standards ISO 9001 and incorporates other elements, especially concepts and practices of the EFQM model, TJC standards and legal standards and accreditation of Autonomous Communities.
SanaCERT Suisse	**Quality standards for hospitals and clinics** *Manual für die Selbst- und Fremdbewertung, Normative Grundlage für die Zertifizierung von Spitälern und Kliniken* **Quality standards for long-term care** *Qualitätsstandards für die Akutsomatik und die Langzeitpflege*	CH	http://www.sanacert.ch	It is a non-governmental organisation that certifies quality management systems of hospitals and nursing homes in CH. It collaborates with other organisations in the certification for quality labels (e.g. the Swiss Cancer Foundation, the Swiss Society for Palliative Care). It is accredited by the Swiss authorities for the certification of management systems, based on ISO/EN 17021:2011.

49. Information in English: http://www.pasq.eu/Portals/PaSQ/Hospital%20accreditation%20in%20Poland.pdf.

Table 5a. *(Cont.)*

Entity	Programme/standards name(s)	Countries (Europe)	Website	General description
Office of Quality and Accreditation in Health – Ministry of Health *Saglikta Kalite ve Akkreditasyon Daire Baskanligi, Saglik Bakanligi*	**Standards of Accreditation in Health, Ministry of Health, Turkey – Version 5, 2013** *Saglikta Akreditasyon Standartlari, Saglik Bakanligi, Turkiye 5. versiyon*	TR	http://www.kalite.saglik.gov.tr/content/files/duyurular_201½201½014/sas_hastane_ingilizce_son_baski.pdf	It is a voluntary accreditation programme managed by the Ministry of Health targeted mainly at hospitals.
CHKS Accreditation; previously Health Quality Service, King's Fund Organisational Audit*	**Different National and International Accreditation Programmes. Areas covered: Addiction Treatment Centres, Care Homes, Hospices, Hospital Accreditation, Mental Health Providers, Primary Care Teams, Records & Information Management, Oncology services*, Risk and Patient Safety, Leadership and Corporate Management, Maternity and Neonatal care**	CY, IE, IT, PT, UK	http://www.chks.co.uk	It is accredited-ISO by the UKAS to ISO17021:2011 and therefore clients who work with their standards can achieve ISO 9001:2008 certification. Its programme is UKAS approved and is linked to other UK initiatives like CQC Standards. There is also an international accreditation programme.
QHA Trent Accreditation	**Standards for Healthcare Providers Accreditation Plus**	UK	http://www.qha-trent.co.uk	QHA Trent provides a clinical accreditation scheme for hospitals, clinics and other healthcare providers. General, specific and additional standards are available.
Joint Commission International (JCI)	**Hospital Standards, Ambulatory Care Standards, Care Continuum Standards, Clinical Laboratories Standards, Standards for Primary Care Centers, Clinical Care Program Certification, Long Term Care Standards, Home Care Standards**	AT, BE, BG, CZ, DE, DK, ES, GR, HU, IE, IT, NL, PT, RO, TR	http://www.jointcommissioninternational.org	It is a nonprofit organisation and is the largest accreditor of healthcare organisations in the US. JCI is the international arm of TJC and applies a revised version of US standards in order to accredit or certify different kinds of health services, such as hospitals, nursing homes, medical transport, etc. The Clinical Care Program Certification (CCPC) focuses on the treatment of a single disease and relies on the application of evidence-based guidelines.
Accreditation Canada International (ACI)*	**Qmentum International Accreditation Program**	IT, SI	http://www.internationalaccreditation.ca	The Qmentum International accreditation programme is based on the Canadian healthcare quality model. Organisations in all health sectors use the core standards; service-specific standards are applied for clinical services based on their service profile.

Table 5b. *ISQua accredited organisations active in Europe (as of March 2015)*

Country and name		ISQua accreditation		
		Organisation – Valid until	Standards	Training
Canada	Accreditation Canada	2018	Core and Service Excellence Standards	Yes
DK	Danish Institute for Quality and Accreditation	2015	Pre-hospital care, Community Pharmacies	Yes
ES	*Agencia de Calidad Sanitaria de Andalucía*	No	Clinical Management Unit	Yes
ES	Aliad Knowledge and Service	No	SEP Accreditation Model	No
FR	*Haute Autorité de Santé*	2018	No	Yes
NL	Netherlands Institute for Accreditation in Healthcare	2017	General Quality Standard for Health Care Organisations	Yes
NO	Det Norske Veritas (DNV) GL Business Assurance	2018	Hospitals	No
TR	Ministry of Health Turkey	No	Accreditation in Health, Ministry of Health, Oral and Dental Health Centres	Yes
UK	CHKS Accreditation Unit	2017	Addiction Treatment Centres and Psychological Rehabilitation	Yes
UK	QHA Trent Accreditation	No	Healthcare providers	No
USA	Joint Commission International	2015	Hospital, Ambulatory, Care Continuum, Primary Care Centres, Long term care, Home care	Yes

5.2.3. *Unregulated, voluntary, cancer-specific schemes*

Among the schemes retrieved, 15 have specific requirements for cancer and they can be classified in two categories:

- Schemes characterised by requirements for cancer in general, with no site-specific recommendations.
- Schemes characterised by a set of standards common to every type of cancer, and site-specific recommendations (*e.g.* for breast cancer, for lung cancer, for colorectal cancer, *etc.*).

The nine schemes included in the second category will be described in the *Breast cancer-specific schemes* paragraph only. This is the case for National Cancer Peer Review Programme (NCPR) in UK and for the German quality assurance

Programme name	Entity	Target country	NR of centres awarded in Europe	Duration (years)	Type	Website	Notes
Cancer treatment authorisation ***Les autorisations de traitement du cancer***	National Institute for Cancer and Health Ministry *Institut National du Cancer*	FR	Information not available on the website	Information not available on the website	National legislation	http://www.e-cancer.fr/soins/la-structuration-de-loffre-de-soins/traitements-du-cancer-les-etablissements-autorises/les-autorisations-de-traitement-du-cancer [available in English and French]	National hospital standards are considered as a prerequisite
Personnel, technical and organisational criteria defining the status of Comprehensive Cancer Centre and Children's Cancer Centre	Czech Republic Health Ministry	CZ	13	Information not available on the website	National legislation	http://www.linkos.cz/czech-cancer-centre-network/criteria-defining-the-status-of-comprehensive-cancer-centre/	Personnel, technical and organisational criteria define the status of Comprehensive Cancer Centre and Children's Cancer Centre
Accreditation and designation programme	The Organisation of European Cancer Institutes (OECI)	Europe	14 accredited (BE, ES, FI, FR, HU, IT, LT, NL, PT, UK) and 15 in process	5	Private accreditation	http://oeci.selfassessment.nu/cms/	Centres classification: Cancer Unit; Clinical Cancer Centre; Cancer Research Centre; Comprehensive Cancer Centre
American College of Pathology Accreditation	American College of Pathology	World	Not clear how many are awarded with cancer checklist	2	Private professional quality assurance scheme	http://www.cap.org/web/home/lab/accreditation?_adf.ctrl-state=zkyolupnj_4&_afrLoop=90006393045771	Checklists for oncology markers available
Qmentum International Accreditation Program	Accreditation Canada International	World	5 IT, 16 SI (but not clear how many with the Cancer Care Services standards)	3	Private accreditation organisation	http://www.internationalaccreditation.ca/Accreditation/AccreditationProgram/qiap.aspx	Three levels of accreditation: Gold, Platinum, Diamond. Standards Cancer Care Services specific for cancer
Oncology services accreditation	CHKS Accreditation	World	Not clear how many are awarded with the Oncology Services Module	Information not available on the website	Private accreditation organisation	http://www.chks.co.uk/Assurance-and-Accreditation	-

system for cancer. In DE the National Cancer Plan requires that Comprehensive Cancer Centres are certified by German Cancer Aid (DKH) and Oncology and Organ Cancer Centres by the German Cancer Society (DKG). The other six schemes are reported in *Table 6*. This is a heterogeneous group as well, that includes national requirements included in legilsations, public systems, private accreditation systems, certification of particular services (laboratory). They can be considered in between organisational and clinical assessment, with a different profile according to each scheme.

5.3. Breast cancer-specific schemes

5.3.1. General characteristics

Nine breast cancer-specific schemes fulfilling the eligibility criteria were retrieved; it is worth noting that the total number of schemes addressing breast cancer in Europe would be 17 if we also consider those that were not analysable due to language barriers. General characteristics of eligible schemes are reported in *Table 7*. From now on the schemes are identified by the acronym reported in that table. When an official acronym of the scheme was not retrieved, an alternative abbreviation was proposed. In *Annex V*, a specific synthesis form for each of the schemes is provided.

Six schemes are managed by private entities and three by public organisations. The number of centres awarded goes from three (EUREF) to 277 (DKG/DGS), with a median number of 23 and a mode of 15, and the number of countries that host at least one certified centre is 10 (AT, BE, CH, ES, FR, IT, LT, NL, PL, UK). As occurred in the previous scheme categories, the geographical distribution is likely to be biased by the presence of schemes whose requirements are not available in one of the languages known by the reviewers of the JRC Healthcare Quality Team; schemes not eligible due to the unavailability of the requirements in a suitable language came from AT, DE, HU, NL, SE. Considering only the eligible schemes, some countries had more than one scheme present: CH (BCC, DKG/DGS, EUREF, SSS), DE (DKG/DGS, KM), IT (BCC, DKG/DGS), UK (NCPR, NHSBSP). The type of designation awarded to the centre is called 'certification' in five cases (BCC, DKG/DGS, EUREF, KM, SSS), 'accreditation' in two cases (SESPM, SIS/ISS), 'quality assurance' in one case (NHSBSP) and 'peer review' in another case (NCPR). In fact, for NHSBSP and NCPR there is not a 'certificate' or an 'award' that is delivered to the centre at the end of the quality assessment process, as the process is comparable to a peer review. Almost all the schemes have several connections with public institutions, professional societies, patients' organisations and regulatory bodies. Schemes with the higher number of awarded centres are usually the ones working closer to the regulatory entities in their own countries. BCC awards a certification in compliance with the international regulation on certification ISO/IEC 17065.

They are all specialty-based certifications, in two cases (DKG/DGS and NCPR) belonging to a broader national quality assurance programme for cancer.

For KM only first level information was available in a suitable language, thus the scheme only appears in *Table 7*.

Table 7: *Breast cancer-specific schemes: general characteristics.*

Short name	Programme name	Entity	Countries	NR of centres awarded	Relation with regulators and stakeholders involvement	Type
BCC	**Breast Centres Certification**	Breast Centres Certification / European Society of Breast Cancer Specialists	BE, CH, IT, NL	15	It is in compliance with the international regulation on certification ISO/IEC 17065. It is managed in collaboration with ITALCERT Conformity Assessment Body. Eusoma requirements are referred to by the *European Parliament resolution of 2006 on breast cancer in the enlarged European Union* and national legislations (*e.g.* Italy).	Private
DKG/DGS	**Certification system for breast cancer centres from the German Cancer Society and German Society for Breast Diseases** ***Zertifizierungssystem der Deutschen Krebsgesellschaft und der Deutschen Gesellschaft für Senologie für Brustkrebszentren***	German Cancer Society / German Society for Breast Diseases	AT, CH, DE, IT,	277	This certification is part of the three-stage-model of oncological care according to the National Cancer Plan (initiated by the Federal Ministry of Health, the Work Group of German Cancer Registries, the DKG, and the DKH). The Certification institute of the DKG (OnkoZert) is accredited by the DAKKS (NAB) for ISO-certifications. Entities involved in the definition of requirements are: DKH; DKG; Association of the Scientific Medical Societies of Germany; German Society of Obstetrics and Gynaecology, plus other 29 professional associations.	Private
EUREF	**Voluntary certification of high quality diagnostic breast imaging and breast screening services**	European Reference Organisation for Quality Assured Breast Screening and Diagnostic Services	CH	3	It has been developed for the EC by EUREF in co-operation with the European Network of Breast Screening Programmes, competent departments of EC, European agencies and other interested national authorities in MSs. EC, WHO, and Europa Donna were involved in the drafting of the guidelines.	Private
KM	**Mammography screening certification** ***Zertifizierung nach § 22 Krebsfrüherkennungs-Richtlinie***	Mammography Cooperative *Kooperationsgemeinschaft Mammographie GbR*	DE	94	KM is the same entity managing the screening programme. Relations with sickness funds and National Association of Statutory Health Insurance. Other detailed information not available in English.	Public
NCPR	**National Cancer Peer Review Programme**	National Cancer Action Team	UK	152 peer-reviewed in 2012 – 2013	NICE, CQC, and NHS are involved in the project that includes all cancer sites, with a specific section for breast cancer. It is an integral part of the NHS Cancer Reform Strategy (2007) and the overall NHS Cancer Programme, led by the National Cancer Director. The patient safety issues are regulated and inspected in the frame of the CQC activity.	Public
NHSBSP	**Quality Assurance in National Health Service Breast Screening Programme**	National Health Service National Breast Screening Programme	UK	80	All the NHS UK breast cancer screening units active in the programme are subject to the scheme. The activity is internal to the NHS.	Public
SESPM	**National protocol of accreditation of breast cancer units**	Senology and Breast Pathology Spanish Society	ES	24	Information not retrieved on the website.	Private

Table 7. *(Cont.)*

Short name	Programme name	Entity	Countries	NR of centres awarded	Relation with regulators and stakeholders involvement	Type
SIS/ ISS	**International Accreditation Program for Breast Centres/Units**	Senologic International Society / International School of Senology	FR, LT, PL	4	Collaboration foreseen with Union for International Cancer Control (UICC) and US National Accreditation Program for Breast Centers (NAPBC).	Private
SSS	**Breast Centres Certification** ***Label de qualité***	Anticancer Swiss League / Senology Swiss Society	CH	15	There is a special fast procedure for centres already awarded by Eusoma and/or DKG/DGS. Swiss Medical Association (FMH) is cited as the source of qualifications for health professionals. Europa Donna, Ligue Suisse contre le Cancer, and *Vivre comme avant* were also involved.	Private

5.3.2. Scope

The denomination of the BCSs targeted by the certifications or peer reviews is heterogeneous: 'breast centre' (BCC, SIS/ISS, SSS), 'breast cancer centre' (DKG/DGS) 'breast unit' (SESPM, SIS/ISS), 'breast screening unit' (NHSBSP), 'diagnostic breast imaging unit' (EUREF), 'diagnostic breast assessment unit' (EUREF), 'loco-regional breast screening programme' (EUREF), 'European reference centre for breast screening' (EUREF), 'breast service' (NCPR). Contents of the requirements were classified according to the stages of breast cancer care (screening, diagnosis, treatment, follow-up, rehabilitation), plus research (conducted in the centre) and training (provided to other centres). All the schemes covered more than one stage of breast cancer care, and four schemes covered all the mentioned categories (BCC, DKG/DGS, SIS/ISS, SSS). One scheme focused on screening and diagnosis only (EUREF), whilst the other ones also covered treatment. Requirements for diagnosis were included in all schemes, and requirements for screening were available in all the schemes except SESPM. Most schemes also included requirements for follow-up, palliative care, research and training.

Table 8. *Stages of breast cancer care and services covered by the schemes.*

Scheme	Screening	Diagnosis	Treatment	Follow-up	Rehabilitation	Research	Training
BCC	X	X	X	X	X	X	X
DKG/DGS	X	X	X	X	X	X	X
EUREF	X	X	-	-	-	-	-
NCPR	X	X	X	-	X	X	-
NHSBSP	X	X	X	-	-	-	-
SESPM	-	X	X	X	X	X	X
SIS/ISS	X	X	X	X	X	X	X
SSS	X	X	X	X	X	X	X

5.3.3. Standards/requirements

Requirements: structure and development

The terms used by the scheme for referring to their own expectations can vary; the words most frequently used are 'requirement' (BCC, DKG/DGS, SIS/ISS), 'standard' (SIS/ISS), 'criteria' (EUREF, SSS), 'measure' (NCPR).

The reviewed schemes are not homogeneous regarding the structure of requirements: if the classification in chapters or topics and subsections is frequently used, the formulation of the requirement itself may vary, going from a narrative description (SSS) to a single sentence (BCC), to more complex descriptions, also encompassing explanations, measurable criteria, checklists, *etc*. In healthcare accreditation, most programmes use a hierarchy of headings (chapters for general content, then each chapter has a number of 'principles' giving the rationale; each principle has a number of standards; each standard has a number of criteria); among breast cancer schemes only NCPR follows this kind of organisation. Most schemes also propose numerical indicators for monitoring performance. NHSBSP scheme is composed of a certain number of 'manuals' for each professional profile; DKG/DGS proposes a coupled approach where the certification of 'clinical' parts is given according to national evidence-based guidelines (S3 Guidelines) and the certification of the quality management system according to ISO 9000 or other recognised systems for quality management in healthcare.

The raw number of requirements goes from ten (SESPM) to more than 200 (DKG/DGS, NHSBSP). Requirements are usually developed by consensus and according to experts' opinion on the basis of external sources, although some schemes mention guidelines as a source (DKG/DGS: S3 Guidelines; NHSBSP and EUREF: the *European Guidelines*; SSS: Europen Society for Medical Oncology and St. Gallen) and others refer to specific development procedures for the recommendations (DKG/DGS: RAND/UCLA methodology; NCPR: NICE). Eusoma requirements are totally or partially adopted by three schemes (BCC, SESPM, SSS).

All the schemes for which this information was retrieved developed the requirements in collaboration with other stakeholders, including patients' associations (BCC, DKG/DGS, EUREF, NHSBSP, SSS) (see *Table 9*). For most schemes the requirements' set has been updated in the last three years.

Scoring information was not retrieved for all the schemes and, therefore, is not reported in the table. It is worth mentioning that only BCC uses 'Nonconformity' (the inability to comply with a mandatory requirement) and 'Recommendation' (the non satisfaction of a non mandatory requirement), as in the ISO models, as it is run under ISO 17065:2012.

Requirements' topics

Due to the fact that the average number of requirements present in each scheme is high and that the form in which they are

Table 9. *General description of breast cancer-specific schemes requirements.*

Programme name	Number and organisation	Development	External reference	Year of last update
BCC	147 requirements (57 mandatory, 90 recommended) organised in topics and expressed as a sentence. After the transitory period January-December 2014 another 36 requirements switches to mandatory.	Developed by international Eusoma experts during different consensus conferences and workshops, using available literature references.	Eusoma "The requirements of a specialists breast centre" (27)	2013
DKG/DGS	187 Requirements for Breast Centres + 225 Evidence-based Statements from interdisciplinary S3 guidelines + quality system management indicators (*e.g.* ISO 9000).	FAB questionnaire items are based on existing guidelines and legal requirements. S3 guidelines are developed following an evidence-based pathway.	The evidence based guidelines are part of the scheme. Full access to the methodology used for the guidelines definition is accessible on the web. RAND/UCLA methodology was used for developing indicators.	2012 (guidelines) and 2014 (questionnaire)
EUREF	67 requirements organised by topic and centre category.	Derived from the *European Guidelines* 4th edition and its supplements.	The *European Guidelines*.	2013
NCPR	25 requirements, for each an objective, measure, notes and evidence is provided, classified according to key themes.	Based on requirements that are: objective; measurable; specific, clear and unambiguous; verifiable; stating who exactly is responsible for what; discriminating; achievable; developmental. Based on the NICE Improving Outcome Guidance.	NICE Improving Outcome Guidance.	2013
NHSBSP	Hundreds of requirements with different structure classified for professional profile.	Defined by national coordinating committees with representatives of regional quality assurance groups and relevant professional organisations.	The *European Guidelines*.	Depending on the requirements' set (most recent 2013)
SESPM	List of 10 general quality criteria and supporting explanations, indicators, questionnaires.	Consensus process into the SESPM. In some cases Eusoma criteria are included.	Eusoma criteria.	2010
SIS/ISS	Requirements are not expressed in a unique way. Seven chapters.	Information not retrieved on the website.	AJCC/UICC TNM protocol for examination of specimens. American Society of Clinical Oncology and the College of American Pathologists recommendations for receptors.	Information not retrieved on the website
SSS	98 requirements classified in chapters and expressed in a narrative way. Subset of 59 requirements expressed as single statements and classified in nine areas.	Developed by consensus by a multidisciplinary working group on the basis of Eusoma requirements. References (published papers) are reported for some requirements.	There is reference to the following entities and requirements: Eusoma, *Société Suisse de Radiologie, European Parliament resolution of 2006 on breast cancer in the enlarged European Union*, ESMO, St. Gallen recommendations.	2014

expressed varies, it has been difficult to find a way to reflect the main differences across schemes.

The first 'art-wise' attempt was the image that appears in this Report's fore page: it has been generated using a word map with the list of chapter headings from all the schemes as a source. Secondly, as already expressed in the *Methods* section, three external references has been adopted in this report. Thirdly, a special focus was given to topics that will be key for the definition of the *European QA scheme*. **None of the following tables is meant to be a judgment or a score on the validity and completeness of the schemes themselves. The aim is to provide the readers, and in particular to the future members of the QASDG, with a framework for comparing existing schemes and for extracting the most useful information for building the future *European QA scheme*.**

In this way, the requirements covering one or more of the topics included in the standards adopted in the *European legal framework* and/or in the requirements for quality management in hospitals, are easily identified and summarised in tables for further analysis. *Tables 10* to *12* show results obtained using as reference ISO 15189, ISQua and QMSI, respectively. YES corresponds to a full presence of requirements, PARTIAL to a partial presence of requirements and NO to an absence of requirements targeting that specific issue. An asterisk means that the family of requirements is covered not by the scheme itself, but by another external quality assessment system that is a pre-requisite or a companion of that scheme. In fact, for NCPR, the CQC standards,[50] that are a pre-requisite, are considered as well in the assessment of that scheme; likewise, ISO 9000 is considered when scoring DKG/DGS. For EUREF the *European Guidelines* are considered as part of the scheme. Anyway, it must be noted that most schemes are currently in place in BCSs where one or more of the general schemes described in the previous paragraphs are also implemented, and some of the requirements may be satisfied by the adherence to a general quality management scheme, although not specifically by the examined breast cancer scheme.

As regards ISO 15189, the requirements most covered by the reviewed schemes are those related to organisation and management (*e.g.* definition of organisation and responsibilities of the service), ethics (*e.g.* informed consent, counselling), advisory services (*e.g.* multidisciplinary meetings), preventive actions and continuous improvement (*e.g.* indicators and continuous monitoring), and examination procedures (*e.g.* reference to clinical guidelines). Only in few cases the schemes provided requirements for document control (*e.g.* procedure for the management of documents, records, *etc.*), external services and supplies (*e.g.* establishing purchasing procedures), accommodation and environmental conditions (*e.g.* procedures for environmental safety), information systems (*e.g.* requirement for hardware and software).

50. http://www.cqc.org.uk/content/essential-standards.

The comparison with the ISQua reference confirms the strengths and weaknesses observed when using the ISO reference, highlighting also the scarce presence in the schemes of requirements related to the cultural and spiritual sensitivity of users (*e.g.* providing access to spiritual care, and training staff on the cultural beliefs and needs of different groups served) and the widespread paucity of risk management and safety requirements. CQC standards linked to NCPR are the only ones addressing this topic.

The comparison using QMSI highlighted that all the schemes complied with the item 'Medical/clinical audit (various disciplines work together to assess and improve the results of care delivery)', strongly linked to multidisciplinary meetings, and with 'Development of care pathways/process redesign', that is one of the core issues in specialty external quality assessment schemes. Like for the ISQua comparison, patient safety requirements (*e.g.* adverse events reporting) were among the items less present in the schemes examined.

Table 10. *Analysis of breast cancer-specific schemes' requirements according to 15189:2012.*

	BCC	DKG/DGS	EUREF	ISS/SIS	NCPR	NHSBSP	SESPM	SSS
Organisation and management 4.1, 4.1.1, 4.1.2	YES	YES	YES	YES	YES	YES	PARTIAL	YES
Ethics 4.1 "bis" Annex C	PARTIAL	PARTIAL	PARTIAL	PARTIAL	PARTIAL*	YES	PARTIAL	PARTIAL
Quality system 4.2, 4.2.1, 4.2.2	PARTIAL	PARTIAL	PARTIAL	PARTIAL	PARTIAL*	YES	PARTIAL	PARTIAL
Document management 4.3	NO	YES	NO	NO	YES*	PARTIAL	NO	NO
Purchasing of external services 4.4, 4.4.1, 4.4.2	PARTIAL	YES*	NO	NO	NO	NO	NO	PARTIAL
Examination by referral consultants 4.5, 4.5.1, 4.5.2	PARTIAL	YES*	NO	NO	PARTIAL*	NO	NO	PARTIAL
External services and supplies 4.6	NO	YES	NO	NO	NO	PARTIAL	NO	NO
Advisory services 4.7	YES	PARTIAL	YES	YES	YES	YES	PARTIAL	YES
Management of complaints 4.8	NO	PARTIAL	PARTIAL	NO	YES*	PARTIAL	NO	YES
Identification and management of nonconformities 4.9	NO	YES	PARTIAL	NO	YES*	YES	NO	NO

Table 10. *(Cont.)*

	BCC	DKG/DGS	EUREF	ISS/SIS	NCPR	NHSBSP	SESPM	SSS
Corrective actions 4.10	NO	YES	YES	NO	YES*	YES	NO	NO
Preventive actions 4.11	YES	YES	YES	PARTIAL	PARTIAL*	YES	PARTIAL	YES
Continuous improvement 4.12	PARTIAL	YES	YES	PARTIAL	PARTIAL*	YES	PARTIAL	PARTIAL
Control of quality and technical records 4.13	NO	YES*	PARTIAL	NO	PARTIAL*	PARTIAL	NO	NO
Evaluation and internal audits 4.14, 4.14.1, 4.14.2, 4.14.3, 4.14.4, 4.14.5, 4.14.6, 4.14.7, 4.14.8	NO	YES*	PARTIAL	NO	NO	YES	NO	NO
Quality management system review 4.15, 4.15.1, 4.15.2, 4.15.3, 4.15.4, 4.15.5	PARTIAL	YES*	PARTIAL	PARTIAL	PARTIAL*	YES	NO	PARTIAL
Personnel 5.1, 5.1.1, 5.1.2, 5.1.3, 5.1.4, 5.1.5, 5.1.6, 5.1.7, 5.1.8, 5.1.9	PARTIAL	YES	PARTIAL	PARTIAL	YES*	YES	NO	PARTIAL
Facilities and environmental conditions 5.2, 5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.2.5, 5.2.6	NO	NO	NO	NO	YES*	PARTIAL	NO	NO
Equipment 5.3	PARTIAL	YES*	NO	PARTIAL	YES*	YES	NO	PARTIAL
Pre-examination 5.4, 5.4.1, 5.4.2, 5.4.3, 5.4.4, 5.4.5, 5.4.6, 5.4.7	NO	PARTIAL	PARTIAL	NO	NO	YES	NO	PARTIAL
Examination 5.5, 5.5.1, 5.5.2, 5.5.3	YES	YES	YES	PARTIAL	YES*	YES	YES	YES
Quality control of examination processes 5.6, 5.6.1, 5.6.2, 5.6.3	PARTIAL	YES	PARTIAL	PARTIAL	PARTIAL	YES	NO	NO
Post-examination 5.7, 5.1.7, 5.7.2	YES	PARTIAL	YES	YES	YES*	YES	NO	PARTIAL
Test results 5.8, 5.8.1, 5.8.2, 5.8.3, 5.9, 5.9.1, 5.9.2	PARTIAL	PARTIAL	PARTIAL	PARTIAL	PARTIAL*	PARTIAL	PARTIAL	PARTIAL
Information system 5.10, 5.10.1, 5.10.2, 5.10.3	NO	NO	NO	NO	NO	YES	NO	NO

* Requirements covered by a companion scheme.

Table 11. *Analysis of breast cancer-specific schemes' requirements according to ISQua.*

	BCC	DKG/DGS	EUREF	NCPR	NHSBSP	SESPM	SIS/ISS	SSS
Quality Improvement								
1.1 Defined mission, values, ethics, strategic objectives	PARTIAL	PARTIAL	YES	YES	YES	PARTIAL	PARTIAL	PARTIAL
1.2 Defined responsibilities for quality improvement	PARTIAL	YES*	YES	YES	YES	PARTIAL	PARTIAL	PARTIAL
1.3 Defined responsibilities for governance, management	YES	YES	PARTIAL	YES*	PARTIAL	NO	NO	PARTIAL
1.4 Information to public on services, quality	NO	YES	YES	YES*	YES	NO	NO	NO
1.5 Key policies, procedures plans	YES	YES*	NO	YES*	PARTIAL	PARTIAL	PARTIAL	YES
1.6 Quality improvement system	PARTIAL	YES*	YES	YES*	YES	PARTIAL	PARTIAL	PARTIAL
1.7 Key indicators/measures	YES	YES	YES	YES*	YES	PARTIAL	PARTIAL	YES
1.8 Data evaluation, analysis, use for improvement	NO	PARTIAL	YES	YES	YES	NO	NO	PARTIAL
1.9 Integration of law, health policy	PARTIAL	PARTIAL	PARTIAL	YES*	PARTIAL	NO	NO	PARTIAL
Patient/Service User Focus								
2.1 Patient/Service user rights	YES	PARTIAL	YES	YES*	YES	NO	NO	YES
2.2 Complaint system	NO	YES	NO	YES	PARTIAL	NO	NO	YES
2.3 Patient/Service user involvement in own care/services	PARTIAL	YES	YES	YES	YES	NO	NO	PARTIAL
2.4 Cultural and spiritual sensitivity	NO	PARTIAL	NO	YES	PARTIAL	NO	NO	NO
2.5 Access to services	PARTIAL	PARTIAL	PARTIAL	YES*	PARTIAL	PARTIAL	PARTIAL	PARTIAL
2.6 Patient/Service user assessment	PARTIAL	PARTIAL	YES	YES	YES	NO	NO	PARTIAL
2.7 Patient/Service user care/service planning	YES	YES	PARTIAL	YES*	PARTIAL	PARTIAL	PARTIAL	YES
2.8 Monitoring progress, revising care/service plans	PARTIAL	YES	PARTIAL	YES*	PARTIAL	PARTIAL	PARTIAL	PARTIAL
2.9 End of service planning	NO	PARTIAL	Not applicable	YES	Not applicable	NO	NO	PARTIAL

Table 11. *(Cont.)*

	BCC	DKG/DGS	EUREF	NCPR	NHSBSP	SESPM	SIS/ISS	SSS
Organisational Planning and Performance								
3.1 Staff planning	YES	YES	YES	YES*	YES	PARTIAL	PARTIAL	YES
3.2 Orientation, skills and experience	PARTIAL	YES	YES	YES*	YES	PARTIAL	PARTIAL	YES
3.3 Credentialling, defined scope of practice	PARTIAL	PARTIAL	PARTIAL	YES*	PARTIAL	PARTIAL	PARTIAL	YES
3.4 Performance/competency evaluation, ongoing training	YES	YES	YES	YES*	YES	PARTIAL	PARTIAL	YES
3.5 Following standards, evidence based guidelines	PARTIAL**	YES	PARTIAL**	YES	PARTIAL**	PARTIAL**	PARTIAL**	PARTIAL**
3.6 Involvement of patients/service users and staff in planning	PARTIAL	YES	PARTIAL	YES*	PARTIAL	NO	NO	PARTIAL
3.7 Measurement of identified desired results	PARTIAL	PARTIAL	YES	YES	YES	PARTIAL	PARTIAL	PARTIAL
3.8 Service planning based on strategic direction	NO	PARTIAL	YES	YES*	YES	NO	NO	NO
3.9 Coordinated planning of activities and development	PARTIAL	YES	YES	YES*	YES	PARTIAL	PARTIAL	YES
3.10 Efficient use of resources evaluated, plans and budgets	NO	NO	YES	YES*	YES	NO	NO	NO
Safety								
4.1 Planned risk management	NO	NO	NO	YES*	NO	NO	NO	NO
4.2 Risk management plan monitoring	NO	NO	NO	YES*	NO	NO	NO	NO
4.3 Incident/Adverse event reporting/investigation system	NO	NO	PARTIAL	YES*	PARTIAL	NO	NO	NO
4.4 Staff health and safety protection	NO	NO	PARTIAL	YES*	PARTIAL	NO	NO	NO
4.5 Staff training on equipment	NO	NO	YES	YES*	YES	NO	NO	NO
4.6 Safety law, building and equipment safety	NO	NO	YES	YES*	YES	NO	NO	NO
4.7 Clinical risk assessment	NO	NO	NO	YES*	NO	NO	NO	NO
4.8 Infection control programme	NO	NO	Not applicable	YES*	Not applicable	NO	NO	NO

Table 11. *(Cont.)*

	BCC	DKG/DGS	EUREF	NCPR	NHSBSP	SESPM	SIS/ISS	SSS
Safety								
4.9 Patient safety issues/priority safety areas	NO	NO	NO	YES*	NO	NO	NO	NO
4.10 Patient/Service user records	NO	NO	PARTIAL	YES*	PARTIAL	NO	NO	PARTIAL

Requirements that have been scored only partially due to not applicability in the diagnostic context are reported in italics.
* Requirements covered by a companion scheme.
** A full evidence-based process for identifying the scheme requirements could not be retrieved by the reviewing team.

Table 12. *Analysis of breast cancer-specific schemes' requirements according to QMSI.*

	BCC	DKG/DGS	EUREF	NCPR	NHSBSP	SESPM	SIS/ISS	SSS
Quality policy documents	YES	YES	NO	NO	YES	NO	NO	YES
Quality monitoring by the board	YES	YES	YES	YES	YES	YES	YES	YES
Training for professionals	YES	YES	YES	YES	YES	YES	YES	YES
Formal protocols for infection control	NO	YES	Not applicable	YES	YES	NO	NO	NO
Formal protocols for medications and patients handling	NO	NO	Not applicable	YES	Not applicable	NO	NO	NO
Analysing performance of care processed	YES	YES	YES	YES	YES	YES	YES	YES
Analysing performance of professionals	YES	YES	YES	NO	YES	YES	YES	NO
Analysing feedback of patients experiences	NO	YES	NO	YES	YES	NO	NO	YES
Evaluating results	YES	YES	YES	YES	YES	YES	YES	YES

Indicators

All the schemes included propose a list of quantitative indicators for monitoring, between 14 (BCC) to over 100 (NHSBSP). A detailed description of the indicators collected is foreseen in a future JRC report on breast cancer data collection in Europe (see *Table 3*). Almost all the reviewed schemes require the presence of a database, although with different degrees of inter-operability across the BCSs working under a certain scheme and / or with the other data collections in place. Some schemes also collect individual or aggregated data from the centres that are used for benchmarking and monitoring (BCC, DKG/DGS, NCPR, NHSBSP, SSS). However, only one scheme, DKG/DGS, was found to have a public website with the results of the indicator monitoring (anonymised).

Table 13. *Indicators required by the breast cancer-specific schemes.*

Name	Name of database	Requirements	Review process	Indicators (N)
BCC	The database has to be validated by Eusoma on the basis of successful data transfer showing correct data completeness and calculation of indicators http://www.eusoma.org/Engx/BreastUnits/Default.aspx?cont=qt	Must have a database for the purpose of monitoring quality indicators. Data manager identified. Participation to external benchmark activities. Use of data for annual review meeting.	Not retrieved on the website	14
DKG/DGS	Not available in English	A system of tumour documentation that contains patient data for a period of at least 3 months must be in place at the time of initial certification. The dataset used must correspond with the basic dataset used by the *Arbeitsgemeinschaft Deutscher Tumorzentren* (Working Group of German Tumour Centres or ADT).	Data must be assessed and analysed every year. Matrix of the quality results to be regularly submitted. OnkoZert performs a formal check and an on-site assessment by the auditor.	28 Anonimysed national key figures are annually presented http://www.onkozert.de/brustkrebszentren.htm
EUREF	-	Keep a record of mammogram results and monitor number of recalls (category 1). Monitor data and feedback of results (category 2). Keep a formal record of mammogram results, assessment and outcomes (category 2). Ensure satisfactory epidemiological support (category 3-4). Collect and monitor data according to the *European Guidelines* (category 3-4). Evaluate and report on the performance of the programme annually (category 3-4).	Not retrieved on the website	Not applicable
NCPR	Cancer Quality Improvement Network System (CQuINS)	CQuINS is a secure web-based database that supports each stage of the cancer peer-review process.	Not retrieved on the website	40
NHSBSP	QARC KC62	Requirements on computer system, data protection are given. Requirements on data audits and checks are given.	Not retrieved on the website	>100
SESPM	-	It is required to have a clinical database and a collection of indicators.	Not retrieved on the website	22
SIS/ISS	-	A database for conducting an audit should be available, with records dating back to the previous year (first accreditation) or to three years (further accreditations).	Indicators are expected to be introduced in the database 3-5 years after the granting of the accreditation.	23

Table 13. *(Cont.)*

Name	Name of database	Requirements	Review process	Indicators (N)
SSS	Quality-Dashboard http://www.liguecancer.ch/fr/acces_reserve_aux_specialistes/label_de_qualite_centres_de_senologie/label_de_qualite_centres/ http://assets.krebsliga.ch/downloads/quality_dashboard_2014_f.xlsx	Database compatible with the data requirements of Eusoma and SSS. Transfer of data to CH cancer registries.	Data transfer at least once per year to the SSS database for benchmarking. Continuous update of data on diagnosis, treatment, pathology and clinical evolution.	20

Specific professional requirements – Volume of cases

Almost all schemes define a minimum number of procedures that must be performed by the BCS in order to be eligible for the certification, with the exception of SESPM (that explicitly declares that a minimum number of cases is not foreseen in the scheme). For NHSBSP the information was not found, however, it is known that dimensions and localisations of screening centres in UK is decided at National Health Authority level. The Eusoma threshold of 150 primary cases per year is proposed by BCC and by DKG/DGS (but only after three years and

Table 14. *Volume of cases treated annually by the BCS as required by the schemes.*

BCC	Eusoma: 150 primary cases each year, on a population base of about 250 000
DKG/DGS	100 primary cases each year. After 3 years the main location should treat ≥ 150 primary cases. >50 cases if collaborating centre with pre-existing collaboration and cooperative centre with 2 locations >150 cases. At least 50 chemotherapy treatments per year for breast cancer patients or at least 200 chemotherapy treatments per year (for various types of tumours). Case number of the pathological institute given. At least 1 000 histological examinations, incl. cytological examinations
EUREF cat 1	1 000 mammograms/year
EUREF cat 2	2 000 mammograms/year
EUREF cat 3	5 000 mammograms/year – 20 000 women eligible in the target population
EUREF cat 4	10 000 mammograms/year – 20 000 women eligible in the target population
NCPR	The multidisciplinary team should discuss at least 100 new breast cancer patients per year at the meetings. The departments of the network should be delivering a combined total of at least 40 000 (health needs adjusted using the Malthus tool) fractions of external beam radiation therapy per million of the network's radiotherapy catchment population, per year
NHSBSP	Information not retrieved on the website
SESPM	No requirement
SIS/ISS	Numeric requirements only for diagnostic breast imaging centre: 2 000 mammograms/year The surgeon must treat at least 50 primary cases per year
SSS	125 primary cases each year

for the main location, for the other BCSs the threshold being set to 100 or 50 depending on other conditions); SSS requires 125 cases, NCPR requires 100 new cases discussed at multidisciplinary meeting, SIS/ISS requires at least 50 cases/year for the surgeon (that may be translated in a volume for the BCS itself). A minimum volume for mammograms is also defined: 2000/year for SIS/ISS, from 1000 to 10000 for EUREF according to the category of the centre. Volumes may be defined also for other procedures like chemotherapy (DKG/DGS), pathology examinations (DKG/DGS), radiotherapy (NCPR).

Specific professional requirements – Workload

The presence of numerical thresholds for the number of procedures is retrievable also for the professional profiles that are usually present in a BCS. As the regulation of healthcare professions is different according to the individual countriy it has not always been possible to have a total correspondence between professional profiles, like in the case of the gynaecologist (can work as a surgeon or as a medical oncologist according to the country). In *Table 15a* and *15b*, the workload for each professional profile is summarised; it should be noted that the same profile can include different backgrounds and goals according to the scheme. For radiographers requirements for both imaging and radiotherapy were included.

Each scheme has at least one workload requirement for the professional profiles (in some cases also according to the number of inhabitants in the area or the number of patients treated) and some of them also include recommendations about inclusion in the core multidisciplinary team (not reported in *Table 15ab*) and/or the hours of training required in order to keep the position. The radiologist and the surgeon appear to be the profiles for which the schemes consistently give specific recommendations, with the number of mammograms read per year going from 500 (EUREF category 1) to 5000 (BCC for screening, DKG/DGS, EUREF category 4, SESPM for screening,) and the number of surgical operations going from 30 (NHSBSP, SSS) to 50 (BCC, DKG/DGS, SIS/ISS), respectively.

Few schemes have requirements for: geneticist, physiotherapist, data manager (that is sometimes referred to as administrative staff responsible for data) and psychiatrist or psychologist.

Table 15a. *Workload requirements for professionals (diagnostic area and data manager).*

	Radiologist	Radiographer	Pathologist	Geneticist	Data manager
BCC	≥2 dedicated radiologists 1 000 mammograms per year (5 000 if screening). At least 30% of working time in breast imaging	≥2 dedicated radiographers 1 000 mammograms per year	≥2 pathologists (1 lead) ≥50 primary resections At least 50% of working time in breast disease for the lead pathologist, for the other 25%	≥1 dedicated geneticist	No workload requirements
DKG/DGS	>5 000 mammograms per year if screening. Periodic assessment of mammograms of 1000 patients >25 preoperative markings	≥2 radiographers per accelerator	≥2 pathologists ≥200 routine histological samples from breast tissue per year >3 000 histological examinations per year	No workload requirements	0.5 full-time employee per 200 primary cases and 0.1 full-time employer per 200 follow-up cases
EUREF cat 1	>500 mammograms per year	No workload requirements	-	-	-
EUREF cat 2	>1 000 mammograms per year	No workload requirements	No workload requirements	-	-
EUREF cat 3	>5 000 mammograms per year	No workload requirements	No workload requirements	-	No workload requirements
EUREF cat 4	>5 000 mammograms per year	No workload requirements	No workload requirements	-	No workload requirements
NCPR	No workload requirements	-	No workload requirements	-	No workload requirements
NHSBSP	No workload requirements	1.3, 1.5 and 1.6 whole time equivalent radiographers per 10 000 eligible according to the uptake rate (65-75; 76-85; 86-90%)	≥50 primary breast cancer resections	-	One whole time equivalent member for every 12 000 eligible women invited for screening, with at least one member of staff at a management/supervisory grade
SESPM	>1 000 mammograms; >5 000 if screening	No workload requirements	No workload requirements	-	No workload requirements
SIS/ISS	>1 000 mammograms; >5 000 if screening	if screening working a minimum of two days per week – at least 20 mammograms per week	No workload requirements	-	No workload requirements
SSS	≥2 radiologists 1 000 mammograms per year (2 000 in the centre)	≥1 radiographers according to the *Société Suisse de Radiologie* requirements ≥1 radiographers according to the *Société Suisse de Radio-oncologie*	≥2 pathologists ≥300 specimens per year ≥150 new cases	No workload requirements	No workload requirements

Table 15b. *Workload requirements for professionals (therapeutic area).*

	Breast surgeon	Medical oncologist	Breast care nurse	Reconstructive surgeon	Radiation oncologist	Psychiatrist/ psychologist	Physiotherapist
BCC	≥2 surgeons ≥50 primary cases per year (less if supervising surgeon). At least 50% of working time in breast disease	≥2 medical oncologists At least 50% of working time in breast cancer	≥2 nurses, full time to breast disease	≥1 reconstructive surgeons	≥2 radiation oncologists At least 40% of working time in breast cancer	≥2 radiation oncologists At least 40% of working time in breast cancer	≥1 specialist in lymphatic drainage
DKG/DGS	≥50 primary cases per year. In cases where 150 primary procedures have been performed in 5 years, annual proof is no longer required. New breast surgeons: at least 60 primary mammary carcinoma procedures during the previous 3 years	No workload requirements	≥1 nurses	No workload requirements	≥2 radiation oncologists	At least 0.5 psychoncologists for 150 patients	-
EUREF	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
NCPR	≥2 surgeons	No workload requirements	≥2 nurses	-	-	-	-
NHSBSP	≥ 10 screen-detected cases/year (averaged over a 3-year period). If low caseload ≥ 30 cases/year	-	Minimum of 0.1 whole time equivalent clinical nurse specialist per 10 000 screening population	-	-	-	-
SESPM	No workload requirements	No workload requirements	No workload requirements	No workload requirements	No workload requirements	No workload requirements	-
SIS/ISS	≥50 primary cases per year	No workload requirements	No workload requirements	No workload requirements	No workload requirements	No workload requirements	-
SSS	≥2 surgeons ≥30 primary cases per year	≥2 medical oncologists ≥200 per year cycles ≥100 palliative and neo-adjuvant	≥1 nurses At least two consultations proposed	≥1 reconstructive surgeons A consultation once a week ≥30 reconstructive operations per year	≥2 radiation oncologists ≥50 radiotherapies per year	No workload requirements	No workload requirements

5.3.4. Survey and awarding process

Finally, a description of the audit and the certification/accreditation procedure is given for each scheme in *Table 16* and the following ones.

For all the schemes a sequence of preparation/site visit/follow-up is present. The preparation step always includes the compilation of a questionnaire by the applying centre, with a variable complexity up to a formal self-assessment (DKG/DGS and NCPR); NHSBSP and SESPM also require documents for a pre-visit review. The site visit, if described, is always one-day long, with the sole exception of DKG/DGS with a two-day visit; it usually includes interviews with the personnel (profession-specific sessions for NHSBSP), revision of medical records and other relevant documents (*e.g.* mammograms, technical records), inspection of facilities, assessment of multidisciplinary meetings (direct observation for BCC, SESPM, SIS/ISS). The minimum number of auditors goes from two (EUREF category 1, SESPM, SIS) to seven or more (NHSBSP) and an audit for specific profiles is frequently mentioned. Usually auditors are medical doctors; the presence of a nurse is explicitly reported by BCC and NHSBSP. Only one scheme (NCPR) mentions the presence of a patient representative in the audit team. Information on the identity, training and evaluation of assessors was not consistently retrieved.

As a conclusion of the audit, a written report is always released and the follow-up is variable according to the scheme and to the presence of mandatory or non-mandatory requirements. NCPR and NHSBSP are not certification schemes and, therefore, a formal award is not issued. BCC implements the ISO system of follow-up of nonconformities. In some cases, an intermediate visit or indicator monitoring is required before the following re-certification visit. No public audit reports were retrieved for any of the schemes. The time between two full assessments is three or five years.

Table 16. *Survey procedure: preparation of the on-site visit.*

Programme name	Screening for eligibility	Self-assessment	Background information
BCC	Three entry requirements: 1. critical mass of 150 newly diagnosed cases of primary breast cancer / year 2. clinical director 3. database validated by Eusoma.	The applicant unit first fulfils an application form and then an on-line questionnaire whose answers will be considered for the Initial Audit feasibility.	The application form includes the entry requirements and information on the number of sites, number of breast cancer specialists, and outsourced services. If the unit is compliant, contractual documents are sent (agreement, certification rules and regulation, regulation on the use of the logo, privacy) and they must be sent back signed to ITALCERT. The centre is also requested to send the outcome results of the Eusoma indicators.
DKG/DGS	No eligibility gate	The FAB questionnaire (reporting the breast centres requirements) is used for self-assessment, it is filled in and reviewed before the site visit.	The FAB questionnaire include all the requirements foreseen by the scheme: 1. general information on the breast centre 2. organ specific diagnostics (consultation, diagnostics) 3. radiology 4. nuclear medicine 5. surgical oncology 6. drug/medical oncology 7. radiotherapy 8. pathology 9. palliative care 10. tumour documentation and outcome quality. Information on the revision by the auditors is not available in English.
EUREF	Different criteria are applied according to the unit category (see *Table 14*).	The professional coordinator has to fill in an application form that includes a check-list.	Check-list items not available on the website.
NCPR	No eligibility gate.	Each centre does an annual self-assessment and an internal validation of self-assessment every other year using the measures contained within the Manual of Cancer Services. At the end of the external desktop review process, the internal validation can be confirmed (green), confirmed with exceptions (amber), unconfirmed (red).	Assessment against the measures and the supporting report are uploaded on the CQuINS national database each year. Documents uploaded include self-assessment against each measure, and documents supporting the evidence, i.e. operational policy, annual report, work programme. The review team normally request 5 sets of anonymised patient notes in order to check compliance against the measures. Records of attendance and meeting dates are also required to demonstrate compliance with the corresponding requirement.
NHSBSP	The scheme is applicable to NHS screening services only.	Checklist or questionnaires for assessment of professional performance are required for some profiles.	General information about the unit is sent to the coordinating centre at least 1 month before, plus an 'information pack' 2 weeks before. This information pack includes: 1. map 2. list of screening personnel 3. list of visitors 4. programme for the day 5. data pack for the unit, that includes data such as demographic information, performance statistics, information on multidisciplinary meetings and equipment 6. copy of the last quality assurance visit report 7. checklists/questionnaires used to assess professional performance.

Table 16. *(Cont.)*

Programme name	Screening for eligibility	Self-assessment	Background information
SESPM	1. independent breast unit established at least 3 years before 2. multidisciplinary unit 3. accredited continuos education 4. protocols in place 5. support services and information for patients 6. database with clinical registry at least 3 years before 7. member of SESPM.	After the request for accreditation, a questionnaire is filled in by the centre and documents are reviewed by a three people multidisciplinary accreditation board (selected among the list of 4 auditors) within 40 days.	1. situation of the Unit within the hospital's organigram. 2. internal structure and staffing policy 3. work in multidisciplinary team 4. healthcare agenda, availability of diagnostic and treatment protocols.
SIS/ISS	Be member of affiliated society of the SIS.	Complete an application form that is reviewed by the Accreditation Committee.	The application form includes: 1. certification of application by the hospital director 2. composition of the breast centre by specialty 3. reference services list 4. diagnosis and treatment protocols 5. non-medical personnel list 6. specification of diagnostic imaging equipment 7. records of the care activity over the last year 8. record of scientific research and teaching activities.
SSS	No eligibility gate.	Submission of a quality dashboard and a questionnaire on structural requirements to a decision board. The centre is invited to check their compliance with the criteria before the assessment. The centre receives a feedback after 8 weeks, with explanation on the on-site visit and a vademecum for the preparation. At this point, the centre can submit the request for the audit though a pre-defined questionnaire.	The first submission to the *bureau du label de qualitè* includes the quality dashboard and the questionnaire of structural requirements that includes the following information: 1. general information on the services provided and contracts 2. list of healthcare professionals and specialties present in the centre 3. equipment 4. research activity.

Table 17. *Survey procedure: on-site visit.*

Programme name	Type and duration	Assessors team	Visit agenda	Records reviewed
BCC	There are different types of audits: pre-audit; initial audit; surveillance audit; re-audit; unplanned/extra audit. The initial audit duration is 1.5-day	Lead Auditor, a surgeon, a radiologist, a pathologist, a breast care nurse.	Initial audit agenda: 1. documental audit (the first half-day) 2. meeting with the breast centre 3. separate visits by the different auditors, including inspections of clinical areas and equipment, facilities, and interviews with different healthcare professionals 4. multidisciplinary meeting observation 5. meeting with the visiting team 6. feedback to the centre.	Documents that the centre has been asked to provide at the time of the Initial Audit confirm. Information literature provided to patients.
DKG/DGS	2-day	Three auditors from OnkoZert (oncology specialists with training in audit).	1. inspection of facilities and clinical areas 2. assessment of indicators 3. randomly sampled documents and records revision 4. staff interview. Other detailed information not available in English.	Randomly sampled documents and records are reviewed, in particular with respect to the results of indicators and on the self-assessment. Other detailed information not available in English.
EUREF	Not reported. Other types of visit are available: advisory and pre-certification	The visiting team for the category 1 will consist of a radiologist and a radiographer, for category 2 a physicist and a pathologist in addition. The visiting teams for category 3 and category 4 will also have an epidemiologist. For certain certification visits also a specialist breast surgeon.	All visits will include a review of films, technical records and patient facilities.	Films and technical records.
NCPR	One day for the locality/trust and 1 day for the network team(s)	Peer-review visit is done by a multidisciplinary group of clinicians, managers and patients/carers.	1. review team to review evidence in preparation for meeting 2. meeting with the service. At the end the review team meets to write the report.	At the visit, reviewers will need access to one hard copy of the self assessment documentation provided, plus contextual information: 1. general description of the organisation and its cancer services, 2. items from previous peer review visit or assessment reports of relevance to the visit, 3. outcomes of the National Cancer Patient Experience Survey Programme, 4. any other key intelligence obtained from other sources such as clinical governance, audit or CQC reports.

Table 17. *(Cont.)*

Programme name	Type and duration	Assessors team	Visit agenda	Records reviewed
NHSBSP	The visit lasts 1 day with a specific audit for each professional profile	Led by the regional quality assurance director or his/her nominee, it includes the radiologist, radiographer, pathologist, surgeon, breast cancer nurse, administrative and clerical staff, medical physicist. May be included: health promotion programme manager, public health specialist.	1. tour of the unit (optional) 2. review of cases (optional) 3. profession-specific sessions 4. final discussion with external stakeholders (trust, health authority).	A list of record for review is given for each professional profile (see list in *Assessors team*).
SESPM	Informaiton not retrieved	The site visit is conducted by two or three members of the board.	1. evaluation of documents sent 2. meeting with the unit 3. review of individual records 4. multidisciplinary meeting observation 5. visit to environments and facilities 6. feedback to the unit.	Individual records.
SIS/ISS	1-day	Two/three members of the SIS appointed by the Director of the SIS/ISS, one of who will serve as Coordinator and another as Secretary.	1. verification of the information provided in the application form 2. meeting with the coordinator of the centre and specialists (at least one for each specialty) 3. multidisciplinary meeting observation 4. review of clinical histories (5 historical and 5 waiting for visit the same day) 5. visit to all the facilities 6. meeting of the members of the Accreditation Committee (assessors) 7. final meeting with the breast centre members, with suggestions for addressing shortcomings.	1. radiology report 2. pathology report 3. care report 4. informed consent forms 5. information on clinical trials 6. information/health education written documents for patients.
SSS	1-day	Three auditors (at least one surgeon or medical oncologist) nominated from a list held by the scientific secretariat office.	Initial audit agenda: 1. documental audit (the first half-day) 2. meeting with the breast centre 3. separate visits by the different auditors, including inspections of clinical areas and equipment, facilities, and interviews with different healthcare professionals 4. multidisciplinary meeting observation 5. meeting with the visiting team 6. feedback to the centre.	1. activity reports published 2. personnel list 3. organigram 4. patients leaflets 5. patients' rights 6. patients complaint and feedback forms 7. clinical protocols 8. medical records.

Table 18. *Survey procedure: follow-up and awarding.*

Programme name	Report	Ajudication/granting of award	Award duration (years)	Periodic data reporting
BCC	An audit report signed by the Lead Auditor is sent, including recommendations, nonconformities and observations.	The breast centre will send a proposal for corrective actions and then evidence documents for nonconformities. If all are satisfied the decision on certification is issued.	3	At least 10 months after the date of the initial audit there is the first surveillance audit and at least 12 months after the first surveillance audit the second surveillance audit takes place. At least 4 months before the expiration of the certificate there is the re-audit. Unplanned and extra audits can be required in special cases (detailed in the certification procedure).
EUREF	The full written report in draft will be sent to the nominated representative of the local unit within six weeks of the date of the visit. A formal reply must be made by the local unit within a further four weeks responding to issues of accuracy or interpretation.	A final report will be issued within three weeks and will state whether certification has been granted or withheld. There will be a mechanism for the right of appeal in cases of dispute. When all procedures have been satisfactorily completed, full 'diagnostic breast imaging' or 'breast screening' certification will be issued.	5	Information not retrieved on the website.
NCPR	The draft reports is written by the reviewers and signed off by the zonal quality director and or clinical lead. The cancer network and its trusts have the opportunity to comment on the factual accuracy of the report before it is made available on the CQuINS website. Immediate Risks and Serious Concerns identified at internal validation, self assessment or peer review are followed up.	NCPR is a peer-review and does not provide a certificate or an award.	There is not a pre-defined periodicity. Each centre does an annual self assessment and an internal validation of self-assessment every other year.	Individual reports regarding individual teams or services published following self-assessments, external verifications or full peer review visits. Annual Cancer Peer Review Reports provide overarching information about all services within a particular Cancer Network or providing a national summary.

Table 18. *(Cont.)*

Programme name	Report	Ajudication/granting of award	Award duration (years)	Periodic data reporting
NHSBSP	A final structured report with global recommendations is sent to the unit, to superior levels and external stakeholders. The regional quality assurance director is responsible for monitoring actions taken after the visit, with specific recommendations for each professional figure.	NHSBSP is a quality assurance site visit system and does not provide a certificate or an award. Responsibility for implementing the recommendations made in the quality assurance report and resolving any problems rests with the breast screening unit, the trust chief executive andthe commissioning health authority. The regional director and professional coordinators must monitor the actions taken by the breast screening unit.	3 (screening round duration)	Information not retrieved on the website.
SESPM	The report is sent by the Accreditation Committee within 30 days, with suggestions for improvements, if necessary.	If 100% requirements are satisfied the unit is accredited; if 90% requirements are satisfied there are 12 months for the unit in order to meet the standards; if less than 90% requirements are satisfied the unit is not accredited and a report with improvement suggestion is sent by the auditors.	5+5	An annual report must be sent to the Coordinator of the Accreditation Committee, including: 1. the annual clinical activity. 2. the results of the quality indicators during that period. 3. participation of the breast centre members in training courses on breast diseases. 4. research and teaching activities performed. 5. changes in diagnosis and treatment protocols, if any.
SIS/ISS	The report is sent by the Accreditation Committee within 30 days, with suggestions for improvements, if necessary.	1. 100% requirements fulfilled: one stage accreditation 2. 90% fulfilment: request to achieve 100% within 12 months (two stage accreditation) 3. <90% fulfilment: request to achieve 100% within 12 months 24 month (three stage accreditation).	5	An annual report must be sent to the Coordinator of the Accreditation Committee, including: 1. the results of the quality indicators during that period. 2. participation of the breast centre members in training courses on breast diseases. 3. research and teaching activities performed. 4. changes in diagnosis and treatment protocols, if any.
SSS	Each requirement is scored and then a report is sent to the breast centre.	If each compulsory requirement is satisfied, the centre is certified. If not, an improvement plan is to be sent.	4	Each year a report based on the Quality Dashboard shall be submitted to the bureau.

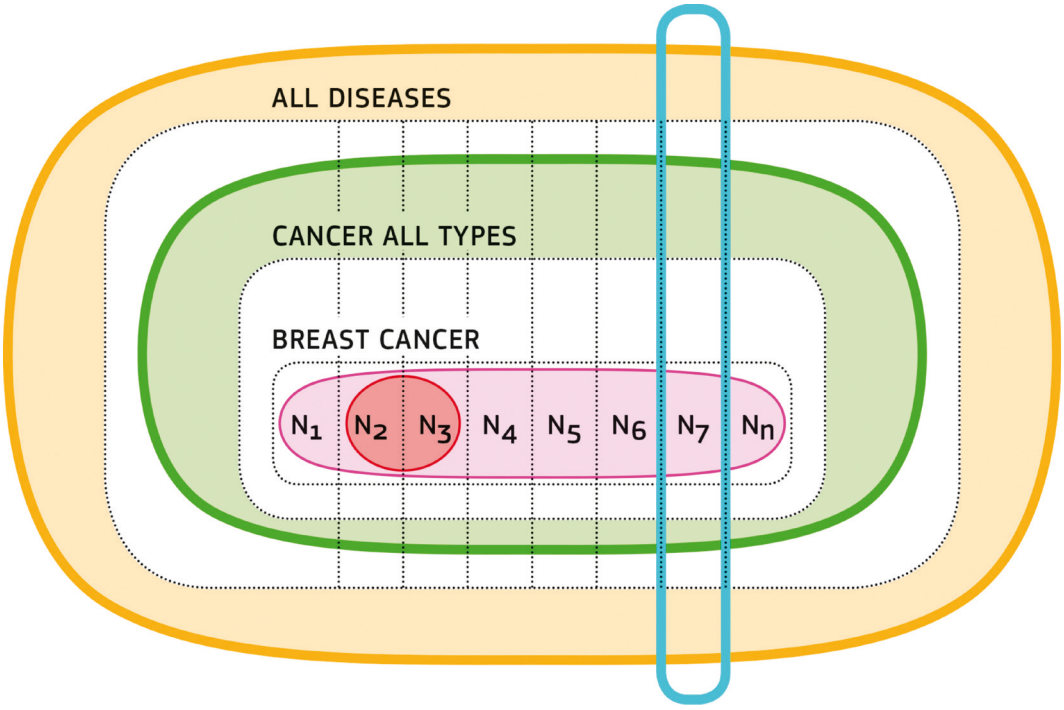
6. Conclusions

6.1. Conceptual framework from the schemes retrieved

If we consider breast cancer care as diveded into stages, each of them is, in turn, made up of different steps (see *Figure 2*: N1, N2, N3, Nn, can correspond to screening, diagnosis, surgical treatment, medical treatment, palliative care, *etc.*), we have retrieved schemes that cover **some of the steps** (EUREF, NHSBSP) and schemes that cover **the entire breast cancer pathway** (*e.g.* BCC, DKG/DGS, SESPM, SIS/ISS). We have found also schemes that accredit or certify **cancer care in general** (see *Unregulated, voluntary, cancer-specific schemes* paragraph) and others that are applicable to **all diseases,** treated in hospitals or in different settings (see *Unregulated, voluntary, generic schemes* paragraph). Most ISO standards are applicable to only one stage or sub-stage of breast cancer care, but **cross-cutting** all the diseases and even specific tasks (*e.g.* ISO 15189:2012 for laboratories).

Therefore, the breast cancer pathway can be seen as a sum of 'bricks' that can be viewed 'horizontally', according to the patients' journey, or 'vertically', considering all the other diseases and patients that can be treated in the same facilities, by the same healthcare professionals, organisational structures,

Figure 2. *Graphical conceptual framework of external quality assessment in breast cancer care.*



etc. General schemes can encompass a big number of relevant aspects for healthcare quality, but they may miss essential aspects for breast cancer and, viceversa, breast cancer-specific schemes may not always be aware that breast cancer is just one disease in the big number of cases treated in the same healthcare facility and good practices developed for other diseases and other services should be considered in a coordinated way. *Figure 2* provides an outline of the complexity of quality in healthcare and, as such, does not aim to cover all the possible cases, rather provides an overview to support further reasoning on optimised use of the available tools.

6.2. Limitations and future developments of the research

Although this Report provides an overview of breast cancer external assessment schemes in Europe that have not been published before, complemented by detailed information on the standards development process and on the assessment and awarding phase for each scheme, some limitations, most depending on the inclusion criteria applied and the data gathering procedure, need to be highlighted for a fit-for-purpose use of this Report and its conclusions.

- The language limitation of the search and analysis did not allow including schemes whose only publication language was not among the languages known by JRC Healthcare Quality Team and even other schemes that may have not been even retrieved through the English search string applied. Very relevant experiences may have been excluded and the geographical distribution description can be biased by that language barrier.

- Schemes from outside Europe were not covered in this Report, despite some of them targeting breast cancer. The suggestion of the peer reviewer of this Report (Charles SHAW) to include them will be discussed with the ECIBC working groups and possibly covered in a future JRC document.

- Relying only on public and current information, not verified with the schemes' owners, may have resulted in incomplete data or not including the most recently updated data. Readers that would make use of the information provided in this report should check the information at the original source for possible updates.

- Information on expired programmes has not been collected and it is known that about half of all new accreditation programmes fail [22]. Therefore, exclusion of non-functioning schemes may imply an incomplete coverage of schemes, even if applied at present in breast cancer services in an informal manner. It would also be relevant for a *'learn from mistakes'* strategy: to know the reasons for discontinuance would help the development of strategies for preventing similar risks for the *European QA scheme*.

- Retrieval and description of quality schemes for other pathologies and clinical services is not covered, but may give useful

hints to the QASDG and may help to overcome difficult steps in the development/piloting/implementation of the *European QA scheme*. Further to that, as the *European QA scheme* is meant as a blueprint for other evidence-based schemes, coverage of other schemes might help better shape future applications outside breast cancer. The suggestion of the peer reviewer of this Report to include other diseases will be discussed with the ECIBC WGs and possibly covered in a future JRC document.

- The evaluation of coverage of ISQua, QMSI and ISO 15189:2012 requirements may in some cases be subjective and different assessors may give different judgments for the schemes reviewed; in particular, the reference to ISO 15189:2012 requirements beyond the diagnostic and testing steps was a choice made by this Reports' authors, not based on the original scope of the standard-ISO. As the authors are aware of the weaknesses of the methods used, we recommend that the evaluations proposed, although they provide an interesting perspective, should be considered simply as a comparison framework rather than a judgement.

Most of these limitations have been highlighted by the peer reviewer of this Report. However, due to the need to structure the information, covered by the series of JRC reports listed in *Table 3*, and to continue the ECIBC project, the initial scope of the Report (and the study design) was kept while acknowledging the limitations.

Upon inputs from the ECIBC WGs, future studies and surveys may be planned to cover (some of) the limitations mentioned above, for instance directly contacting the schemes' owners and getting useful information that may not be accessible to the public via their respective websites.

6.3. Impact on the results on the ECIBC and final remarks

- For 25 countries out of 39 (64.1%), at least one general scheme was detected, and at least one breast cancer-specific scheme was detected in ten (25.6%) (see *Figure 3*). Relevant certification schemes having publicly available information only in languages unknown by the JRC Healthcare Quality Team could not be fully covered in this Report, even if they may be of high relevance and quality.

- The number of BCS holding at least one award is 664 (41.7% represented by the DKG/DGS awarded BCSs); this number is only partially informative as it counts twice BCSs holding more than one certificate, BCSs applying schemes other than breast cancer-specific, applying one of the nine non-analysable schemes, and applying schemes in the ISO frame other than BCC. However, it shows that a big number of BCSs are already engaged in a structured quality improvement process for breast cancer and it may suggest both a future wide interest in the *European QA scheme* and a good level of preparedness to quality assessment.

- The breast cancer-specific schemes retrieved always included requirements related to the clinical management of breast cancer (or breast cancer diagnosis), plus a list of organisational requirements, whose presence, number and complexity vary according to the specific scheme. Patient safety requirements were systematically addressed in only one scheme. Due to the presence of concurrent general schemes in some countries, the *European QA scheme* should find an efficient way in order to guarantee the coverage of clinical, organisational and quality & safety requirements without creating duplications, but also avoiding that the focus on breast cancer clinical aspects would exclude other important outcome determinants, like, *e.g.* patients safety.

- A deep analysis of the clinical requirements and the indicators included in each scheme is beyond the scope of this Report, but at a general level, no major disagreement among the various breast cancer-specific schemes was observed.

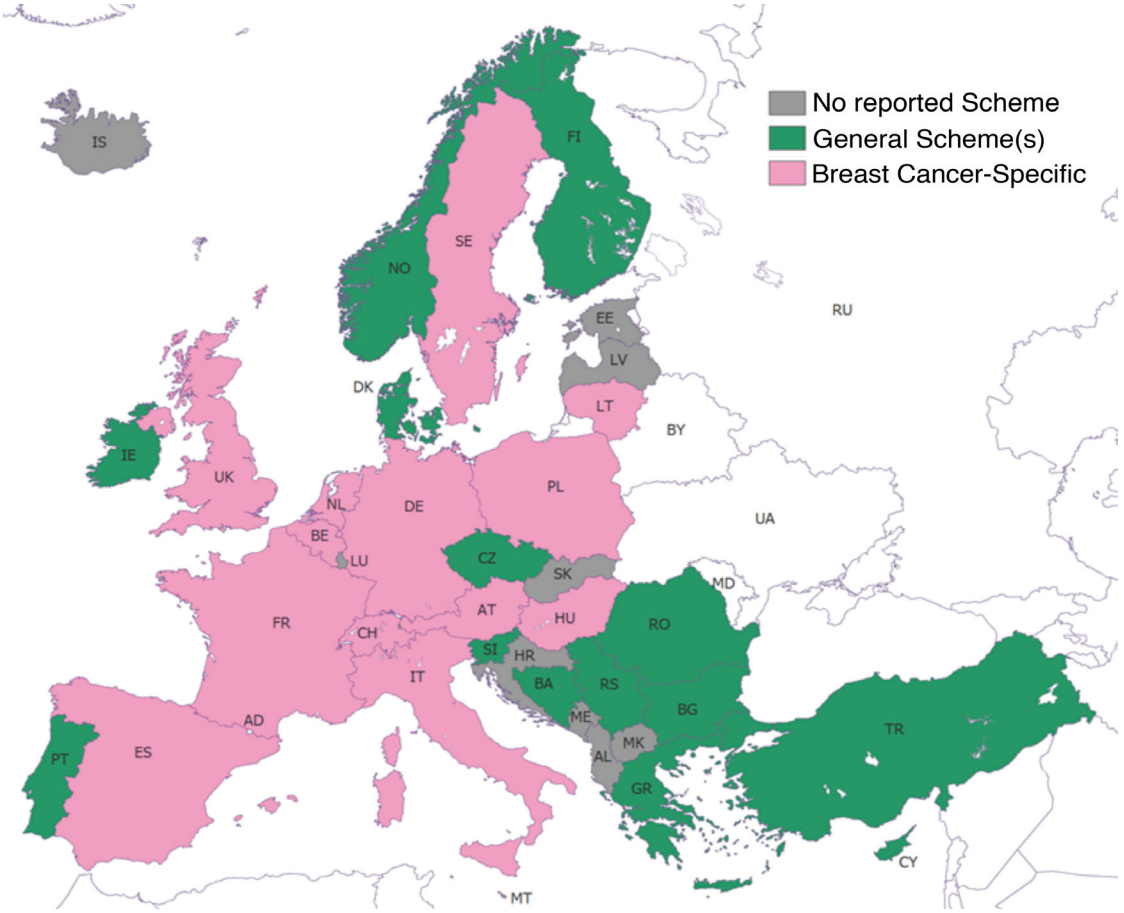
- Both ISO and healthcare accreditation models foresee similar sets of major requirements' areas (*e.g.* professional qualification, infrastructure requirements, communication/reporting), although the headings and the organisation of requirements may be different. The synopsis table provided in *Annex II* may be useful for guiding the QASDG in the framing of the *European QA scheme* requirements, as well as the different graphical solutions provided by the schemes analysed. The presence of an increasing number of entities providing both qualifications, the existence of a 'hybrid' experience as the ISAS standards (that is translating ISO requirements in a format common to accreditation schemes included in the scope of 'clinical service accreditation'), and the fact that BCC awards a certification under ISO/IEC 17065, might suggest a convergence across different models. This would be essential in a context where putting boundaries and classifying external quality assessment schemes according to traditional categories would not be useful.

- Interesting experiences in breast cancer external quality assessment are present outside Europe, namely: BreastScreen Australia Quality Improvement Program (National Advisor Committee to BreastScreen Australia), National accreditation program for breast centres (American College of Surgeons), Mammography Quality Assurance Program (The Royal Australian and New Zealand College of Radiologists), the American College of Radiologists and the Canadian Association of Radiologists accreditation programs for different breast cancer imaging techniques. The *European QA scheme* should take inspiration also from successful stories coming from other continents. This point may be tackled by a future JRC document, upon input of the ECIBC working groups.

To conclude, the authors hope that this Report would provide the readers with useful information and the QASDG members with a collection of inspiring features for the definition of the *European QA scheme*, both from a requirement definition point of view

as well as for the organisation of the on-site visit and its follow-up until the awarding of the BCS. Several schemes have close connections with scientific societies, and/or are supported by patient's organisations and/or they have some links with the individual country's legal framework for healthcare; this may result in a different approach to the quality of breast cancer care and in a country-specific implementation of recommendations derived from evidences or good practices. A European-wide scheme aims to harmonise the situation in Europe and ensure that European citizens receive the same quality of care, at least for the essential aspects, regardless of where they live. However, the diversity of organisational settings of breast cancer care in individual countries will, in any case, pose challenges to such a scheme. The involvement in the ECIBC of experts and individual citizens coming from a variety of professional and national settings, plus the public consultation foreseen for the draft *European QA scheme* will support JRC in the objective of including and integrating existing experiences and developments, a process that the authors have initiated with an intense search and networking activity and that was concretised with this Report.

Figure 3. *European countries with at least one general quality assessment scheme and one breast cancer-specific scheme in place.*



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Annex I: *Definition of variables and descriptors*

ANNEX I. Table 1. *Definition of variables.*

Variable name	Code	Definition	General	Cancer-specific	Breast cancer-specific
Entity	Free text	Official name of the organisation that assesses or awards a healthcare institution according to a certification or accreditation scheme	X	X	X
Programme/ standards name	Free text	Name of the set of standards/requirements and/or the corresponding manual	X	X	X
Countries	ISO 3166	European countries where a healthcare institution is awarded by the scheme	X	X	X
Website	url	Website accessed on 1 March 2015	X	X	X
General description	Free text	Summary of the entity/programme scope, according to the website	X	-	-
Target country	ISO 3166; Europe, World	Whether a cancer-specific scheme has a national or international focus, and where awarded centres are	-	X	-
Number of centres awarded in europe	Number	Number and location of awarded centres in Europe	-	X	-
Award duration	Number (years)	Periodicity of full renewal of award	-	X	X
Type	Free text: public, national legislation, private	Ownership and characteristics of the scheme	-	X	-
Relation with regulators/stakeholders	Free text	Public, private and governmental organisation that has a link with the scheme in terms of participation to the definition of the requirements, partnership, *etc.*	-	-	X
Stages and services		See *Glossary*	-	-	X
Number and organisation (of requirements)	Free text	Number of requirements and their formal structure (areas, chapters, headings, sub-headings, criteria, *etc.*)	-	-	X
Development (of requirements)	Free text	Methodology adopted for the definition of the requirements	-	-	X
External reference (of requirements)	Free text	External sources referenced by the requirements, such as guidelines, professional recommendations, *etc.*	-	-	X

ANNEX I. Table 1 *(Cont.)*

Variable name	Code	Definition	General	Cancer-specific	Breast cancer-specific
Year of last update (of requirements)	YYYY	Year of publication of the edition of requirements actually used	-	-	X
Name of database	Free text	Identification of the database of the scheme	-	-	X
Requirements for data	Free text	Summary of the scheme's requirements addressing the collection and analysis of performance data	-	-	X
Review process (for data)	Free text	How the results of performance indicators are monitored by the scheme	-	-	X
Indicators	Number	Number of quantitative indicators required for monitoring by the scheme (mandatory or not)	-	-	X
Professional profiles	Free text	See *Annex I, Table 2*	-	-	X
Screening for eligibility	Free text	Eligibility criteria for requesting the audit	-	-	X
Self-assessment	Free text	Elements self-assessed by the centres before the audit	-	-	X
Background information	Free text	Information reviewed by the scheme and/or the auditors before the site visit	-	-	X
Duration (of on-site visit)	Number (days)	Number of days of on-site visit	-	-	X
Assessors team	Free text	Number and professional profiles of auditors	-	-	X
Agenda (of on-site visit)	Free text	List of areas, topics, items audited during the visit	-	-	X
Records reviewed	Free text	Records reviewed during the visit, such as mammograms, medical records, etc.	-	-	X
Report (of on-site visit)	Free text	Procedure for issuing the report	-	-	X
Adjudication/granting of award	Free text	How are the requirements scored and the award granted	-	-	X
Periodic data reporting	Free text	Whether a periodic data reporting and monitoring is foreseen before the re-audit	-	-	X

ANNEX I. Table 2. *Professional profiles definitions.*

Specialist breast centre definition	Specialist breast centre requirement	Corresponding code in this Report
Breast radiologist	A specialist in the imaging for diagnosis (including interventional procedures), further assessment and follow-up of breast cancer patients	Radiologist
Breast radiographer	A technician that is specialised in performing mammography and committed to achieving mammographic quality	Radiographer
Breast surgeon and reconstructive surgeon	A specialist in general surgery, reconstructive surgery or gynaecology with a special interest in breast disease	Breast surgeon Reconstructive surgeon
Breast pathologist	A board certified specialist in pathology with a special interest in breast disease	Pathologist
Breast medical oncologist	A specialist in medical oncology with a special interest in breast disease	Medical oncologist
Breast radiation oncologist	A specialist in radiation oncology with a special interest in breast disease	Radiation oncologist
Breast clinical oncologist	In some countries clinical oncologists carry out both radiation therapy and medical treatment. Throughout this paper, clinical oncology can be understood wherever medical or radiation oncologist is written	-
Breast care nurse	A nurse with specialised training in breast care nursing	Breast care nurse
Breast data manager	A trained and dedicated person responsible for breast data management	Data manager
Clinical geneticist	A medical specialist concerned with the assessment of genetic risk and counselling for individuals or families with increased risk of breast cancer	Geneticist
Psychologist	Dedicated to the psychological support to breast patients. Not usually medically qualified and, therefore, not authorised to prescribe pharmacological therapies	Psychologist / Psychiatrist
Psychiatrist	Medically qualified specialist in psychological and pharmacological treatment of patients with psychiatric and psychological problems	Psychologist / Psychiatrist
Physiotherapist	Dedicated to the physical support of patients after breast surgery	Physiotherapist

Source: *European Parliament resolution of 2006 on breast cancer in the enlarged European Union.*

Annex II: *Criteria for the comparison of schemes*

ANNEX II. Table 1. *Synopsis of ISQua, QMSI, SANITAS, ISO 15189.*

ISQua area	QMSI	SANITAS	ISO 15189:2012
Quality Improvement		**Mission & Governance, Safety Management Systems**	
1.1 Defined mission, values, ethics, strategic objectives	Balanced score card	/	4.1 Organisation and management 4.1 "bis" Annex C: Ethics
1.2 Defined responsibilities for quality improvement	• The hospital board (management) has established formal roles for quality leadership • The hospital board (management) makes it clear what is expected from healthcare professionals with regards to quality improvement	/	4.2 Quality system
1.3 Defined responsibilities for governance, management	Not present	/	4.1 Organisation and management 5.1 Personnel
1.4 Information to public on services, quality	Not present	/	4.3 Document management
1.5 Key policies, procedures plans	Not present	/	4.3 Document management
1.6 Quality improvement system	• Quality improvement plan at hospital level • Written description of a formally agreed quality policy • Internal audit (all components of the quality system are periodically assessed with regard to appropriate functioning, i.e. whether all procedures are adhered to and are effective)	/	4.12 Continuous improvement 5.1 Personnel
1.7 Key indicators/measures	Data used from clinical indicators to evaluate and adjust care processes	/	4.11 Preventive actions 4.15 Quality management system review
1.8 Data evaluation, analysis, use for improvement	• Data used from complication registration to evaluate and adjust care processes • Data used from incident reporting system to evaluate and adjust care processes • Complaints analysis (the periodic evaluation of complaints is used to implement improvements) • Data used from interviews/surveys with/among patients to evaluate and adjust care processes • Adverse event reporting and analysis • The hospital (management) board knows and uses performance data for quality improvement • Benchmarking	/	4.9 Identification and management of nonconformities 4.10 Corrective actions 4.11 Preventive actions 4.12 Continuous improvement
1.9 Integration of law, health policy	Not present	/	Not present

ANNEX II. Table 1. *(Cont.)*

ISQua area	QMSI	SANITAS	ISO 15189:2012
Patient/Service User Focus		**Patient Orientation**	
2.1 Patient/Service user rights	Not present	/	4.1 Organisation and management
2.2 Complaint system	Not present	/	4.8 Management of complaints
2.3 Patient/Service user involvement in own care/ services	Monitoring the options of patients (patients are periodically requested to give their opinions on the care provided; includes surveys on patient views)	/	4.1 "bis" Annex C: Ethics in Laboratory Medicine
2.4 Cultural and spiritual sensitivity	Not present	/	Not present
2.5 Access to services	Not present	/	4.1 "bis" Annex C: Ethics in Laboratory Medicine 4.1 Organisation and management
2.6 Patient/Service user assessment	Not present	**Clinical practice and patient care**	5.4 Pre-examination
2.7 Patient/Service user care/service planning	Not present	**Clinical practice and patient care**	Not present – Not applicable
2.8 Monitoring progress, revising care/service plans	Not present	**Clinical practice and patient care**	Not present – Not applicable
2.9 End of service planning	Not present	/	Not present – Not applicable

ANNEX II. Table 1. *(Cont.)*

ISQua area	QMSI	SANITAS	ISO 15189:2012
Organisational Planning and Performance		**Workforce**	
3.1 Staff planning	/	/	5.1 Personnel
3.2 Orientation, skills and experience	• Care professionals are trained by the organisation to do their job • Care professionals are trained in teamwork • Care professionals are trained in patient safety procedures • Care professionals follow at least one training session a year to further develop their professional expertise	/	5.1 Personnel
3.3 Credentialling, defined scope of practice	Care professional licenses are reviewed by a regulatory body	/	5.1 Personnel
3.4 Performance/competency evaluation, ongoing training	• Care professionals receive feedback information on the results of their treatment of patients • Monitoring individual physicians' performance (physicians undergo systematic and documented performance assessments) • Monitoring individual nurses' performance (nurses undergo systematic and documented performance assessments) • Middle management is trained in quality improvement methods • Care professionals are trained in quality improvement methods	/	5.1 Personnel
3.5 Following standards, evidence based guidelines	Development of care pathways/process redesign (all tests and treatments for a specific patient group are efficiently organised to deliver evidenced based care)	**Clinical practice and patient care**	5.5 Examination Procedures
3.6 Involvement of patients/service users and staff in planning	Not present	/	4.15 Quality management system review
3.7 Measurement of identified desired results	• The hospital (management) board monitors the execution of quality improvement plans • Data used from results of internal audits to evaluate and adjust care processes	/	5.1 Personnel
3.8 Service planning based on strategic direction	Not present	/	5.1 Personnel
3.9 Coordinated planning of activities and development	Medical/clinical audit (various disciplines work together to assess and improve the results of care delivery)	/	4.7 Advisory Services
3.10 Efficient use of resources evaluated, plans and budgets	Not present	/	5.1 Personnel

ANNEX II. Table 1. *(Cont.)*

ISQua area	QMSI	SANITAS	ISO 15189:2012
Safety		**Mission & Governance, Safety Management Systems**	
4.1 Planned risk management	Risk management (a systematic process of identifying, assessing and taking action to prevent or manage clinical events in the care process)	/	Not present
4.2 Risk management plan monitoring	The hospital board (management) assesses, on an annual or bi-annual basis, whether care professionals comply with day-to-day patient safety procedures	/	Not present
4.3 Incident/Adverse event reporting/investigation system	• Care professionals are trained in patient safety procedures • Adverse event reporting and analysis • Data used from incident reporting system to evaluate and adjust care processes • Root-cause analysis of incidents • Care professionals are encouraged to report incidents and adverse events	/	4.9 Identification and management of nonconformities 4.10 Corrective actions
4.4 Staff health and safety protection	Not present	/	5.2 Facilities and environmental conditions 5.3 Equipment
4.5 Staff training on equipment	Not present	/	5.3 Equipment
4.6 Safety law, building and equipment safety	Not present	**Hospital facilities management**	5.3 Equipment
4.7 Clinical risk assessment	• Up-to-date hospital protocol for medication reconciliation • Up-to-date hospital protocol for the prevention of medication errors	**Medication**	5.2 Facilities and environmental conditions
4.8 Infection control program	• Up-to-date hospital protocol for use of prophylactic antibiotics • Up-to-date hospital protocol for prevention of central line infection • Up-to-date hospital protocol for prevention of surgical site infection • Up-to-date hospital protocol for prevention of hospital-acquired infections • Up-to-date hospital protocol for prevention of ventilator-associated pneumonia	**Hygiene and Infection**	5.2 Facilities and environmental conditions

ANNEX II. Table 1. *(Cont.)*

ISQua area	QMSI	SANITAS	ISO 15189:2012
4.9 Patient safety issues/ priority safety areas	• Up-to-date hospital protocol for medication reconciliation • Up-to-date hospital protocol for the handover of patient information to another care unit • Up-to-date hospital protocol for the use of medical aids (e.g. crutches, bandages, etc.) • Up-to-date hospital protocol for the prevention of medication errors	**Surgery, Interventional Procedures & Anaesthesia** **Medication** **Human tissue and transfusion**	Not present
4.10 Patient/Service user records	Systematic patient record review (systematic reviews of patient records are used to determine adverse events and priorities for quality improvement)	**Records and Communication**	4.3 Document management 4.13 Control of quality and technical records
Not present	Hospital (management) board 'walk rounds' to identify quality problems and issues (the management visits the work units to discuss quality and safety issues)	/	Not present
	Monitoring the opinions of care professionals (physicians and nurses are periodically asked about their satisfaction with their work, workload, the terms of employment, etc.)	/	/
Not present	Not present	/	4.4 Purchasing of external services
Not present	Not present	/	4.5 Examination by referral consultants
Not present	Not present	/	4.6 External Services and Supplies
Not present	Not present	/	5.3 "bis": Annex B in Laboratory information system

ANNEX II. Table 2. *ISQua criteria for the analysis of breast cancer-specific schemes.*

ISQua area	Qualitative criteria
Quality Improvement	
1.1 Defined mission, values, ethics, strategic objectives	1. size and scope 2. mission or purpose 3. values 4. ethics or code of behaviour 5. strategic objectives
1.2 Defined responsibilities for quality improvement	Responsibilities for quality improvement defined for: 1. governance 2. management 3. clinicians 4. other staff 5. volunteers
1.3 Defined responsibilities for governance, management	Responsibilities for governance defined
1.4 Information to public on services, quality	Inform the public of: 1. the services they provide 2. the quality and performance of the services
1.5 Key policies, procedures plans	Policies, procedures or processes and plans for all key functions in the organisation are: 1. documented 2. authorised 3. kept current and 4. implemented
1.6 Quality improvement system	Approach to quality improvement that: 1. is systematic 2. is continuous 3. is organisation-wide 4. covers all aspects of performance 5. supports innovation 6. incorporates monitoring, including all high risk processes and procedures, and evaluation
1.7 Key indicators/measures	Key care and service processes and outcomes are measured through the use of: 1. performance indicators 2. patient/service user satisfaction surveys/assessments and 3. other performance measures
1.8 Data evaluation, analysis, use for improvement	Evaluation and analysis of data from: 1. patient/service user 2. satisfaction assessments and other performance measures 3. complaints 4. near misses 5. incidents and adverse events

ANNEX II. Table 2. *(Cont.)*

ISQua area	Qualitative criteria
1.9 Integration of law, health policy	Law, regulations and health policy are recognised and integrated into the standards. They regard: 1. employment 2. health and safety 3. building 4. environmental protection 5. reportable diseases 6. waste management 7. food and hygiene 8. health professional registration 9. health information 10. medicines 11. technical standards
Patient/Service User Focus	
2.1 Patient/Service user rights	The standards cover the rights of patients/service users to: 1. dignity and respect 2. privacy 3. confidentiality 4. safety and security
2.2 Complaint system	The standards require a system for receiving, investigating and resolving patient/service user complaints and concerns in a fair and timely way
2.3 Patient/Service user involvement in own care/ services	The standards require staff to involve patients/service users in their own care and services by: 1. respecting their preferences and choices 2. informing them about their options for care and treatment 3. obtaining their informed consent
2.4 Cultural and spiritual sensitivity	The standards require taking into consideration the cultural and spiritual sensitivities of patients: 1. the service provides access to spiritual care or advice that meets patients' /service users' needs 2. staff is trained on the cultural beliefs, needs and activities of different groups served 3. separate facilities and services are provided for women and men, where appropriate, for cultural reasons
2.5 Access to services	The standards cover access to services for patients/service users, including: 1. a range of services based on the needs of the community and the scope of the organisation 2. appropriate access for individuals with disabilities and special needs 3. coordinated admission or entry processes
2.6 Patient/Service user assessment	The standards require that the assessments of patients/service users are comprehensive, are completed and documented in a timely manner, involve relevant disciplines and cover: 1. medical physical examination 2. mental, behavioural and emotional status 3. nutritional status 4. functional status 5. pain 6. presence of abuse and neglect

ANNEX II. Table 2. *(Cont.)*

ISQua area	Qualitative criteria
2.7 Patient/Service user care/service planning	The standards require that individual care/service plans are prepared and documented: 1. based on the assessment of patient/service user needs, including the results of diagnostic tests where relevant 2. involve patients/service users and their families 3. include the goals or desired results of treatment, care or service
2.8 Monitoring progress, revising care/service plans	The standards require that health professionals: 1. follow the care/service plans 2. monitor the progress of patients/ service users in achieving the goals or desired results of treatment, care or service 3. reassess patients'/service users' needs when indicated 4. revise the care/service plan according to results
2.9 End of service planning	The standards require that referral, transfer of care, discharge or end of service is planned: 1. planning commences on first contact with the organisation and is ongoing 2. planning includes patients/service users and their families 3. planning involves making links with referral agencies, other levels of health service and other organisations 4. if death is the expected outcome of the service, planning includes the preparation of patients and their families for death, the management of pain and symptoms, linkage with support groups, counselling, and addressing spiritual and cultural needs
Organisational Planning and Performance	
3.1 Staff planning	The standards require that: 1. organisations use a planning process to determine the level of staffing and skill mix required to meet the needs of the services provided 2. the plan takes into account the number of staff and independent practitioners needed, the levels of seniority and experience required 3. the different disciplines and roles to match the needs of services to be provided 4. the planning process is documented and able to be evidenced
3.2 Orientation, skills and experience	The standards require that, for the positions they hold, staff, independent practitioners and volunteers where applicable, have relevant and current: 1. orientation and training 2. education 3. knowledge 4. skills 5. experience
3.3 Credentialling, defined scope of practice	The standards require that: 1. those permitted by law and by the organisation to practice are credentialed and their scope of practice defined 2. procedures for assessing or accepting healthcare professional training are in place 3. credentials and scopes of practice are documented and regularly reviewed
3.4 Performance/competency evaluation, ongoing training	The standards require that staff, independent practitioners and volunteers where applicable: 1. have their performance and competency evaluated on a regular basis 2. receive relevant ongoing education and skill training 3. are provided with internal and external development opportunities

ANNEX II. Table 2. *(Cont.)*

ISQua area	Qualitative criteria
3.5 Following standards, evidence based guidelines	The standards require staff to follow current accepted standards, protocols and evidence based clinical practice guidelines
3.6 Involvement of patients/service users and staff in planning	The standards require healthcare organisations to involve patients/ service users, their families, staff and where possible the wider community in planning for the provision of services
3.7 Measurement of identified desired results	The standards require: 1. organisational planning to identify desired or expected service and organisational results and measure progress in achieving them 2. strategic and operational plans including long and short term goals, and objectives for the organisation and its services 3. progress in achieving these goals and objectives through defined activities which are measured and reported on a regular basis
3.8 Service planning based on strategic direction	The standards require service planning to be based on the organisation's strategic direction and to consider environmental and financial factors
3.9 Coordinated planning of activities and development	The standards require the planning of functions, activities and the development of departments and services to include provisions for coordination with each other and with relevant external services
3.10 Efficient use of resources evaluated, plans and budgets	The standards require that: 1. the efficient use of resources is regularly reviewed and is evaluated against organisational plans and budgets 2. staff occupation, equipment, supplies and space are efficiently used
Safety	
4.1 Planned risk management	The standards require a planned and structured approach to risk management that addresses all significant risks faced by the organisation and its services: 1. policy 2. context 3. scope and objectives and criteria for assessing risk 4. risk management responsibilities and functions 5. staff training 6. a list of identified risks – strategic, operational, financial and hazard 7. a risk register or similar with an analysis of the risks and their corresponding level 8. summary of risk treatment plans for major risks 9. processes for communicating with stakeholders
4.2 Risk management plan monitoring	The standards require: 1. that a risk management plan is monitored and reviewed for effectiveness and results are communicated within the organisation 2. a routine surveillance of actual performance is undertaken and compared with required performance 3. periodic investigation of the current situation and specific issues 4. results from the monitoring and review processes for improvement are used

ANNEX II. Table 2. *(Cont.)*

ISQua area	Qualitative criteria
4.3 Incident/Adverse event reporting/investigation system	The standards require healthcare organisations to have processes for reporting and investigating safety incidents, adverse events and near misses affecting patients/service users, staff or visitors and for using findings to improve services. The system may include: 1. training for staff 2. means for documenting and reporting incidents/events 3. root-cause analysis 4. processes for informing patients/ 5. service users of adverse events
4.4 Staff health and safety protection	The standards require the organisation to protect the health and safety of staff by: 1. using protective clothing and equipment for staff 2. carrying out workplace assessments 3. monitoring workload and stress management 4. carrying out staff vaccination 5. preventing needlestick or manual handling injuries 6. protecting from occupational hazards
4.5 Staff training on equipment	The standards require healthcare organisations to train staff on the safe operation of equipment, including medical devices, and ensure only trained and competent people handle specialised equipment
4.6 Safety law, building and equipment safety	Standards require healthcare organisations to ensure that: 1. relevant safety law and regulations are met 2. the buildings, space, equipment and supplies necessary for the stated services are provided 3. facilities and equipment are inspected, tested, maintained and updated or replaced in a planned and systematic way
4.7 Clinical risk assessment	The standards require healthcare organisations to undertake clinical risk assessments to safeguard patients/service users from unintended consequences of care/ treatment. They cover: 1. medication management 2. allergies and antibiotic resistance 3. equipment risks, e.g. fire/injury risks from use of lasers 4. risks resulting from long term conditions
4.8 Infection control programme	The standards require healthcare organisations to have a planned and systematic programme for preventing and controlling infections which includes at least: 1. handwashing and cleaning requirements 2. structures and resources 3. use of isolation and precaution techniques 4. use of antibiotics 5. sterilisation activities 6. monitoring 7. collection, analysis and use of infection event data 8. reporting 9. staff education

ANNEX II. Table 2. *(Cont.)*

ISQua area	Qualitative criteria
4.9 Patient safety issues/ priority safety areas	The standards provide guidance to assist organisations to manage issues of patient/service user safety relevant to the care sector, including any appropriate safety priority areas from the WHO Global Patient Safety initiative: 1. the safe management and use of blood and blood products 2. right patient/right side/right site interventions 3. safe practices before, during and after surgery, anaesthesia, moderate/deep sedation and invasive procedures 4. safe medication management, including: prescribing/ordering, transporting, storing and disposing, preventing, monitoring and documenting, responding promptly to adverse effects and medication errors
4.10 Patient/Service user records	Requirements on the clinical records: 1. legible, dated, timely and signed entries 2. alert notifications 3. progress notes, observations, consultation reports, diagnostic results 4. all significant events such as alteration to patients'/service users' condition and responses to treatment and care 5. any near misses, incidents or adverse events 6. confidentiality procedures 7. security and storage 8. use of only recognised abbreviations 9. procedures for retaining and destroying records

ANNEX II. Table 3. *ISO 15189 criteria for the analysis of breast cancer-specific schemes.*

ISO 15189 subparagraph	Items requested
Organisation and management 4.1, 4.1.1, 4.1.2	1. define the organisation and responsibilities in the service 2. define the number of cases/patients normally treated by the structure and the stages covered
Ethics 4.1 "bis" Annex C	1. ethical committee 2. informed consent procedure 3. provision of counselling (for genetic tests, for high risk women, for women positive to the test) 4. procedure to manage patients with different beliefs 5. declaration of conflict of interests
Quality system 4.2, 4.2.1, 4.2.2	1. have a quality manual 2. have a quality manager 3. the quality manual includes the list of equipment for which quality control is required 4. the quality manual includes the list of professional profiles for which quality control is required 5. the quality manual includes the list of services/processes for which quality control is required 6. internal quality audits are a part of the quality management system 7. external quality audits and external quality assurance programs are part of the quality management system 8. all the requirements above apply to every service/process covered by the scheme

ANNEX II. Table 3. *(Cont.)*

ISO 15189 subparagraph	Items requested
Documents management 4.3	1. procedure to approve and review documents 2. procedure to prevent the unintended use of obsolete documents 3. procedure to retain documents 4. all procedures above apply (but not exclusively) to: clinical guidelines, protocols, operating instructions, checklists, procedures, invitation letters, health records forms, leaflets, written material given to women, websites, online applications
Purchasing of external services 4.4, 4.4.1, 4.4.2	1. formal agreements with external partners are requested (external partners providing tests or procedures included in the women pathway like laboratories, external radiology units, outsourced services, *etc.*) 2. regular review of contracts 3. contracts with external partners shall include all requirements (*e.g.* patient safety) covered by 15189
Examination by referral consultants 4.5, 4.5.1, 4.5.2	1. procedure for selection of external partners 2. determination of requirements for services provided by external partners 3. procedure for review of external partners activity (*e.g.* quality indicators, feedback of patients referred) 4. procedure for handling results from external partners
External services and supplies 4.6	1. establish purchasing procedures for services and materials 2. procedures for verification of new supplies against standard specifications 3. establish inventory control system 4. procedures for rating / exclusion of providers
Advisory services 4.7	1. multidisciplinary meetings are required 2. multidisciplinary core group composition is set (additional members can be selected upon need and, in this case, must participate) 3. a multidisciplinary meetings procedure exists, and includes points such as frequency, information to be discussed, way to record results, way to communicate results
Management of complaints 4.8	1. collection of complaints 2. procedure for managing and answering complaints 3. criteria and procedure for classifying complaints 4. recording informal communication (positive and negative) from patients and other stakeholders 5. customer satisfaction surveys 6. staff satisfaction surveys
Identification and management of nonconformities 4.9	1. a list of nonconformities is defined 2. procedure to report or monitor nonconformities 3. procedure to respond and correct problems 4. procedure to assess the result of follow-up actions 5. nonconformities include reporting of at least two of the following: interval cancers, complications, adverse events, sentinel events, near misses, wrong side surgery, infections, discordance between pre- and post-operative diagnosis, delay in waiting times, equipment faults
Corrective actions 4.10	1. procedure to investigate problems 2. reviewing results of correcting actions 3. monitoring results of corrective actions
Preventive actions 4.11	1. list of indicators for monitoring 2. target values are set 3. continuous monitoring is in place 4. indicators are the Eusoma ones or other internationally recognised dashboards 5. indicators include managerial and safety items (*e.g.* infections, adverse events, *etc.*)

ANNEX II. Table 3. *(Cont.)*

ISO 15189 subparagraph	Items requested
Continuous improvement 4.12	1. management review of all operational procedures at intervals defined by the quality management system 2. evidence of *plan do check act* approach
Control of quality and technical records 4.13	1. indexing (list) of records (clinical charts, images, quality logs.) 2. requirements for storage of records (archiving facilities, environment, access control) 3. access / confidentiality of records 4. retention schedule 5. legibility of records 6. records retrieval and disposal procedures
Evaluation and internal audits 4.14, 4.14.1, 4.14.2, 4.14.3, 4.14.4, 4.14.5, 4.14.6, 4.14.7, 4.14.8	1. responsibilities for internal audits 2. schedule of internal audits 3. reporting of internal audits 4. follow-up actions derived from results of internal audits 5. internal audits apply to every section of women's care (radiology, pathology, surgery, *etc.*)
Quality management system review 4.15, 4.15.1, 4.15.2, 4.15.3, 4.15.4, 4.15.5	1. yearly management review 2. list of quality indicators to be reviewed 3. reporting findings and actions 4. management review results in an improvement plan 5. informing staff of results and actions
Personnel 5.1, 5.1.1, 5.1.2, 5.1.3, 5.1.4, 5.1.5, 5.1.6, 5.1.7, 5.1.8, 5.1.9	1. personnel policies 2. job descriptions 3. personnel records including job descriptions, references, certifications, *etc.* 4. minimum requirements for number of specialists vs. number of patients or service dimension 5. education and experience required to hold the position (credentialing) 6. orientation program contents and procedures 7. regular competency assessment (*e.g.* proficiency testing) 8. requisites in order to maintain the position 9. authorisation necessary to carry-out specific activities 10. education program includes at least: ethics and confidentiality, safety, quality management system and procedures in addition to updates specific for the professional profile 11. procedure for incident, accident and occupational hazard 12. all of the above apply to: director, radiologist, radiographer, surgeon, medical oncologist, nurse, psychologist, others
Facilities and environmental conditions 5.2, 5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.2.5, 5.2.6	1. design and environmental conditions of the breast unit 2. general procedure for hygiene (room cleaning, *etc.*) 3. procedure for fire safety 4. procedure for electrical safety 5. procedure for hand hygiene 6. procedure for waste disposal 7. procedure for cleaning, sterilisation, etc. of equipment 8. procedure for safe handling and disposal of chemical, radioactive and biological materials 9. procedure for privacy of examinations 10. procedure for preventing the loss of information 11. procedure for management of patients with disabilities

ANNEX II. Table 3. *(Cont.)*

ISO 15189 subparagraph	Items requested
Laboratory equipment 5.3	1. list of minimal equipment required 2. procedure for inventory (records for each equipment piece) 3. programme of preventive maintenance 4. handling defective equipment 5. safety requirements for equipment and personnel 6. requirements apply to every service covered by the scheme (mammography, ultrasounds, operating room, *etc.*)
Pre-examination 5.4, 5.4.1, 5.4.2, 5.4.3, 5.4.4, 5.4.5, 5.4.6, 5.4.7	1. procedure for unique identification of patient 2. procedure for sample traceability 3. criteria for request forms 4. clinical information to be recorded before the procedure 5. requirements apply to every service covered by the scheme
Examination 5.5, 5.5.1, 5.5.2, 5.5.3	1. reference clinical guidelines 2. item nr 1 applies to every service addressed by the scheme (*e.g.* radiology, pathology radiotherapy, surgery, medical oncology, follow-up) 3. clinical record formats
Quality control of examination processes 5.6, 5.6.1, 5.6.2, 5.6.3	1. quality control details for each equipment used 2. inter-centre comparisons 3. external centre must be accredited 4. item nr 1 applies to every equipment involved into the scheme
Post-examination 5.7, 5.1.7, 5.7.2	1. review of results of examinations (*e.g.* during multidisciplinary meetings) 2. requirements for further examinations (*e.g.* recall criteria) 3. storage of samples (pathology) 4. safe disposal of samples (pathology)
Test results 5.8, 5.8.1, 5.8.2, 5.8.3, 5.9, 5.9.1, 5.9.2	1. list of contents to be reported (when applicable) 2. applies to every report involved in the scheme (radiology, surgical, discharge letter, *etc.*) 3. terminology according to international standards 4. turnaround times established 5. procedure for alteration of results 6. procedure for communication of results to the patient 7. procedure for communication of results to the general practictioner (when applicable) 8. communication of results to cancer registries 9. reporting of data to Eusoma database or other internationally recognised database
Information system 5.10, 5.10.1, 5.10.2, 5.10.3	1. minimum requirements for hardware and software 2. contingency plans in case of information system failure 3. procedure to assess the correctness of data input (*e.g.* input of radiological results) 4. procedure for information backup 5. management of system maintenance 6. procedure for accessing data (reading and editing rights) 7. procedure for preventive maintenance for computer hardware

YES = ≥75% compliance to the requirement

PARTIAL= 25%-75% compliance to the requirement

NO= <25% of compliance to the requirement

Annex III: *List of eligible papers*

1. Knutson AC, McNamara EJ, McKellar DP, Kaufman CS, Winchester DP. The role of the American College of Surgeons' cancer program accreditation in influencing oncologic outcomes. J Surg Oncol. 2014 Oct;110(5):611-5.

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Name	Organisation	Reason for exclusion	Website/references
Breast Centres Network Registration	Breast Centres Network	No audit	http://www.breastcentresnetwork.org/
Breast Imaging Center of Excellence designation	American College of Radiologists	Not present in Europe (USA)	http://www.acr.org/Quality-Safety/Accreditation/BICOE
Breast MRI Accreditation Program	American College of Radiologists	Not present in Europe (USA)	http://www.acr.org/Quality-Safety/Accreditation/BreastMRI
BreastScreen Australia Quality Improvement Program	National Advisory Committee to BreastScreen Australia	Not present in Europe (Australia)	http://www.cancerscreening.gov.au/internet/screening/publishing.nsf/Content/breast-screen-about#accreditation
Certification System of Breast Cancer Centres *ÄKzert die Zertifizierungsstelle*	ÄKZert	Detailed information not available in English	Not retrieved
Doc-Cert	Information not retrieved	Information in German	http://www.doc-cert.com/
ESMO recognition as an 'ESMO Designated Centre of Integrated Oncology and Palliative Care'.	European Society for Medical Oncology (ESMO)	Not clear whether an audit actually takes place	http://www.esmo.org/Patients/Apply-to-Become-an-ESMO-Designated-Centre
Harmonisatie Kwaliteitbeoordeling in de Zorgsector	Information not retrieved	No information in English (NL)	Not retrieved
JCI Clinical Care Program Certification Breast cancer programme	Joint Commission International	Not present in Europe	http://www.jointcommissioninternational.org/improve/get-certified/
Mammography Accreditation Program	American College of Radiologists	Not present in Europe (USA)	http://www.acr.org/Quality-Safety/Accreditation/Mammography
Mammography Accreditation Program (MAP)	Canadian Association of Radiologists	Not present in Europe (USA)	http://www.car.ca/en/accreditation/map.aspx
Mammography Quality Assurance Program	The Royal Australian and New Zealand College of Radiologists	Not present in Europe (Australia, New Zealand)	http://www.ranzcr.edu.au/quality-a-safety/radiology/practice-quality-activities/mqap
Mammography Quality Standards Act (MQSA) Mammography Quality Standards Reauthorization Acts (MQSRA)	Food and Drug Administration	Not present in Europe (USA)	http://www.fda.gov/Radiation-Emitting-Products/MammographyQualityStandardsActandProgram/AbouttheMammography-Program/
National accreditation program for breast centres	American College of Surgeons	Not present in Europe (USA)	https://www.facs.org/quality-programs/napbc
National Breast Cancer Care Protocol	Hungary Ministery of Health	Information not available in English	Not retrieved
National Quality Assurance Standards for Symptomatic Breast Disease Services	Health Information and Quality Authority (HIQA)	Not active anymore	http://www.hiqa.ie/standards/health/symptomatic-breast-disease

Name	Organisation	Reason for exclusion	Website/references
Nationella Arbetsgruppen för Mammografi	Information not retrieved	Information in Swedish	Not retrieved
ProCumCert	Information not retrieved	Information in German	http://www.procumcert.de/Unternehmen.177.0.html
Project for the realisation of a site visit system for quality assurance of Italian screening programmes *Progetto per la realizzazione di un sistema di site visit per l'assicurazione di qualità dei programmi di screening italiani*	Screening National Observatory *Osservatorio Nazionale Screening*	Pilot	http://www.osservatorionazionalescreening.it/sites/default/files/allegati/Grazzini%20site%20visit%20Palermo.pdf
Quality assurance system in Stockholm/Gotland	Information not retrieved	Information in Swedish	Not retrieved
Radiation Oncology Practice Accreditation Program	American College of Radiologists	Not present in Europe (USA)	http://www.acr.org/Quality-Safety/Accreditation/RO
Recertification program for quality assurance	*Kassenärztliche Vereinigung Bayerns", KVB* Bavarian Statutory Healthcare Administration	No information in English, apart from a paper published in 2004	Riesmeier J, Eichelberg M, Hellemann HP, Kieschke J, Wilkens T. Experiences with a workstation prototype for softcopy reading within the Bavarian mammography recertification program: workstations and education. T. Acad Radiol. 2004 Apr;11(4):407-18.
Regionalt Undersökningsregister Mammografi Hälsokontroll	Information not retrieved	Information in Swedish	Not retrieved
Royal Decree for accreditation of Breast Cancer Care Programmes	Belgium Health Ministry	No audit	Not retrieved
Senonetwork Registration	Senonetwork	No audit	http://www.senonetwork.it/
Stereotactic Breast Biopsy Accreditation Program	American College of Radiologists	Not present in Europe (USA)	http://www.acr.org/Quality-Safety/Accreditation/StereotacticBreast

Annex V: *Individual breast cancer-specific schemes' description*

Programme name
Breast Centres Certification
Entity
Breast Centres Certification (BCC)– European Society of Breast Cancer Specialists (Eusoma) (private)
General characteristics
The scheme is a voluntary certification process in compliance with the international regulation on certification ISO/IEC 17065. The procedure is a collaboration between ITALCERT, a certification body in the field of management system, product and services, and BCCert, a no profit society aiming at promoting and diffusing an high quality standard of care in breast cancer. It has been appointed by Eusoma to carry out the voluntary process of Certification of Breast Units in Europe according to Eusoma criteria published in the document 'The requirements of a Specialist Breast Unit' (27). Eusoma criteria were originally developed in the last 90s and more recently updated in 2010 and then in 2013. Previously, BCC was called European Cancer Care Certification.
Countries
15 centres certified (BE, CH, IT, NL)
Stages
Screening, Diagnosis, Treatment, Follow-up, Rehabilitation, Training, Research
Levels
-
Procedure for accreditation/certification
Certification lasts 5 years. If the unit is compliant with 3 entry requirements (database, critical mass, clinical director), contractual documents are sent (agreement, certification rules and regulation, regulation on the use of the logo, privacy) and an online questionnaire is filled in. The site visit is conducted by a multidisciplinary team of highly specialised European experts and includes: evaluation of documents, meeting with the centre, separate visits of the auditors, multidisciplinary meeting observation, and final feedback to the unit. An audit report is sent: a Nonconformity is the inability to comply with a mandatory requirement and a Recommendation is the non-satisfaction of a non-mandatory requirement. The breast centre will send a proposal for corrective actions and then evidence documents for nonconformities. If all are satisfied the decision on certification is issued. At least 10 months after the date of the initial audit there is the first surveillance audit and at least 12 months after the first surveillance audit the second surveillance audit takes place. At least 4 months before the expiration of the certificate there is a re-audit.
Development of requirements
Developed by international Eusoma experts during consensus conferences and workshops, using available literature references. Indicators have been developed by consensus after a literature review.
Structure and characteristics of requirements
147 requirements (57 mandatory, 90 recommended) organised in topics and expressed as a sentence. After the transitory period January-December 2014 another 36 requirements switch to mandatory. Structured in 27 Topics: Breast Centre; Critical mass; Clinical Lead; Protocols; Audit; Multidisciplinary case management meetings; Communication of the diagnosis and, treatment plan; Patient information; Teaching; Research; Core Team; Breast radiology; Breast surgery and reconstructive surgery; Breast pathology; Breast Medical oncologists; Breast radiation oncologist; Breast care nursing; Clinics; Clinical genetics clinics; New patients clinics; Advanced breast cancer clinics; Second opinion; Psychological support; Follow-up of primary breast cancer; Prosthesis; Physiotherapy and lymphedema; Nuclear medicine; Palliative Care. Each requirement is expressed as a sentence. There are also 14 indicators.
Website and references
http://www.cancercarecert.biostatistica.net/ - Requirements http://www.eusoma.org/doc/The_requirements_of_a_specialist_Breast_Centre_2013.pdf - Requirements published on Eur J Cancer http://www.cancercarecert.biostatistica.net/procedure.php - Procedure http://www.cancercarecert.biostatistica.net/certified_units.php - Certified centres

ANNEX V. *Individual breast cancer-specific schemes' description (Cont.)*

Programme name
Certification system for breast cancer centers from the German Cancer Society and German Society for Breast Diseases *Zertifizierungssystem der Deutschen Krebsgesellschaft und der Deutschen Gesellschaft für Senologie für Brustkrebszentren*
Entity
German Cancer Society and German Society of Breast Diseases (DKG/DGS) (private)
General characteristics
It is a nationwide dual certification programme based on the certification of breast cancer services according to national evidence-based guidelines (S3 Guidelines) plus the certification of the quality management system according to ISO 9000 or KTQ. After a pilot phase in 2001-2003, in 2006 and 2014 updated versions of the questionnaire were published; in 2012 an updated version of the S3 Guidelines was published as well. The National Cancer Plan requires that Comprehensive Cancer Centres are certified by German Cancer Aid (DKH) and Oncology and Organ Cancer Centres by the German Cancer Society. Guidance for auditors, auditing procedures and evaluations via OnkoZert, an accredited certification institute that is independent of the DKG both financially and with regard to personnel.
Countries
277 centres certified (AT, CH, DE, IT)
Stages covered
Screening, Diagnosis, Treatment, Follow-up, Rehablitation, Research, Training
Levels
-
Procedure for accreditation/certification
The certification lasts 3 years. The FAB questionnaire (reporting the breast centres requirements) is filled in and reviewed before the site visit. Auditors are not voting members of the Certification Commission. Then there is a two-day audit with three auditors from OnkoZert (oncology specialists with training in audit). Facilities and clinical areas are inspected, randomly sampled documents and records are reviewed, the staff is interviewed. External partners are inspected too. Recommendations are given and random annual site visits are done. The process for scoring and noncompliances is not available in English.
Development of requirements
FAB questionnaire items are based on general requirements, existing guidelines and legal requirements. It is developed by consensus in collaboration with scientific societies and updated by a DKG-appointed Certification Committee. S3 guidelines are developed following an evidence-based pathway. Quality indicators are developed according to the RAND/UCLA methodology. An interdisciplinary Certification Commission (20-30 people) nominated by professional societies and patients representatives compiles the list of specialist requirements on the basis of current guidelines.
Structure and characteristics of requirements
Requirements are three-fold: 187 Requirements for Breast Centres (FAB questionnaire 2014 in German) + 225 Evidence-based Statements from interdisciplinary S3 guidelines + ISO 9000/KTQ requirements. FAB requirements are divided into sections and subsections: General information on the breast centre (structure of the network, interdisciplinary cooperation, cooperation referrer and aftercare, psycho-oncology, social work and rehabilitation, patient involvement, study management, care, general coverage areas); Organ specific diagnostics (consultation, diagnostics); Radiology; Nuclear medicine; Surgical Oncology (inter-institutional surgical therapy, organ-specific operational oncology); Drug/Medical Oncology (hematology and oncology, organ-specific drug therapy oncology); Radiotherapy; Pathology; Palliative Care; Tumour documentation and Outcome quality. Evidence-based S3 Statements are classified in: General; Loco-regional primary disease; Recurrent or metastatic breast cancer; Treatment, care and support; Care coordination and quality management and quality indicators.
Website and references
http://www.onkozert.de/brustkrebszentren.htm - OnkoZert, breast cancer certification (German website) http://www.oncomap.de/ - Certified centres http://www.deutsche-krebsgesellschaft.de/ - General certification page of Germal Cancer Society

ANNEX V. *Individual breast cancer-specific schemes' description (Cont.)*

Programme name
Voluntary certification of high quality diagnostic breast imaging and breast screening services
Entity
European Reference Organisation for Quality Assured Breast Screening and Diagnostic Services (EUREF) (private)
General characteristics
Quality standards developed in 2006 by EUREF in cooperation with European Network of Breast Screening Programmes, EC and authorities in MSs in order to certify the achievement of the requirements from the *European Guidelines*. In 2013, the official supplement (or update) regarding this European Protocol for the Quality Control of the Physical and Technical Aspects of Mammography Screening of the 4th edition of the *European Guidelines* was published and released by the EC. The tomosynthesis protocol is in progress. It is a pan European organisation, widely drawn from different MSs and is operated on a non-profit basis. It also provides training with respect to different physico-technical aspects.
Countries
Ongoing certification processes in EU, three centres certified in CH
Stages covered
Screening, Diagnosis
Levels
Category 1: Diagnostic Breast Imaging Unit; Category 2: Diagnostic Breast Assessment Unit; Category 3: Loco-regional Breast Screening Programme; Category 4: European Reference Centre for Breast Screening. The number of requirements increases from the first to the last one.
Procedure for accreditation/certification
The certification lasts 5 years. After a screening for eligibility, a site visit is performed by a radiologist, a radiographer (always), a physicist (from level 2), a pathologist (from level 2), an epidemiologist (from level 3), acknowledged experts from European centres. The visit includes a review of films, technical and patient facilities. A written report is sent within 6 weeks, a formal reply must be made within further 4 weeks. Following this a final report is sent informing whether the certification is granted or withheld. The scoring system was not retrieved on the website.
Development of requirements
They were established by expert consensus and also refer to the *European Guidelines*, developed by expert consensus on the basis of a literature review. The radiation protection requirements refer to EURATOM Council Directive.
Structure and characteristics of requirements
Requirements are organised for topics (General; Physico-Technical; Radiographers; Radiologists; Pathology support; Multidisciplinary activities; Referral, assessment and feedback; Identification and peer review of interval cancers and screen-detected cases; Epidemiology support, Invitation Scheme; Training) and for levels (7 requirements for category 1; 11 for category 2; 23 for category 3; 26 for category 4). Requirements are organised as sentences grouped in topics. All the requirements are mandatory.
Website and references
http://www.euref.org/ - General homepage http://www.euref.org/european-guidelines/physico-technical-protocol#tomo - Physico-technical certification protocol http://www.euref.org/certification/results-certification-visits - Certified centres http://www.euref.org/european-guidelines - *European Guidelines*

ANNEX V. *Individual breast cancer-specific schemes' description (Cont.)*

Programme name
National Cancer Peer Review Programme (NCPR)
Entity
National Cancer Action Team (public)
General characteristics
It is a national quality assurance programme for NHS cancer services, involving both self-assessment by cancer service teams and external reviews of teams conducted by professional peers. It covers all cancer types and all stages of the patient's journey. The programme is managed by the National Cancer Action Team and is an integral part of the NHS Cancer Reform Strategy (2007) and the overall NHS Cancer Programme, led by the National Cancer Director. The first *Manual of Cancer Service Standards* (2000) was used to support the first peer review programme in 2001. The 2004-07 programme was underpinned by the *Manual for Cancer Services 2004* and was coordinated nationally. The revised *Manual for Cancer Services* (2008) has therefore been drawn up to incorporate the recommendations contained within such guidance including the new guidelines published by NICE. The patient safety issues are regulated and inspected in the frame of the CQC activity.
Countries
152 breast cancer teams in UK were assessed in 2012-2013
Stages covered
Diagnosis, Treatment, Rehabilitation, Research
Levels
-
Procedure for accreditation/certification
Each centre does an annual self assessment and an internal validation of self-assessment every other year using the measures contained within the *Manual of Cancer Services*. After an internal validation, an external check (desktop review) is done by the zonal coordinating team in order to ensure that every service is verified at least once every five years. At the end of the process, the internal validation can be confirmed (green), confirmed with exceptions (amber), unconfirmed (red). When a service is considered to be at risk a Peer Review visit is done by a multidisciplinary group of clinicians, managers and patients/carers. The visit usually lasts one day for the locality/trust and one day for the network team(s) and includes a review of evidence and a meeting with the service. A written report is given and the follow-up of the recommendations is up to the trust and the clinical corporate governance systems. Immediate Risks and Serious Concerns Identified at internal validation, self assessment or peer review are followed up.
Development of requirements
Based on the NICE Improving Outcome Guidance.
Structure and characteristics of requirements
Manual for Cancer Services – Breast Cancer Measures include 25 requirements, for each an objective, measure, notes and evidence is provided, classified according to key themes: Structure and function of the service; Coordination of care/ patient pathways; Patient experience; Clinical outcomes/indicators. Forty clinical indicators classified in: Size; Demographics; Specialist team; Throughput; Waiting times; Practice; Outcomes and recovery; Patient experience. Other relevant manuals are: Chemotherapy, Specialist palliative care, Acute oncology, Radiotherapy.
Website and references
http://www.nationalpeerreview.nhs.uk/ - General website http://www.cquins.nhs.uk/?menu=about-us-ncpr - Procedure http://www.cquins.nhs.uk/?menu=resources - Cancer-specific resources http://www.cquins.nhs.uk/download.php?d=resources/measures/Breast_April2013.pdf - Breast cancer measures http://www.cquins.nhs.uk/download.php?d=NCPR_Handbook_2011.pdf - NCPR Handbook – 2011

ANNEX V. *Individual breast cancer-specific schemes' description (Cont.)*

Programme name
Quality Assurance in National Health Service Breast Screening Programme
Entity
National Health Service National Breast Screening Programme (NHSBSP) (public)
General characteristics
Each NHS region has a quality assurance director for breast screening and a quality assurance reference centre with a regional quality assurance team. The quality assurance reference centres collect and collate data about the performance and outcomes of the breast screening programme and conduct regular quality assurance visits to breast screening units. The guidelines on quality assurance visits were published in 2000 and are linked with subsets of specific standards, for professional profiles and for technology, which are updated on a continuous basis (*e.g.* standards for breast nurses updated in 2012, for surgeons in 2009, etc.).
Countries
80 NHS breast cancer screening units in UK
Stages
Screening, Diagnosis, Surgery
Levels
-
Procedure for accreditation/certification
The site visit process should be repeated every 3 years (round duration). General information about the unit is sent to the coordinating centre at least 1 month before, plus an 'information pack' 2 weeks before. The visit lasts 1 day with a specific audit for each professional profile and includes the following steps: tour of the unit (optional), review of cases (optional), profession-specific sessions, final discussion with external stakeholders (trust, health authority). A final structured report with global recommendations is sent to the unit, to superior levels and external stakeholders. The regional quality assurance director is responsible for monitoring the actions taken after the visit, with specific recommendations for each professional figure. The visiting team is led by the regional quality assurance director or his/her nominee and members of the team should at least include the following profiles: radiologist, radiographer, pathologist, surgeon, breast cancer nurse, administrative and clerical staff, medical physicist. It also may include: health promotion programme manager, public health specialist.
Development of requirements
Defined by national coordinating committees with representatives of regional quality assurance groups and relevant professional organisations. Consultation with scientific societies.
Structure and characteristics of requirements
Hundreds of requirements with different structure classified for professional profile: Radiologist; Radiographer; Pathologist; Surgeon; Breast nurse; Administrative and clerical staff; Medical physicist; Programme Manager.
Website and references
http://www.cancerscreening.nhs.uk/breastscreen/quality-assurance.html - General webpage http://www.cancerscreening.nhs.uk/breastscreen/quality-assurance.html - Guidelines on quality assurance visits http://www.cancerscreening.nhs.uk/breastscreen/publications/monitoring-nhsbsp-standards-v3.pdf - Guide for quality assurance reference centres http://www.cancerscreening.nhs.uk/breastscreen/publications/nhsbsp60v2.pdf - Guidance on standards http://www.cancerscreening.nhs.uk/breastscreen/publications/nhsbsp-47-qa-13.pdf - Quality assurance guidelines for administrative and clerical staff http://www.cancerscreening.nhs.uk/breastscreen/publications/nhsbsp59.pdf - Quality assurance guidelines for breast cancer screening radiologists http://www.cancerscreening.nhs.uk/breastscreen/publications/nhsbsp63.pdf - Quality assurance guidance for mammography including radiographic quality control http://www.cancerscreening.nhs.uk/breastscreen/publications/nhsbsp02.pdf - Quality assurance guidelines for breast pathology services http://www.cancerscreening.nhs.uk/breastscreen/publications/nhsbsp20.pdf - Quality assurance guidelines for surgeons in breast cancer screening http://www.cancerscreening.nhs.uk/breastscreen/publications/nhsbsp29.pdf - Interim Quality Assurance Guidelines for Clinical Nurse Specialists in Breast Cancer Screening, 5th edition http://www.cancerscreening.nhs.uk/breastscreen/publications/nhsbsp33.pdf - Quality assurance guidelines for medical physics services http://www.cancerscreening.nhs.uk/breastscreen/publications/mammography-equipment.html - Mammography equipment requirements - control

ANNEX V. *Individual breast cancer-specific schemes' description (Cont.)*

Programme name
National protocol of accreditation of breast cancer units *Protocolo nacional de acreditacion de las unidades de mama*
Entity
Senology and Breast Pathology Spanish Society (*Sociedad Española de senologia y patologia mamaria* - SESPM) (private)
General characteristics
First Spanish accreditation standards for breast cancer care were published in 1997 by the SESPM; they were updated in 2010. In Spain other quality assurance programmes for breast cancer care have been organised by the Ministry of Health, and the Andalusian Health Quality Agency, but information is not retrievable on the web. The programme is on a voluntary basis.
Countries
24 centre in ES
Stages
Diagnosis, Treatment, Follow-up, Rehabilitation, Training, Research
Levels
-
Procedure for accreditation/certification
Accreditation lasts 5 years (+5 further years), but every year the accredited unit has to send a quality report to the accreditation board, that can withdraw the accreditation. After the request of accreditation, a questionnaire is filled in by the centre and documents are reviewed by a three people multidisciplinary accreditation board (selected among a list of 4 auditors). The site visit is conducted by two or three members of the board and includes: evaluation of documents sent, meeting with the unit, review of individual records, multidisciplinary meeting observation, visit to environment and facilities, feedback to the unit. If 100% of requirements are satisfied the unit is accredited; if 90% of requirements are satisfied, the unit has 12 months to meet the standards; if less than 90% of requirements are satisfied the unit is not accredited and a report with improvement suggestions is sent by the auditors.
Development of requirements
Development process as a consensus process within the SESPM. In some cases it is a revision of Eusoma criteria, with the exception of some (*e.g.* the minimum number of cases).
Structure and characteristics of requirements
There is a list of 10 general quality criteria: Length of activity; Multidisciplinarity; Continuous staff education; Clinical guidelines; Type of services provided; Patient supporting services; Database; Information to patients; Activity recording; SESPM membership. There are further documents explaining the quality criteria, plus a questionnaire and a list of indicators.
Website and references
http://www.sespm.es/unidades - General website (Spanish website) http://www.sespm.es/unidades/solicitar - Requirements (Spanish website) http://www.sespm.es/unidades/unidades - Accredited centres (Spanish website)

ANNEX V. *Individual breast cancer-specific schemes' description (Cont.)*

Programme name
International accreditation program for breast centers/units
Entity
Senologic International Society / International School of Senology (SIS/ISS) (private)
General characteristics
It is a voluntary programme, offered to breast centers with medical teams integrated by colleagues who are members of affiliated societies of the SIS. Goals of accreditation through this system are: universality (accessibility to women regardless of the geographical location of their home) and uniformity (quality indicators equal for all breast centres).
Countries
4 centers awarded in Europe (FR, LT, PL)
Stages
Screening, Diagnosis, Treatment, Follow-up, Palliative Care, Training, Research
Levels
-
Procedure for accreditation/certification
The accreditation lasts 5 years, renewable every 5 years. In order to ask for the certification, the centre has to complete an application form that is reviewed by the Accreditation Committee, that consists of two/three members of the SIS appointed by the Director of the SIS/ISS. The Committee has 40 days to study all the documentation. The site visit agenda includes: verification of the information provided in the application form; meeting of the members of the Accreditation Committee with the coordinator of the centre and specialists responsible for the diagnosis and treatment processes and quality indicators (at least one representative for each speciality); multidisciplinary meeting observation; review of clinical histories; visit to all the facilities; final meeting with the breast centre members. The Accreditation Committee has a period of 30 days to prepare a report on the status of accreditation of the centre. When the centre meets all the requirements, the Accreditation Committee issues a favourable report and the SIS grants an 'accredited centre certification'. In case the centre meets 90% of the quality standards a two stage accreditation is foreseen, with the request to fulfil all the requirements in 12 months. In case the centre meets less than 90% of the quality standards a three stage accreditation is foreseen, with the request to fulfil all the requirements in 24 months. An annual report (that includes results of the quality indicators and other updates on training, research and major changes) must be sent to the Coordinator of the Accreditation Committee.
Development of requirements
Information not retrieved.
Structure and characteristics of requirements
Requirements are not expressed in a unique way. They are classified in 7 chapters: Goals of accreditation; Breast center components; Breast center specialist members; Services provided by the breast centers; Pathology – Quality Assurance/ Quality Control; Radiology – Guidelines for quality assurance in breast cancer screening and diagnosis; Surgery. Plus 23 indicators.
Website and references
http://www.sisbreast.org/accreditation/ibca/ – General website http://www.sisbreast.org/wp-content/uploads/2014/10/SIS-SCHOOL-BREAST-CENTERS-ACCREDITATION-PROGRAM-1.pdf – Requirements and procedure

ANNEX V. *Individual breast cancer-specific schemes' description (Cont.)*

Programme name
Breast Centres Certification *Certification de centres du sein*
Entity
Ligue Suisse contre le *cancer* / Société Suisse de *Senologie* (SSS) (private)
General characteristics
It is a voluntary scheme developed in 2011 by the *Société Suisse de Senologie* with the *Ligue Suisse contre le cancer* for the certification of breast cancer centres in CH. It is inspired by the Eusoma requirements. An updated version of the requirements was published in October 2014.
Countries
15 centres certified in CH
Stages
Screening, Diagnosis, Treatment, Follow-up, Rehabilitation, Training, Research
Levels
-
Procedure for accreditation/certification
The certification lasts 4 years. In order to ask for the certification, the centre has to submit a quality dashboard and a questionnaire on structural requirements to a decision board. Then there is a 1-day site visit that is conducted by three auditors (at least one surgeon or medical oncologist) nominated from a list held by the scientific secretariat office. Each requirement is scored (satisfied, partially satisfied, not satisfied) and then a report is sent to the breast centre. If each compulsory requirement is fully satisfied, the centre is certified. If not, an improvement plan is sent to the commission with a fixed term to get compliance. In case of exceptional circumstances the certification can be withdrawn. The certified centres have to regularly fill in the Quality Dashboard and self-evaluate against the criteria.
Development of requirements
Developed by consensus by a multidisciplinary working group on the basis of Eusoma requirements.
Structure and characteristics of requirements
98 requirements (plus a quality dashboard with indicators) classified in: General requirements; Personnel; Equipment; Process; Know-how; Data; Training; Research. Fifty-nine requirements are considered to be compulsory and are classified as: Responsibilities; Multidisciplinary care; Optimisation of diagnosis, treatment and follow-up; Patient information; Patient rights; Palliative care; Follow-up; Indicators; Training and research. The 98 criteria are expressed in a narrative way, the 57 criteria are expressed as single statements.
Website and references
http://www.legacancro.ch/fr/acces_reserve_aux_specialistes/label_de_qualite_centres_de_senologie/label_de_qualite_centres/ – General website (French website) https://assets.krebsliga.ch/downloads/sgs_kriterien_final_f.pdf – Criteria and literature references (French website) http://assets.krebsliga.ch/downloads/reglement_f.pdf – Certification procedure (French website) http://assets.krebsliga.ch/downloads/qualitatskriterien_f.pdf – Quality requirements (French website) http://assets.krebsliga.ch/downloads/leitfaden_zur_audit_vorbereitung_f.pdf – Audit vademecum (French website) http://www.legacancro.ch/fr/acces_reserve_aux_specialistes/label_de_qualite_centres_de_senologie/centres_certifies/ – List of certified centres (French website) http://www.legacancro.ch/fr/acces_reserve_aux_specialistes/label_de_qualite_centres_de_senologie/label_de_qualite_actuel.cfm – Assessors training (French website)

European Commission
EUR 27413 EN – Joint Research Centre – Institute for Health and Consumer Protection

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Author(s): Silvia Deandrea, Donata Lerda, Jesús López-Alcalde, Luciana Neamtiu, Zuleika Saz-Parkinson, Aslı Ulutürk

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Abstract

Background. The Joint Research Centre, the European Commission's in-house science service, was assigned with the task of developing a voluntary *European Quality Assurance scheme for breast cancer services* (the *European QA scheme*) based on the *European legal framework on accreditation*. This task, among others, are part of the European Commission Initiative on Breast Cancer (ECIBC).
Methods. A search of external quality assessment schemes for breast cancer care already in place in Europe was carried out using different strategies in: MEDLINE, website of relevant scientific societies, and EC Reports. Only schemes fully implemented, with evidence of current activity, with at least one centre in Europe currently holding the certificate awarded by that organisation and foreseeing a third-party audit / on-site survey were considered.
Results. Seventeen schemes specifically addressing breast cancer were identified in Europe and thirteen countries have at least one scheme in place. For eight schemes the requirements and procedures were available in a language known to the JRC Healthcare Quality Team and were thus included in this research. The number of breast cancer services implementing such schemes goes from three to 277 with a median of 23. In some countries, more than one scheme is present, with a maximum of 4 schemes present in one country. Six schemes are managed by private entities and two by public organisations. All the schemes covered more than one stage of breast cancer care, with requirements for diagnosis included in all the schemes. Requirements are highly variable, as in the format, wording and organisation of these. However, they always included requirements related to the clinical management of breast cancer (or breast cancer diagnosis), as well as a list of organisational requirements and quality indicators. For all the schemes the awarding process includes a preparation phase, a site visit and a follow-up. The duration of the award is usually 3 or 5 years.
Conclusion. This research provides a collection of relevant features for the definition of the *European QA scheme*, both from a requirement definition point of view as well as for the organisation of the on-site visit and its follow-up. A European-wide scheme could help harmonise the situation in Europe and ensure that European citizens receive the same quality of care, at least for the essential aspects, regardless of where they live.

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