



European
Commission

J R C T E C H N I C A L R E P O R T S

Report of a European Survey
on the **Implementation**
of **Breast Units**

*ECIBC–supporting information
for breast cancer care policies and initiatives*

Zuleika Saz Parkinson, Anke Bramesfeld,
Silvia Deandrea, Jesús López-Alcalde,
Luciana Neamțiu, Liisa Pylkkänen,
Aslı Ulutürk, Donata Lerda

2017



This publication is a Technical report by the Joint Research Centre (JRC), the European Commission's science and knowledge service. It aims to provide evidence-based scientific support to the European policymaking process. The scientific output expressed does not imply a policy position of the European Commission. Neither the European Commission nor any person acting on behalf of the Commission is responsible for the use that might be made of this publication.

Contact information

Name: Donata Lerda
Address: Joint Research Centre, Directorate F – Health, Consumers and Reference Materials, Unit F.1 – Health in Society
Via Enrico Fermi 2749, TP 127, 21027 Ispra (VA), Italy
E-mail: jrc-cancer-policy-support@ec.europa.eu
Tel.: +39 0332 78 6201
Fax: +39 0332 78 9059

Web Site

<http://ecibc.jrc.ec.europa.eu>

JRC Science Hub

<https://ec.europa.eu/jrc/>

JRC106816

EUR 28621 EN

PDF	ISBN 978-92-79-69024-2	ISSN 1831-9424	doi:10.2760/070213	KJ-NA-28621-EN-N
Print	ISBN 978-92-79-69023-5	ISSN 1018-5593	doi:10.2760/897944	KJ-NA-28621-EN-C

Luxembourg: Publications Office of the European Union, 2017

© European Union, 2017

The reuse of the document is authorised, provided the source is acknowledged and the original meaning or message of the texts are not distorted. The European Commission shall not be held liable for any consequences stemming from the reuse.

How to cite: Zuleika Saz Parkinson, Anke Bramesfeld, Silvia Deandrea, Jesús López-Alcalde, Luciana Neamțiu, Liisa Pylkänen, Asli Ulutürk, Donata Lerda; Report of a European Survey on the Implementation of Breast Units; EUR 28621 EN; doi:10.2760/070213.

All images © European Union, 2017, except: cover image © tashatuvango.



Report of a European Survey
on the **Implementation**
of **Breast Units**

*ECIBC – supporting information
for breast cancer care policies and initiatives*

Zuleika Saz Parkinson, Anke Bramesfeld,
Silvia Deandrea, Jesús López-Alcalde,
Luciana Neamțiu, Liisa Pylkkänen,
Aslı Ulutürk, Donata Lerda

2017

Affiliations of the authors

Zuleika Saz Parkinson,^a Anke Bramesfeld,^a Silvia Deandrea,^a Jesús López-Alcalde,^b
Luciana Neamțiu,^b Liisa Pylkkänen,^a Aslı Ulutürk,^a Donata Lerda.^a

^a European Commission, Directorate-General Joint Research Centre,
Directorate F–Health, Consumers and Reference Materials,
Unit F.1–Health in Society, Ispra, Italy.

^b Former JRC GH30.

Table of contents

<i>Affiliations of the authors</i>	2
Foreword	5
<i>List of acronyms and abbreviations</i>	7
EXECUTIVE SUMMARY	9
1. Introduction	11
1.1. Background	11
1.2. The European Commission Initiative on Breast Cancer (ECIBC)	11
2. Scope of the survey	13
3. Survey organisation	16
Methods	16
Technical aspects	18
Data analysis	18
Timeframe	20
Participants	20
4. Survey results	24
General overview	24
<i>Section 1: Contact details and geographical responsibility</i>	25
<i>Section 2: Organisation of healthcare</i>	27
<i>Section 3: General questions on breast units</i>	27
<i>Section 4: Implementation stage of mandatory requirements for breast units</i>	29
<i>Section 5: Implementation stage of other requirements for breast units</i>	45

5. Overview and discussion	57
6. Conclusions	65
Acknowledgments	69
Bibliography	70
<i>Annex Ia</i> ECIBC National Contact questionnaire	71
<i>Annex Ib</i> ED National Representative questionnaire	117
<i>Annex II</i> Communications	157
<i>Annex III</i> Detailed replies from ECIBC National Contacts and ED National Representatives	177

Foreword

The authors describe the state of implementation of the Breast Units as defined in 2006 in the European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis. They provide updated information on how the requirements for those units have been followed in Member States and other European Countries.

Even though the 2006 breast units model is widely recognised as a valid and innovative instrument to address breast cancer care, the figures provided by the survey also show that its implementation remains a challenge, and different approaches have been followed. Of the numerous requirements defined in 2006 for breast units, some countries did not implement those which were mandatory, whilst others were prioritised. Implementation of 2006 breast units' requirements was often voluntary and in very few cases by law.

Analysis of survey results on how the 2006 breast unit model was implemented vis-à-vis the approach proposed by the ongoing European Commission Initiative on Breast Cancer (ECIBC) and by other EU initiatives, *e.g.* the joint actions EPAAC and CanCon, highlights the importance of using an evidence-basis and deep knowledge about countries' healthcare models and cancer plans when proposing requirements. This approach, besides making the EU added value evident, can provide Member States—and other concerned countries—and stakeholders with real-life examples, which can be of mutual interest. The report provides a useful input to ascertain the state of play on an important aspect of cancer prevention and control policies, allowing comparisons and providing basis for improvement across Europe. Moreover, it gives a vision for the implementation of the future *European QA scheme*.

John F. Ryan

Director

European Commission, DG Health and Food Safety, Directorate C—Public Health

List of Acronyms and Abbreviations

European Guidelines	European guidelines for quality assurance in breast Cancer screening and diagnosis, 4 th edition (2006)
BU	Breast Unit
CME	Continued Medical Education
DG SANTE	Directorate General for Health and Food Safety (EC)
EC	European Commission
ECIBC	European Commission Initiative on Breast Cancer
ED	Europa Donna
EPAAC	European Partnership for Action Against Cancer
European QA scheme	European Quality Assurance scheme for Breast Cancer Services (<i>currently under development as one of the objectives of the ECIBC</i>)
European Breast Guidelines	European guidelines on breast cancer screening and diagnosis (<i>currently under development as one of the objectives of the ECIBC</i>)
JRC	Joint Research Centre (EC)

EXECUTIVE SUMMARY

The 4th edition of the *European guidelines for quality assurance in breast cancer screening and diagnosis* [1][6], issued in 2006, included a chapter providing indications for a model centralising breast cancer care in the so-called breast units and requirements for those units. Ten years after issuing that model and following-up the European Parliament (EP) resolution of 2006 on breast cancer in the enlarged European Union¹ (which called on Member States to ensure nationwide provision of interdisciplinary breast units by 2016 and on the Commission to deliver a progress report on this every two years), the survey described in this report was envisaged to provide up-to-date information on how and where these requirements have been implemented across Europe.

The aim of the report is to factually describe the implementation status of each requirement across Europe based on the results of the survey. No appraisal regarding the level or quality of care provided in each country is implied. The obtained results will also be used to inform the development and implementation of the voluntary European Quality Assurance scheme for Breast Cancer Services (the *European QA scheme*), one of the main pillars of the ECIBC.²

In order to capture the healthcare provider perspective and the patient perspective, the survey was conducted in parallel with two different groups of stakeholders:

1. ECIBC National Contacts, nominated via Members States' Health Attachés, to ensure that the EC receives official information to support the ECIBC, and
2. ED National Representatives to take into account patient advocates' feedback on the status of breast units in their respective countries.

Overall, 30 of 34 countries contacted responded to the survey. The main findings include:

1. <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%03A52006IPo449>.
2. <http://ecibc.jrc.ec.europa.eu>.

- breast units are only required by law in a few countries, though they are recommended in 17 out of the 30 countries that responded to the survey;
- even if the 2006 breast unit model proved to be innovative and well known both by professionals and patients' advocates, this report shows that the implementation of the model is not harmonised across all countries; in particular, a great diversity in the number and selection choices among the 25 requirements to be implemented was observed;
- of the 25 requirements listed in the 2006 European Guidelines, four were considered to be mandatory, although the implementation of these particular requirements was reported as compulsory in only two countries (IT and CZ). Of these four mandatory requirements, the volume requirement was implemented less frequently than the other three;
- among the remaining 21 requirements, those most implemented, in a compulsory manner, across Europe were the provision of adjuvant therapy, the provision of imaging equipment, the multidisciplinary case management meetings and provision of radiotherapy;
- regarding the two sets of responses (from ECIBC National Contacts and ED National Representatives), discrepancies were found in replies related to some key requirements—showing that there is room for improvement in the dissemination of breast cancer policies;
- differences in awareness about requirements implementation were observed between the two groups of respondents; this is of particular concern for countries where the replies of the ECIBC National Contact indicated that a requirement was compulsory, and the ED National Representative indicated the same requirement as not being in place.

A Europe-wide scheme, like the one being developed by the ECIBC, could take into account the 2006 breast unit model, as well as other existing schemes and sources, to develop its requirements. The *European QA scheme* is being developed in a harmonised, evidence-based and flexible way to grant equal and quality-benchmarked treatment to patients. In this respect, particular attention is devoted to substantiating, whenever possible and appropriate, proposed requirements with evidence; this ensures that any potential impact of quality requirements on outcomes is credible, reliable and valid.

1. Introduction

1.1. Background

Since 1987, the EC has supported cancer policies. In that same year, the ‘Europe Against Cancer’ Programme was launched and was instrumental in funding the actions to develop the series of *European guidelines for quality assurance in breast cancer screening and diagnosis* (European Guidelines).

Under the coordination of the EC, four editions of guidelines for breast cancer screening and diagnosis have been issued to support the implementation of screening programmes as indicated by the 2003 European Council recommendation [5].³ The 4th edition of the European Guidelines [1], issued in 2006, also included a chapter that provided indications for a model centralising breast cancer care in so-called breast units. The survey described in this report was envisaged to provide updated information on the implementation of breast units as defined in the 2006 (4th) edition of the European Guidelines.

1.2. The European Commission Initiative on Breast Cancer (ECIBC)

The ECIBC is a person-centred sustainable initiative aiming to improve and harmonise breast cancer care in Europe. The ECIBC is coordinated by the JRC under the auspices of DG SANTE. As the EC’s in-house science service, the JRC provides an inclusive and transparent platform for engaging all stakeholders while remaining independent of any national, commercial, and private interests. Within the JRC, the Healthcare Quality Team is dedicated to the fulfilment of the initiative.

Why the ECIBC?

Breast cancer is the most common type of cancer in Europe – accounting for approximately one in six cancer-related deaths. However, breast cancer incidence

3. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:327:0034:0038:EN:PDF>.

and mortality rates vary greatly between countries. This variation reflects large inequalities, which are also attributable to diversity in quality of care. Consequently, there is considerable potential to reduce the burden of breast cancer and inequalities in outcomes at European level.

Member States acknowledged the need for coordinated action against the burden of cancer through the Council conclusions of 2008;⁴ and in 2012 the EC launched the ECIBC. The ECIBC aims to ensure that all breast cancer care processes are appropriate, high quality (as defined by evidence) and accessible to all citizens. The ECIBC will work towards achieving this goal in collaboration with experts and the support of patients, including ECIBC working groups,⁵ ECIBC National Contacts,⁶ and other stakeholders.⁷

The primary **objectives** of the ECIBC are to establish:

1. a voluntary **European Quality Assurance scheme** for Breast Cancer Services (the *European QA scheme*) addressing all care processes, including screening, diagnosis, treatment, rehabilitation, survivorship care, and palliative care;⁸
2. evidence-based recommendations supporting the *European QA scheme*, including:
 - a. the **European guidelines for breast cancer screening and diagnosis** (the *European Breast Guidelines*);
 - b. the **ECIBC Guidelines Platform**⁹ covering all care processes;
3. a European **training template** for radiographers and radiologists on digital breast screening;
4. a web interface (the ECIBC web hub¹⁰) of **complete and updated information** and host to all ECIBC and ECIBC-related documents and materials, including the ECIBC concept, objectives and life-cycle processes, the first four recommendations on breast cancer screening, as well as a list of breast cancer services adhering to the *European QA scheme*. Key information, in particular information targeting women and patients, will also be made available in all official EU languages.

4. http://www.eu2008.si/en/News_and_Documents/Council_Conclusions/June/0609_EPSCO-cancer.pdf.

5. <http://ecibc.jrc.ec.europa.eu/working-groups>.

6. <http://ecibc.jrc.ec.europa.eu/national-contacts>.

7. <http://ecibc.jrc.ec.europa.eu/stakeholders>.

8. Embedded in the European accreditation legal framework.

9. See the dedicated chapter in the ECIBC Concept document (<http://ecibc.jrc.ec.europa.eu/documents/20181/22500/ECIBC+Concept+Document.pdf/1940c19e-3935-4a54-9fc5-b66f016c8b9e>) for further details.

10. <http://ecibc.jrc.ec.europa.eu/>.

2 . Scope of the survey

The survey was organised by the JRC in collaboration with the chair and co-chair of the 10th European Breast Cancer Conference (EBCC 10), Fatima Cardoso and Susan Knox, on behalf of ED, to provide an informative tool for breast cancer care policies, to complement the European Breast Units Manifesto launched at that conference,¹¹ and to follow-up the EP resolution of 2006 on breast cancer in the enlarged EU.¹² This resolution called on Member States: ‘to ensure nationwide provision of interdisciplinary breast units in accordance with the EU guidelines by 2016, since treatment in an interdisciplinary breast unit has been proved to raise chances of survival and to improve the quality of life, and calls on the Commission to deliver a progress report on this every two years’.

Member States are responsible for breast cancer services organisation, including planning and implementing Breast Units. The main scope of the survey was to map out in detail the implementation of 2006 breast unit model requirements within the diverse healthcare and breast care organisational models that have been adopted across Europe.

Such detailed mapping would complement other JRC findings¹³ on the status of breast cancer care in Europe and provide:

- a. the basis of information for the development and implementation of the *European QA scheme*, in particular as regards the legal frameworks to be respected by the scheme, and
- b. a resource for stakeholders, and particularly policy makers, for identifying which requirements were implemented more frequently and how.¹⁴

11. Available at [http://www.ejcancer.com/article/S0959-8049\(16\)32527-8/fulltext](http://www.ejcancer.com/article/S0959-8049(16)32527-8/fulltext).

12. <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%03A52006IP0449>.

13. <http://ecibc.jrc.ec.europa.eu/-/report-lbnaz7382>; <http://ecibc.jrc.ec.europa.eu/-/report-lbnaz7382enn>; <http://ecibc.jrc.ec.europa.eu/-/report-lbnaz6591>.

14. More frequently implemented requirements are likely to be considered more feasible and relevant. Consequently, given the diversity of healthcare settings in various countries, an updated definition *e.g.* via the *European QA scheme* may offer better support for patient-centred, quality care.

This mapping took into account:

- a. results from previous JRC surveys and analyses,¹⁵ most notably the survey conducted with support from former EPAAC National Contacts,¹⁶ and
- b. the realisation that, even if the concept of breast units has greatly evolved since 2006, the call of the EP clearly refers to definitions given in the 2006 European Guidelines.

Therefore, given the scope of the survey, the aim of this report is to present participants' responses regarding the implementation of the requirements for breast units (as described in the 2006 European Guidelines and within the context of previous JRC findings) – with the goal of providing supporting information (a) to policy makers regarding breast cancer care and (b) towards the development of the *European QA scheme* and its future implementation.

The resulting map of responses shows the current status of implementation (*i.e.* which requirements have been implemented and where implementation has occurred) and is by no means an appraisal or valuation of a any country's provision of breast cancer care services or quality of care.

The main limitations of the survey are:

- most country responses are based on the opinions and input of a single designated person deemed responsible for providing the health authority's perspective and, as not all ECIBC National Contacts are part of an official health authority, their responses may not be a fully accurate depiction of implementation in their respective countries;
- survey questions are based on definitions found in the 2006 European Guidelines where, on some occasions, more than one concept was addressed in a single question; this may have introduced response bias as the respondent's reply may refer to only part of the question; and

15. <http://ecibc.jrc.ec.europa.eu/-/report-lbna27382>; <http://ecibc.jrc.ec.europa.eu/-/report-lbna27382enn>; <http://ecibc.jrc.ec.europa.eu/-/report-lbna26591>.

16. <http://bookshop.europa.eu/en/report-of-a-european-survey-on-the-organisation-of-breast-cancer-care-services-pbLBN-A26593/>.

- many countries that have implemented the requirements did so not out of compliance with the 2006 European Guidelines but in response to common practices within those countries; therefore, implementation status may not be a true reflection of compliance in countries where implementation occurred before 2006 or as part of a national/regional mandate or recommendation unrelated to the guidelines (see *Annex III, Tables 1-15*).

3. Survey organisation

Methods

The survey was conducted in parallel with two different stakeholder profiles:

- a. ECIBC National Contacts, who were nominated via Members States' Health Attachés to ensure that the EC receives official information from each country in relation to the ECIBC, in particular with respect to the implementation status of the breast unit requirements included in the 2006 European Guidelines, and
- b. ED National Representatives to take into account patient advocates' feedback on the status of 2006 breast unit model in their respective countries.

Two questionnaires were developed for the survey. Each questionnaire offered similar content; however, the amount of detail and the number of mandatory questions differed. The more detailed questionnaire, which also included a greater number of mandatory questions, was sent to the ECIBC National Contacts, while the other, less detailed questionnaire was sent to the ED National Representatives. Survey participants received a single PDF document, which included the questionnaire and a data protection form – covering the consent for publication of the data (*Annexes I a and I b*).

The personal data protection section included a privacy statement and also requested consent for publication, which all participants agreed to. Further requests for consent will be made in the event of data publication in the future.

Each questionnaire was divided into seven sections:

1. Administrative details
 - a. Contact details
 - b. Geographical responsibility
2. Healthcare organisation

- a. Changes that have occurred since 2012-2013
- b. Brief description of healthcare organisation
3. References and definitions
 - Definitions reported in the 2006 European Guidelines
4. General questions on breast units
 - a. Existence of breast units
 - b. Existence required by law or recommended
 - c. National or regional/local accreditation/certification of breast units
 - d. Mandatory or voluntary accreditation/certification systems
5. Implementation stage of mandatory requirements for breast units
 - a. Critical mass
 - b. Core team composition, training and continuing medical education
6. Implementation stage of other requirements for breast units
 - a. Regulation of imaging equipment
 - b. Regulation of radiotherapeutic equipment
 - c. Regulation of new patient clinics
 - d. Regulation of communication of diagnosis and treatment plan
 - e. Regulation of multidisciplinary case management meetings
 - f. Regulation of provision of physiotherapy
 - g. Regulation of provision of adjuvant therapies
 - h. Regulation of management of advanced and recurrent breast cancer
 - i. Regulation of follow-up of primary breast cancer
 - j. Regulation of management of benign disease
 - k. Regulation of management of family history/genetics
 - l. Regulation of breast screening management
 - m. Regulation of patient information
 - n. Regulation concerning extra psychological support
 - o. Regulation of plastic surgery
 - p. Regulation of geneticist's advice
 - q. Regulation of provision of palliative care
 - r. Regulation of provision of prosthesis
 - s. Regulation of provision of physiotherapy and lymphoedema treatment
 - t. Regulation of research management
 - u. Regulation of management of teaching
7. Personal data protection, consent to data publication and form submission.

Technical aspects

Adobe LiveCycle Designer® was used to design, distribute, collect and manage the information. This tool allows the creation of interactive PDF forms with automatic submission (*e.g.* e-mail) and the flexibility of a multiple user interface. Communication occurred via a functional mail-box (jrc-cancer-policy-support@ec.europa.eu) accessible to all JRC Healthcare Quality Team members; thereby, allowing full-time assistance and support to all participants in the survey.

Data analysis

ECIBC National Contacts

30 of the 32 questions regarding breast units were mandatory (denoted by an asterisk on the form and controlled by the software used to ensure a response) and the remaining two questions were optional. However, countries were encouraged to report additional information, whenever possible.

ED National Representatives

None of the breast unit questions were mandatory. In addition, response options in the sections covering *General questions on breast units*, *Implementation stage of mandatory requirements*, and *Implementation stage of other requirements* differed slightly – with ECIBC National Contacts having more options to choose from.

ECIBC National Contacts' response options:

1. YES, MANDATORY
2. YES, VOLUNTARY
3. NO, BUT PLANNED
4. NO and NOT PLANNED
5. I do not know

While the ED National Representatives had the following three options:

1. YES
2. NO
3. I do not have this information

However, when analysing the answers received by the ECIBC National Contacts and ED National Representatives, the JRC has assumed that a ‘YES’ for the ED National Representatives is equivalent to ECIBC National Contact options 1 or 2 (‘YES, MANDATORY’ AND ‘YES, VOLUNTARY’). Therefore, these two categories were combined in order to allow for comparisons. Once all of the data had been received and entered into the database, a manual data cleaning procedure was performed. Missing data and inconsistencies were cross-checked with each respondent.

Countries were coded according to the International Organisation of Standardisation (ISO) 3166 standard (*Table 1*).

Table 1. ISO country codes.

Country Name	ISO Code	Country Name	ISO Code
Austria	AT	Italy	IT
Belgium	BE	Lithuania	LT
Bulgaria	BG	Luxembourg	LU
Switzerland	CH	Latvia	LV
Cyprus	CY	Montenegro	ME
Czech Republic	CZ	Malta	MT
Germany	DE	Netherlands	NL
Estonia	EE	Norway	NO
Spain	ES	Poland	PL
Denmark	DK	Portugal	PT
Finland	FI	Romania	RO
France	FR	Serbia	RS
Greece	GR	Sweden	SE
Croatia	HR	Slovenia	SI
Hungary	HU	Slovakia	SK
Ireland	IE	Turkey	TR
Iceland	IS	United Kingdom	UK

Timeframe

All potential respondents (ECIBC National Contacts, ED National Representatives and possible delegated individuals) were contacted by e-mail via the JRC Cancer Policy Support functional mailbox. The same mailbox was used to correspond with participants for the duration of the survey.

1. On 21 January 2015, participants were informed about the survey and asked to confirm willingness to participate by 13 February 2015.
2. On 27 February 2015, a second email was sent to those countries confirming participation, including additional and more detailed information about the survey content and timeline.
3. The survey was launched on 8 April 2015 and the deadline for completion was 22 May 2015.
4. On 6 and 18 May 2015, participants that had not returned a questionnaire were contacted and offered support to complete it as well as being reminded of the upcoming deadline.
5. After a period of follow-up to ensure the highest possible response, the last questionnaire was received on 13 August 2015.
6. Countries providing inconsistent or incomplete responses were sent requests for clarification or more details on 17 December 2015. The last completed surveys were received on 10 February 2016.
7. All responses were harmonised and edited for language and style.
8. Aggregated results were presented at EBCC 10 on 9 March 2016.
9. On 3 August 2016, participants were asked to provide their final approval for publication of responses by 5 September 2016.
10. On 26 August 2016, participants received a reminder by email, which included a 'silence gives consent' clause to ensure that the final approval process could be terminated by the deadline.

Participants

Table 2 provides the list of 25 participating countries, the ECIBC National Contacts, and the collaborators responsible for completing the questionnaire. *Table 3* includes the list of participating ED National Representatives and their respective countries of representation.

Table 2. List of ECIBC National Contact participants.

Country	Survey Respondent	Collaborator(s)	Affiliation
BE	Saskia VAN DEN BOGAERT		Federal Public Service of Public Health, Brussels
BG	Ivan GAVRILOV		National Hospital of Oncology
CH	Manfred LANGENEGGER		Federal Office of Public Health
CY	Myrto AZINA- CHRONIDES		Ministry of Health, Nicosia
CZ	Petra TESAROVA	Jan DANES	PT: Oncology Department. First Faculty of Medicine, Charles University, Prague JD: Radiology Department. First Faculty of Medicine, Charles University, Prague
DE	Simone WESSELMANN	Vanessa KÄAEB-SANYAL Andrea GILLES	SW: Bereichsleiterin Zertifizierung – Deutsche Krebsgesellschaft e.V., Berlin VKS: Kooperationsgemeinschaft Mammographie GbR; Berlin AG: ÄKzert Ärztekammer Westfalen- Lippe, Münster
FI	Minna TANNER		Tampere University Hospital, Tampere
FR	Emmanuelle SALINES		Department of health, Ministry of health, Paris
GR	Lydia IOANNIDOU-MOUZAKA		Nominated by the Hellenic Ministry of Health & President of the Hellenic Senologic Society, Athens
HU	Lajos DÖBRÖSSY		National Office of Chief Medical Officer, Budapest
IE	Michael CONROY		Department of Health, Dublin
IT	Antonio FEDERICI		Ministry of Health, Roma
LT	Rūta BRIEDIENĖ		National Cancer Institute, Vilnius
LU	Astrid SCHARPANTGEN		Ministère de la Santé, Luxembourg
LV	Alinta HEGMANE		Riga East University Hospital, Oncology Center of Latvia, Riga
MT	Miriam DALMAS	Richard ZAMMIT Patricia GALEA Stefan LASPINA	MD: Office of the Chief Medical Officer, Ministry for Energy and Health, Valletta RZ: DG Healthcare Regulation – Dpt. PH Regulation PG: Director Healthcare Standards – Dpt. PH Regulation SL: Clinical Chair for Haematology & Oncology –Oncology Centre, Mater Dei Hospital

Table 2. (cont.)

Country	Survey Respondent	Collaborator(s)	Affiliation
MT (cont.)		Christopher BARBARA Salvina ZRINZO Joseph DEBONO Gordon CARUANA DINGLI James DEGAETANO Doreen PACE	CB: Clinical Chair for Pathology – Mater Dei Hospital SZ: Clinical Chair for Radiology – Mater Dei Hospital JD: Clinical Chair for Surgery – Mater Dei Hospital GCD: Breast Cancer Surgeon – Mater Dei Hospital JD: Lead Histopathologist – Mater Dei Hospital DP: Lead Palliative Care consultant – Oncology Centre, Mater Dei Hospital
NO	Leif NORDBOTTEN		Norwegian Directorate of Health, Oslo
PL	Elzbieta SENKUS-KONEFKA		Medical University of Gdansk
PT	Nuno MIRANDA		General Directorate of Health, Lisbon
RO	Alexandru ENIU		Institute of Oncology Prof. Dr. Ion Chiricuta – Cluj-Napoca
RS	Verica JOVANOVIC	Radan DZODIC Zorica MILOSEVIC Ana JOVICEVIC Dragan ILIC	Institute for Public Health of the Republic of Serbia
SE	Göran ZETTERSTRÖM		The National Board of Health and Welfare, Stockholm
SI	Simona BORŠTNAR		Institute of Oncology, Ljubljana
SK	Kamil POHLODEK		University Hospital of Bratislava
UK*	Chris HOLCOMBE		Breast Clinical Reference Group, NHS England

*UK data refers to England only.

Table 3. List of ED National Representatives participants.

Country	Survey Respondents
AT	Walter NEUNTEUFEL
CH	Donatella CORBAT
CY	Stella KYRIAKIDES
CZ	Marta KOSTROVÁ
EE	Tiiu-Liis TIGANE
ES	Carmen BORONAT JIMÉNEZ
FR	Martine CASTRO
GR	Elizabeth Kay MEIER
IE	Tara BYRNE
IT	Elisabetta SESTINI
LU	Mariette FISCHBACH
MT	Doris FENECH
NL	Ellen VERSCHUUR-VAN DER VOORT
NO	Inger Margrethe HOLTER
SE	Elizabeth BERGSTEN NORDSTRÖM
SI	Mojca SENČAR
TR	Violet AROYO
UK	Margaret SPITTLE OBE

4. Survey results

The countries that did not respond to the survey are not included in Results tables but are reported in *Annex III*. Detailed participant responses are provided in *Annex III* and completed questionnaire forms are available upon request. Participants' responses were expressed as a percentage and rounded to the nearest whole number.

General overview

The invitation to participate in the survey was sent to the 34 ECIBC National Contacts, 26 confirmed their willingness to participate, and 25 completed the survey (74% response rate). By comparison, 31 ED National Representatives were sent the invitation, 21 confirmed their willingness to participate, and 18 completed the survey (58% response rate). Overall the country coverage of the survey was 88% (in 30 countries out of the 34 contacted at least one respondent provided the requested information). However,

- Twelve countries provided information from both the ECIBC National Contact and the ED National Representative.
- The ECIBC National Contact for the UK provided information for only England, while the ED National Representative responses reflect the situation within the entire UK.

An overview of country level response is reported in *Figure 1*. All participants gave their consent for data publication.

In the following sections, responses for each of the seven parts of the survey are analysed, described and evaluated for their impact on policy decisions. Detailed responses are reported in *Annex III*.

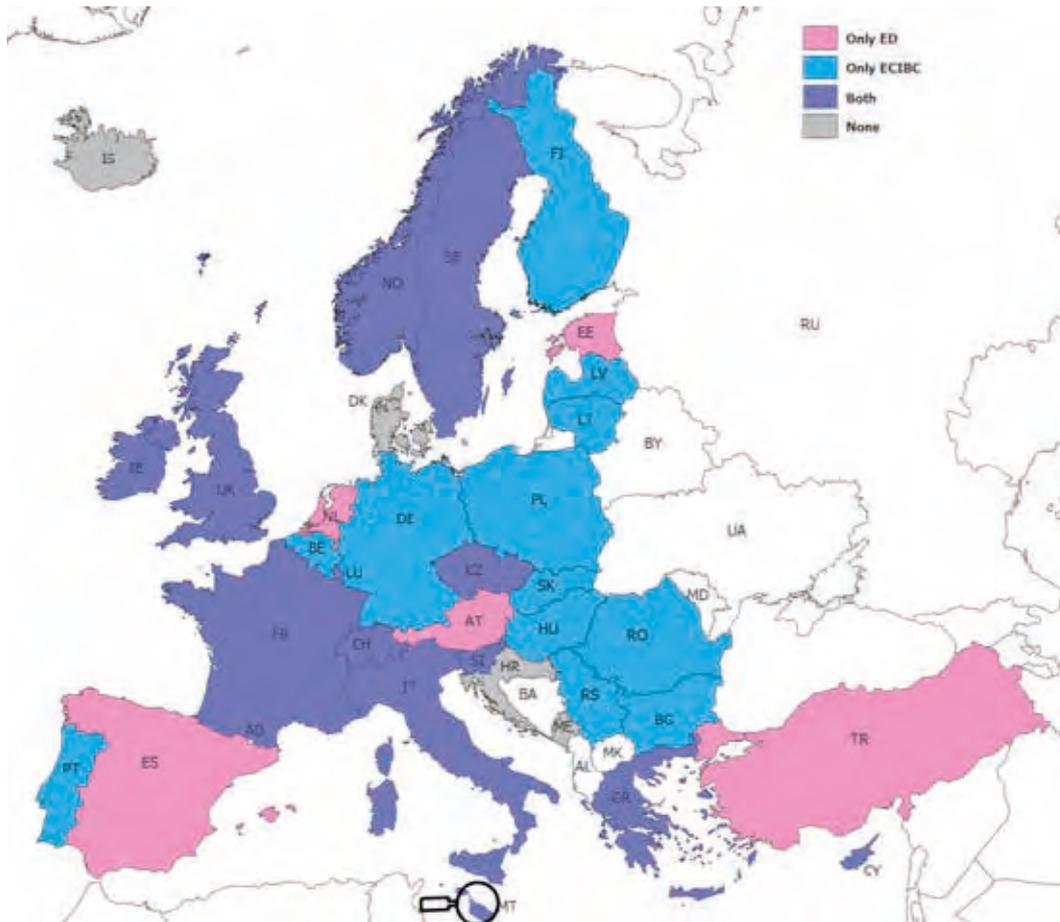


Figure 1a. Country participation map.

The magnified area corresponds to Malta.

Section 1: Contact details and geographical responsibility

As regards the ECIBC National Contacts geographical area of responsibility, 22 out of 25 participants had a national mandate and three had a regional mandate (BG, LT, and FI). 13 (52%) participants were national ministry of health employees, while the remaining 12 participants were affiliated with research centres or hospitals. In all cases, due to the official nature of the nomination, they were responsible for the information provided regarding their own country. In the case of Germany, in addition to the National Contact’s response, they provided a regional perspective as well as a point of view from the national screening programme;

Country invited to participate		ECIBC National Contact	ED National Representative
AT	Austria		YES
BE	Belgium	YES	
BG	Bulgaria	YES	
CH	Switzerland	YES	YES
CY	Cyprus	YES	YES
CZ	Czech Republic	YES	YES
DE	Germany (only ECIBC)	YES	
DK	Denmark		
EE	Estonia		YES
ES	Spain		YES
FI	Finland	YES	
FR	France	YES	YES
GR	Greece	YES	YES
HU	Hungary	YES	
HR	Croatia		
IE	Ireland	YES	YES
IS	Iceland		
IT	Italy	YES	YES
LT	Lithuania	YES	
LU	Luxembourg	YES	YES
LV	Latvia	YES	
ME	Montenegro (only ECIBC)		
MT	Malta	YES	YES
NL	Netherlands		YES
NO	Norway	YES	YES
PL	Poland	YES	
PT	Portugal	YES	
RO	Romania	YES	
RS	Serbia (only ECIBC)	YES	
SE	Sweden	YES	YES
SI	Slovenia	YES	YES
SK	Slovakia	YES	

Figure 1b. Country participation table. White cells correspond to participants that did not provide a response.

Country invited to participate		ECIBC National Contact	ED National Representative
TR	Turkey		YES
UK*	United Kingdom	YES	YES

*UK data refers to England only.

White cells correspond to participants that did not provide a response.

Figure 1b. (cont.)

however, with respect to the implementation status of the 2006 breast unit requirements, only responses provided by the ECIBC National Contact were considered.

In addition to the ECIBC National Contacts, 15 collaborators were involved in the completion of the questionnaire (*Table 2*).

Section 2: Organisation of healthcare

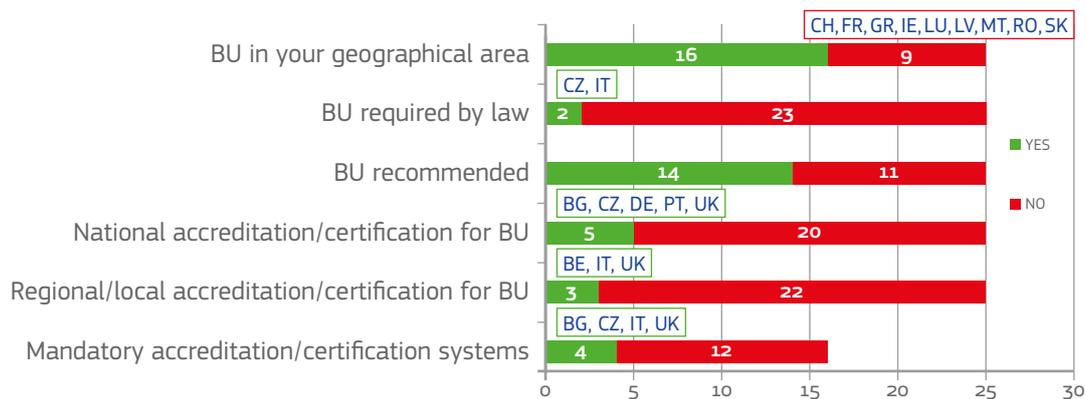
Information on healthcare organisation was previously obtained in a JRC survey conducted with National Contacts regarding the organisation of breast cancer care services and is presented elsewhere.¹⁷ Responses to the present survey were received from an additional five countries (CH, GR, PL, PT, and RS); however, five countries that participated in the 2012 survey (AT, EE, ES, HR, and NL) did not provide input from an ECIBC National Contact in the current survey. Meanwhile, HU, SE, and UK noted that they had undergone changes in the geographical organisation/responsibility allocation of healthcare since the last survey.

Section 3: General questions on breast units

With regard to the general questions on breast units, ECIBC National Contacts' responses are shown in *Figure 2*, while *Figure 3* presents the responses for ED National Representatives.

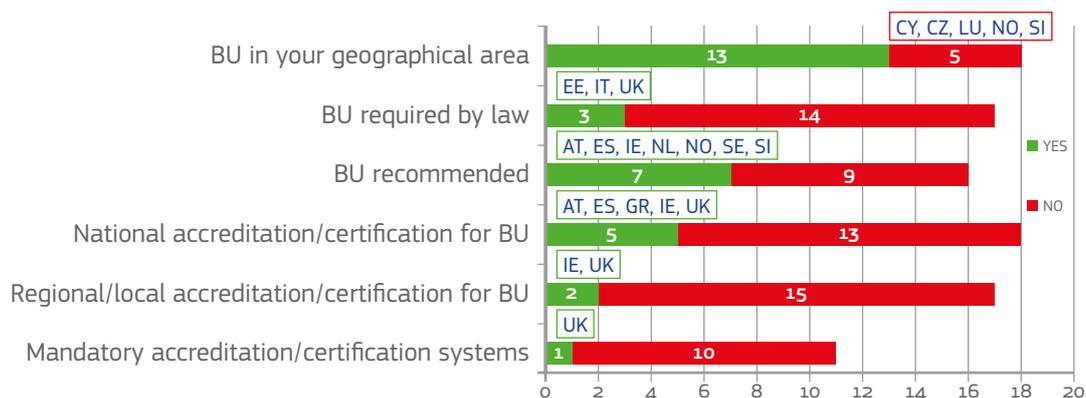
The majority of countries reported having breast units in their geographical area; however, only two countries (CZ and IT) required them by law. Accreditation or certification systems for these breast units were reported as compulsory in a few

17. <http://ecibc.jrc.ec.europa.eu/documents/20181/22500/Report+LBNA26593.pdf/cf44edb3-657c-4755-b62a-6442d06f2d30>.



Countries listed in boxes are those identified as having (green bordered box) or not having (red bordered box) BUs and a mandatory accreditation/certification scheme.

Figure 2. ECIBC National Contact responses to general breast unit questions.



Countries listed in boxes are those identified as having (green bordered box) or not having (red bordered box) BUs and a mandatory accreditation/certification scheme.

Figure 3. ED National Representative responses to general breast unit questions.

countries and as voluntary in some others; this was reported at national and regional level throughout Europe (see Figures 2 and 3). With respect to these results, the 2012 survey asked ECIBC National Contacts about the status of accreditation and certification schemes (in development or implemented) for breast cancer ser-

vices (those results are presented elsewhere for comparison).¹⁸ However, it should be noted that any inconsistencies between the results of the two surveys may be due to the fact that the 2012 survey covered breast cancer services, while the current survey focussed on the specific types of breast cancer services which are defined by the 2006 breast unit model.

Section 4: Implementation stage of mandatory requirements for breast units

The mandatory requirements defined in the 2006 European Guidelines, include:

- A definition of the volume (critical mass) of cases necessary in order to set up breast units: ‘A Unit must be of sufficient size to have more than 150, newly diagnosed cases of primary breast cancer (at all ages and stages) coming under its care each year’.
- A definition of the composition of the core team working in the breast unit which should have ‘special training in breast cancer’; it includes a Clinical Director of Breast services, breast surgeons, breast radiologists, breast pathologists, breast oncologists, breast diagnostic radiographers, data managers, and patient support staff (such as breast care nurses). This core team was expected to also have a minimum experience (minimum surgeries performed, mammograms read per year, etc.).
- Each member of the core team must have special training in breast cancer, and
- each member of the breast unit core team must undertake continuing professional education (CME) on a regular basis.

Figure 4 shows the implementation status of these four mandatory requirements according to ECIBC National Contacts.

The responses from ED representatives are shown in *Figure 5*.

For each of the four mandatory requirements, detailed descriptions and maps are provided in the following sections.

18. <http://bookshop.europa.eu/en/report-of-a-european-survey-on-the-organisation-of-breast-cancer-care-services-pbLB-NA26593/>.

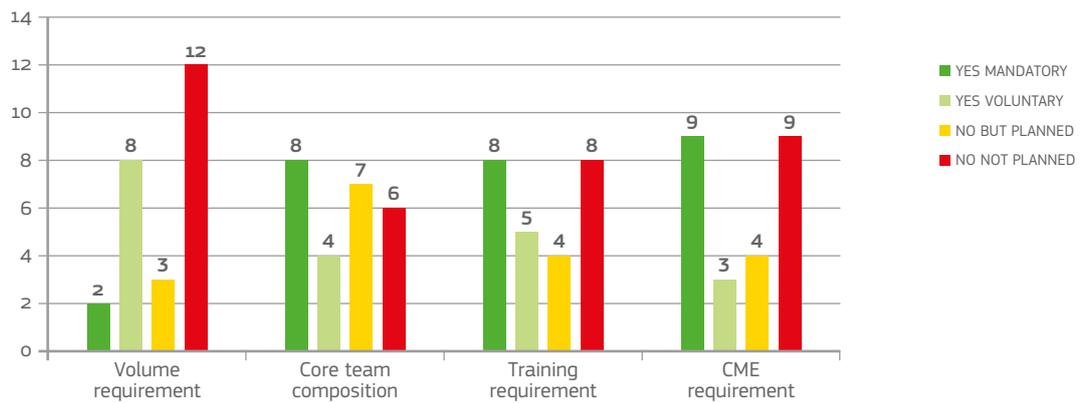


Figure 4. Implementation of mandatory requirements according to ECIBC National Contacts.

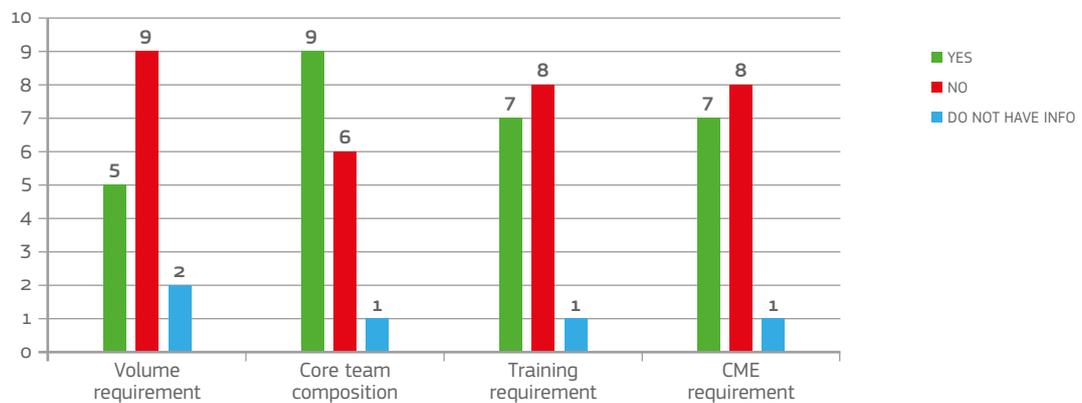


Figure 5. Implementation of mandatory requirements according to ED National Representatives.

Volume requirement (150 newly diagnosed cases/year)

ECIBC National Contacts

Only CZ and IT reported this requirement as compulsory by law since 2010 and 2014, respectively. In CZ, this requirement has also been in use since 2002 at national and regional level as the basis for level of insurance reimbursement for breast care interventions, and as an institutional licencing requirement since 2003. This requirement has also been part of a non-public quality assurance scheme

ED National Representatives

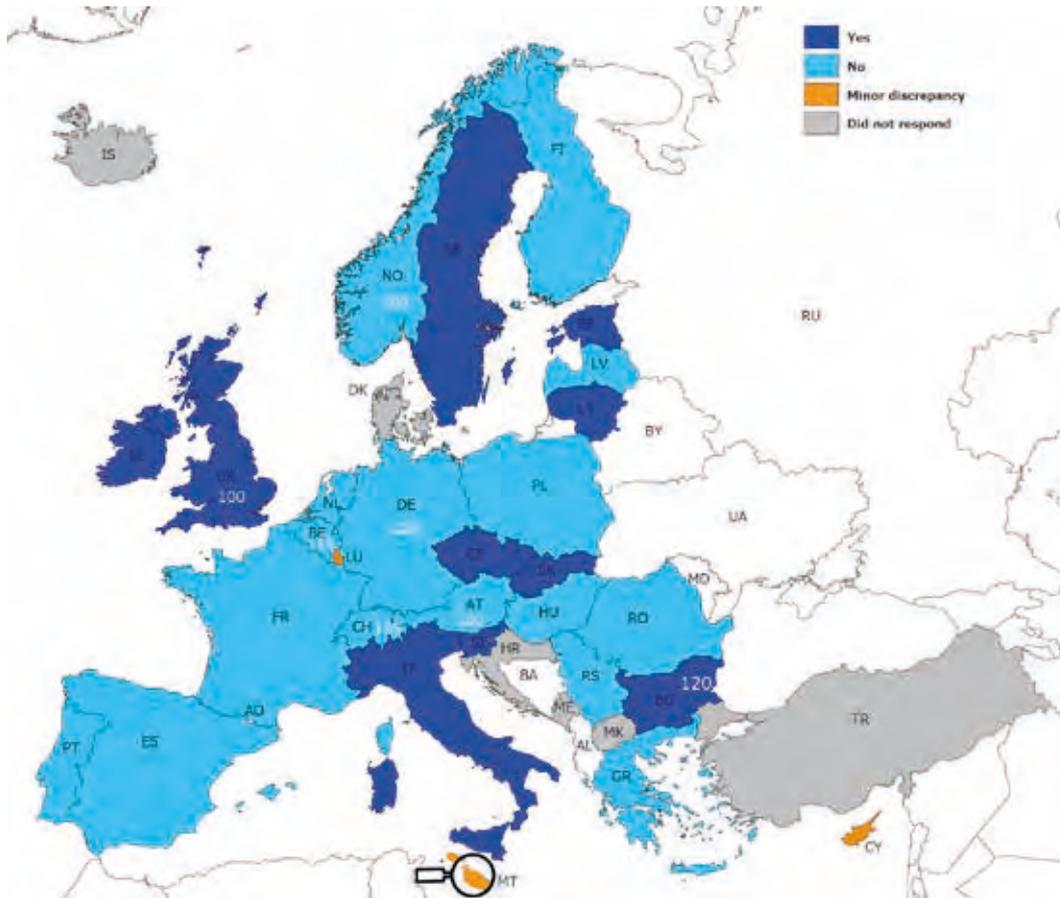
Representatives from EE, IE, IT, MT, and SI reported the volume requirement was set at 150 new cases/year. No other information was provided.

A detailed overview of how the volume requirement has been implemented/not implemented and the use of other thresholds (*e.g.* 125 in BE and CH, 100 in AT, DE and NO) is provided in *Annex III*.

The map in *Figure 7* summarises the responses of ECIBC National Contacts and ED National Representatives regarding the implementation of a volume requirement (thresholds differing from 150 are reported on the map). Minor discrepancies (*i.e.* the ECIBC National Contact reported that the requirement was voluntary and the ED National Representative replied that the requirement was not in place, or the ECIBC National Contact replied that implementation was planned and ED National Representative stated that the requirement was already in place) between respondents from same country were also highlighted.

Despite whether countries have implemented the volume requirement or not, *Figure 8* shows that the majority of breast cancers in Europe are treated in centres whose volume is greater than 150 new cases/year. It should be noted that the 150 new cases/year minimum volume requirement was implemented in IT by law in 2014. Therefore, it would be interesting to see if in the future this leads to changes in the number of breast cancer cases treated per centre.²⁰ Detailed responses from all respondents are reported in *Annex III*.

20. At the time of this survey, IT stated that although 'centres whose volume is higher than 150 new cases/year exist, most cases are treated in low-volume centres'.



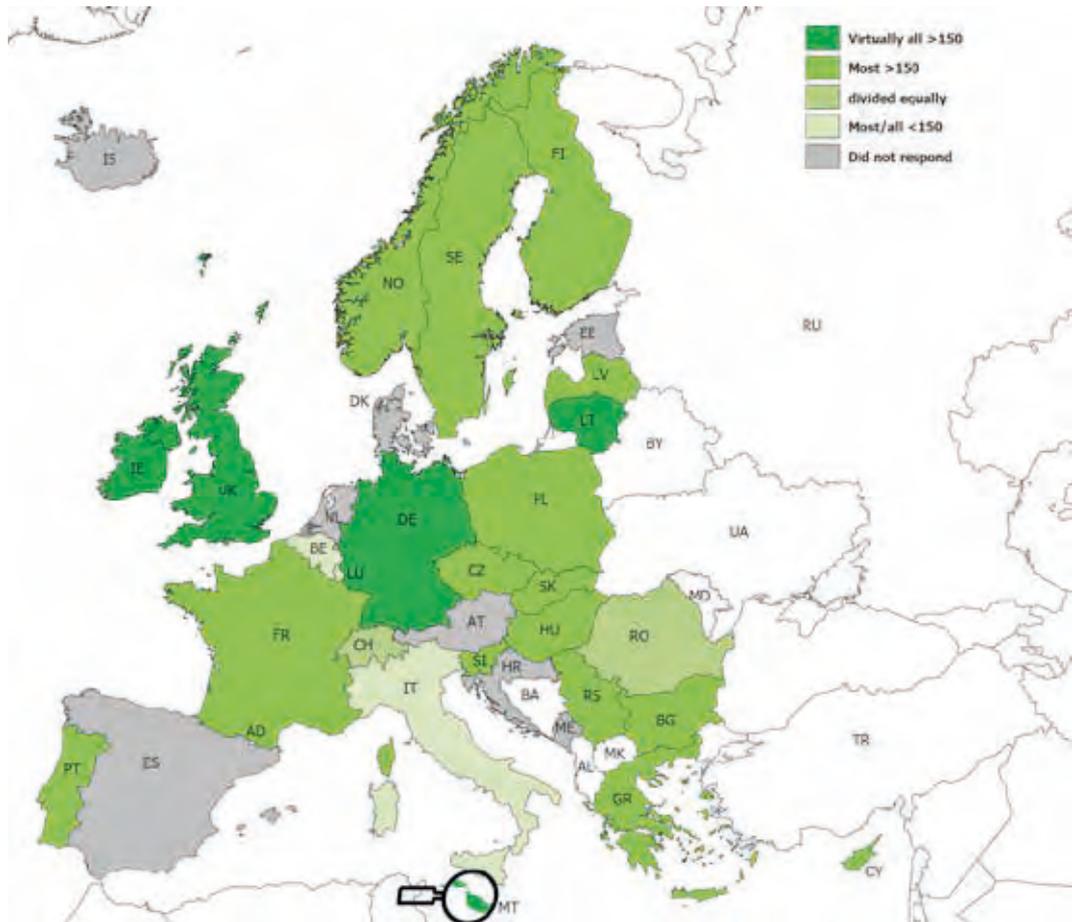
The numbers on the map represent alternative volumes reported by respondents.

Figure 7. Implementation of volume requirement according to ECIBC National Contacts and ED National Representatives.

Core team requirement

ECIBC National Contacts

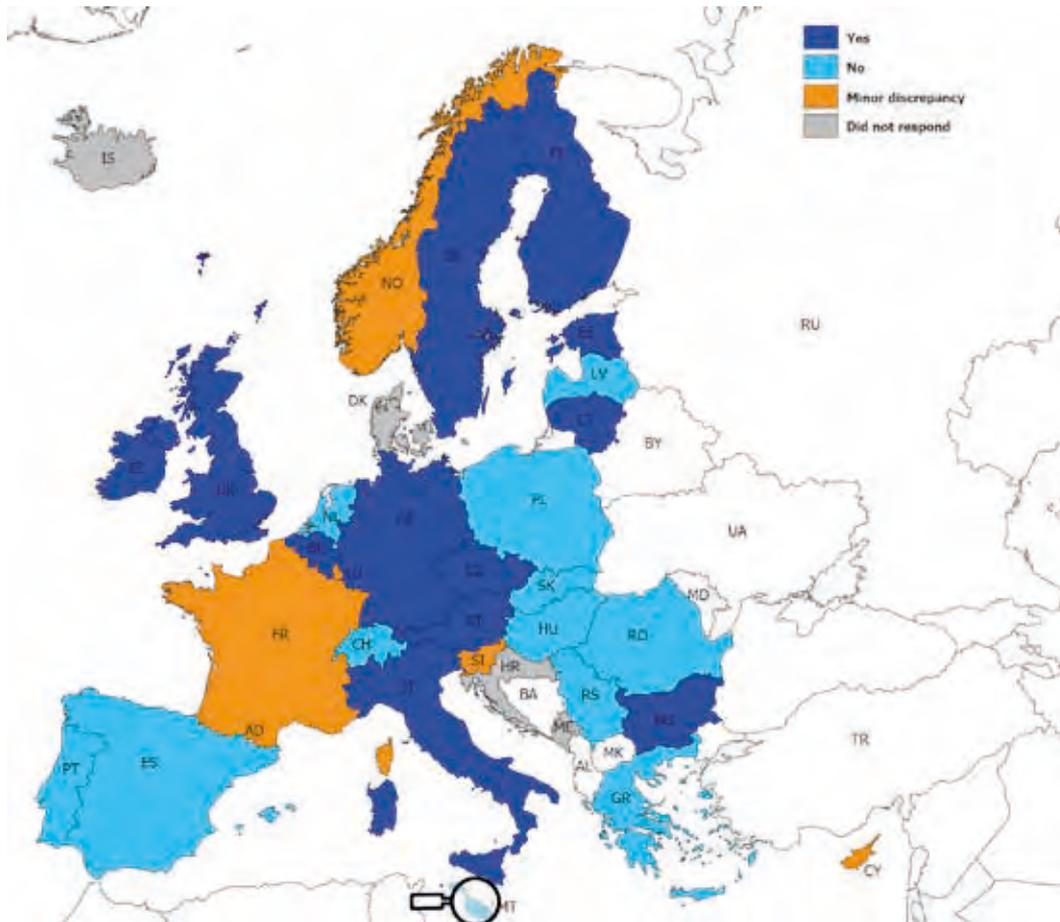
Twelve countries have implemented the requirement that regulates the composition of the core team: eight countries (BE, BG, CZ, DE, FI, IT, LT, and UK) have made it compulsory and four (CY, IE, LU, and SE) have implemented the requirement on a voluntary basis. ECIBC National Contacts from NO and SI stated that although the requirement had not been implemented, there were plans to do. It



The ‘Most/all <150’ category in the legend is the sum of two replies’ categories: (1) even though centres whose volume is higher than 150 new cases/year exist, **most** cases are treated in low-volume centres, and (2) virtually **all** primary breast cancer cases are treated in a centre whose volume is lower than 150 new cases/year.

Figure 8. *Distribution of primary breast cancer cases in breast centres according to ECIBC National Contacts.*

may also be worth mentioning that the ECIBC National Contact from RS reported that, while the requirement is not yet in place (but planned to be implemented), breast cancer treatment decisions are currently made by a breast cancer board, which is composed of a surgeon, radiologist, radiation oncologist, and chemotherapist, among others.



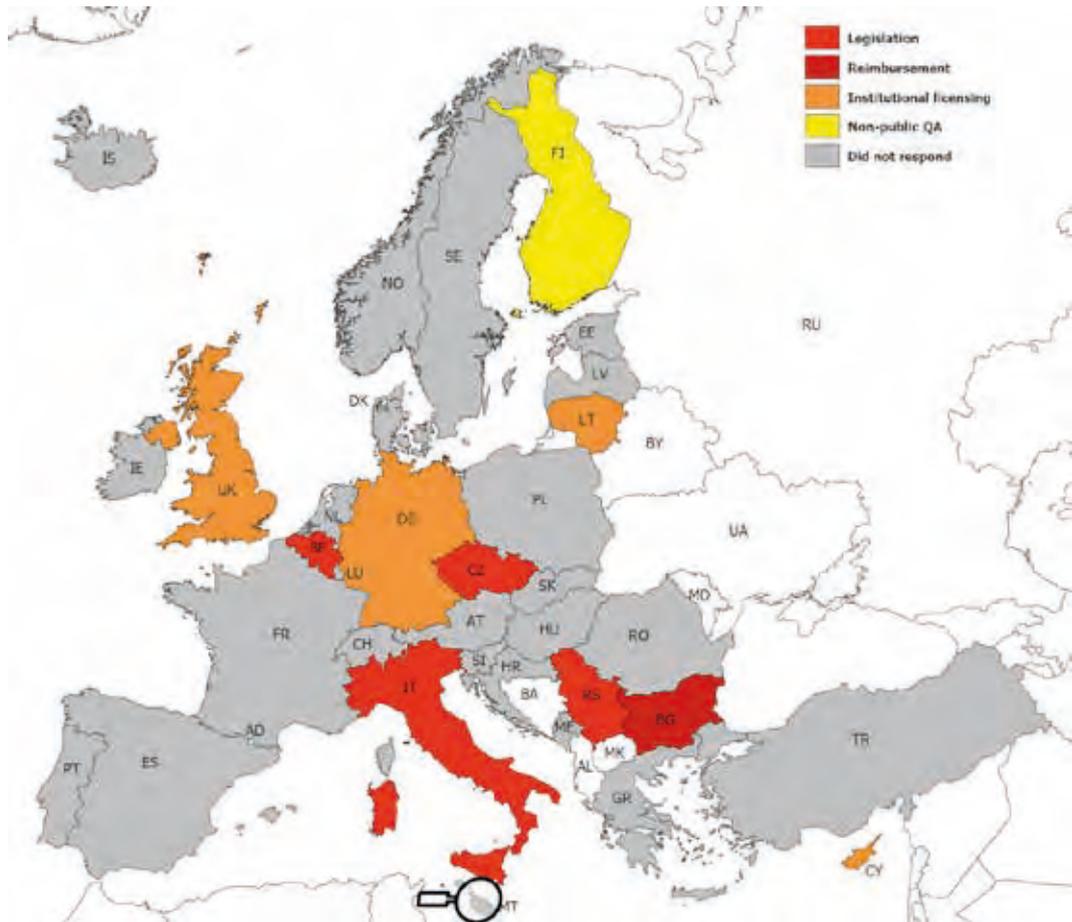
'Minor discrepancy' refers either to the fact that the ECIBC National Contact replied it was voluntary and the ED National Representative replied it was not in place, or that the ECIBC National Contact replied that implementation was planned and ED National Representative replied that the requirement was already in place.

Figure 9. Implementation of core team requirement: responses from ECIBC National Contacts and ED National Representatives.

ED National Representatives

In contrast to their ECIBC National Contact counterparts, ED National Representatives from AT, EE, and FR reported that the core team requirement was in place in their countries as well.

The status of implementation of the core team requirement is presented in *Figure 9*.

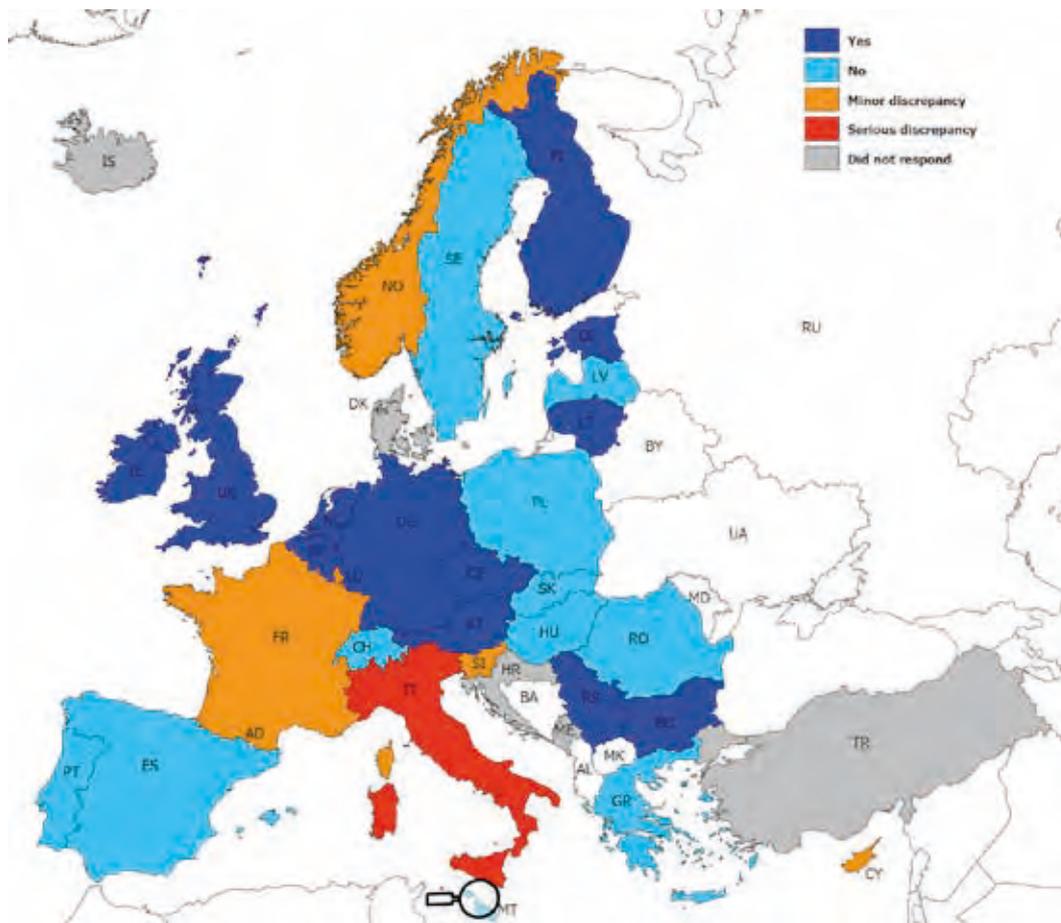


Some countries have several implementation frameworks; in these cases only one of the options is coloured, but further explanation is found in text and in *Annex III*.

Figure 10. Implementation framework of core team composition requirement according to ECIBC National Contacts.

In addition to the question regarding the core team requirement, ECIBC National Contacts were also asked about the implementation framework involved. Responses regarding the implementation framework of the core team requirement are presented in *Figure 10*.

Comparing *Figures 9* and *10*, it is evident that for BE, CZ, IT, and RS the core team requirement has been embedded in national/regional legislation since 2007, 2002, 2015 and 1980, respectively; however, not yet implemented but planned.



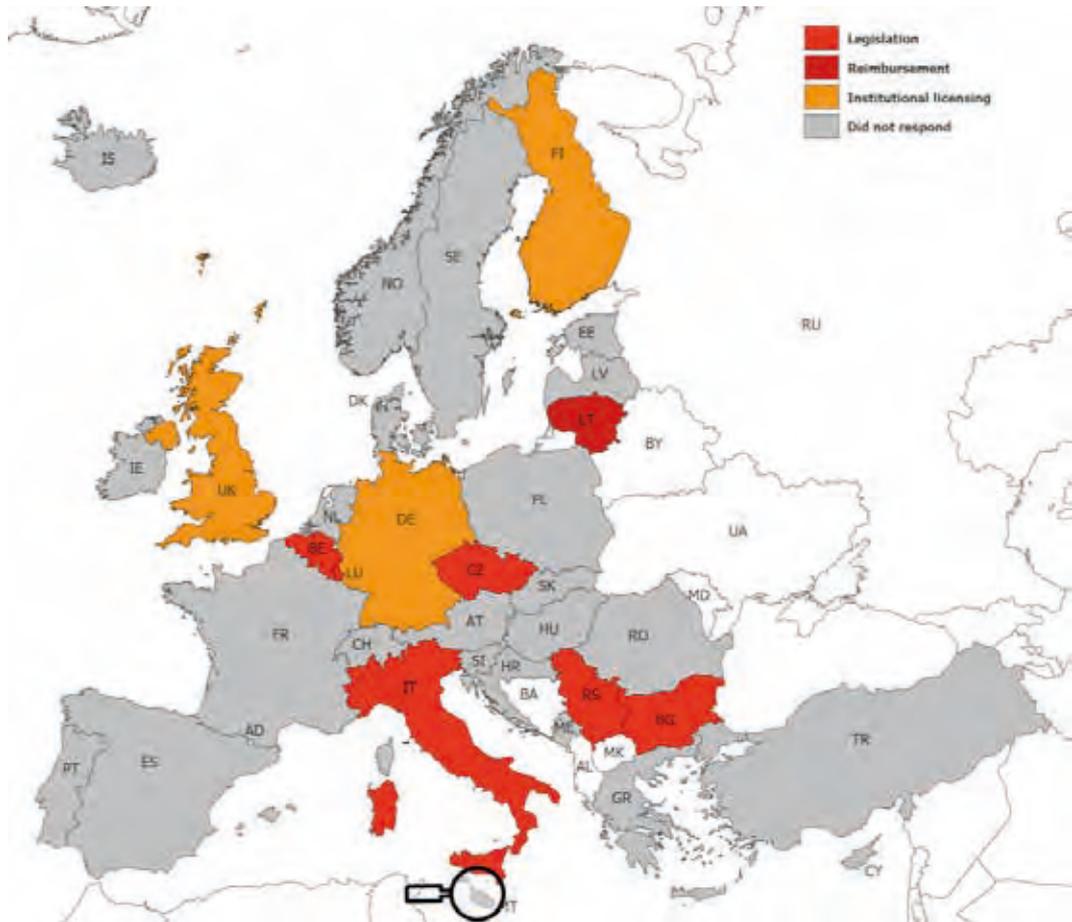
'Minor discrepancy' refers either to the fact that the ECIBC National Contact replied it was voluntary and the ED National Representative replied it was not in place, or that the ECIBC National Contact replied that implementation was planned and the ED National Representative replied that the requirement was already in place. 'Serious discrepancy' refers to an answer where the ECIBC National Contact replied that the requirement was implemented in a mandatory way and the ED National Representative replied that it was not in place.

Figure 11. Implementation of core team training requirement: responses from ECIBC National Contacts and ED National Representatives.

Core team training

ECIBC National Contacts

According to ECIBC National Contacts, a requirement regulating the training standards of the core team exists in 13 countries: compulsory in eight countries



Some countries have several implementation frameworks. In these cases, only one of the options is coloured and further details are provided in the report and in *Annex III*.

Figure 12. Implementation framework of core team training requirement according to ECIBC National Contacts.

(BE, BG, CZ, DE, IT, LT, RS, and UK) and on a voluntary basis in five countries (CY, FI, IE, LU, and NO).

ED National Representatives

Representatives from AT, EE, FR, NL, and SI indicated that this requirement was in place in their countries as well. The status of implementation of the core team training requirement, it is presented in *Figure 11*. See *Annex III* for individual responses.

With regard to the implementation framework, the ECIBC National Contacts had an additional question concerning this topic. This requirement is embedded in national/regional legislation in BE (since 2007), BG (since 1987), CZ (since 2010), IT (since 2014), LU (since 2003) and RS. It is used as a reference for insurance reimbursement at national/regional level in BG (since 2005), CZ (since 2002), and in LT, and it is used as an institutional licencing requirement at national/regional level in CZ (since 2002), in DE (since 2003), in FI, RS, and in the UK (since 2000). A summary of the responses is presented in *Figure 12* and individual responses are reported in *Annex III*; it is however worth highlighting that the ECIBC National Contact reported on IT that the core team training requirement is embedded in legislation and mandatory, whilst the ED National Representative reported that this requirements is not implemented at all.

[Continuing medical education](#)

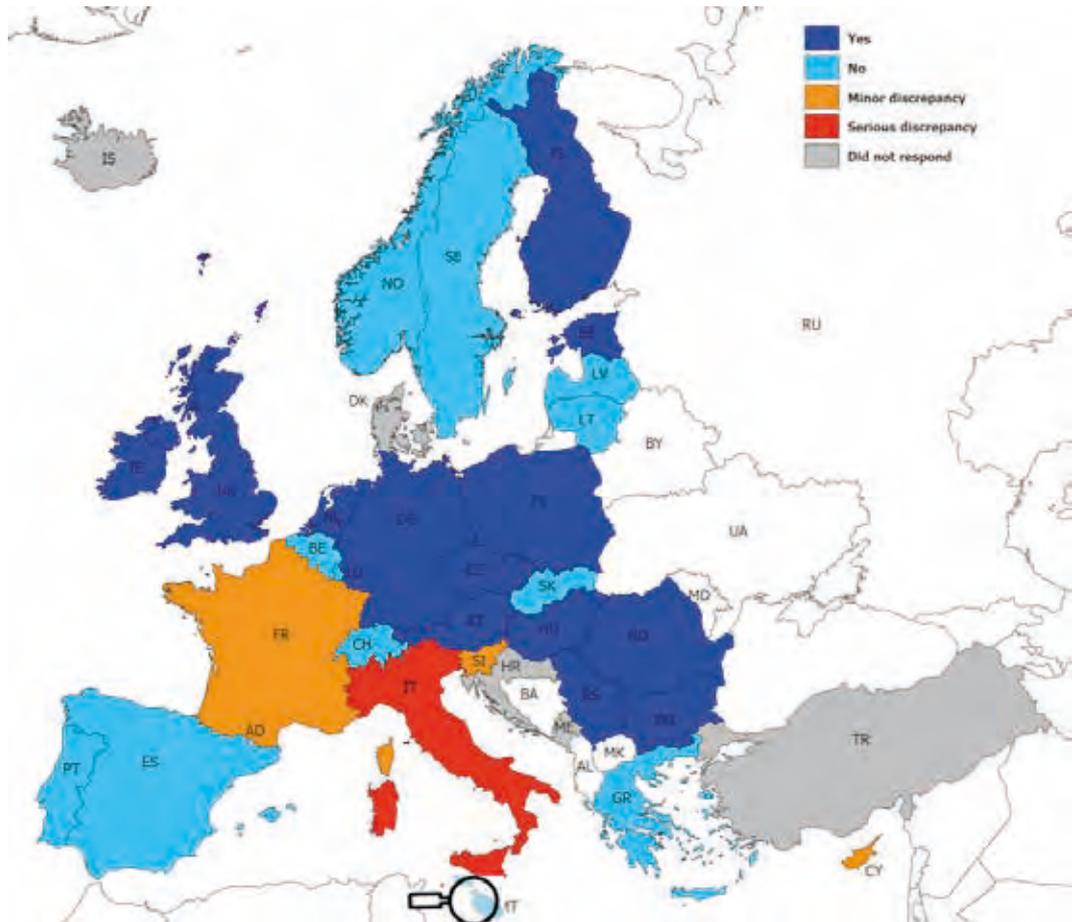
ECIBC National Contacts

The regulation regarding continuing medical education of the core team has been implemented in 12 countries; although, it is compulsory in only nine (CZ, DE, HU, IE, IT, PL, RO, RS, and UK).

ED National Representatives

According to ED National Representatives in AT, EE, FR, NL, and SI, the CME requirement has been implemented in their countries as well.

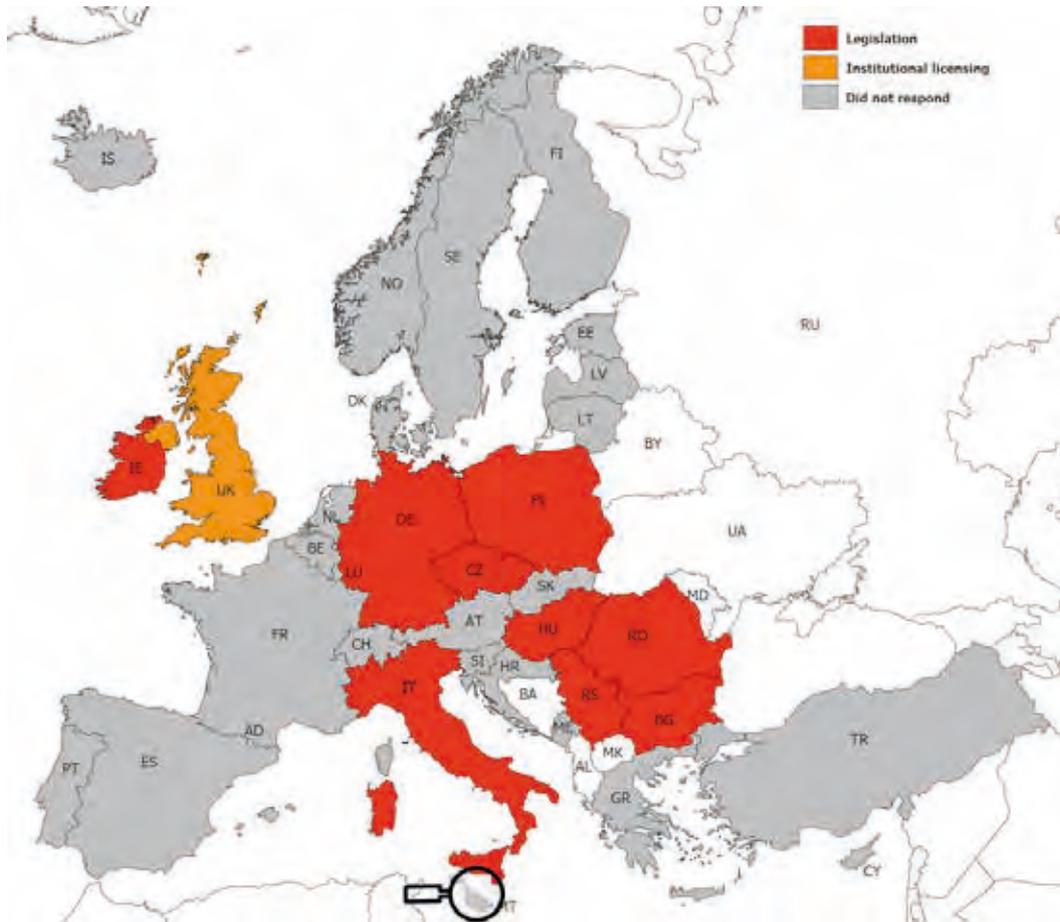
CME is present in most countries. However, only a few countries reported that it is formally or specifically regulated for the core team. This is perhaps one of the questions where it may not have been completely clear that the implementation of the CME requirement referred only to the core team. Therefore, some countries may have replied 'NO' with the understanding that there is no specific CME requirement for the core team; while some replied 'YES' with the clarification that it is not specific for the core team. The status of implementation of the CME requirement is presented in *Figure 13*. Individual responses are available in *Annex III*.



'Minor discrepancy' refers either to the fact that the ECIBC National Contact replied it was voluntary and the ED National Representative replied it was not in place, or that the ECIBC National Contact replied that implementation was planned and the ED National Representative replied that the requirement was already in place. 'Serious discrepancy' refers to an answer where the ECIBC National Contact replied that the requirement was implemented in a mandatory way and the ED National Representative replied that it was not in place.

Figure 13. Implementation of CME requirement: responses from ECIBC National Contacts and ED National Representatives.

The ECIBC National Contacts had an additional question regarding the implementation of CME. The CME requirement is part of national/regional legislation in BG (since 2000, although it is voluntary), CZ (since 2010), DE, HU (since 2005), IE, IT, PL (since 1997), RO (since 1995), and RS, and it is used as an institutional licencing requirement at national and regional level in IT (in addition to legislation) and UK (since 1995). Responses are summarised and presented in *Figure 14*.



Some countries have several implementation frameworks. In these cases, only one of the options is coloured and further details are provided in the report and in *Annex III*.

Figure 14. Implementation framework of CME requirement according to ECIBC National Contacts.

Individual responses are reported in *Annex III*.

Overview of the four mandatory requirements

Although there is some discrepancy in responses provided by ED National Representatives compared to ECIBC National Contacts regarding the status of implementation of the four mandatory requirements of the 2006 breast unit model, approximately one-third of countries reported implementation of the volume requirement, while the remaining three mandatory requirements, are reported to

have been implemented in approximately half of the countries that responded (see *Figures 4 and 5*).

In order to provide an overview of the agreement between the responses from the ECIBC National Contact and the ED National Representative for the four mandatory requirements, responses received for a specific question by both types of participants for the same country were analysed (*Figure 15*).

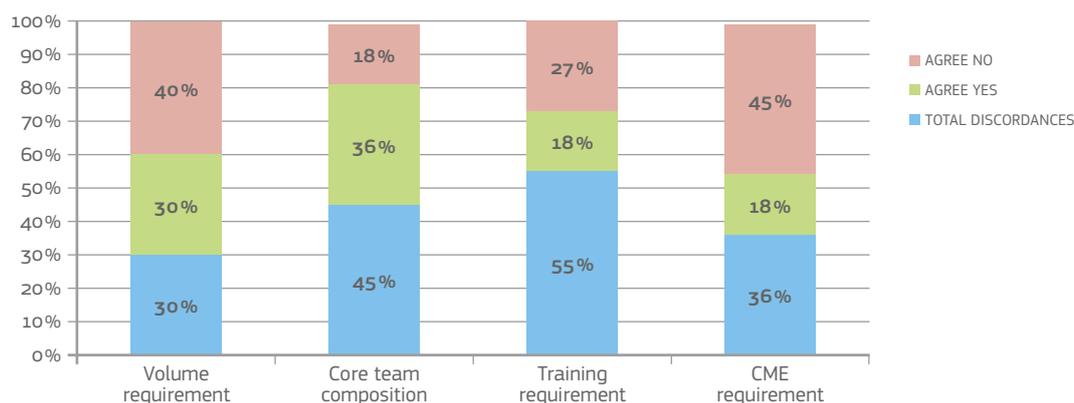


Figure 15. *Agreements (on YES or on NO replies) and discrepancies between responses from ECIBC National Contacts and ED National Representatives regarding the implementation of mandatory breast unit requirements.*

The highest degree of disagreement between ECIBC National Contacts and ED National Representatives responses was for the question regarding the training requirement. In six out of 11 countries for which both ECIBC and ED participants responded (CY, FR, IT, LU, NO, and SI), discordant responses were provided. In four cases, the ECIBC National Contact reported that the requirement was present while the ED National Representative reported that it was not. *Figures 16 and 17* present the implementation status of the four mandatory requirements of the 2006 breast unit model across Europe.

According to the responses received, the volume requirement is the least implemented of the four mandatory requirements across Europe. In fact, only two of 25 responding countries reported that implementation was compulsory (*Figure 4*).

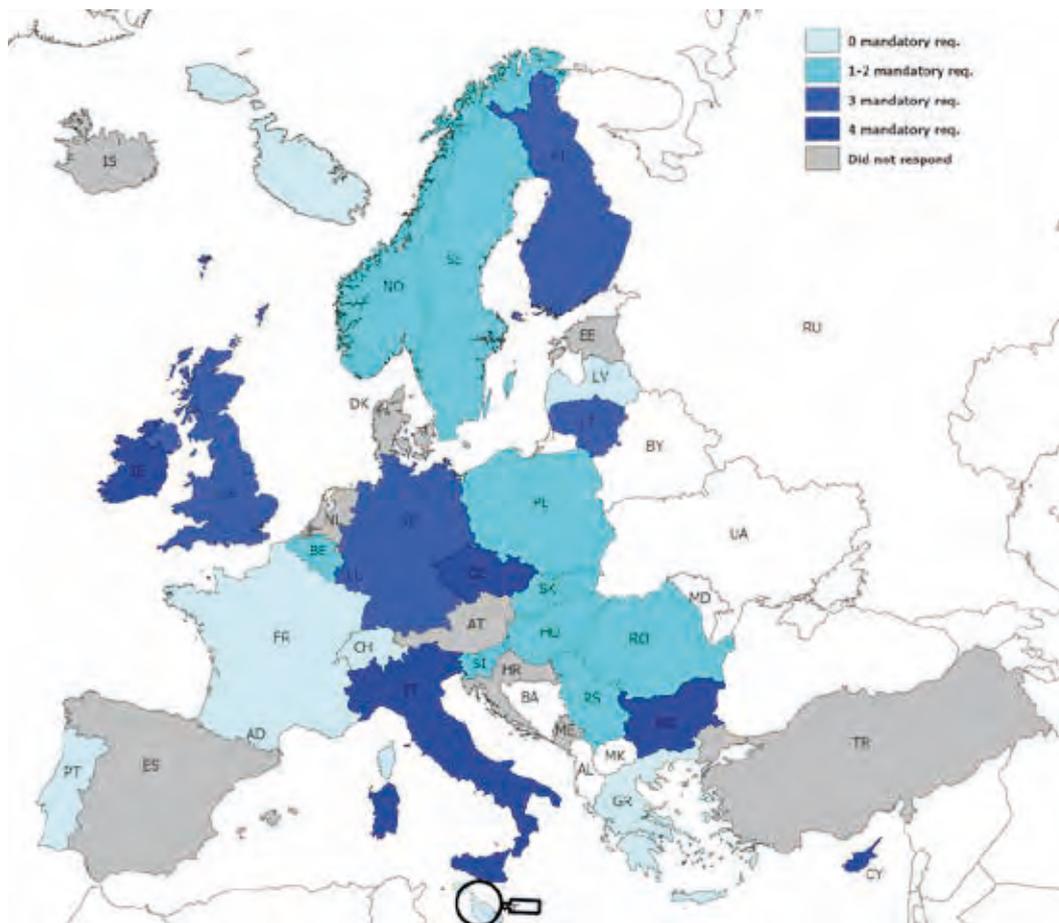


Figure 16. Implementation of mandatory requirements: responses from ECIBC National Contacts.

Furthermore, due to the fact that this particular requirement showed the least amount of disagreement between ECIBC National Contacts and ED National Representatives (*Figure 15*), the result can be considered as an accurate reflection of the current status of implementation.

These results show that further enquiry is needed in order to consider possible inclusion of the volume requirement in the future *European QA scheme*. Indeed within the ECIBC, the JRC has examined the evidence regarding the definition of a minimum threshold requirement for breast cancer services and has found that, although women in need of diagnosis, cancer treatment or other breast services

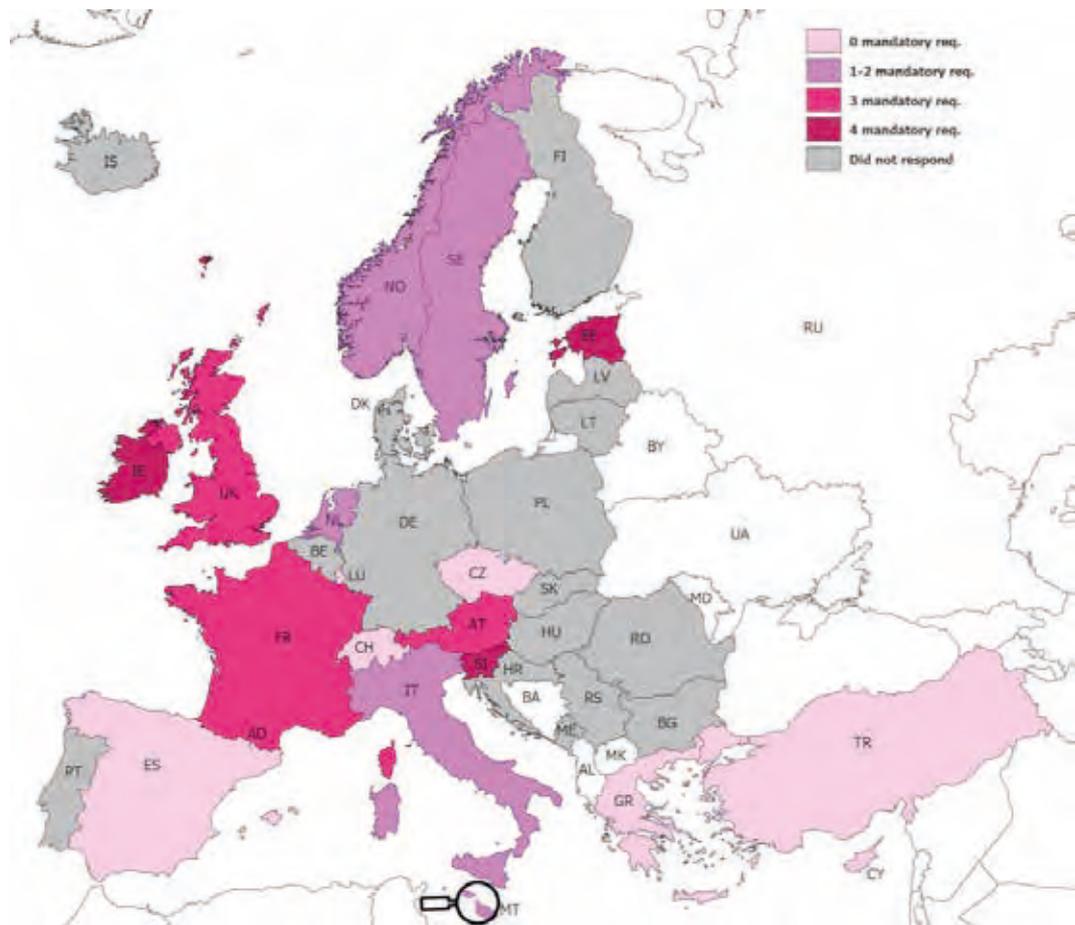


Figure 17. Implementation of mandatory requirements: responses from ED National Representatives.

are recommended to be referred to high-volume hospitals, due to the diversity of studied thresholds, the cut-off values should be defined in accordance with local organisation and available resources [4].

The implementation of the other three mandatory requirements of 2006 breast unit model (team composition, training and CME) was more balanced—with approximately half of the countries implementing them while the other half do not (*Figures 4 and 5*) and, in most cases, when they are implemented, they are

compulsory. As regards training, the ECIBC is **planning a prioritisation of core team competences and training requirements**. In parallel, and in relation to screening programmes, the ECIBC **includes the development of a harmonised training template for screening radiologists and radiographers**. Given the population-based nature of the initiative, this was considered the most urgent action needed to ensure an essential level of competence that is compatible with both local and national legislation.

Section 5: Implementation stage of other requirements for breast units

The definitions used in this section and throughout the entire survey are in line with those used in the 2006 European Guidelines. These definitions were included in both versions of the questionnaire (*Annex I*).

In order to facilitate understanding of the overall status of implementation, the other requirements included in the 2006 breast unit model have been grouped by areas or topics and correspond to the relevant chapter in the 2006 European Guidelines. Results are summarised in the following figures and detailed responses listed by country are available in *Annex III*.

Three figures characterise each topic:

- i. the first figure presents answers provided by the ECIBC National Contact (number of responses are directly reported on the bars and pie-charts of the figures);
- ii. the second figure presents answers provided by the ED National Representative (number of responses are directly reported on the bars and pie-charts of the figures); and
- iii. the last figure presents the amount of agreement and discordance (expressed as a percentage) between the ECIBC National Contacts and the ED National Representatives in response to the same question.

It should be noted that contradictory responses within one country, are often a case of the ECIBC National Contact indicating that a particular requirement has been implemented on a voluntary basis while their ED counterpart reported that

the requirement was not in place. This contradiction may be due to the fact that voluntary implementation may mean that the requirement is not fulfilled in every breast unit and the perception from patient advocates maybe related to this partial implementation. This type of disagreement is considered minor; therefore, all requirements presented in *Section 5* are not described on a country-by-country basis. In addition to a short possible interpretation of disagreement for the screening requirement, only serious disagreements are presented in this section. For more details, see participant response tables included in *Annex III*.

Equipment and facilities

- Equipment – imaging equipment (9.6.1); radiotherapy equipment (9.6.2).
- Facilities – new patient clinic establishment (9.7.1).

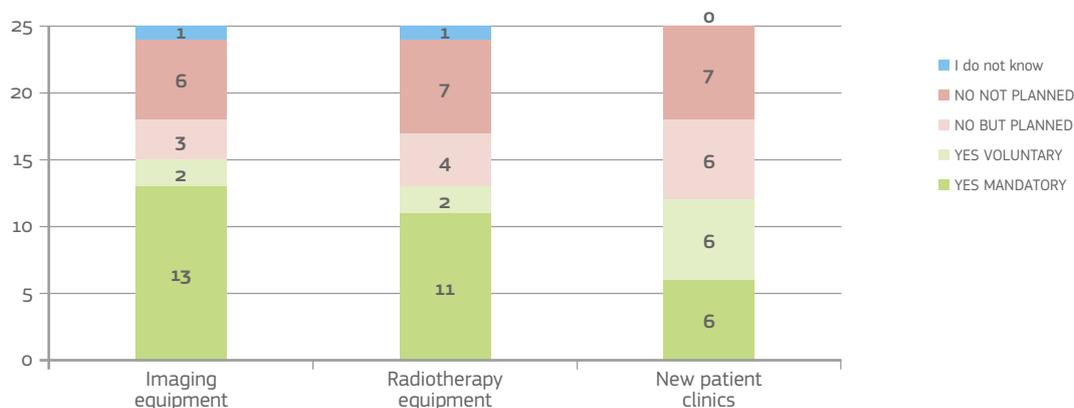


Figure 18. Implementation of requirements related to equipment and facilities: responses from ECIBC National Contacts.

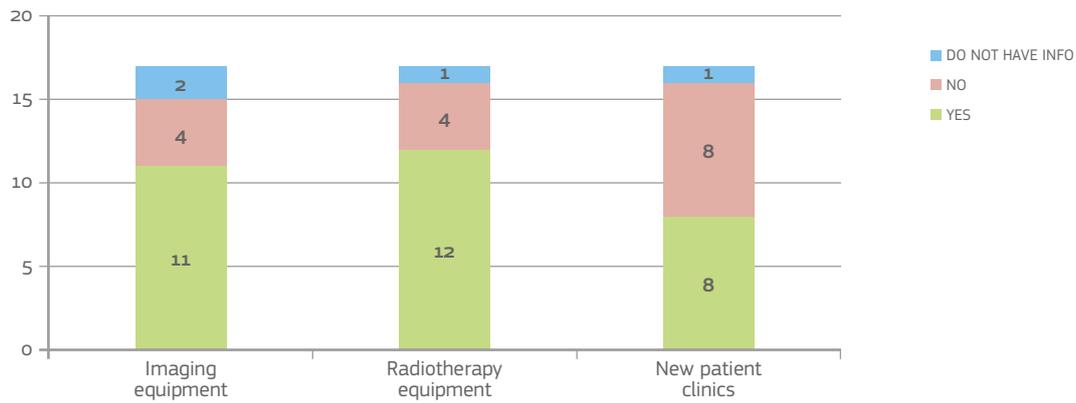


Figure 19. Implementation of requirements related to equipment and facilities: responses from ED National Representatives.

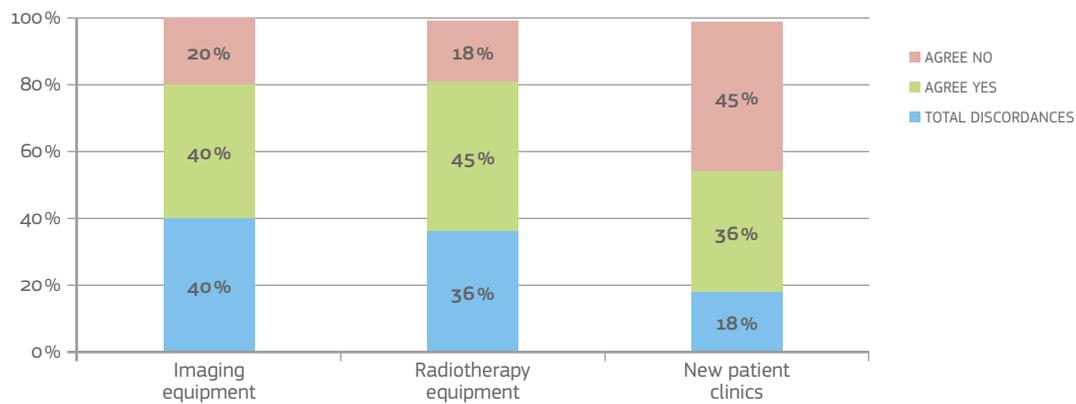


Figure 20. Agreements (on YES or on NO replies) and discrepancies between responses from ECIBC National Contacts and ED National Representatives regarding the implementation of requirements related to equipment and facilities.

Breast screening

- Breast cancer screening management (9.7.11).

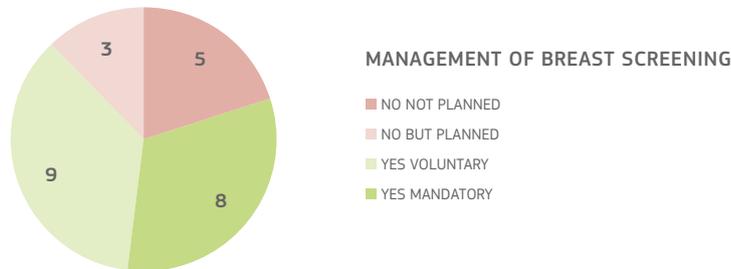


Figure 21. Implementation of the management of breast screening requirement: responses from ECIBC National Contacts.

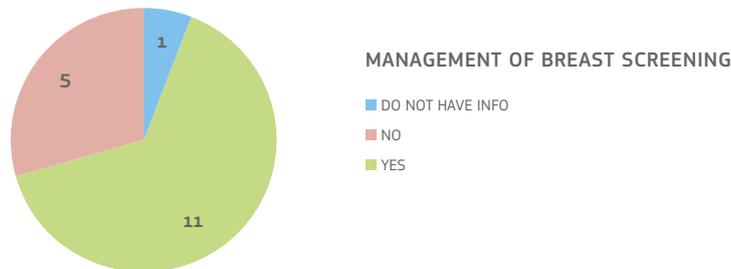


Figure 22. Implementation of the management of breast screening requirement: responses from ED National Representatives.

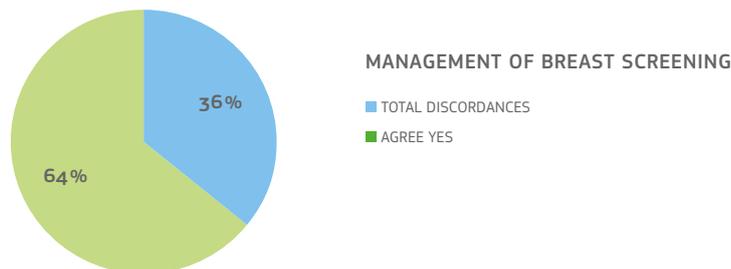


Figure 23. Agreements (on YES or on NO replies) and discrepancies between responses from ECIBC National Contacts and ED National Representatives regarding the implementation of the management of breast screening requirement.

Regarding this requirement, part of the discrepancies could be the result of a misunderstanding of terminology, as the term ‘screening’ could have been understood to mean population-based screening by some and opportunistic screening by others.

Services (usually provided within the breast unit)

- Multidisciplinary case management Meetings (MDM) (9.7.3).
- Provision of appropriate adjuvant therapies (9.7.5).
- Management of advanced and recurrent breast cancer (9.7.6).
- Follow-up of primary breast cancer (9.7.7).

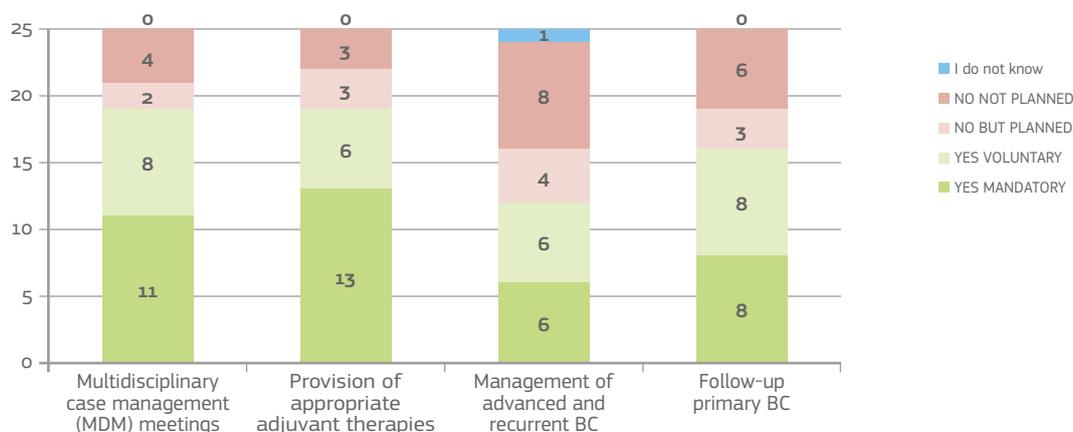


Figure 24. Implementation of requirements related to services usually provided within a breast unit: responses from ECIBC National Contacts.

Other services (usually provided outside breast units but they are closely connected to breast units)

- Provision of extra psychological support (9.8.1).
- Palliative care (9.8.4).
- Physiotherapy provision for post-operative recovery (9.7.4) together with Physiotherapy for treatment of lymphoedema (9.8.6).
- Plastic surgeon availability (9.8.2).
- Prosthesis (9.8.5).
- Management of benign disease (9.7.8).

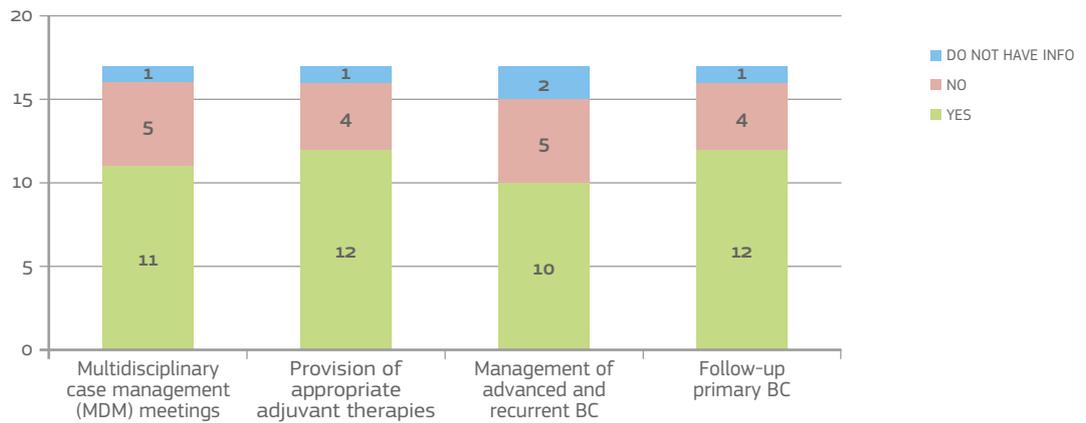


Figure 25. Implementation of requirements related to services usually provided within a breast unit: responses from ED National Representatives.

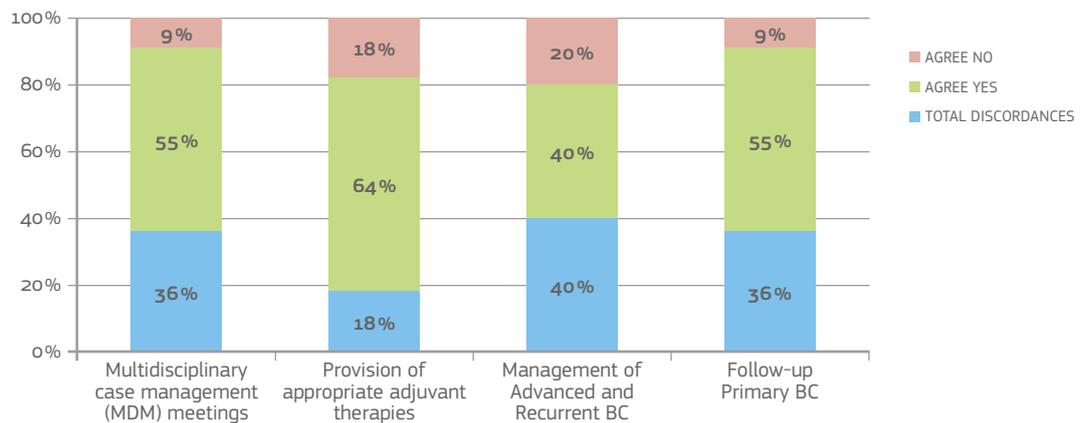


Figure 26. Agreements (on YES or on NO replies) and discrepancies between responses from ECIBC National Contacts and ED National Representatives regarding the implementation of requirements related to services usually provided within a breast unit.

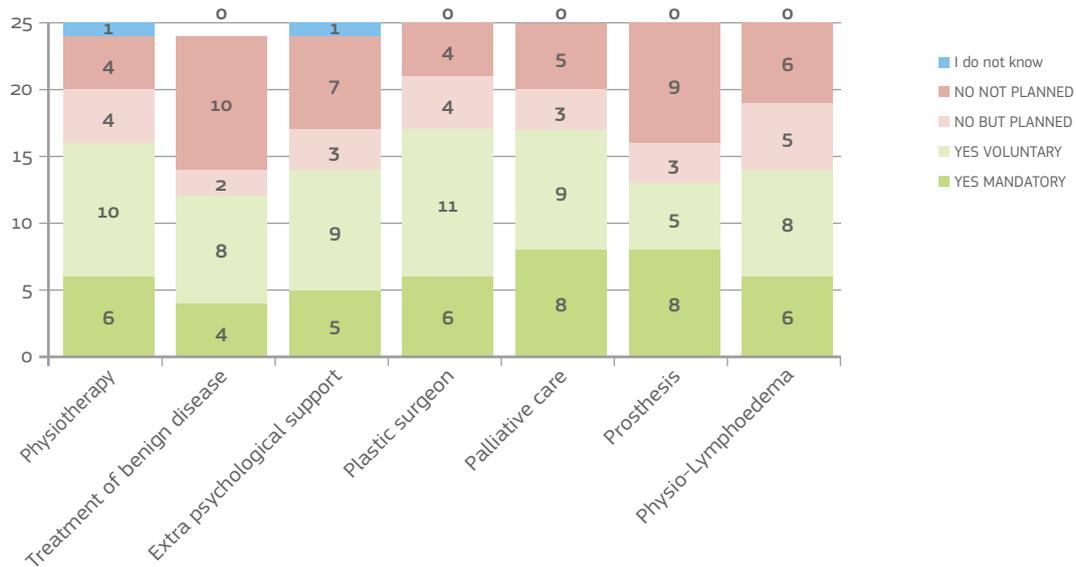


Figure 27. Implementation of requirements related to services usually provided outside a breast unit: responses from ECIBC National Contacts.

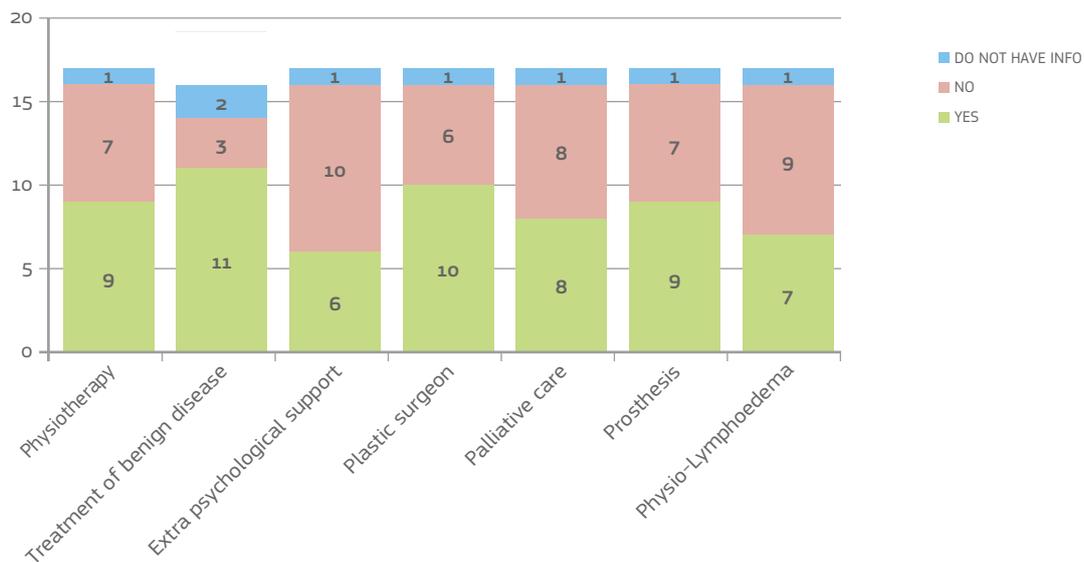


Figure 28. Implementation of requirements related to services usually provided outside a breast unit: responses from ED National Representatives.

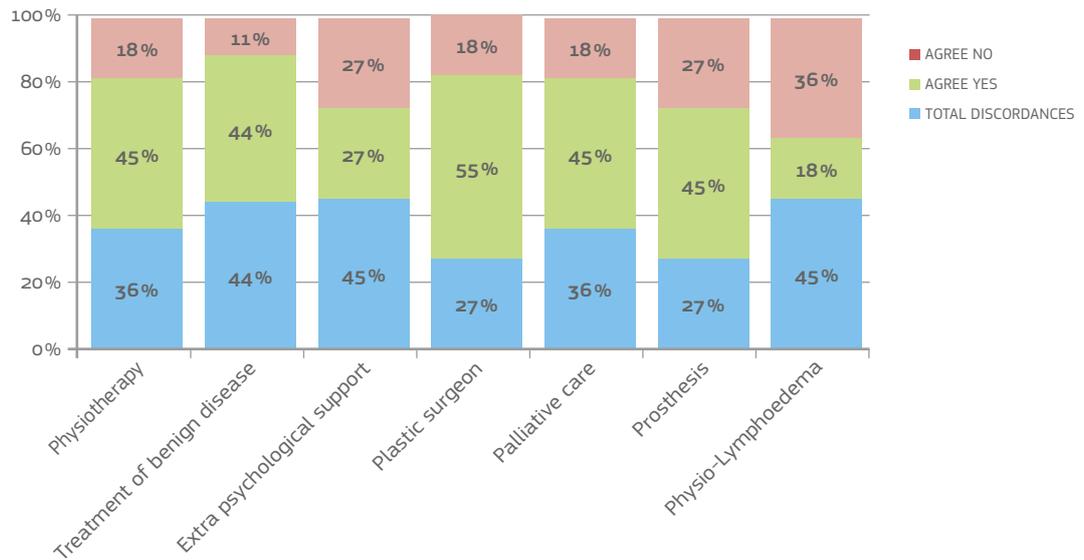


Figure 29. Agreements (on YES or on NO replies) and discrepancies between responses from ECIBC National Contacts and ED National Representatives regarding the implementation of requirements related to services usually provided outside a breast unit.

With regard to the palliative care requirement, in addition to the usual minor discrepancies (the ECIBC National Contact reporting that a requirement is implemented in a voluntary manner and the ED National Representative reporting that that requirement is not in place), a serious discrepancy was detected for LU and NO, where ECIBC National Contacts reported that the requirement was compulsory, while the ED National Representative reported that it was not in place. **These two discrepancies may be of great concern as despite it being a mandatory requirement, patients may not be benefitting from specialist palliative care service ‘for the referral of patients with advanced breast cancer’ and to ‘ensure that breakdowns in continuity of care do not occur’ (2006 European Guidelines).**

Communication/advice

- Communication of diagnosis and treatment plan (9.7.2).
- Patient information (9.7.11).
- Family history/genetics (9.7.9).
- Geneticist-genetic risk communication (9.8.3).

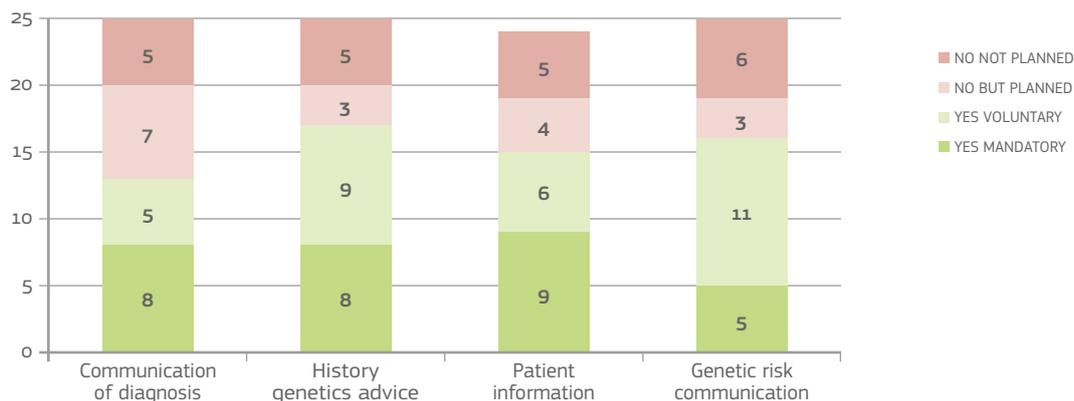


Figure 30. Implementation of requirements related to communication and advice: responses from ECIBC National Contacts.

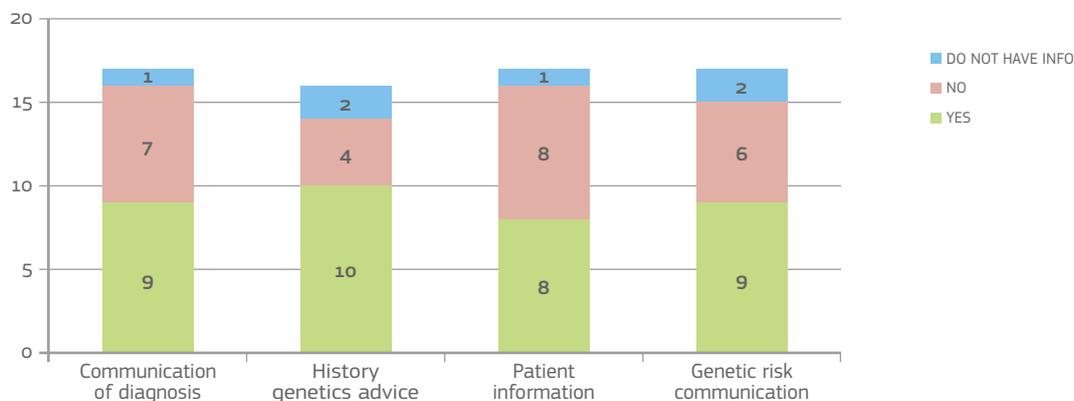


Figure 31. Implementation of requirements related to communication and advice: responses from ED National Representatives.

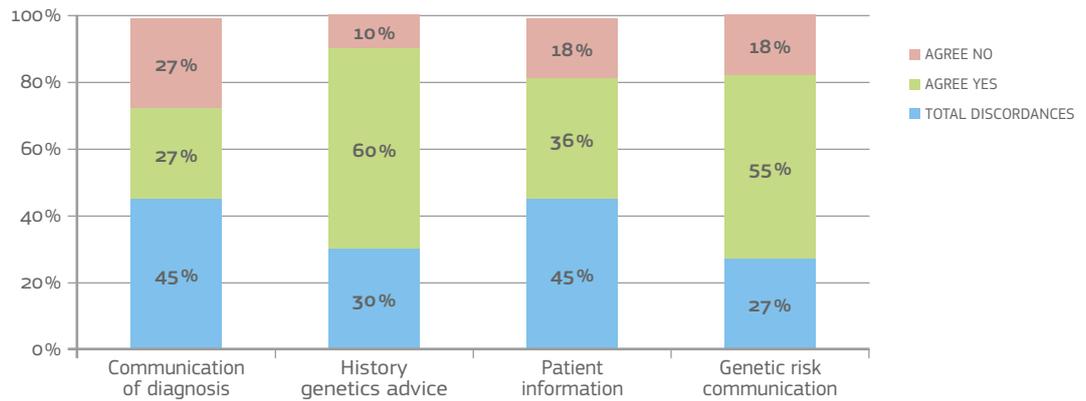


Figure 32. Agreements (on YES or on NO replies) and discrepancies between responses from ECIBC National Contacts and ED National Representatives regarding the implementation of requirements related to communication and advice.

Research and teaching

(these are always linked together in hospitals and breast units)

- Research carried out (9.9).
- Provision of teaching for staff or students (9.10).

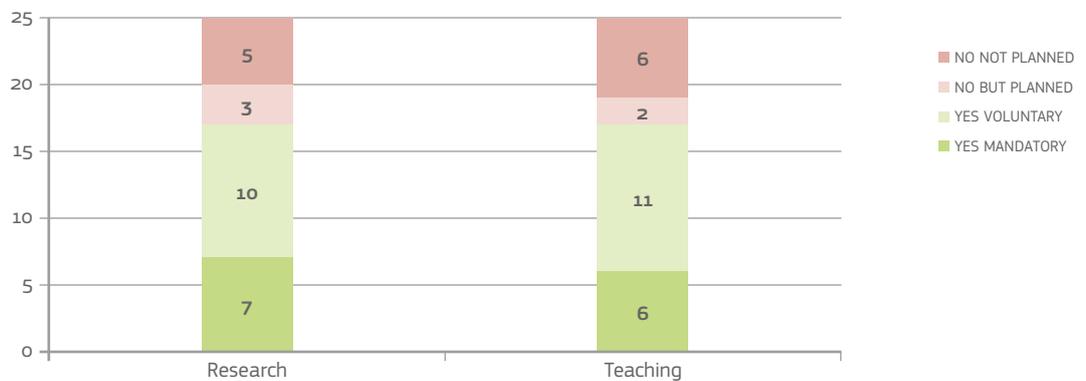


Figure 33: Implementation of research and teaching requirements: responses from ECIBC National Contacts.

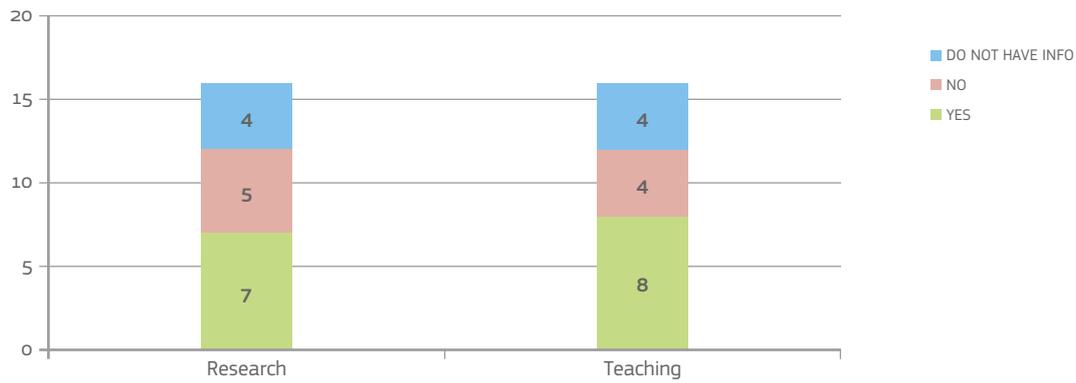


Figure 34. Implementation of research and teaching requirements: responses from ED National Representatives.

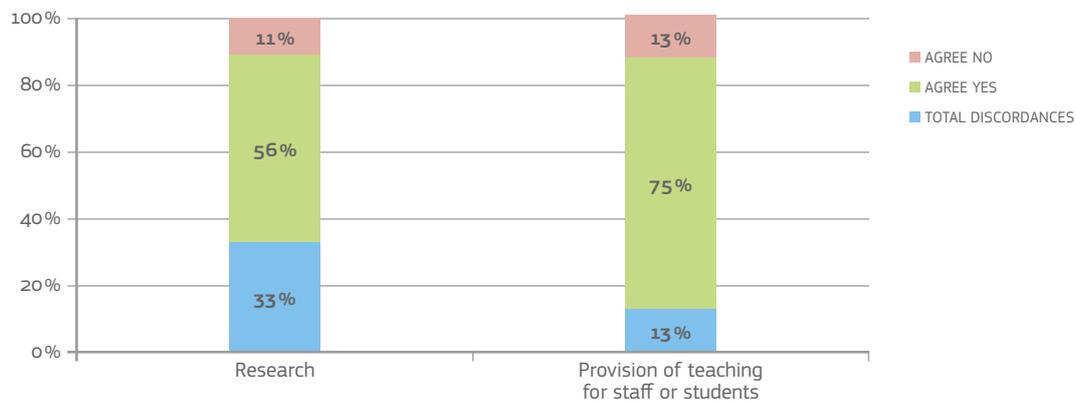


Figure 35. Agreements (on YES or on NO replies) and discrepancies between responses from ECIBC National Contacts and ED National Representatives regarding the implementation of research and teaching requirements.

Overview of inconsistencies

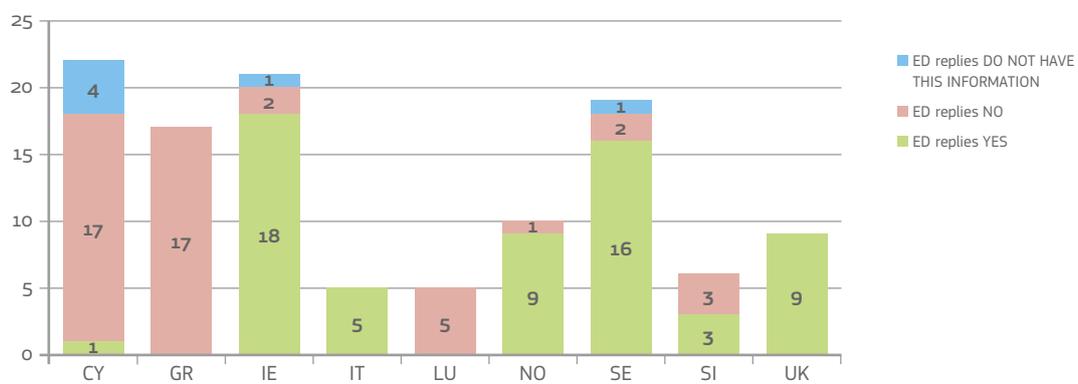


Figure 36. Voluntary implementation of requirements according to ECIBC National Contacts vs implementation according to ED National Representatives.

5. Overview and discussion

Due to the complexity of the 2006 breast unit model, two simplifications were introduced in order to get a clearer picture of the overall implementation status of the model across Europe:

- a. all the requirements of the 2006 breast unit model, in accordance with the 2006 European Guidelines, were considered as equally relevant (whether they were in the group of mandatory requirements or not); and
- b. voluntary and mandatory implementation were considered as equivalent (which realistically may not be the case, at least in terms of population impact).

Figures 37 to 44 show the extent of implementation of the complete set of 25 requirements from the ECIBC National Contacts and ED National Representatives' of view.

There was quite a bit of variation across Europe with regard to the number of requirements implemented – from no requirements implemented in CH, FR, LV, and MT to the complete implementation of all 25 requirements in BG, CY, and CZ. FR indicated that the organisation of screening and diagnostics was distinct from the organisation of treatment. Therefore, it was not possible for French respondents to answer the questions as they were presented. The distribution of the number of requirements implemented on a compulsory basis is presented in *Figure 38*.

Based on the overall responses, it appears that DE, LT, and IT are the countries in which the greatest number of requirements (23, 21 and 19, respectively) have been implemented in a compulsory way, while none of the requirements are compulsory in GR, LV, MT, and SE.²¹

21. As previously stated, the ECIBC National Contact from France indicated that the questions regarding the organisation of their breast units was different from that which has been defined in the 2006 European Guidelines.

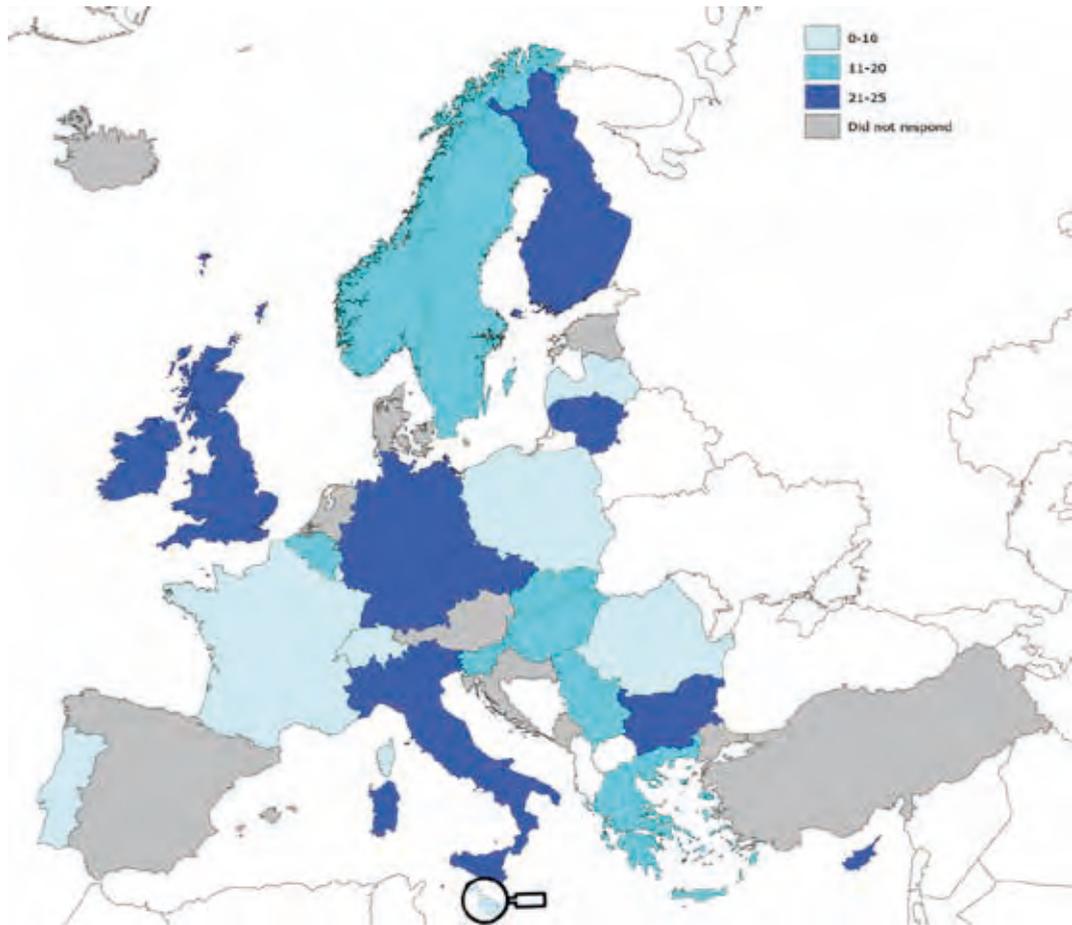


Figure 37. Overall implementation of the 25 breast unit requirements (voluntary or compulsory) across European countries according to ECIBC National Contacts.

According to the ED National Representatives, the majority of the requirements have been implemented in UK, IT, and EE and none of the requirements are implemented in ES or GR. The CH representative indicated that they did not have information in order answer all of the questions related to implementation of the 25 breast unit requirements within their country. CZ did not provide answers to these questions as they had replied ‘NO’ to all of the general questions related to breast units in *Section 4* of the survey and thus, per the survey’s instructions, they did not complete *Sections 5* and *6*.



Figure 38. Number of breast unit requirements implemented on a compulsory basis across Europe according to ECIBC National Contacts.

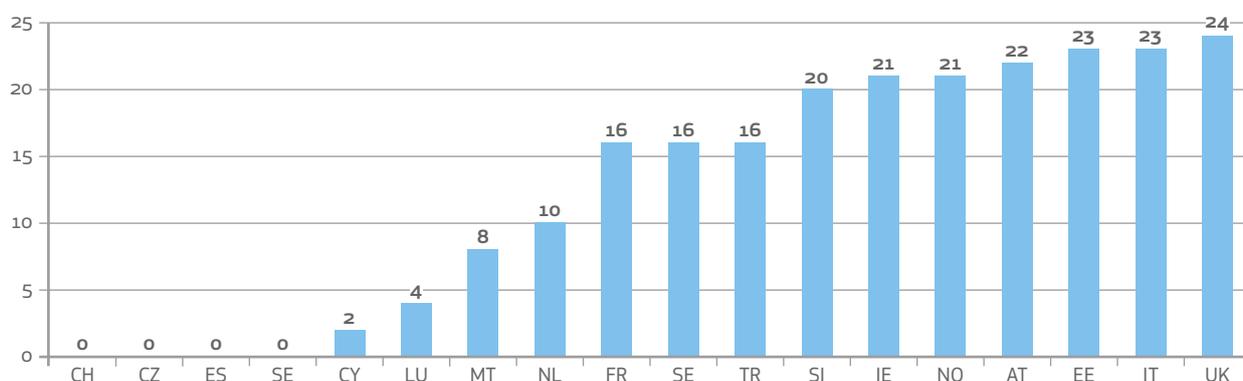


Figure 39. Number of breast unit requirements implemented across Europe according to ED National Representatives.

Figure 40 presents the requirements that are implemented most frequently (compulsory or voluntary) across Europe.

The two most implemented requirements across all countries are the **multidisciplinary case management (MDM) meetings** and the **provision of appropriate adjuvant therapy**, present in 19 out of 25 countries (76%). Indeed, within the ECIBC, the JRC has examined the evidence regarding improvements in health

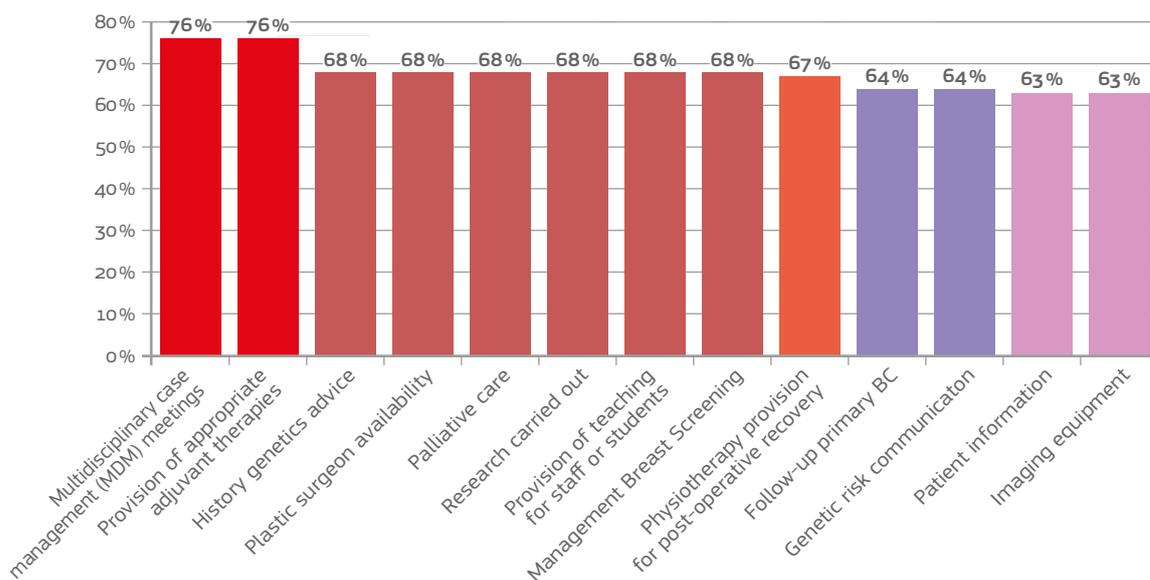


Figure 40. Most implemented breast unit requirements across Europe according to ECIBC National Contacts.

outcomes for women whose breast cancer case has been discussed in a multi-disciplinary meeting [2]. The results from this review show that, although **there is very low certainty in the evidence that ‘on-site’ multidisciplinary meetings (MDM) compared to non-MDM reduces 5-year mortality from breast cancer and breast-cancer specific survival**, women assessed in MDM are more likely to be treated with standard best practices—thereby increasing equity of care. However, there is also uncertainty about the magnitude of the resources required and cost-effectiveness.

After **MDM meetings** and the **provision of adjuvant therapy**, the **provision of extra psychological support, physiotherapy for treatment of lymphoedema, radiotherapy equipment, management of benign disease, training requirement for core team, communication of diagnosis and prosthesis** were implemented in more than half of the reporting countries (*Figure 41*). Within this group of requirements, the **training for core team requirement** had been implemented in only 13 countries, although it is considered to be a mandatory requirement for breast units according to the 2006 European Guidelines.

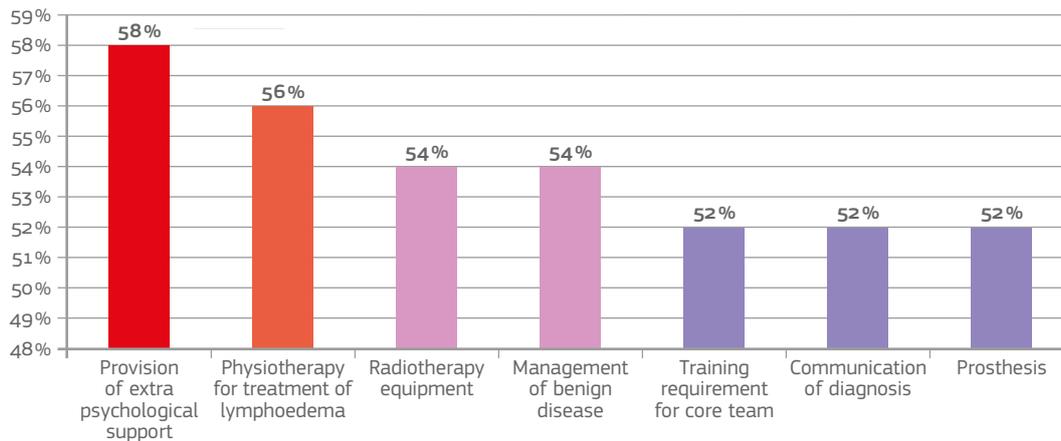


Figure 41. Breast unit requirements implemented (compulsory or voluntary) in approximately half of the countries according to ECIBC National Contacts.

In contrast, the five requirements least frequently implemented were: **management of advanced and recurrent BC, core team, continuing medical education, new patient clinics, and the volume requirement** (Figure 42).

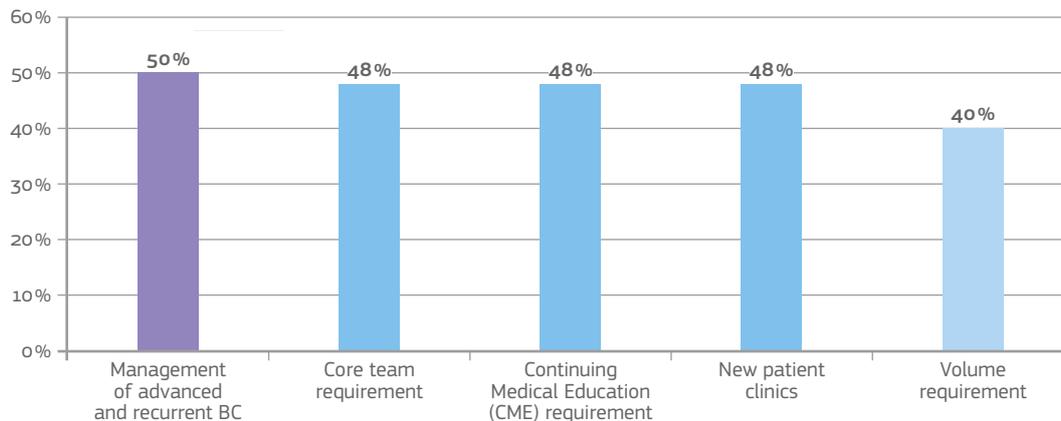


Figure 42. The least implemented breast unit requirements (compulsory or voluntary) across Europe according to ECIBC National Contacts.

It is interesting that three of the least implemented requirements (*i.e.* the **volume requirement**, the **core team requirement** and the **CME requirement**) are those that were considered mandatory for breast units in the 2006 European Guidelines.

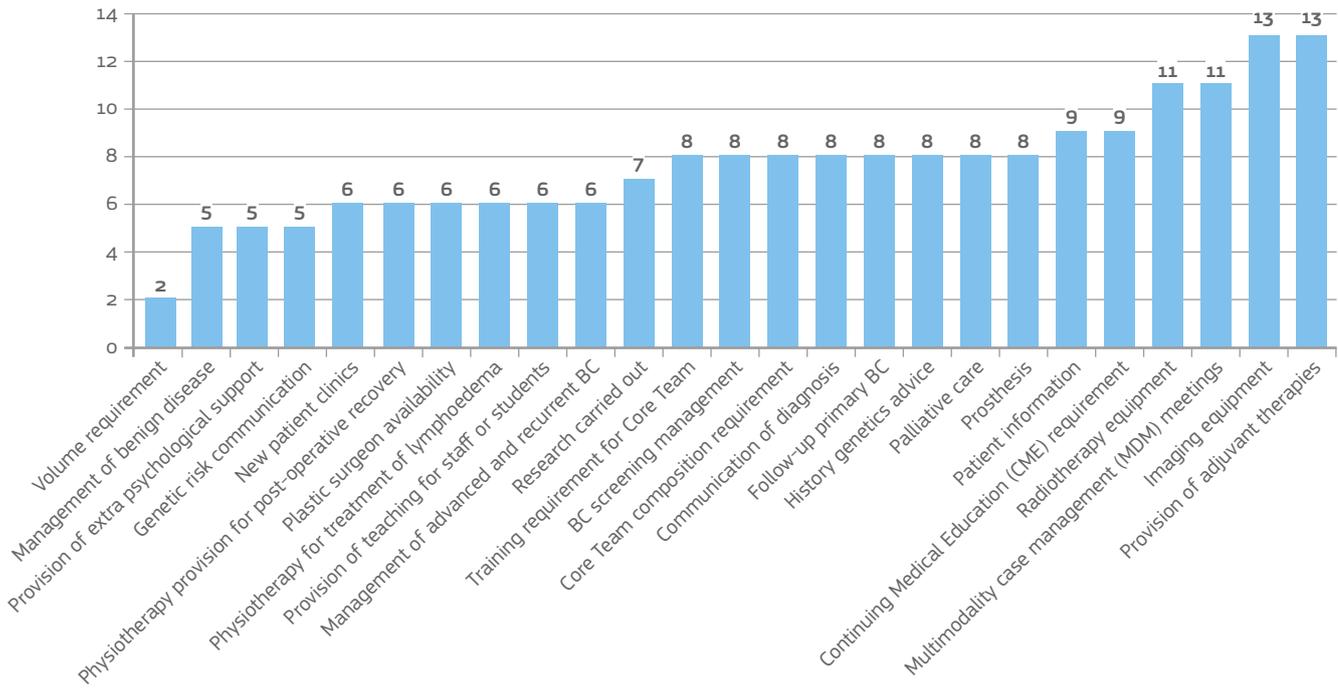


Figure 43. Number of countries each of the breast unit requirements on a compulsory basis according to ECIBC National Contacts.

The lower implementation of these requirements could possibly be related to organisational, economic, and legislative factors. For example, in the case of the **volume requirement**, the infrastructure of breast cancer services varies greatly across Europe;²² while in the case of **CME**, many countries have general legislation for professionals but do not have a specific **CME** for the members of the core team. Compulsory implementation of the 25 breast unit requirements according to ECIBC National Contacts is presented in *Figure 43*.

Provision of adjuvant therapies and **imaging equipment** present in breast units are the requirements that are compulsory in approximately half of the participating countries, closely followed by the requirement concerning the **multidiscipli-**

22. <http://bookshop.europa.eu/en/report-of-a-european-survey-on-the-organisation-of-breast-cancer-care-services-pbLB-NA26593/>.

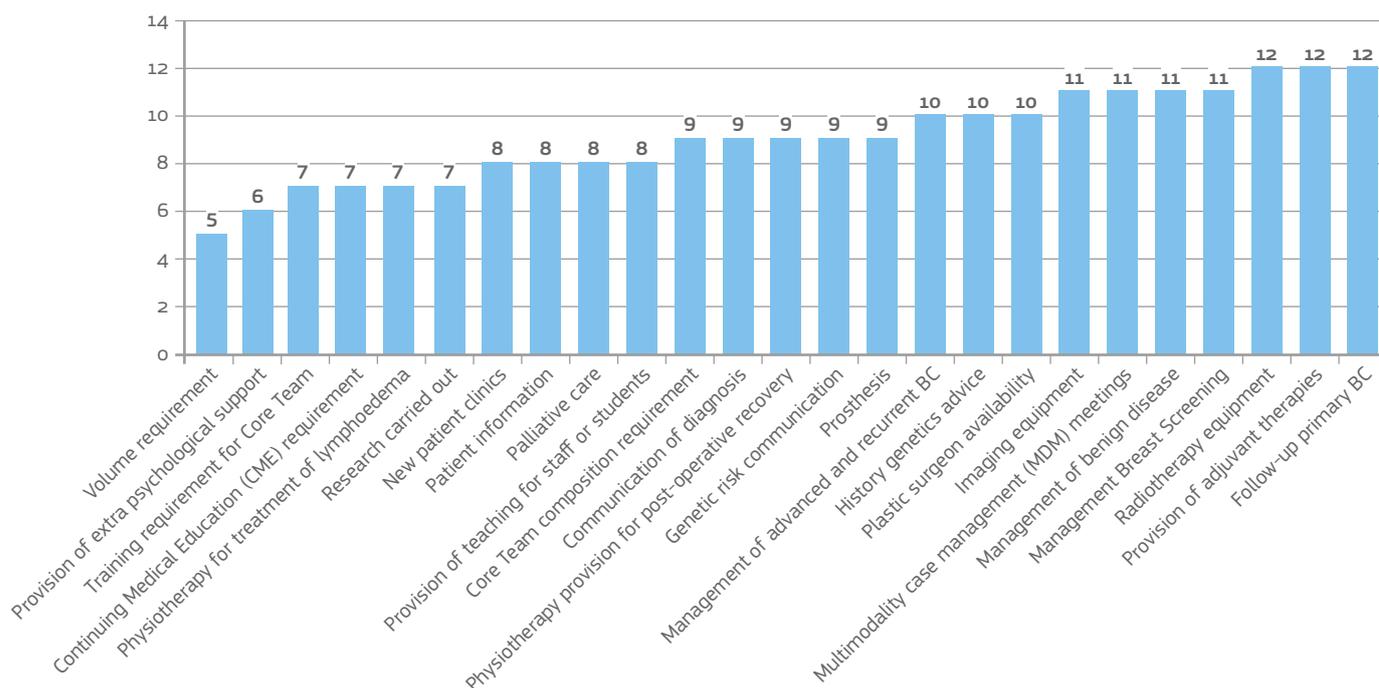


Figure 44. Number of countries across Europe implementing breast unit requirements, compulsory or voluntary, according to ED National Representatives.

nary case management meetings and the requirement regarding **radiotherapy equipment**. Apparently, these four requirements are seen as most beneficial from the healthcare perspective as they are believed to impact health outcomes; thereby, assuring the proper provision of imaging equipment, multidisciplinary discussion of cases for diagnostic purposes and the provision of adequate therapies (*e.g.* adjuvant therapies); unlike the volume requirement which is compulsory in only two countries. However, due to the design of the ED National Representatives questionnaire, it is not possible, to know how many countries have implemented the requirements on a compulsory or voluntary basis. *Figure 44* presents the status of implementation from an ED perspective.

As with their ECIBC counterparts, ED National Representatives also reported that the **requirement implemented less frequently is the one related to volume**. Five out of 18 countries replied that the volume requirement was implemented

(EE, IE, IT, MT, and SI) compared to the ECIBC National Contacts who reported implementation in SI and IE, planned implementation in MT and no response from the EE National Contact.

Provision of adjuvant therapies, the requirement concerning the **radiotherapeutic** and **imaging equipment** present in breast units, and the **multidisciplinary case management meetings** are among the requirements that are most frequently implemented across countries. This finding mirrored the responses provided by ECIBC National Contacts.

6. Conclusions

General considerations

Even though the results of this survey do not cover all of the invited countries, taking into account the two stakeholder's responses (74% of ECIBC National Contacts and 58% of ED National Representatives), information was collected for 30 out of 34 countries (88% coverage)–the only countries not represented being DK, HR, IS, and ME. Furthermore, considering that the great majority of discrepancies between the two sets of responses were of minor importance, the overall response rate can be considered satisfactory and paints a reliable picture of the current European situation in terms of implementation.

The JRC considers the collected information as essential with respect to (a) how the 25 breast unit requirements (defined in the 2006 European Guidelines) have been implemented over the last ten years, and (b) how differences in knowledge between those responsible for the implementation of these requirements (*e.g.* Ministries of Health) and patient advocates can be improved to ensure that all those involved in the provision of quality healthcare are fully aware of which requirements are in place and which requirements are in need of implementation. Indeed, it would be particularly valuable for countries to focus on those requirements where the responses of the ECIBC National Contact indicated that the requirement was compulsory and the ED National Representative said that the requirement was not in place. This would be the case for the **core team training** and **CME requirements** in IT, the **establishment of new patient clinics** in CY, the **management of advanced and recurrent breast cancer** in SI, and the **provision of palliative care** in LU and NO.

Summary of results

Based on the responses provided, the results can be summarised as follows. **Although only a few countries require breast units by law, 17 out of 30 responding countries reported that they are recommended.**

- Compulsory implementation of the **four mandatory requirements** has only occurred in two countries (**IT** and **CZ**).
- In addition to the recommended threshold for the volume requirement, other thresholds ranging from **100 to 125 new cases per year have been reported** in six countries (AT, BE, CH, DE, NO and UK).
- Countries that have implemented the majority of the requirements on a compulsory basis are: **DE** (23/25 requirements), **LT** (21/25 requirements) and **IT** (19/25 requirements).
- The **most frequently implemented requirements**, on a compulsory basis, include the **provision of adjuvant therapy** (13 countries), the **provision of imaging equipment** (13 countries), the **multidisciplinary case management meetings** (11 countries) and the **provision of radiotherapy** (11 countries).
- The least **implemented requirement**, on a compulsory basis, is the **volume requirement** (two countries) – which is considered by the 2006 European Guidelines as a mandatory requirement for a breast unit.
- **Management of benign disease**, the **provision of extra psychological support** and **genetic risk communication** are three requirements which are implemented on a compulsory basis in only five countries.
- The **greatest discrepancies** in responses between ECIBC National Contacts and ED National Representatives are with regard to the requirements concerning **communication of diagnosis**, **patient information**, **physiotherapy for treatment of lymphoedema** and the **provision of extra psychological support**. For these requirements, there was disagreement in 45% of the countries where both the ECIBC National Contact and the ED National Representative provided a response.
- The **greatest concordance**, on the other hand, was in the requirement for **provision of teaching for staff or students**; disagreement was recorded in only one out of eight countries where both the ECIBC National Contact and the ED National Representative provided a response.

From these results it can be concluded that adoption of the 2006 breast unit model appears to be somewhat of a challenge. On the one hand, it is very well known by both policy makers/professionals and patient advocates; however, as this report clearly shows, implementation of that model is not harmonised across all countries, and there is a great deal of diversity in the number and which of the 25 requirements are implemented.

Impact of the results – The *European QA scheme* perspective

A Europe-wide scheme, like the *European QA scheme* being developed under the auspices of the ECIBC, will need to take into account all existing schemes and models, certainly also the 2006 breast unit model. Developers of the *European QA scheme* should carefully examine the results of this report.

Looking at the scattered implementation of the 2006 breast unit model, and considering that the *European QA scheme* will be voluntary, it will be critical to ensure a consistent implementation across countries. For this reason it was decided (i) to work in close collaboration with countries in order to determine which models would be feasible for all countries involved in the ECIBC [3] and how they can be implemented; (ii) to embed the *European QA scheme* in the accreditation legal framework providing an existing European infrastructure – the National Accreditation Bodies – which will oversee the accreditation and certification process and ensure harmonised assessment of adherence of breast cancer services to the *European QA scheme* requirements; and (iii) to involve patients, experts, and all other stakeholders in all stages of the scheme’s development and implementation processes.

The results of this survey related to low implementation of some 2006 breast unit model mandatory requirements vis-à-vis higher implementation of other requirements not only triggered some targeted systematic reviews, *e.g.* about volumes impact on outcomes, but confirmed the need to substantiate with evidence, whenever possible and appropriate, the requirements to be included in the *European QA scheme*. For this reason, ECIBC incorporates guidelines (the evidence) and the *QA scheme* in the same initiative. Having a systematic methodology of evidence use to underpin the scheme, on one side ensures that any potential impact of quality requirements on outcomes is credible, reliable and valid and, from another perspective, that any quest to policy makers towards an increased adherence to the scheme is supported by data showing an improvement of outcomes.

The 2006 breast units unit model originated some collection of breast cancer care data that helped in obtaining new evidence; the *European QA scheme* wishes to start from that good example and therefore foresees a systematic collection of data

related to its requirements. This will not only be an additional tool, beside the on-site audits, for assessing breast cancer services compliance to the requirements, but also a way to produce new evidence.

Impact of the results – The policy makers' perspective

The 2006 breast unit model was, and still is, an innovative model for providing appropriate care to women. The model was translated in a set of recommendations, but without a country mandate. Therefore, the diversity about the model's implementation status found in this survey should not be surprising.

Assuming that the most frequently implemented requirements were those considered the most feasible in relation to best practices and relevant for outcomes, the results can guide countries in prioritising implementation. Policy makers willing to implement the 2006 breast unit model (and possibly adhere to the *European QA scheme* in the future) may also wish to look at the evidence that is being produced within the ECIBC that will underpin the *European QA scheme*, to see which of the 2006 breast units model requirements would be in line with the future *European QA scheme* requirements and take this information under consideration when prioritising implementation of an appropriate set of breast unit model requirements. However, evidence may be weak or non-existent – making the choice on how to adopt some or all of 2006 breast unit requirements in national and local settings somewhat difficult.

Results can also be used by policy makers to see what other countries with similar organisational settings, population distribution, and level of investment in healthcare, prioritised for implementation and how the 2006 breast unit model requirements were actually implemented.

Acknowledgments

We would like to thank the co-organisers and 10th European Breast Cancer Conference (EBCC 10) chairs, Fatima CARDOSO and Susan KNOX on behalf of Europa Donna for their input and support in the development and launch of the survey, and in providing the list of contacts. We are indebted to Carmen MARTOS (JRC) for having revised the manuscript at internal level and to Manuel FLORENSA-MOLIST (JRC) for his editorial support. Most of all, we would like to express our gratitude to all who responded to the survey and for the extremely valuable information they provided.

Bibliography

- [1] Perry N, Broeders M, de Wolf C, Törnberg S, Holland R, von Karsa L, editors. *European guidelines for quality assurance in breast cancer screening and diagnosis*. 4th ed. Luxembourg: European Commission, Office for Official Publications of the European Communities, 2006.
- [2] Deandrea S, Bramesfeld A, Ambrosio M, Bocchi G, Dimitrova N, Lerda D, *et al.* *Efficacy of multidisciplinary meetings on breast cancer outcomes: a systematic review and pooled analysis*. ECIBC, Quality Assurance Scheme Development Group, and Iberoamerican Cochrane Centre contributed. 36th European Society of Surgical Oncology (ESSO) Conference, Krakow, 14-16 September 2016.
- [3] Lerda D, Deandrea S, Freeman C, López-Alcalde J, Neamțiu L, Nicholl C, *et al.* *Report of a European survey on the organisation of breast cancer care services*. Ispra: European Commission, Joint Research Centre, 2014.
- [4] Pylkkänen L, Deandrea S, Bramesfeld A, Neamțiu L, Saz Parkinson Z, Ulu-türk A, *et al.* *Can an annual minimum caseload for breast cancer services be determined?* 2016 UICC World Cancer Congress, Paris, 31 October-3 November 2016.
- [5] 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.
- [6] Wilson AR, Marotti L, Bianchi S, Biganzoli L, Claassen S, Decker T, *et al.* The requirements of a specialist breast centre. *Eur J Cancer*, 2013;49(17):3579-3587.

Annex Ia

ECIBC National Contact questionnaire



Survey on implementation of Breast Units

Dear participant to the survey, **thank you** for dedicating some of your time to complete this questionnaire

This survey is organised by JRC in collaboration with the chair of the European Breast Cancer Conference 10th edition (EBCC 10), Fatima Cardoso, and co-chair, Europa Donna, to follow-up the European Parliament (EP) resolution of 2006 on breast cancer in the enlarged European Union. It called on *Member States to ensure nationwide provision of interdisciplinary breast units in accordance with the EU guidelines by 2016, since treatment in an interdisciplinary breast unit has been proved to raise chances of survival and to improve the quality of life, and calls on the Commission to deliver a progress report on this every two years*.

The European Commission (EC) keeps a neutral position on how care is organised at Member States, however wishes to **fulfil the call of the European Parliament** and provide a progress report by beginning 2016, in correspondence with the deadline indicated in the resolution.

The reference document mentioned in the EP resolution is the *European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis*, which last edition is dated 2006 (and herein after mentioned as *European Guidelines 2006*), while the new version will be developed by the Guidelines Development Group under the governance of DG SANTE and the coordination of the JRC.

With the aim of facilitating the compilation of this questionnaire, specific references are cited at questionnaire sections when relevant and appropriate.

We are conscious of the effort that will be required in answering the questions. It is possible that it will require the input of several respondents (e.g. when the health system is organised at regional level) but the survey organiser needs to clearly identify the person responsible for the information provided in each questionnaire.

As already described in the second communication, the PDF form makes it possible:

to save a partially filled-in copy and send it later to us upon completion	You are responsible for the information provided
to save a partially filled-in copy and send it to other experts to complete it before sending it back to us	You are responsible for the information provided
to distribute the questionnaire to regional/local authorities asking them to send it back to you (in which case you will have to send all the forms back to JRC)	You are responsible for the information provided
to distribute the questionnaire to regional authorities asking them to send it directly back to us	Each respondent will be held responsible for the information provided

We would wish to stress the importance of receiving as many comprehensive responses as possible in order to ensure a complete overview of the situation in European Countries (and regions). Comments and considerations on the requirements will be as well very useful and appreciated.

The text in boxes and in blue is reproduced from the European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis (2006).

The questionnaire is structured around the following sections:

1. **Professional contact details**
2. **The organisation of healthcare in your country**
3. **References and Definitions**
4. **General questions on Breast Units**
5. **Breast Units mandatory requirements implementation stage**
6. **Breast Units non-mandatory requirements implementation stage**
7. **Personal data protection, Consent to publication and Form submission**

Instructions to complete the form:

1) Please provide as much information as possible. **The fields marked with an asterisk (*) are mandatory.** You will not be able to send the application via the submission button if you have not filled-in all the mandatory fields.

2) This application form has to be filled-in and submitted using 'Adobe Acrobat Reader'. Partially completed forms can be saved and retrieved later or forwarded to others to complete. Please activate the 'Highlight existing fields' function at top right corner.

3) Once completed, you will find at the end of the form a button for sending the application: **'Submit by email'**. Please check that your email account supports PDF forms.

4) Should you need clarifications on the information requested, or on technical questions related to the use of this form, please send an email to the following address: JRC-Cancer-Policy-Support@ec.europa.eu, or contact Donata Lerda at 0039-0332-786201, or Zuleika SAZ-PARKINSON at 0039-0332-789131 and Luciana NEAMTIU at 0039-0332-783034.

**Deadline for submission:
22/05/2015, 17:00 Ispra (Italy) local time**

1. PROFESSIONAL CONTACT DETAILS

Important: This information is used to identify your submission. If you want to update any other section of this form please re-submit the PDF without changing the information under this section.

Name*				
Surname (in capital letters)*				
Title* <small>(both professional and personal)</small>	Professional	Mr	Ms	Do not indicate
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Institution*				
Address*				
Postal code*				
Town*				
Country*				
Telephone (+ int. prefix)*				
Mobile phone				
E-mail*				

Geographical responsibility/mandate of your affiliation*

National	Regional	Local	Other
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If you choose 'Other', please provide a more detailed description

--

Denomination of the geographical area*

--

2. THE ORGANISATION OF HEALTHCARE IN YOUR COUNTRY

The two questions in this section were as well included in a previous survey organised by JRC. Please see the published report at the link [EU Bookshop](#) for the organisational aspects reported for your country in 2012-2013 and check the corresponding box in case any change occurred.

Please specify if any change in the geographical organisation / responsibility allocation of healthcare occurred since 2012-2013; please indicate NOT APPLICABLE in case your country was not included in that report*:

YES	NO	NOT APPLICABLE
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If NO, skip the following two pages and just go to section 4.

If YES or NOT APPLICABLE, please fill in the following fields:

In your country, healthcare and breast cancer care in particular is organised:

Nationally	Regionally	Regionally under National coordination	Locally	Locally under Regional / National coordination	Other
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If you choose 'Other', please provide a more detailed description

In the geographical area under your organisation's responsibility, healthcare and breast cancer care in particular is provided by:

A - Public entities exclusively	B - Public entities mainly	C - Private entities mainly	Other
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If you choose 'Other', please provide a more detailed description

--

If you choose B, are the public entities also responsible for the initial evaluation and the follow-up quality checks of external services provided by private entities?

YES	NO
<input type="radio"/>	<input type="radio"/>

If you choose C:

Are the private entities supervised by public entities?	Are the private entities initially evaluated by public entities and then followed up for the quality of services provided?	Are the private entities required to be accredited / certified along defined National or European standards?	None of the previous
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

3. REFERENCES AND DEFINITIONS

1. P6_TA(2006)0449

European Parliament resolution on breast cancer in the enlarged European Union.
Available at <http://www.europarl.europa.eu/sides/getDoc.do?type=MOTION&reference=B6-2006-0528&language=EN>

Recitals K, L, M and E are of specific relevance for this survey.

2. European Guidelines 2006

You can find the full version of the guidelines at the link: <http://bookshop.europa.eu/en/european-guidelines-for-quality-assurance-in-breast-cancer-screening-and-diaqnosis-pbND7306954/>.

Chapters 9 - *The requirements of a specialist Breast Unit* and, when referred to in chapter 9, also Chapter 10 - *Guidelines for training*, are of specific relevance for this survey.

For a facilitated filling-in of the questionnaire, you can find below the definitions reported at the beginning of Chapter 9 of the *European Guidelines 2006*:

Unit	Essentially a group of specialists in breast cancer and need not necessarily be a geographically single entity, although the separate buildings must be within reasonable proximity, sufficient to allow multidisciplinary working
Clinic	used to mean a session, usually around 3 hours at which a number of patients are seen for clinical examination and investigations
Specialists	Completed training and certified in own discipline (e.g.) Surgery, Radiology etc and for Core Team members, spending half their working time (clinics, operating, pathology or imaging reading, multidisciplinary meetings, inpatient care etc.) in breast cancer
Radiologist	a specialist in imaging for diagnosis
Radiographer	a technician, taking the mammograms and responsible for mammographic quality
Radiation Oncologist	specialist in radiotherapy only
Medical Oncologist	specialist in medical oncology
Breast Care Nurse	qualified nurse, trained to give psychological support to breast cancer patients (especially at the time diagnosis is given) and to act in follow up as link between patient and breast team
Psychiatrist	medically qualified specialist in pharmacological treatment of patients with psychiatric and psychological problems
Psychologist	not usually medically qualified and therefore unable to prescribe pharmacological therapies
Surgeon	gynaecological surgeons specialising in breast cancer are included in this term

The general requirements for Breast Units, as reported from 9.4.1 to 9.4.10 of the *European Guidelines 2005* are:

- A. **9.4.1 Recognition of a Breast Unit must be based on mandatory requirements.**
- B. 9.4.2 A European process of voluntary accreditation of Breast Units, based on the fulfilment of mandatory requirements should be established. To give uniformity a standard database should be made available.
- C. 9.4.3 Units must record the basic data on diagnosis, pathology, primary treatment and clinical outcomes. The data must be available for audit and the Unit team should hold regular audit meetings inspecting separate topics and designing and amending protocols and QA systems. These meetings must be minuted. Performance and audit figures must be produced yearly and set alongside defined quality objectives and outcome measures, such as those laid down in the EUSOMA Guidelines on the various aspects of care (12, 13, 14, 15, 16) or in other suitable guidelines.
- D. 9.4.4 The Unit must have written protocols for diagnosis and for the management of cancer at all stages (primary and advanced cancer). All protocols must be agreed upon by the core team members. New protocols and protocol amendments should be discussed by the core team at the audit meetings (see 9.4.3).
- E. 9.4.5 Breast Units will most often be established in large or medium sized hospitals; they should generally cover one-quarter to one-third of a million total population. Some highly specialised units will be larger.
- F. 9.4.6 Population Breast Screening programmes should be based within or be closely associated with a recognised Breast Unit and not work as a separate service. The radiologists, surgeons and pathologists working in the screening programme must be core members of the associated Breast Unit.
- 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.
- H. 9.4.8 A Breast Unit should hold outreach clinics for symptomatic referred women, screening assessment and follow-up, in the smaller hospitals in the neighbourhood if these are at a distance from the Breast Unit. In areas with low population density, out-reach arrangements are preferable to the establishment of small Breast Units without the clinical volume to allow expertise. In that circumstance outreach clinics may be only held as infrequently as once per month; such scheduling may prolong waiting times for appointments but clinical evaluation by an expert team is considered preferable to maintaining short waiting times.
- I. 9.4.9 Breast Units must provide care of breast disease at all its stages - from screening through to the care of advanced disease. Occasionally the patient may need to be sent to an associated large oncology centre for radiotherapy but the patient must essentially be managed and followed-up at her Breast Unit.
- J. 9.4.10 Breast Units should manage their own budget, covering all the work of the unit.

4. GENERAL QUESTIONS ON BREAST UNITS

Please note that the following questions are preparatory to the next questionnaire sections 5 and 6 where more detailed questions will be asked with reference to mandatory and non-mandatory requirements for Breast Units as defined in the *European Guidelines 2006*.

- i. Are there any Breast Units as defined by the European Guidelines 2006 in the geographical area under your organisation's responsibility?*

YES	NO	Comments/ Details
<input type="radio"/>	<input type="radio"/>	

- ii. Are Breast Units required by law in the geographical area under your organisation's responsibility?*

YES	NO	Comments/ Details
<input type="radio"/>	<input type="radio"/>	

- iii. Are Breast Units not required by law but just recommended in the geographical area under your organisation's responsibility?*

YES	NO	Comments/ Details
<input type="radio"/>	<input type="radio"/>	

- iv. Is there a national accreditation/certification system for Breast Units in the geographical area under your organisation's responsibility?*

YES	NO	If Yes, please provide details
<input type="radio"/>	<input type="radio"/>	

- v. Are there regional/local accreditation/certification systems for Breast Units in the geographical area under your organisation's responsibility?*

YES	NO	If Yes, please provide details
<input type="radio"/>	<input type="radio"/>	

- vi. Are these accreditation/certification systems mandatory or voluntary in the geographical area under your organisation's responsibility?

Mandatory	Voluntary	If Yes, please provide details
<input type="radio"/>	<input type="radio"/>	

- vii. If you wish, please add below your comments / considerations on Breast Units organisational concept as defined in the *European Guidelines 2006*.

5. BREAST UNITS MANDATORY REQUIREMENTS IMPLEMENTATION STAGE

Please note that as the following are MANDATORY requirements they can only be either fulfilled or not. Partial fulfilment (e.g. a critical mass of 100 instead of 150 cases, a core team not including all the profiles or not reaching the number for each profile) simply means non-fulfilment.

1. Critical mass

Definition from the European Guidelines 2006

A Unit must be of sufficient size to have **more than 150**, newly diagnosed cases of primary breast cancer (at all ages and stages) coming under its care each year.

Note: these are newly diagnosed breast cancers. They may have been diagnosed elsewhere but if they have received any prior treatment and have been transferred, for example, to receive radiotherapy, they should not be counted.

All primary treatment must be carried out under the direction of the Unit (operation must be in the unit, adjuvant therapies must be directed by the unit but may have been received in other settings e.g. RT and chemotherapy). Follow up should be under the control of the Unit.

The reason for recommending a minimum number is to ensure a caseload sufficient to maintain expertise for each team member and to ensure cost-effective working of the Breast Unit: the establishment of a clinic staffed by experts is expensive and must have a high through-put of patients.

A number of Units will be recognised as teaching centres, nationally or internationally. They may be recognised for teaching over all breast cancer management or special aspects (e.g.) screening, reconstruction, pathology.

1.1. In the geographical area under your organisation's responsibility is there any kind of requirement that regulates at more than 150 the number of newly diagnosed cases of primary breast cancer cases yearly treated in individual Breast Units?*

YES, MANDATORY	YES, VOLUNTARY	NO, PLANNED	BUT	NO and NOT PLANNED	I do not know
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>

1.2. If you replied YES, MANDATORY or VOLUNTARY, please report below the implementation framework of the requirement and the respective year of implementation (*more than one answer is possible*)

	Embedded in national / regional legislation	Used as reference for reimbursement from insurances at National / Regional level	Institutional licencing requirement at National / Regional level	Used in a non-public quality assurance scheme under National / Regional governance	Used in a non-public quality assurance scheme NOT under National / Regional governance
Implementation framework	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Year of implementation	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

1.3. If you replied YES, please provide a more detailed description: name of legislation/quality assurance scheme, link to the text or reference document

1.4. Please select the scenario that you think is better representing you country with respect to the critical mass at more than 150 the number of newly diagnosed cases of primary breast cancer cases yearly treated in individual Breast Units*:

Virtually all primary breast cancer cases are treated in a centre whose volume is higher than 150 new cases/year	<input type="radio"/>
Most primary breast cancer cases are treated in a centre whose volume is higher than 150 new cases/year, but a small amount of cases are treated in centres with a lower volume	<input type="radio"/>
Primary breast cancer cases are equally divided in centres with more and less than 150 new cases/year	<input type="radio"/>
Even though centres whose volume is higher than 150 new cases/year exist, most cases are treated in low-volume centres	<input type="radio"/>
Virtually all primary breast cancer cases are treated in a centre whose volume is lower than 150 new cases/year	<input type="radio"/>

1.5. If you have requirements, but your threshold is different from 150, please provide the number

<table border="1"><tr><td></td></tr></table>	

1.6. If you wish, please add below your comments / considerations on critical mass mandatory requirement.

--

2. Core Team

Definition from the *European Guidelines 2006*

Each member of the core team must have special training in breast cancer; for standards see Chapter 10 (pages 356 – 365 <http://bookshop.europa.eu/en/european-guidelines-for-quality-assurance-in-breast-cancer-screening-and-diagnosis-pbND7306954/>).

Each member of the breast unit core team must undertake continuing professional education on a regular basis. Breast Unit budgets must include provision for this.

9.5.2.1 The Breast Unit must have **an identified Clinical Director of Breast Services**.

9.5.2.2 Breast Surgeons (including Gynaecologists performing breast surgery)

Two or more nominated surgeons specially trained in breast disease, each of whom must personally carry out the primary surgery on **at least 50 newly diagnosed cancers per annum and must attend at least one diagnostic clinic per week**. For an average sized unit the surgeons will need at least eight identified ca. 4 hr sessions per week in Breast Disease. These sessions will allow for operating time, participation in diagnostic clinics, a follow-up clinic and, where appropriate, screening assessment clinics. A session must be allowed for attendance at a weekly team case management and audit meeting.

A Unit team must provide breast surgical reconstruction when required for those patients not suitable for breast conserving therapy and be able to apply special techniques for patients with extensive local disease. The breast surgeons in the team should be able to undertake basic reconstruction or recontouring and there should be a standard arrangement or joint reconstruction clinic with one or two nominated Plastic Surgeons (non-core team member) who take a special interest in breast reconstructive and recontouring techniques.

9.5.2.3 Breast Radiologists

There must be at least two nominated radiologists, fully trained and with continuing experience in all aspects of breast disease and associated imaging, tissue sampling and localisation procedures under image control. Ideally any radiologist investigating breast patients should participate in the screening programme in countries in which this is established and must participate in a national or regional QA scheme. They must fulfil the volume requirements as laid down for breast assessment in Chapter 5 and the previously published document 'Quality Assurance in the Diagnosis of Breast Disease', reading a minimum of **1000 mammograms per year (5000 for those participating in a screening programme)**.

They must attend multidisciplinary meetings for case management and audit purposes.

They must be present in diagnostic assessment clinics with the surgeon. Each radiologist must attend at least one diagnostic clinic per week for symptomatic patients or screening assessment.

9.5.2.4 Breast Pathologists

A lead pathologist plus usually not more than one other nominated pathologist, specialising in Breast Disease, will be responsible for all breast pathology and cytology.

Pathologists carrying out these roles must have contractual sessions to attend team case management and audit meetings. They must be familiar with national and/or European performance quality standards and guidelines. They must take part in available European, National and Regional quality assurance schemes.

9.5.2.5 Breast Oncologists

¹ Perry N, on behalf of EUSOMA Working Party. Quality Assurance in the diagnosis of breast disease. *Eur J Cancer*, 2001, 37, 159-172.

(a) **A nominated radiation oncologist** must arrange the appropriate delivery of radiotherapy¹. He/she must hold advanced disease clinics with other members of the breast team at the Breast Unit and must take part in the case management and audit meetings of the Unit.

(b) In some countries, Clinical Oncologists carry out both radiation therapy and prescribe the chemotherapy. In centres in which a **Medical Oncologist gives the chemotherapy** he/she should be a member of the core team and take a full part in case management and audit meetings.

9.5.2.6 Breast Diagnostic Radiographers (Technicians)

Radiographers with the necessary expertise and training in mammography are essential members of the team. They must fulfil the training and working practice recommendations as laid down in Chapters 3, 5, and 10. They must be responsible for taking the mammograms, which must not be performed by radiographic or nonradiographic personnel without the above training.

9.5.2.7 Data Managers

There must be a system covering audit. **A data manager** must enter data on diagnosis, treatment, pathology and clinical outcomes contemporaneously.

9.5.2.8 Patient Support staff

Regular support (advice, counselling, psychological help) is given by Breast Care Nurses in some countries and psychologically professionally trained persons with expertise in Breast Cancer in others. These persons must be members of the core team. They must be available to counsel and offer practical advice and emotional support to newly diagnosed patients at the time the diagnosis is given, so as to further explain treatment plans. They should also be available on demand from patients in the Primary Breast Cancer Follow up clinic and in the Advanced Breast Clinic. Particularly they must be present to support women when the diagnosis is given that the disease has become advanced. **At least two Breast Care Nurses are needed per breast unit.**

2a COMPOSITION

2a.1. Is there, in the geographical area under your organisation's responsibility, any kind of requirement that regulates the composition of the core team as defined in the *European Guidelines 2006*?

YES, MANDATORY	YES, VOLUNTARY	NO, PLANNED	BUT	NO and NOT PLANNED	I do not know
<input type="radio"/>					

2a.2. If you replied YES, please provide a more detailed description of the team (i.e. the clinical and radiation oncologist role, number of radiographers, additional members of the core team, e.g. higher numbers and/or additional professional profiles – e.g. plastic surgeons – than foreseen in the *European Guidelines 2006*)

¹ Kurtz J, for the EUSOMA Working Party. The curative role of radiotherapy in the treatment of operable breast cancer. *Eur J Cancer*, 2002, 38, 1961-1974

2a.3. If you replied YES, please report below the implementation framework of the team composition requirements and the respective year of implementation (*more than one answer is possible*)

	Embedded in national / regional legislation	Used as reference for reimbursement from insurances at National / Regional level	Institutional licencing requirement at National / Regional level	Used in a non-public quality assurance scheme under National / Regional governance	Used in a non-public quality assurance scheme NOT under National / Regional governance
Implementation framework	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Year of implementation	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

2a.4. If you replied YES, please provide a more detailed description (*i.e.* name of legislation/quality assurance scheme, link to the text or reference document)

2a.5. If you wish, please add below your comments / considerations on core team composition mandatory requirement.

2b. TRAINING

2b.1. Is there, in the geographical area under your organisation's responsibility, any kind of requirement that regulates the training standards of the core team as defined in the *European Guidelines 2006*?

YES, MANDATORY	YES, VOLUNTARY	NO, PLANNED	BUT	NO and NOT PLANNED	I do not know
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>

2b.2. If you replied YES, please provide a more detailed description of the training standards, in particular of any deviation from those standards (e.g. training in imaging in mammography - both film-screen and digital)

2b.3. If you replied YES, please report below the implementation framework of the team's training standards and the respective year of implementation (*more than one answer is possible*)

	Embedded in national / regional legislation	Used as reference for reimbursement from insurances at National / Regional level	Institutional licencing requirement at National / Regional level	Used in a non-public quality assurance scheme under National / Regional governance	Used in a non-public quality assurance scheme NOT under National / Regional governance
Implementation framework	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Year of implementation	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

2b.4. If you replied YES, please provide a more detailed description (i.e. name of legislation/quality assurance scheme, link to the text or reference document)

2b.5. If you wish, please add below your comments / considerations on core team's training standards mandatory requirement.

--

2c. CONTINUING MEDICAL EDUCATION

2c.1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the CME of the core team as defined in the *European Guidelines 2006*?

YES, MANDATORY	YES, VOLUNTARY	NO, PLANNED	BUT	NO and NOT PLANNED	I do not know
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>

2c.2. If you replied YES, please provide a more detailed description of the continuing medical education contents / organisation (e.g. is CME outsourced to licenced trainers? How is licencing awarded?)

--

2c.3. If you replied YES, please report below the implementation framework of the team's CME and the respective year of implementation (*more than one answer is possible*)

	Embedded in national / regional legislation	Used as reference for reimbursement from insurances at National / Regional level	Institutional licencing requirement at National / Regional level	Used in a non-public quality assurance scheme under National / Regional governance	Used in a non-public quality assurance scheme NOT under National / Regional governance
Implementation framework	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Year of implementation	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

2c.4. If you replied YES, please provide a more detailed description (i.e. name of legislation/quality assurance scheme, link to the text or reference document)

2c.5. If you wish, please add below your comments / considerations on core team's CME mandatory requirement.

6. BREAST UNITS NON-MANDATORY REQUIREMENTS IMPLEMENTATION STAGE

A. Equipment (9.6.1)

Definition from the *European Guidelines 2006*

9.6.1 The unit must be in possession of all necessary imaging equipment for complete and adequate breast diagnosis.

A1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the imaging equipment requirement 9.6.1 as defined above?*

YES, MANDATORY	YES, VOLUNTARY	NO, PLANNED	BUT	NO and NOT PLANNED	I do not know
<input type="radio"/>					

A2. If you replied YES, please provide a more detailed description (i.e. name of legislation/quality assurance scheme, link to the text or reference document)

A3. If you wish, please add below your comments / considerations on the imaging equipment voluntary requirement.

B. Equipment (9.6.2)

Definition from the European Guidelines 2006

9.6.2 The minimum equipment in a department giving radiotherapy must be two megavoltage units, a brachytherapy unit, a simulator and a computerised planning system. The department must have a radiotherapeutic quality control programme for breast cases.

B.1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the radiotherapeutic equipment requirement 9.6.2 as defined above?*

YES, MANDATORY	YES, VOLUNTARY	NO, PLANNED	BUT	NO and NOT PLANNED	I do not know
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>

B.2. If you replied YES, please provide a more detailed description (i.e. name of legislation/quality assurance scheme, link to the text or reference document)

B.3. If you wish, please add below your comments / considerations on the radiotherapeutic equipment voluntary requirement.

C. Facilities / Services (9.7.1)

Definition from the *European Guidelines 2006*

Clinics (see definition in Section 9.4). Consultations for Breast patients should be held separately, i.e., not as part of general surgery.

New patient clinics

At least one clinic per week for newly referred symptomatic women must be held. A Unit diagnosing 150 new cancers per year must expect over 1500 new referrals of symptomatic women (= approximately 30 per week).

Suggested outcome measures for the waiting times are given in Chapter 5. A suggested good practice is that all newly referred women with breast symptoms should be offered an appointment within 10 working days of receipt of the referral.

Clinics to which patients are referred or self-referred must be staffed by a surgeon, a radiologist and radiographers from the breast care team. Multidisciplinary working must allow all standard investigations for triple assessment (clinical examination and all appropriate imaging and tissue diagnostic procedures) to be completed at one visit. Where possible the finding of no abnormality or a confirmed diagnosis of a benign lesion should be communicated to the patient at that visit.

C.1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the new patient clinics as defined above?*

YES, MANDATORY	YES, VOLUNTARY	NO, PLANNED	BUT	NO and NOT PLANNED	I do not know
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>

C.2. If you replied YES, please provide a more detailed description (i.e. name of legislation/quality assurance scheme, link to the text or reference document)

C.3. If you wish, please add below your comments / considerations on the new patient clinic voluntary requirement.

D. Facilities / Services (9.7.2)

Definition from the *European Guidelines 2006*

Communication of the Diagnosis and Treatment Plan

It may not be possible (now that core biopsy is most often used) or may not be considered appropriate by the unit to give the diagnosis of cancer at the initial visit. Women found to have breast cancer should receive that diagnosis within 5 working days. The diagnosis should be ideally communicated personally by the surgeon; if it is communicated by the radiologist, then the surgeon (±) the oncologist must personally advise the patient on treatment. It is recommended that a breast care nurse (or) psychologically trained person (see 9.5.2.8) be present to discuss fully with the patient the options for treatment and to give emotional support.

If a patient has clear advanced breast cancer it may be more appropriate that an oncologist rather than a surgeon gives the diagnosis if the patient's treatment does not involve surgery.

A suitable room with sufficient privacy must be available. In units in which preoperative irradiation or primary medical therapies are used, cases which might be suitable for these should be seen jointly by a surgeon and radiation or medical oncologist before treatment commences.

A diagnosis should not be given to a patient by letter or on the telephone, unless at the specific request of the patient given adequate and full informed choice.

D.1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the communication of the diagnosis and treatment plan as defined above?*

YES, MANDATORY	YES, VOLUNTARY	NO, PLANNED	BUT	NO and NOT PLANNED	I do not know
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>

D.2. If you replied YES, please provide a more detailed description (i.e. name of legislation/quality assurance scheme, link to the text or reference document)

D.3. If you wish, please add below your comments / considerations on the communication of the diagnosis and treatment plan voluntary requirement.

E. Facilities / Services (9.7.3)

Definition from the *European Guidelines 2006*

Multidisciplinary Case Management Meetings (MDM's)

All members of the core team must attend the Multidisciplinary Meeting (MDM), which must be held at least weekly.

The following should be discussed:

- cases in which the diagnosis is as yet uncertain *e.g.*, following core biopsy
- cases in whom the diagnosis of cancer is confirmed and who may be considered for primary medical therapy
- all cases following surgery on receipt of the histopathology for discussion of further care and
- cases in follow-up who recently have undergone diagnostic investigations for possible symptoms of recurrent or advanced disease

It is possibly more convenient to have two MDM's per week:

- one for cases in diagnosis attended by surgeons, radiologists and pathologists and
- one for post-operative consideration of prognosis and adjuvant therapies and for cases investigated for disease recurrence (oncologists, surgeons, radiologists and pathologists)

E.1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the MDMs as defined above?*

YES, MANDATORY	YES, VOLUNTARY	NO, BUT PLANNED	NO and NOT PLANNED	I do not know
<input type="radio"/>				

E.2. If you replied YES, please provide a more detailed description (*i.e.* name of legislation/quality assurance scheme, link to the text or reference document)

E.3. If you wish, please add below your comments / considerations on the MDMs voluntary requirement.

F. Facilities / Services (9.7.4)

Definition from the *European Guidelines 2006*

Physiotherapy

Physiotherapy must be available for the post-operative recovery period to ensure good shoulder mobility, etc.

F.1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the provision of physiotherapy as defined above?*

YES, MANDATORY	YES, VOLUNTARY	NO, PLANNED	BUT	NO and PLANNED	NOT	I do not know
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>		<input type="radio"/>

F.2. If you replied YES, please provide a more detailed description (i.e. name of legislation/quality assurance scheme, link to the text or reference document)

F.3. If you wish, please add below your comments / considerations on the physiotherapy voluntary requirement.

G. Facilities / Services (9.7.5)

Definition from the *European Guidelines 2006*

Adjuvant therapies

The multidisciplinary team (MDT) must decide on the appropriate adjuvant therapies in light of the pathology of the surgical specimen.

- Radiotherapy may be delivered within the same hospital or patients may have to travel to a Radiotherapy Unit in another Hospital (at which the core team radiation oncologist must be able to supervise their treatment).
- The administration of cytotoxic therapy as adjuvant therapy or for advanced disease must be by an accredited oncologist (member of the core team) with proper facilities. Cytotoxic therapies may be given in another hospital but the decisions regarding their application must be made by the MDT of the Unit.

G.1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the provision of adjuvant therapies as defined above?

YES, MANDATORY	YES, VOLUNTARY	NO, PLANNED	BUT	NO and NOT PLANNED	I do not know
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>

G.2. If you replied YES, please provide a more detailed description (i.e. name of legislation/quality assurance scheme, link to the text or reference document)

G.3. If you wish, please add below your comments / considerations on the adjuvant therapy voluntary requirement.

H. Facilities / Services (9.7.6)

Definition from the *European Guidelines 2006*

Advanced and recurrent Breast Cancer

- There must be one Advanced Breast Cancer Clinic at least every 2 weeks at the Breast Unit, separate from the general oncology clinics (although sometimes combined with gynaecological oncology) and attended by the Clinical Oncologist ± Medical Oncologist (see 9.5.2.5 b). The surgeon must be available if required for consultation and must be in full attendance if the breast surgeons supervise the endocrine therapies. Patients with distant metastases locally advanced primary breast cancer and local or regional recurrence, must be managed in this clinic according to protocols agreed by the multidisciplinary team.
- Patients who have received radiotherapy or chemotherapy at another Cancer Centre should normally be referred back to the Breast Team at their Breast Unit for further follow-up and decision making in the Advanced Breast Cancer Clinic
- A palliative care/pain control service must be easily accessible

H.1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the management of advanced and recurrent breast cancer as defined above?*

YES, MANDATORY	YES, VOLUNTARY	NO, PLANNED	BUT	NO and NOT PLANNED	I do not know
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>

H.2. If you replied YES, please provide a more detailed description (i.e. name of legislation/quality assurance scheme, link to the text or reference document)

H.3. If you wish, please add below your comments / considerations on the management of advanced and recurrent breast cancer voluntary requirement.

I. Facilities / Services (9.7.7)

Definition from the *European Guidelines 2006*

Follow-up of primary breast cancer

- All patients with primary breast cancer must be followed-up in a Clinic directly supervised by one of the surgeons. Any necessary imaging or other investigations should be carried out at the same visit.
- Although the patient may have to visit a separate Hospital to receive radiotherapy or specialised chemotherapy, the decisions on the case management and the subsequent follow-up should be by the team members of her Breast Unit. The skills of the diagnostic breast team are then available for the detection and investigation of a possible recurrence.

I.1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the follow-up of primary breast cancer as defined above?*

YES, MANDATORY	YES, VOLUNTARY	NO, PLANNED	BUT	NO and NOT PLANNED	I do not know
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>

I.2. If you replied YES, please provide a more detailed description (i.e. name of legislation/quality assurance scheme, link to the text or reference document)

I.3. If you wish, please add below your comments / considerations on the follow-up of primary breast cancer voluntary requirement.

J. Facilities / Services (9.7.8)

Definition from the *European Guidelines 2006*

Benign disease

The Breast Unit must also advise and where necessary treat women with benign disease (e.g.) cysts, fibroadenoma, mastalgia, inflammatory conditions, mammillary fistula and phyllodes tumour.

J.1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the management of benign disease as defined above?*

YES, MANDATORY	YES, VOLUNTARY	NO, PLANNED	BUT	NO and NOT PLANNED	I do not know
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>

J.2. If you replied YES, please provide a more detailed description (i.e. name of legislation/quality assurance scheme, link to the text or reference document)

J.3. If you wish, please add below your comments / considerations on the management of benign disease voluntary requirement.

K. Facilities / Services (9.7.9)

Definition from the *European Guidelines 2006*

Family History / genetics

Advice is best given in a multidisciplinary clinic, the specialists involved are a clinical geneticist and from the team a breast surgeon with reconstructive skills, radiologist and psychiatrist or clinical psychologist. Gene probing must be available when required and ideally a molecular geneticist should be accessible for consultation by the specialists in the clinic.

K.1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the management of family history / genetics as defined above?*

YES, MANDATORY	YES, VOLUNTARY	NO, PLANNED	BUT	NO and NOT PLANNED	I do not know
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>

K.2. If you replied YES, please provide a more detailed description (i.e. name of legislation/quality assurance scheme, link to the text or reference document)

K.3. If you wish, please add below your comments / considerations on the management of family history / genetics voluntary requirement.

J. Facilities / Services (9.7.8)

Definition from the *European Guidelines 2006*

Benign disease

The Breast Unit must also advise and where necessary treat women with benign disease (e.g.) cysts, fibroadenoma, mastalgia, inflammatory conditions, mammillary fistula and phyllodes tumour.

J.1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the management of benign disease as defined above?*

YES, MANDATORY	YES, VOLUNTARY	NO, PLANNED	BUT	NO and NOT PLANNED	I do not know
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>

J.2. If you replied YES, please provide a more detailed description (i.e. name of legislation/quality assurance scheme, link to the text or reference document)

J.3. If you wish, please add below your comments / considerations on the management of benign disease voluntary requirement.

K. Facilities / Services (9.7.9)

Definition from the *European Guidelines 2006*

Family History / genetics

Advice is best given in a multidisciplinary clinic, the specialists involved are a clinical geneticist and from the team a breast surgeon with reconstructive skills, radiologist and psychiatrist or clinical psychologist. Gene probing must be available when required and ideally a molecular geneticist should be accessible for consultation by the specialists in the clinic.

K.1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the management of family history / genetics as defined above?*

YES, MANDATORY	YES, VOLUNTARY	NO, PLANNED	BUT	NO and NOT PLANNED	I do not know
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>

K.2. If you replied YES, please provide a more detailed description (i.e. name of legislation/quality assurance scheme, link to the text or reference document)

K.3. If you wish, please add below your comments / considerations on the management of family history / genetics voluntary requirement.

For requirement 9.7.10 (Reconstruction) see requirement 9.8.2)

L. Facilities / Services (9.7.11)

Definition from the *European Guidelines 2006*

Breast Screening

Ideally breast screening centres should be a part of Breast Units and the same radiologists should be members of the Unit team and work in screen detection and the diagnosis of symptomatic disease. Assessment centres should be placed in Breast Units.

L1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the breast screening management as defined above?*

YES, MANDATORY	YES, VOLUNTARY	NO, PLANNED	BUT	NO and NOT PLANNED	I do not know
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>

L2. If you replied YES, please provide a more detailed description (i.e. name of legislation/quality assurance scheme, link to the text or reference document)

L3. If you wish, please add below your comments / considerations on the breast screening management voluntary requirement.

M. Facilities / Services (9.7.11)

Definition from the *European Guidelines 2006*

Patient information

Women must be offered clear written and oral information regarding their diagnosis and/or treatment options. The Breast Unit should also provide written information concerning local out-patient support groups and advocacy organisations and should also respect the patients rights as outlined in the Breast Cancer Resolution of the European Parliament (OJ C 68 E (18.03.2004), p.611). Patients should be provided with a list of their rights as outlined in the breast cancer resolution.

M.1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the patient information as defined above?*

YES, MANDATORY	YES, VOLUNTARY	NO, PLANNED	BUT	NO and NOT PLANNED	I do not know
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>

M.2. If you replied YES, please provide a more detailed description (i.e. name of legislation/quality assurance scheme, link to the text or reference document)

M.3. If you wish, please add below your comments / considerations on the patient information voluntary requirement.

N. Associated Services and non-core personnel (9.8.1)

Definition from the *European Guidelines 2006*

These are services for which it cannot be expected that staff will spend the majority of their time on breast disease.

Extra Psychological Support

If the patient is experiencing psychological morbidity that cannot be dealt with effectively by members (usually breast care nurse or psycho-oncologist) of the Unit team, she should be referred to a psychiatrist with whom there are particular arrangements to see breast patients for the Breast Unit (non-core team member).

N.1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the extra psychological support as defined above?*

YES, MANDATORY	YES, VOLUNTARY	NO, PLANNED	BUT	NO and NOT PLANNED	I do not know
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>

N.2. If you replied YES, please provide a more detailed description (*i.e.* name of legislation/quality assurance scheme, link to the text or reference document)

N.3. If you wish, please add below your comments / considerations on the extra psychological support voluntary requirement.

O. Associated Services and non-core personnel (9.8.2)

Definition from the *European Guidelines 2006*

Plastic Surgeon

The Breast Unit should make arrangement with one or two nominated plastic surgeons with a special interest in breast reconstructive and recontouring techniques.

0.1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the plastic surgery as defined above?*

YES, MANDATORY	YES, VOLUNTARY	NO, PLANNED	BUT	NO and PLANNED	NOT	I do not know
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>		<input type="radio"/>

0.2. If you replied YES, please provide a more detailed description (i.e. name of legislation/quality assurance scheme, link to the text or reference document)

0.3. If you wish, please add below your comments / considerations on the plastic surgery voluntary requirement.

P. Associated Services and non-core personnel (9.8.3)

Definition from the *European Guidelines 2006*

Geneticists

Women seeking advice with regard to risk, e.g., family history, must be able to receive advice from the Breast team, which must include a clinical geneticist with a specialist interest in breast cancer (see 9.7.9).

P.1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the genetist advice as defined above?*

YES, MANDATORY	YES, VOLUNTARY	NO, PLANNED	BUT	NO and NOT PLANNED	I do not know
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>

P.2. If you replied YES, please provide a more detailed description (i.e. name of legislation/quality assurance scheme, link to the text or reference document)

P.3. If you wish, please add below your comments / considerations on the genetist advice voluntary requirement.

Q. Associated Services and non-core personnel (9.8.4)

Definition from the *European Guidelines 2006*

Palliative Care

A specialist palliative care service must be available for the referral of patients with advanced breast cancer. A close working relationship must be established between members of the Breast Unit (especially the breast care nurse) and the palliative care service to ensure that breakdowns in continuity of care do not occur and also with the local network for home assistance.

Q.1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the provision of palliative care as defined above?

YES, MANDATORY	YES, VOLUNTARY	NO, PLANNED	BUT	NO and NOT PLANNED	I do not know
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>

Q.2. If you replied YES, please provide a more detailed description (i.e. name of legislation/quality assurance scheme, link to the text or reference document)

Q.3. If you wish, please add below your comments / considerations on the provision of palliative care voluntary requirement.

R. Associated Services and non-core personnel (9.8.5)

Definition from the *European Guidelines 2006*

Prosthesis

There must be provision for a Prosthesis fitting service within the unit.

R.1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the provision of prosthesis as defined above?*

YES, MANDATORY	YES, VOLUNTARY	NO, PLANNED	BUT	NO and NOT PLANNED	I do not know
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>

R.2. If you replied YES, please provide a more detailed description (*i.e.* name of legislation/quality assurance scheme, link to the text or reference document)

R.3. If you wish, please add below your comments / considerations on the provision of prosthesis-voluntary requirement.

5. Associated Services and non-core personnel (9.8.6)

Definition from the *European Guidelines 2006*

Physiotherapy and Lymphoedema

An identified Physiotherapist or a Breast Care Nurse for the treatment of lymphoedema and late sequelae.

S.1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the provision of physiotherapy and lymphoedema treatment as defined above?*

YES, MANDATORY	YES, VOLUNTARY	NO, PLANNED	BUT	NO and NOT PLANNED	I do not know
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>

S.2. If you replied YES, please provide a more detailed description (i.e. name of legislation/quality assurance scheme, link to the text or reference document)

S.3. If you wish, please add below your comments / considerations on the provision of provision of physiotherapy and lymphoedema treatment voluntary requirement.

T. Research (9.9)

Definition from the European Guidelines 2006

Research is one of the essential parts of training of specialists. As part of Audit Units must record numbers of patients entered into clinical trials and details of all other research. Units should be encouraged to provide research opportunities and this must be taken into account when assessing units for their suitability for accepting trainees.

T.1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the management of research as defined above?*

YES, MANDATORY	YES, VOLUNTARY	NO, PLANNED	BUT	NO and NOT PLANNED	I do not know
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>

T.2. If you replied YES, please provide a more detailed description (i.e. name of legislation/quality assurance scheme, link to the text or reference document)

T.3. If you wish, please add below your comments / considerations on the management of research voluntary requirement.

U. Teaching (9.10)

Definition from the *European Guidelines 2006*

The Unit must provide teaching, whether simply for junior staff or for students or on a national or international basis. Some units may particularly concentrate on certain areas (e.g.) Reconstruction, Screening, Pathology, etc.

U.1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the management of teaching provision as defined above?*

YES, MANDATORY	YES, VOLUNTARY	NO, PLANNED	BUT	NO and PLANNED	NOT	I do not know
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>		<input type="radio"/>

U.2. If you replied YES, please provide a more detailed description (i.e. name of legislation/quality assurance scheme, link to the text or reference document)

U.3. If you wish, please add below your comments / considerations on the management of teaching provision voluntary requirement.

V. Additional point (9.11)

Definition from the European Guidelines 2006

The implementation of the suggested structure of Breast Units requires a reorganisation of time in each discipline, so that as a consultant spends more time in breast disease, his or her colleagues no longer treat breast cancer and specialise in other areas. Rationalisation of work patterns, in this way would provide sufficient staff for the Breast Units. Such a move would coincide with changes that are already occurring within all disciplines, for example, from General Surgery the emergence of specialist surgeons for urology, microinvasive techniques, vascular surgery, upper GI, hepatic and colon.

All work must be carried out or directly supervised by specialists specifically trained in breast disease. A service provided by a trained specialist is more efficient and more cost effective – diagnostic decisions are made earlier whereas junior staff are more likely to call a patient back several times unnecessarily and to carry out unnecessary investigations; operating by consultants gives better results for technical reasons; the interpretation of imaging techniques and the reading of histology is much more likely to produce definitive opinions if carried out by experts.

We [the guidelines authors] estimate that for a 10 million total population base 30-40 Breast Units are required for the ideal service and that reorganisation in this way will provide considerable financial savings. This could easily be achieved and should be attractive to many countries.

V.1 In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the additional points as defined above?*

YES, MANDATORY	YES, VOLUNTARY	NO, PLANNED	BUT	NO and NOT PLANNED	I do not know
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>

V.2. If you replied YES or OTHER, please provide a more detailed description (i.e. which of the additional points is/are covered, name of legislation/quality assurance scheme, link to the text or reference document)

V.3. If you wish, please add below your comments / considerations on the additional points reported above.

7. Personal data protection, Consent to publication and Form submission

Personal data protection policy

The Commission will ensure that applicants' personal data are processed as required by [Regulation \(EC\) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Union institutions and bodies and on the free movement of such data \(OJ L 8, 12.1.2001\)](#). This applies in particular to the confidentiality and security of such data.

For an overview of the policy: http://ec.europa.eu/dataprotectionofficer/legal_framework_en.htm
For further details on how data are managed at JRC please go to the link <http://ec.europa.eu/dpo-register/details.htm?id=28522> (the example applies to meetings in particular but the policy is the same for personal data protection for surveys).

By ticking the field below I confirm that I have read the information provided on personal data treatment.*

By ticking the field below I accept the European Commission policy for the treatment of the personal data I provided in the remit of this survey.*

Consent to publication of data

In order to ensure that the collected data would be useful, they need to be published. Please provide below your consent to publish them on a JRC report and/or in presentations (e.g. during the ECBC IO dedicated session). Your contribution will always be explicitly recognised

By ticking the field below I provide my consent to publish all the data I provided through this questionnaire*

In case JRC and the co-organisers of this survey should plan to publish the data obtained from this survey on a peer-reviewed journal, your consent (and potentially also additional details) will be explicitly sought before proceeding

Application form submission

- 1) While you are completing the form and when you have finished filling it in, you can save it on your PC (it would be advisable to change the file name, e.g. by adding your initials and/or your country name)
- 2) When you are ready to send the form back to us, please verify that your internet connection is active and that your email account is compatible with PDF forms, then click on the **Submit by Email** button below. The form will be automatically sent to the application mailbox.
- 3) PLEASE NOTE that if the form is not appropriately filled-in (all mandatory fields are completed), an alert box will appear indicating the number of missing fields and you'll not be able to submit the form until you have completed them. When you have finished, please check your form again and try to re-submit it according to step 2.
- 4) Once you have submitted the form, you're advised to save it on your computer as a file in pdf format, for any further confirmation of data the organisers of this survey might request.
- 5) Should you still have any difficulties, please contact the survey helpdesk: JRC-cancer-policy-support@ec.europa.eu

**Deadline for submission:
22/05/2015, 17:00 Ispra (Italy) local time**

Submit by Email

Annex Ib

ED National Representative questionnaire



EUROPEAN COMMISSION
JOINT RESEARCH CENTRE
Institute for Health and Consumer Protection
I.2 Public Health Policy Support



Survey on Implementation of Breast Units

Dear participant to the survey, **thank you** for dedicating some of your time to complete this questionnaire.

This survey is organised by JRC in collaboration with the chair of the European Breast Cancer Conference 10th edition (EBCC 10), Fatima Cardoso, and co-chair, Europa Donna, to follow-up the European Parliament (EP) resolution of 2006 on breast cancer in the enlarged European Union. It called on *Member States to ensure nationwide provision of interdisciplinary breast units in accordance with the EU guidelines by 2016, since treatment in an interdisciplinary breast unit has been proved to raise chances of survival and to improve the quality of life, and calls on the Commission to deliver a progress report on this every two years*.

The European Commission (EC) keeps a neutral position on how care is organised at Member States, however wishes to fulfil the call of the European Parliament and provide a progress report by beginning 2016, in correspondence with the deadline indicated in the resolution.

The reference document mentioned in the EP resolution is the *European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis*, which last edition is dated 2006 (and herein after mentioned as *European Guidelines 2006*), while the new version will be developed by the Guidelines Development Group under the governance of DG SANTE and the coordination of the JRC. Specific references are cited along this questionnaire as relevant and appropriate.

We are conscious of the effort that will be required in answering the questions, but, at the same time, we wish to encourage you to take this effort. It will be very important to receive as many comprehensive responses as possible in order to ensure a complete overview of the situation in European Countries.

The tool used for this questionnaire is a PDF form. In case you should have any difficulty in submitting it please do not hesitate to contact the helpdesk (see at next page).

The text in boxes and in blue is reproduced from the European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis (2006)

The questionnaire is structured around the following sections:

1. **Contact details**
2. **The organisation of healthcare in your country**
3. **References and Definitions**
4. **General questions on Breast Units**
5. **Breast Units mandatory requirements implementation stage**
6. **Breast Units non-mandatory requirements implementation stage**
7. **Personal data protection, Consent to publication and Form submission**

Page 1 of 38

Instructions to complete the form:

1) Please provide as much information as possible. **The fields marked with an asterisk (*) are mandatory.** You will not be able to send the application via the submission button if you have not filled-in all the mandatory fields.

2) This application form has to be filled-in and submitted using 'Adobe Acrobat Reader'. Partially completed forms can be saved and retrieved later or forwarded to others to complete. Please activate the 'Highlight existing fields' function at top right corner.

3) Once completed, you will find at the end of the form a button for sending the application: **'Submit by email'**. Please check that your email account supports PDF forms.

4) Should you need clarifications on the information requested, or on technical questions related to the use of this form, please send an email to the following address: JRC-Cancer-Policy-Support@ec.europa.eu, or contact Donata Lerda at 0039-0332-786201, or Zuleika SAZ-PARKINSON at 0039-0332-789131 and Luciana NEAMTIU at 0039-0332-783034.

**Deadline for submission:
22/05/2015, 17:00 Ispra (Italy) local time**

1. CONTACT DETAILS

Important: This information is used to identify your submission. If you want to update any other section of this form please re-submit the PDF without changing the information under this section.

Name*				
Surname (in capital letters)*				
Title* <small>(both professional and personal)</small>	Professional	Mr	Ms	Do not indicate
	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Address*				
Postal code*				
Town*				
Country*				
Telephone with international prefix*				
Mobile phone				
E-mail*				

Denomination of the country for which you provide the information required in this survey*

--

2. THE ORGANISATION OF HEALTHCARE IN YOUR COUNTRY

The two questions in this section were as well included in a previous survey organised by JRC. Please see the published report at the link [EU Bookshop](#) for the organisational aspects reported for your country in 2012-2013 and check the corresponding box in case you should be aware of a change occurring since 2013 in the organisation of healthcare in your country.

Please specify if any change in the geographical organisation / responsibility allocation of healthcare occurred since 2012-2013; please indicate NOT APPLICABLE in case your country was not included in that report:

YES	NO	NOT APPLICABLE
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If NO, skip the following two pages and just go to section 4.

If YES or NOT APPLICABLE, please fill in the following fields:

To the best of your knowledge, in your country, healthcare and breast cancer care in particular is organised:

Nationally	Regionally	Regionally under National coordination	Locally	Locally under Regional / National coordination	Other	I do not have this information
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If you choose 'Other', please provide a more detailed description:

To the best of your knowledge, in your country, healthcare and breast cancer care in particular is provided by:

A - Public entities exclusively	B - Public entities mainly	C - Private entities mainly	Other	I do not have this information
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If you choose 'Other', please provide a more detailed description:

--

If you choose B, to the best of your knowledge, are public entities also responsible for the initial evaluation and the follow-up quality checks of external services provided by private entities?

YES	NO	I do not have this information
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If you choose C:

Are the private entities supervised by public entities?	Are the private entities initially evaluated by public entities and then followed up for the quality of services provided?	Are the private entities required to be accredited / certified along defined National or European standards?	None of the previous	I do not have this information
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

3. REFERENCES AND DEFINITIONS

1. P6_TA(2006)0449

European Parliament resolution on breast cancer in the enlarged European Union.

Available at: <http://www.europarl.europa.eu/sides/getDoc.do?type=MOTION&reference=B6-2006-0528&language=EN>

Recitals K, L, M and 6 are of specific relevance for this survey.

2. European Guidelines 2006

You can find the full version of the guidelines at the link: <http://bookshop.europa.eu/en/european-guidelines-for-quality-assurance-in-breast-cancer-screening-and-diagnosis-pbND7306954/>.

Chapters 9 - *The requirements of a specialist Breast Unit* and, when referred to in chapter 9, also Chapter 10 - *Guidelines for training*, are of specific relevance for this survey.

For a facilitated filling-in of the questionnaire, you can find below the definitions reported at the beginning of Chapter 9 of the *European Guidelines 2006*:

Unit	Essentially a group of specialists in breast cancer and need not necessarily be a geographically single entity, although the separate buildings must be within reasonable proximity, sufficient to allow multidisciplinary working
Clinic	used to mean a session, usually around 3 hours at which a number of patients are seen for clinical examination and investigations
Specialists	Completed training and certified in own discipline (e.g. Surgery, Radiology etc. and for Core Team members, spending half their working time (clinics, operating, pathology or imaging reading, multidisciplinary meetings, inpatient care etc.) in breast cancer
Radiologist	a specialist in imaging for diagnosis
Radiographer	a technician, taking the mammograms and responsible for mammographic quality
Radiation Oncologist	specialist in radiotherapy only
Medical Oncologist	specialist in medical oncology
Breast Care Nurse	qualified nurse, trained to give psychological support to breast cancer patients (especially at the time diagnosis is given) and to act in follow up as link between patient and breast team
Psychiatrist	medically qualified specialist in pharmacological treatment of patients with psychiatric and psychological problems
Psychologist	not usually medically qualified and therefore unable to prescribe pharmacological therapies
Surgeon	gynaecological surgeons specialising in breast cancer are included in this term

The general requirements for Breast Units, as reported from 9.4.1 to 9.4.10 of the *European Guidelines 2006* are:

- A. **9.4.1 Recognition of a Breast Unit must be based on mandatory requirements.**
- B. 9.4.2 A European process of voluntary accreditation of Breast Units, based on the fulfilment of mandatory requirements should be established. To give uniformity a standard database should be made available.
- C. 9.4.3 Units must record the basic data on diagnosis, pathology, primary treatment and clinical outcomes. The data must be available for audit and the Unit team should hold regular audit meetings inspecting separate topics and designing and amending protocols and QA systems. These meetings must be minuted. Performance and audit figures must be produced yearly and set alongside defined quality objectives and outcome measures, such as those laid down in the EUSOMA Guidelines on the various aspects of care (12, 13, 14, 15, 16) or in other suitable guidelines.
- D. 9.4.4 The Unit must have written protocols for diagnosis and for the management of cancer at all stages (primary and advanced cancer). All protocols must be agreed upon by the core team members. New protocols and protocol amendments should be discussed by the core team at the audit meetings (see 9.4.3).
- E. 9.4.5 Breast Units will most often be established in large or medium sized hospitals; they should generally cover one-quarter to one-third of a million total population. Some highly specialised units will be larger.
- F. 9.4.6 Population Breast Screening programmes should be based within or be closely associated with a recognised Breast Unit and not work as a separate service. The radiologists, surgeons and pathologists working in the screening programme must be core members of the associated Breast Unit.
- 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.
- H. 9.4.8 A Breast Unit should hold outreach clinics for symptomatic referred women, screening assessment and follow-up, in the smaller hospitals in the neighbourhood if these are at a distance from the Breast Unit. In areas with low population density, out-reach arrangements are preferable to the establishment of small Breast Units without the clinical volume to allow expertise. In that circumstance outreach clinics may be only held as infrequently as once per month; such scheduling may prolong waiting times for appointments but clinical evaluation by an expert team is considered preferable to maintaining short waiting times.
- I. 9.4.9 Breast Units must provide care of breast disease at all its stages - from screening through to the care of advanced disease. Occasionally the patient may need to be sent to an associated large oncology centre for radiotherapy but the patient must essentially be managed and followed-up at her Breast Unit.
- J. 9.4.10 Breast Units should manage their own budget, covering all the work of the unit.

4. GENERAL QUESTIONS ON BREAST UNITS

Please note that the following questions are preparatory to the next questionnaire sections 5 and 6 where more detailed questions will be asked with reference to mandatory and non-mandatory requirements for Breast Units as defined in the *European Guidelines 2006*.

If your reply should be NO or I DO NOT HAVE THIS INFORMATION to all the questions of this section, you can skip sections 5 and 6 and directly go to section 7

i. Are there any Breast Units as defined by the European Guidelines 2006 in your country?

YES	NO	I do not have this information	Comments/ Details
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

ii. Are Breast Units required by law in in the geographical area under your organisation's responsibility?

YES	NO	I do not have this information	Comments/ Details
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

iii. Are Breast Units not required by law but just recommended in the geographical area under your organisation's responsibility?

YES	NO	I do not have this information	Comments/ Details
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

iv. Is there a national accreditation/certification system for Breast Units in the geographical area under your organisation's responsibility?

YES	NO	I do not have this information	Comments/ Details
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

v. Are there regional/local accreditation/certification systems for Breast Units in the geographical area under your organisation's responsibility?

YES	NO	I do not have this information	Comments/ Details
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

vi. Are these accreditation/certification systems mandatory or voluntary in the geographical area under your organisation's responsibility?

Mandatory	Voluntary	I do not have this information	Comments/ Details
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

If you wish, please add below your comments / considerations on Breast Units organisational concept as defined in the *European Guidelines 2006*.

5. BREAST UNITS MANDATORY REQUIREMENTS IMPLEMENTATION STAGE

Please note that as the following are all MANDATORY requirements they can only be either satisfied or not. Partial fulfilment (e.g. a critical mass of 100 instead of 150 cases) simply means non-fulfilment.

1. Critical mass

Definition from the *European Guidelines 2006*

A Unit must be of sufficient size to have **more than 150**, newly diagnosed cases of primary breast cancer (at all ages and stages) coming under its care each year.

Note: these are newly diagnosed breast cancers. They may have been diagnosed elsewhere but if they have received any prior treatment and have been transferred, for example, to receive radiotherapy, they should not be counted.

All primary treatment must be carried out under the direction of the Unit (operation must be in the unit, adjuvant therapies must be directed by the unit but may have been received in other settings e.g. RT and chemotherapy). Follow up should be under the control of the Unit.

The reason for recommending a minimum number is to ensure a caseload sufficient to maintain expertise for each team member and to ensure cost-effective working of the Breast Unit: the establishment of a clinic staffed by experts is expensive and must have a high through-put of patients.

A number of Units will be recognised as teaching centres, nationally or internationally. They may be recognised for teaching over all breast cancer management or special aspects (e.g.) screening, reconstruction, pathology.

Is there in your country any kind of requirement that regulates at more than 150 the number of newly diagnosed cases of primary breast cancer cases yearly treated in individual Breast Units?

YES	NO	I do not have this information
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If you wish, please add below your comments / considerations on critical mass mandatory requirement.

2. Core Team

Definition from the *European Guidelines 2006*

Each member of the core team must have special training in breast cancer; for standards see Chapter 10 (pages 356 – 365 <http://bookshop.europa.eu/en/european-guidelines-for-quality-assurance-in-breast-cancer-screening-and-diagnosis-pbND7306954/>).

Each member of the breast unit core team must undertake continuing professional education on a regular basis. Breast Unit budgets must include provision for this.

9.5.2.1 The Breast Unit must have **an identified Clinical Director of Breast Services**.

9.5.2.2 Breast Surgeons (including Gynaecologists performing breast surgery)

Two or more nominated surgeons specially trained in breast disease, each of whom must personally carry out the primary surgery on **at least 50 newly diagnosed cancers per annum and must attend at least one diagnostic clinic per week**. For an average sized unit the surgeons will need at least eight identified ca. 4 hr sessions per week in Breast Disease. These sessions will allow for operating time, participation in diagnostic clinics, a follow-up clinic and, where appropriate, screening assessment clinics. A session must be allowed for attendance at a weekly team case management and audit meeting.

A Unit team must provide breast surgical reconstruction when required for those patients not suitable for breast conserving therapy and be able to apply special techniques for patients with extensive local disease. The breast surgeons in the team should be able to undertake basic reconstruction or recontouring and there should be a standard arrangement or joint reconstruction clinic with one or two nominated Plastic Surgeons (non-core team member) who take a special interest in breast reconstructive and recontouring techniques.

9.5.2.3 Breast Radiologists

There must be at least two nominated radiologists, fully trained and with continuing experience in all aspects of breast disease and associated imaging, tissue sampling and localisation procedures under image control. Ideally any radiologist investigating breast patients should participate in the screening programme in countries in which this is established and must participate in a national or regional QA scheme. They must fulfil the volume requirements as laid down for breast assessment in Chapter 5 and the previously published document 'Quality Assurance in the Diagnosis of Breast Disease', reading a minimum of **1000 mammograms per year (5000 for those participating in a screening programme)**.

They must attend multidisciplinary meetings for case management and audit purposes.

They must be present in diagnostic assessment clinics with the surgeon. Each radiologist must attend at least one diagnostic clinic per week for symptomatic patients or screening assessment.

9.5.2.4 Breast Pathologists

A lead pathologist plus usually not more than one other nominated pathologist, specialising in Breast Disease, will be responsible for all breast pathology and cytology.

Pathologists carrying out these roles must have contractual sessions to attend team case management and audit meetings. They must be familiar with national and/or European performance quality standards and guidelines. They must take part in available European, National and Regional quality assurance schemes.

9.5.2.5 Breast Oncologists

¹ Perry N, on behalf of EUSOMA Working Party. Quality Assurance in the diagnosis of breast disease. *Eur J Cancer*, 2001, 37, 159-172.

(a) **A nominated radiation oncologist** must arrange the appropriate delivery of radiotherapy⁶. He/she must hold advanced disease clinics with other members of the breast team at the Breast Unit and must take part in the case management and audit meetings of the Unit.

(b) In some countries, Clinical Oncologists carry out both radiation therapy and prescribe the chemotherapy. In centres in which **a Medical Oncologist gives the chemotherapy** he/she should be a member of the core team and take a full part in case management and audit meetings.

9.5.2.6 Breast Diagnostic Radiographers (Technicians)

Radiographers with the necessary expertise and training in mammography are essential members of the team. They must fulfil the training and working practice recommendations as laid down in Chapters 3, 5, and 10. They must be responsible for taking the mammograms, which must not be performed by radiographic or nonradiographic personnel without the above training.

9.5.2.7 Data Managers

There must be a system covering audit. **A data manager** must enter data on diagnosis, treatment, pathology and clinical outcomes contemporaneously.

9.5.2.8 Patient Support staff

Regular support (advice, counselling, psychological help) is given by Breast Care Nurses in some countries and psychologically professionally trained persons with expertise in Breast Cancer in others. These persons must be members of the core team. They must be available to counsel and offer practical advice and emotional support to newly diagnosed patients at the time the diagnosis is given, so as to further explain treatment plans. They should also be available on demand from patients in the Primary Breast Cancer Follow up clinic and in the Advanced Breast Clinic. Particularly they must be present to support women when the diagnosis is given that the disease has become advanced. **At least two Breast Care Nurses are needed per breast unit.**

2a. COMPOSITION

Is there in your country any kind of requirement that regulates the composition of the core team as defined in the *European Guidelines 2006*?

YES	NO	I do not have this information
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If you wish, please add below your comments / considerations on core team composition mandatory requirement.

⁶ Kurtz J, for the EUSOMA Working Party. The curative role of radiotherapy in the treatment of operable breast cancer. *Eur J Cancer*, 2002, 38, 1961-1974.

2b. TRAINING

Is there in your country any kind of requirement that regulates the training standards of the core team as defined in the *European Guidelines 2006*?

YES	NO	I do not have this information
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If you wish, please add below your comments / considerations on core team's training standards mandatory requirement.

2c. CONTINUING MEDICAL EDUCATION

Is there in your country any kind of requirement that regulates the CME of the core team as defined in the *European Guidelines 2006*?

YES	NO	I do not have this information
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If you wish, please add below your comments / considerations on core team's CME mandatory requirement.

6. BREAST UNITS NON-MANDATORY REQUIREMENTS IMPLEMENTATION STAGE

A. Equipment (9.6.1)

Definition from the *European Guidelines 2006*

9.6.1 The unit must be in possession of all necessary imaging equipment for complete and adequate breast diagnosis.

Is there in your country any kind of requirement that regulates the imaging equipment requirement 9.6.1 as defined above?

YES	NO	I do not have this information
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If you wish, please add below your comments / considerations on the imaging equipment voluntary requirement.

B. Equipment (9.6.2)

Definition from the European Guidelines 2006

9.6.2 The minimum equipment in a department giving radiotherapy must be two megavoltage units, a brachytherapy unit, a simulator and a computerised planning system. The department must have a radiotherapeutic quality control programme for breast cases.

Is there in your country any kind of requirement that regulates the radiotherapeutic equipment requirement 9.6.2 as defined above?

YES	NO	I do not have this information
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If you wish, please add below your comments / considerations on the radiotherapeutic equipment voluntary requirement.

C. Facilities / Services (9.7.1)

Definition from the *European Guidelines 2006*

Clinics (see definition in Section 9.4). Consultations for Breast patients should be held separately, i.e., not as part of general surgery.

New patient clinics

At least one clinic per week for newly referred symptomatic women must be held. A Unit diagnosing 150 new cancers per year must expect over 1500 new referrals of symptomatic women (= approximately 30 per week).

Suggested outcome measures for the waiting times are given in Chapter 5. A suggested good practice is that all newly referred women with breast symptoms should be offered an appointment within 10 working days of receipt of the referral.

Clinics to which patients are referred or self-referred must be staffed by a surgeon, a radiologist and radiographers from the breast care team. Multidisciplinary working must allow all standard investigations for triple assessment (clinical examination and all appropriate imaging and tissue diagnostic procedures) to be completed at one visit. Where possible the finding of no abnormality or a confirmed diagnosis of a benign lesion should be communicated to the patient at that visit.

Is there in your country any kind of requirement that regulates the new patient clinics as defined above?

YES	NO	I do not have this information
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If you wish, please add below your comments / considerations on the new patient clinic voluntary requirement.

D. Facilities / Services (9.7.2)

Definition from the *European Guidelines 2006*

Communication of the Diagnosis and Treatment Plan

It may not be possible (now that core biopsy is most often used) or may not be considered appropriate by the unit to give the diagnosis of cancer at the initial visit. Women found to have breast cancer should receive that diagnosis within 5 working days. The diagnosis should be ideally communicated personally by the surgeon: if it is communicated by the radiologist, then the surgeon (±) the oncologist must personally advise the patient on treatment. It is recommended that a breast care nurse (or) psychologically trained person (see 9.5.2.8) be present to discuss fully with the patient the options for treatment and to give emotional support.

If a patient has clear advanced breast cancer it may be more appropriate that an oncologist rather than a surgeon gives the diagnosis if the patient's treatment does not involve surgery.

A suitable room with sufficient privacy must be available. In units in which preoperative irradiation or primary medical therapies are used, cases which might be suitable for these should be seen jointly by a surgeon and radiation or medical oncologist before treatment commences.

A diagnosis should not be given to a patient by letter or on the telephone, unless at the specific request of the patient given adequate and full informed choice.

Is there in your country any kind of requirement that regulates the communication of the diagnosis and treatment plan as defined above?

YES	NO	I do not have this information
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If you wish, please add below your comments / considerations on the communication of the diagnosis and treatment plan voluntary requirement

E. Facilities / Services (9.7.3)

Definition from the *European Guidelines 2006*

Multidisciplinary Case Management Meetings (MDM's)

All members of the core team must attend the Multidisciplinary Meeting (MDM), which must be held at least weekly.

The following should be discussed:

- cases in which the diagnosis is as yet uncertain e.g., following core biopsy
- cases in whom the diagnosis of cancer is confirmed and who may be considered for primary medical therapy
- all cases following surgery on receipt of the histopathology for discussion of further care and
- cases in follow-up who recently have undergone diagnostic investigations for possible symptoms of recurrent or advanced disease

It is possibly more convenient to have two MDM's per week:

- one for cases in diagnosis attended by surgeons, radiologists and pathologists and
- one for post-operative consideration of prognosis and adjuvant therapies and for cases investigated for disease recurrence (oncologists, surgeons, radiologists and pathologists)

Is there in your country any kind of requirement that regulates the MDMs as defined above?

YES	NO	I do not have this information
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If you wish, please add below your comments / considerations on the MDMs voluntary requirement.

F. Facilities / Services (9.7.4)

Definition from the *European Guidelines 2006*

Physiotherapy

Physiotherapy must be available for the post-operative recovery period to ensure good shoulder mobility, etc.

Is there in your country any kind of requirement that regulates the provision of physiotherapy as defined above?

YES	NO	I do not have this information
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If you wish, please add below your comments / considerations on the physiotherapy voluntary requirement.

G. Facilities / Services (9.7.5)

Definition from the *European Guidelines 2006*

Adjuvant therapies

The multidisciplinary team (MDT) must decide on the appropriate adjuvant therapies in light of the pathology of the surgical specimen.

- Radiotherapy may be delivered within the same hospital or patients may have to travel to a Radiotherapy Unit in another Hospital (at which the core team radiation oncologist must be able to supervise their treatment).
- The administration of cytotoxic therapy as adjuvant therapy or for advanced disease must be by an accredited oncologist (member of the core team) with proper facilities. Cytotoxic therapies may be given in another hospital but the decisions regarding their application must be made by the MDT of the Unit.

Is there in your country any kind of requirement that regulates the provision of adjuvant therapies as defined above?

YES	NO	I do not have this information
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If you wish, please add below your comments / considerations on the adjuvant therapy voluntary requirement.

H. Facilities / Services (9.7.6)

Definition from the *European Guidelines 2006*

Advanced and recurrent Breast Cancer

- There must be one Advanced Breast Cancer Clinic at least every 2 weeks at the Breast Unit, separate from the general oncology clinics (although sometimes combined with gynaecological oncology) and attended by the Clinical Oncologist ± Medical Oncologist (see 9.5.2.5 b). The surgeon must be available if required for consultation and must be in full attendance if the breast surgeons supervise the endocrine therapies. Patients with distant metastases locally advanced primary breast cancer and local or regional recurrence, must be managed in this clinic according to protocols agreed by the multidisciplinary team.
- Patients who have received radiotherapy or chemotherapy at another Cancer Centre should normally be referred back to the Breast Team at their Breast Unit for further follow-up and decision making in the Advanced Breast Cancer Clinic
- A palliative care/pain control service must be easily accessible

Is there in your country any kind of requirement that regulates the management of advanced and recurrent breast cancer as defined above?

YES	NO	I do not have this information
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If you wish, please add below your comments / considerations on the management of advanced and recurrent breast cancer voluntary requirement.

I. Facilities / Services (9.7.7)

Definition from the *European Guidelines 2006*

Follow-up of primary breast cancer

- All patients with primary breast cancer must be followed-up in a Clinic directly supervised by one of the surgeons. Any necessary imaging or other investigations should be carried out at the same visit.
- Although the patient may have to visit a separate Hospital to receive radiotherapy or specialised chemotherapy, the decisions on the case management and the subsequent follow-up should be by the team members of her Breast Unit. The skills of the diagnostic breast team are then available for the detection and investigation of a possible recurrence.

Is there in your country any kind of requirement that regulates the follow-up of primary breast cancer as defined above?

YES	NO	I do not have this information
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If you wish, please add below your comments / considerations on the follow-up of primary breast cancer voluntary requirement.

J. Facilities / Services (9.7.8)

Definition from the *European Guidelines 2006*

Benign disease

The Breast Unit must also advise and where necessary treat women with benign disease (e.g.) cysts, fibroadenoma, mastalgia, inflammatory conditions, mammillary fistula and phyllodes tumour.

Is there in your country any kind of requirement that regulates the management of benign disease as defined above?

YES	NO	I do not have this information
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If you wish, please add below your comments / considerations on the management of benign disease voluntary requirement.

K. Facilities / Services (9.7.9)

Definition from the *European Guidelines 2006*

Family History / genetics

Advice is best given in a multidisciplinary clinic, the specialists involved are a clinical geneticist and from the team a breast surgeon with reconstructive skills, radiologist and psychiatrist or clinical psychologist. Gene probing must be available when required and ideally a molecular geneticist should be accessible for consultation by the specialists in the clinic.

Is there in your country any kind of requirement that regulates the management of family history / genetics as defined above?

YES	NO	I do not have this information
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If you wish, please add below your comments / considerations on the management of family history / genetics voluntary requirement.

For requirement 9.7.10 (Reconstruction) see requirement 9.8.2)

L. Facilities / Services (9.7.11)

Definition from the European Guidelines 2006

Breast Screening

Ideally breast screening centres should be a part of Breast Units and the same radiologists should be members of the Unit team and work in screen detection and the diagnosis of symptomatic disease. Assessment centres should be placed in Breast Units.

Is there in your country any kind of requirement that regulates the breast screening management as defined above?

YES	NO	I do not have this information
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If you wish, please add below your comments / considerations on the breast screening management voluntary requirement.

M. Facilities / Services (9.7.11)

Definition from the *European Guidelines 2006*

Patient information

Women must be offered clear written and oral information regarding their diagnosis and/or treatment options. The Breast Unit should also provide written information concerning local out-patient support groups and advocacy organisations and should also respect the patients rights as outlined in the Breast Cancer Resolution of the European Parliament (OJ C 68 E (18.03.2004), p.611). Patients should be provided with a list of their rights as outlined in the breast cancer resolution.

Is there in your country any kind of requirement that regulates the patient information as defined above?

YES	NO	I do not have this information
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If you wish, please add below your comments / considerations on the patient information voluntary requirement.

N. Associated Services and non-core personnel (9.8.1)

Definition from the European Guidelines 2006

These are services for which it cannot be expected that staff will spend the majority of their time on breast disease.

Extra Psychological Support

If the patient is experiencing psychological morbidity that cannot be dealt with effectively by members (usually breast care nurse or psycho-oncologist) of the Unit team, she should be referred to a psychiatrist with whom there are particular arrangements to see breast patients for the Breast Unit (non-core team member).

Is there in your country any kind of requirement that regulates the extra psychological support as defined above?

YES	NO	I do not have this information
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If you wish, please add below your comments / considerations on the extra psychological support voluntary requirement.

O. Associated Services and non-core personnel (9.8.2)

Definition from the *European Guidelines 2006*

Plastic Surgeon

The Breast Unit should make arrangement with one or two nominated plastic surgeons with a special interest in breast reconstructive and recontouring techniques.

Is there in your country any kind of requirement that regulates the plastic surgery as defined above?

YES	NO	I do not have this information
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If you wish, please add below your comments / considerations on the plastic surgery voluntary requirement:

P. Associated Services and non-core personnel (9.8.3)

Definition from the *European Guidelines 2005*

Geneticists

Women seeking advice with regard to risk, e.g., family history, must be able to receive advice from the Breast team, which must include a clinical geneticist with a specialist interest in breast cancer (see 9.7.9).

Is there in your country any kind of requirement that regulates the genetist advice as defined above?

YES	NO	I do not have this information
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If you wish, please add below your comments / considerations on the genetist advice voluntary requirement.

Q. Associated Services and non-core personnel (9.8.4)

Definition from the *European Guidelines 2006*

Palliative Care

A specialist palliative care service must be available for the referral of patients with advanced breast cancer. A close working relationship must be established between members of the Breast Unit (especially the breast care nurse) and the palliative care service to ensure that breakdowns in continuity of care do not occur and also with the local network for home assistance.

Is there in your country any kind of requirement that regulates the provision of palliative care as defined above?

YES	NO	I do not have this information
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If you wish, please add below your comments / considerations on the provision of palliative care voluntary requirement.

R. Associated Services and non-core personnel (9.8.5)

Definition from the European Guidelines 2006

Prosthesis

There must be provision for a Prosthesis fitting service within the unit.

Is there in your country any kind of requirement that regulates the provision of prosthesis as defined above?

YES	NO	I do not have this information
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If you wish, please add below your comments / considerations on the provision of prosthesis voluntary requirement.

S. Associated Services and non-core personnel (9.8.6)

Definition from the *European Guidelines 2006*

Physiotherapy and Lymphoedema

An identified Physiotherapist or a Breast Care Nurse for the treatment of lymphoedema and late sequelae.

Is there in your country any kind of requirement that regulates the provision of physiotherapy and lymphoedema treatment as defined above?

YES	NO	I do not have this information
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If you wish, please add below your comments / considerations on the provision of provision of physiotherapy and lymphoedema treatment voluntary requirement.

T. Research (9.9)

Definition from the European Guidelines 2006

Research is one of the essential parts of training of specialists. As part of Audit Units must record numbers of patients entered into clinical trials and details of all other research. Units should be encouraged to provide research opportunities and this must be taken into account when assessing units for their suitability for accepting trainees.

Is there in your country any kind of requirement that regulates the management of research as defined above?

YES	NO	I do not have this information
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If you wish, please add below your comments / considerations on the management of research voluntary requirement.

U. Teaching (9.10)

Definition from the *European Guidelines 2006*

The Unit must provide teaching, whether simply for junior staff or for students or on a national or international basis. Some units may particularly concentrate on certain areas (e.g.) Reconstruction, Screening, Pathology, etc.

Is there in your country any kind of requirement that regulates the management of teaching provision as defined above?

YES	NO	I do not have this information
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If you wish, please add below your comments / considerations on the management of teaching provision voluntary requirement.

V. Additional point (9.11)

Definition from the European Guidelines 2006

The implementation of the suggested structure of Breast Units requires a reorganisation of time in each discipline, so that as a consultant spends more time in breast disease, his or her colleagues no longer treat breast cancer and specialise in other areas. Rationalisation of work patterns, in this way would provide sufficient staff for the Breast Units. Such a move would coincide with changes that are already occurring within all disciplines, for example, from General Surgery the emergence of specialist surgeons for urology, microinvasive techniques, vascular surgery, upper GI, hepatic and colon.

All work must be carried out or directly supervised by specialists specifically trained in breast disease. A service provided by a trained specialist is more efficient and more cost effective – diagnostic decisions are made earlier whereas junior staff are more likely to call a patient back several times unnecessarily and to carry out unnecessary investigations; operating by consultants gives better results for technical reasons; the interpretation of imaging techniques and the reading of histology is much more likely to produce definitive opinions if carried out by experts.

We *(the guidelines authors)* estimate that for a 10 million total population base 30-40 Breast Units are required for the ideal service and that reorganisation in this way will provide considerable financial savings. This could easily be achieved and should be attractive to many countries.

Is there in your country any kind of requirement that regulates the additional points as defined above?

YES	NO	OTHER
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If you wish, please add below your comments / considerations on the additional points reported above.

7. Personal data protection, Consent to publication and Form submission

Personal data protection policy

The Commission will ensure that applicants' personal data are processed as required by [Regulation \(EC\) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Union institutions and bodies and on the free movement of such data \(OJ L 8, 12.1.2001\)](#). This applies in particular to the confidentiality and security of such data.

For an overview of the policy: http://ec.europa.eu/dataprotectionofficer/legal_framework_en.htm
For further details on how data are managed at JRC please go to the link <http://ec.europa.eu/dpo-register/details.htm?id=28522> (the example applies to meetings in particular but the policy is the same for personal data protection for surveys).

By ticking the field below I confirm that I have read the information provided on personal data treatment.*

By ticking the field below I accept the European Commission policy for the treatment of the personal data I provided in the remit of this survey.*

Consent to publication of data

In order to ensure that the collected data would be useful, they need to be published. Please provide below your consent to publish them on a JRC report and/or in presentations (e.g. during the ECBC 10 dedicated session). Your contribution will always be explicitly recognised

By ticking the field below I provide my consent to publish all the data I provided through this questionnaire*

In case JRC and the co-organisers of this survey should plan to publish the data obtained from this survey on a peer-reviewed journal, your consent (and potentially also additional details) will be explicitly sought before proceeding.

Application form submission

- 1) While you are completing the form and when you have finished filling it in, you can save it on your PC (it would be advisable to change the file name, e.g. by adding your initials and/or your country name)
- 2) When you are ready to send the form back to us, please verify that your internet connection is active and that your email account is compatible with PDF forms, then click on the **Submit by Email** button below. The form will be automatically sent to the application mailbox.
- 3) PLEASE NOTE that if the form is not appropriately filled-in (all mandatory fields are completed), an alert box will appear indicating the number of missing fields and you'll not be able to submit the form until you have completed them. When you have finished, please check your form again and try to re-submit it according to step 2.
- 4) Once you have submitted the form, you're advised to save it on your computer as a file in pdf format, for any further confirmation of data the organisers of this survey might request.
- 5) Should you still have any difficulties, please contact the survey helpdesk: JRC-cancer-policy-support@ec.europa.eu

**Deadline for submission:
22/05/2015, 17:00 Ispra (Italy) local time**

Submit by Email

Annex II
Communications

Interim (reminders) and individual communications are not included.

1.1. Initial invitation to participate e-mail (ECIBC National Contact)

Sent: 21 January 2015 13:59

Dear Madam, dear Sir, dear ECIBC National contacts,

We are planning to run a survey to follow-up the European Parliament resolution of 2006 on breast cancer in the enlarged European Union. It called on *'Member States to ensure nationwide provision of interdisciplinary breast units in accordance with the EU guidelines by 2016, since treatment in an interdisciplinary breast unit has been proved to raise chances of survival and to improve the quality of life, and calls on the Commission to deliver a progress report on this every two years'*.

The European Commission (EC) keeps a neutral position on how care is organised at Member States, and therefore does not in particular support Breast Units or any other form of organisation of breast cancer services. However, the EC wishes to fulfil the call of the European Parliament to provide a progress report to be available by beginning 2016, in correspondence with the deadline reported in the resolution. In this respect, we would need to map-out the situation in the European Countries, taking into account:

- the results of the previous survey which JRC ran with the support of EPAAC National Contacts (see the report at the link <http://bookshop.europa.eu/en/report-of-a-european-survey-on-the-organisation-of-breast-cancer-care-services-pbLBNA26593/>) and
- the fact that, even if the concept of Breast Units greatly evolved since 2006, the call of the European Parliament clearly refers to definitions given in the EU guidelines (their last edition is in fact dated back to 2006).

As for other previous and future information needs, for an accurate, factual and complete mapping, we would be grateful if we can count on your support and collaboration as experts in the area and as National Contact nominated for the European Commission Initiative for Breast Cancer (ECIBC).

This survey will be run in parallel with two stakeholders' profiles:

1. Members States' Health Authorities (via you as nominated ECIBC National Contact) to ensure that EC has the official information, and

2. Europa Donna National Representations so to take into account patients' feed-back on the state of art of Breast Units in the respective countries.

The survey is organised in collaboration with Dr Fatima Cardoso, chair of the 2016 European Breast Cancer Conference – EBCC 10, and results will be presented in a dedicated session (European Breast Centres 2016 – Impact in Mortality and Quality of Life) planned for 9 March 2016. Participating countries (YOU!) and Europa Donna will have the opportunity to present their results both orally and with posters.

You will also be involved as collaborating author in the publication of the EC report and possible other publications related to this survey.

We are convinced that, together with scientific evidence, reliable maps of what is in place are precious tools to support policies. Therefore, we would be grateful if you could **confirm within 13 February 2015 your willingness to participate** in this important survey project.

In order to facilitate your preparation to the survey, we will approach you again in few weeks with a time schedule and more details on the survey design and content. Please note that next communications will be sent via the mailbox jrc-cancer-policy-support@ec.europa.eu and we kindly ask you to ensure that this email address would not be classified as junk email.

Looking forward to receiving your feed-back, we would also like to anticipate our thankfulness for your participation.

Best regards,

Donata LERDA & the Healthcare Quality Team



European Commission

DG Joint Research Centre (JRC)

Institute for Health and Consumer Protection

Public Health Policy Support Unit – Healthcare Quality Team

Via E. Fermi 2749

I-21027 Ispra (VA)/Italy
Phone: +39 0332 786201
Fax: +39 0332 783858
donata.lerda@ec.europa.eu
jrc-cancer-policy-support@ec.europa.eu

and

Fatima Cardoso, MD
EBCC 10 Chair
Director Breast Unit, Champalimaud Clinical Center
Av. De Brasília s/n, 1400-038 Lisbon, Portugal

1.2. Initial invitation to participate e-mail (ED National Representative)

Sent: 21 January 2015 14:01

Dear Europa Donna National representatives,

We are planning to run a survey to follow-up the European Parliament resolution of 2006 on breast cancer in the enlarged European Union. It called on *'Member States to ensure nationwide provision of interdisciplinary breast units in accordance with the EU guidelines by 2016, since treatment in an interdisciplinary breast unit has been proved to raise chances of survival and to improve the quality of life, and calls on the Commission to deliver a progress report on this every two years'*.

The European Commission (EC) keeps a neutral position on how care is organised at Member States, and therefore does not in particular support Breast Units or any other form of organisation of breast cancer services: However, the EC wishes to fulfil the call of the European Parliament to provide a progress report to be available by beginning 2016, in correspondence with the deadline reported in the resolution. In this respect, we would need to map-out the situation in the European Countries, taking into account:

- the results of the previous survey which JRC ran with the support of EPAAC National Contacts (see the report at the link <http://bookshop.europa.eu/en/report-of-a-european-survey-on-the-organisation-of-breast-cancer-care-services-pbLBNA26593/>) and
- the fact that, even if the concept of Breast Units greatly evolved since 2006, the call of the

European Parliament clearly refers to definitions given in the EU guidelines (their last edition is in fact dated back to 2006).

In order to ensure that the factual mapping provided by the National Contact nominated for the European Commission Initiative for Breast Cancer (ECIBC) is complemented by the point of view of those needing the service, we would like to ask you to complete a survey.

This survey will be run in parallel with two stakeholders' profiles:

1. Members States' Health Authorities (via the nominated ECIBC National Contacts) to ensure that EC has the official information, and
2. Europa Donna National Representations so to take into account patients' feed-back on the state of art of Breast Units in the respective countries.

The survey is organised in collaboration with Dr Fatima Cardoso, chair of the 2016 European Breast Cancer Conference – EBCC 10, and results will be presented in a dedicated session (European Breast Centres 2016 – Impact in Mortality and Quality of Life) planned for 9 March 2016. Europa Donna (YOU!) and participating countries will have the opportunity to present their results both orally and with posters.

You will also be involved as collaborating author in the publication of the EC report and possible other publications related to this survey.

We are convinced that, together with scientific evidence, reliable maps of what is in place are precious tools to support policies. Therefore, we would be grateful if you could **confirm within 13 February 2015 your willingness to participate** in this important survey project.

In order to facilitate your preparation to the survey, we will approach you again in few weeks with a time schedule and more details on the survey design and content. Please note that next communications will be sent via the mailbox jrc-cancer-policy-support@ec.europa.eu and we kindly ask you to ensure that this email address would not be classified as junk email.

Looking forward to receiving your feed-back, we would also like to anticipate our thankfulness for your participation.

Best regards,

Donata LERDA & the Healthcare Quality Team



European Commission

DG Joint Research Centre (JRC)

Institute for Health and Consumer Protection

Public Health Policy Support Unit – Healthcare Quality Team

Via E. Fermi 2749

I-21027 Ispra (VA)/Italy

Phone: +39 0332 786201

Fax: +39 0332 783858

donata.lerda@ec.europa.eu

jrc-cancer-policy-support@ec.europa.eu

and

Fatima Cardoso, MD

EBCC 10 Chair

Director Breast Unit, Champalimaud Clinical Center

Av. De Brasília s/n, 1400-038 Lisbon, Portugal

2.1. Follow-up email (ECIBC National Contact)

Sent: 27 February 2015 13:23

Dear ECIBC National Contacts,

As anticipated in the previous email, we are coming back to you with some more details, which we hope will facilitate your participation into the survey on breast units' implementation in Europe. It is organised by JRC in collaboration with EBCC 10 chair, Fatima Cardoso and Europa Donna. The scope of the survey is to map out the degree of implementation of Breast Units in Europe with reference to the 2006 Resolution of the European Parliament on breast cancer in the enlarged European Union.

The reference document mentioned in the EP resolution is the European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis, which last edition is dated 2006 (and herein after mentioned as European Guidelines 2006); you can find the full version of the guidelines at the link: <http://bookshop.europa.eu/en/european-guidelines-for-quality-assurance-in-breast-cancer-screening-and-diagnosis-pbND7306954/>.

In particular this survey will refer to chapter 9 – The requirements of a specialist Breast Unit and, when referred to in chapter 9, to chapter 10 – Guidelines for training. As specified in the previous communication, the survey will be run in parallel with two stakeholders' profiles:

Members States' Health Authorities and related entities (via the nominated ECIBC National Contacts) to ensure that EC has the official information, and

Europa Donna National Representations so to take into account patients' feed-back on their awareness of state of art of Breast Units in the respective countries. Europa Donna National Representations will receive a similar questionnaire as for the ECIBC National Contacts, but questions on Breast Units will mostly be non-mandatory.

The questionnaire sections will be:

- CONTACT DETAILS
- REFERENCES AND DEFINITIONS
- THE ORGANISATION OF HEALTHCARE IN YOUR COUNTRY
- THE BREAST UNITS MANDATORY REQUIREMENTS (as listed and defined in the European Guidelines 2006) AND THEIR IMPLEMENTATION STATUS
- THE BREAST UNITS NON-MANDATORY REQUIREMENTS (as listed and defined in the European Guidelines 2006) AND THEIR IMPLEMENTATION STATUS

We are conscious of the effort that will be required in answering the questions. It is possible that it will require the input of several people but JRC as survey organiser needs to clearly identify the person responsible for the information provided in each questionnaire.

For the questionnaire, the PDF form tool will be used. You might not be familiar with it, but you just need to follow the instructions that will be included in the questionnaire. PDF forms make it possible:

To save a partially filled-in copy and send it later to us upon completion	You are responsible for the information provided
To save a partially filled-in copy and send it to other experts to complete it before sending it back to us	You are responsible for the information provided
To distribute the questionnaire to regional/local authorities asking them to send it back to you (in which case you will have to send all the forms back to JRC)	You are responsible for the information provided
To distribute the questionnaire to regional authorities asking them to send it directly back to us	Each respondent will be held responsible for the information provided

As regards the timing, we foresee to send out the questionnaire in the first half of March, in which case the deadline for sending it back will be end of **April 2015**.

We would highlight again the importance of receiving as many comprehensive responses as possible in order to ensure a complete overview of the situation in European countries (and regions). As we still hope to receive some additional participation, we still keep in the loop also those contacts that did not respond to the first communication. The survey will be sent only to those who explicitly confirmed their participation.

We wish to thank in advance the participants to this survey for the effort they engage in providing the information required.

Best regards,

Donata LERDA and the JRC Healthcare Quality Team
Scientific/Technical Project Officer



European Commission
 DG Joint Research Centre (JRC)
 Institute for Health and Consumer Protection
 Public Health Policy Support Unit–Healthcare Quality Team
 Via E. Fermi 2749
 I-21027 Ispra (VA)/Italy
 Phone: +39 0332 786201
 Fax: +39 0332 783858

donata.lerda@ec.europa.eu

http://ihcp.jrc.ec.europa.eu/our_activities/public-health/cancer_policy_support/priority_activities/ECIBC

Fatima Cardoso, MD

EBCC 10 Chair

Director Breast Unit, Champalimaud Clinical Center

Av. De Brasília s/n, 1400-038 Lisbon, Portugal

Susan Knox

Executive Director

Europa Donna – The European Breast Cancer Coalition

Piazza Amendola 3

20149 Milan – Italy

2.2. Follow-up e-mail (ED National Representative)

Sent: 27 February 2015 13:45

Dear Europa Donna National representatives,

As anticipated in the previous email, we are coming back to you with some more details, which we hope will facilitate your participation into the survey on breast units' implementation in Europe. It is organised by JRC in collaboration with EBCC 10 chair, Fatima Cardoso, and Europa Donna. The scope of the survey is to map out the degree of implementation of Breast Units in Europe with reference to the 2006 Resolution of the European Parliament on breast cancer in the enlarged European Union.

The reference document mentioned in the EP resolution is the *European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis*, which last edition is dated 2006 (and herein after mentioned as European Guidelines 2006); you can find the full version of the guidelines at the link: <http://bookshop.europa.eu/en/european-guidelines-for-quality-assurance-in-breast-cancer-screening-and-diagnosis-pbND7306954/>.

In particular this survey will refer to chapter 9 – *The requirements of a specialist Breast Unit* and, when referred to in chapter 9, to chapter 10 – *Guidelines for training*.

As specified in the previous communication, the survey will be run in parallel with two stakeholders' profiles:

1. Members States' Health Authorities and related entities (via the nominated ECIBC National Contacts) to ensure that EC has the official information, and
2. Europa Donna National Representations so to take into account patients' feed-back on the state of art of Breast Units in the respective countries.

Europa Donna National Representations will receive a similar questionnaire as for the ECIBC National Contacts, which covers many details you might not be aware of, but there will be no mandatory question (apart from the contact details) and you will always have the 'non-applicable' and 'do not know' options. Please note that the survey requires, as much as feasible, evidence-based information. In all cases where you should feel that you do not have the information required, just simply click on the option 'do not know'. This response would be very useful in order to have an overview of the dissemination and information sharing aspects for breast units implementation.

The questionnaire sections will be:

- CONTACT DETAILS
- REFERENCES AND DEFINITIONS
- THE ORGANISATION OF HEALTHCARE IN YOUR COUNTRY
- THE BREAST UNITS MANDATORY REQUIREMENTS (as listed and defined in the *European Guidelines 2006*) AND THEIR IMPLEMENTATION STATUS
- THE BREAST UNITS NON-MANDATORY REQUIREMENTS (as listed and defined in the *European Guidelines 2006*) AND THEIR IMPLEMENTATION STATUS

For the questionnaire, the PDF form tool will be used. You might not be familiar with it, but you just need the basic Adobe software and to follow the instructions that will be included in the questionnaire.

As regards the timing, we foresee to send out the questionnaire in the first half of March in which case the deadline for sending it back will be **end of April 2015**.

We would highlight again the importance of receiving as many comprehensive responses as possible in order to ensure a complete overview of the situation in European countries (and regions).

As we still hope to receive some additional participation, we still keep in the loop also those contacts that did not respond to the first communication. The survey will be sent only to those who explicitly confirmed their participation.

We wish to thank in advance the participants to this survey for the effort they engage in providing the information required.

Best regards,

Donata LERDA and the JRC Healthcare Quality Team
Scientific/Technical Project Officer



European Commission

DG Joint Research Centre (JRC)

Institute for Health and Consumer Protection

Public Health Policy Support Unit – Healthcare Quality Team

Via E. Fermi 2749

I-21027 Ispra (VA)/Italy

Phone: +39 0332 786201

Fax: +39 0332 783858

donata.lerda@ec.europa.eu

http://ihcp.jrc.ec.europa.eu/our_activities/public-health/cancer_policy_support/priority_activities/ECIBC

Fatima Cardoso, MD

EBCC 10 Chair

Director Breast Unit, Champalimaud Clinical Center

Av. De Brasília s/n, 1400-038 Lisbon, Portugal

Susan Knox

Executive Director

Europa Donna – The European Breast Cancer Coalition

Piazza Amendola 3

20149 Milan – Italy

3.1. E-mail for sending the PDF form with deadline to fill in questionnaire (ECIBC National Contact)

Sent: 08 April 2015 13:00

Dear Madam, dear Sir, dear ECIBC National Contacts,

We are with this email launching the survey on Breast Units in Europe. We kindly ask you to fill in the attached questionnaire to your best knowledge and submit it by the **22nd of May 2015**.

We suggest that you carefully read the instructions before starting. In case you should need support, please do not hesitate to contact the survey helpdesk at this email or at the phone numbers listed in the form.

We wish to thank you in advance for having engaged in this survey and for the time you are going to spend for providing the information required.

Best regards,

Donata

**Donata LERDA and the JRC Healthcare Quality Team
Group Leader**



European Commission

DG Joint Research Centre (JRC)

Institute for Health and Consumer Protection

Public Health Policy Support Unit – Healthcare Quality Team

Via E. Fermi 2749

I-21027 Ispra (VA)/Italy

Phone: +39 0332 786201

Fax: +39 0332 783858

donata.lerda@ec.europa.eu

<https://ec.europa.eu/jrc/en/research-topic/healthcare-quality?search>

The call for Researchers at JRC is open! <https://ec.europa.eu/jrc/en/working-with-us/jobs/vacancies/function-group-iv-researchers>.

AND

Fatima Cardoso, MD

EBCC 10 Chair

Director Breast Unit, Champalimaud Clinical Center

Av. De Brasília s/n, 1400-038 Lisbon, Portugal

AND

Susan Knox

Executive Director

Europa Donna – The European Breast Cancer Coalition

Piazza Amendola 3

20149 Milan – Italy

3.2. E-mail for sending PDF form with deadline to fill in questionnaire (ED National Representative)

Sent: 08 April 2015 12:13

Dear Europa Donna National representatives,

We are with this email launching the survey on Breast Units in Europe. We kindly ask you to fill in the attached questionnaire to your best knowledge and submit it by the **22nd of May 2015**.

We suggest that you carefully read the instructions before starting. In case you should need support, please do not hesitate to contact the survey helpdesk at this email or at the phone numbers listed in the form.

We wish to thank you in advance for having engaged in this survey and for the time you are going to spend for providing the information required.

Best regards,

Donata

**Donata LERDA and the JRC Healthcare Quality Team
Group Leader**



European Commission

DG Joint Research Centre (JRC)

Institute for Health and Consumer Protection

Public Health Policy Support Unit – Healthcare Quality Team

Via E. Fermi 2749

I-21027 Ispra (VA)/Italy

Phone: +39 0332 786201

Fax: +39 0332 783858

donata.lerda@ec.europa.eu

<https://ec.europa.eu/jrc/en/research-topic/healthcare-quality?search>

The call for Researchers at JRC is open! <https://ec.europa.eu/jrc/en/working-with-us/jobs/vacancies/function-group-iv-researchers>.

AND

Fatima Cardoso, MD

EBCC 10 Chair

Director Breast Unit, Champalimaud Clinical Center

Av. De Brasília s/n, 1400-038 Lisbon, Portugal

AND

Susan Knox

Executive Director

Europa Donna – The European Breast Cancer Coalition

Piazza Amendola 3

20149 Milan – Italy

4.1. E-mail for final approval of data (ECIBC National Contact)

Sent: 26 August 2016

Dear Mr/Ms,

We are coming back to you about last year's Survey on breast units' implementation along the 2006 European Guidelines that you so kindly filled in.

That survey was conducted by the JRC in collaboration with Europa Donna and Fatima Cardoso, in her role of EBCC-10 chair, and we are happy to announce that, thanks to your contribution, after a preliminary presentation of the results at the opening session of the EBCC-10 conference, we are ready to issue the report.

Before publishing the report, we wish to come back to you for the final approval of your responses as they will be published in the report. The responses may also be considered for future publications in peer reviewed journals, and in that case we will re-contact you and ask your contribution and endorsement as contributing author.

We may have proposed changes in the effort of harmonising text and language across the respondents, however doing our best for not changing the meaning; when we had doubts, we either highlighted or commented the text. Please have a look to the attached word file and come back to us.

Please be aware that these responses represent, under your responsibility, the situation in your country in a JRC publicly available report (and potentially in future papers), hence we wish to call your attention on the fact that this is not only the last approval step but also the last occasion for you to check that your responses are correct.

For your convenience, in addition to our proposal (doc), we also attach here the original form you submitted (PDF) and, when an interim check of responses occurred, we also attach the relative documentation (email).

Thanking you again for all the data you provided, we kindly ask you to provide the final approval by the **5.09.2016**.

Kindest regards,

Donata LERDA and Zuleika SAZ-PARKINSON
Healthcare Quality/ECIBC Team



European Commission

Directorate General Joint Research Centre
Directorate F – Health, Consumers and Reference Materials
Unit F1 ‘Health in Society’
via E. Fermi, 2749, TP127
I-21027 Ispra (VA), Italy
+39 0332 786201
JRC-CANCER-POLICY-SUPPORT@ec.europa.eu
ecibc.jrc.ec.europa.eu



AND

Fatima Cardoso, MD

EBCC 10 Chair
Director Breast Unit, Champalimaud Clinical Center
Av. De Brasília s/n, 1400-038 Lisbon, Portugal

AND

Susan Knox
Executive Director
Europa Donna – The European Breast Cancer Coalition

Piazza Amendola 3
20149 Milan – Italy

4.2. E-mail for final approval of data (ED National Representative)

Sent: 03 August 2016

Dear Mr/Ms,

We are coming back to you about the year's Survey on breast units' implementation along the 2006 European Guidelines that you so kindly filled in.

That survey was conducted by the JRC in collaboration with Europa Donna and Fatima Cardoso, in her role of EBCC-10 chair, and we are happy to announce that, thanks to your contribution, after a preliminary presentation of the results at the opening session of the EBCC-10 conference, we are ready to issue the report.

Before publishing the report, we wish to come back to you for the final approval of your responses, as they will be published in a JRC publicly available report.

The responses may also be considered for future publications in peer reviewed journals, and in that case we will re-contact you and ask your contribution and endorsement as contributing author.

We attach here the original form you submitted (PDF) and the language-corrected version we propose (doc).

Thanking you again for all the data you provided, we kindly ask you to provide the final approval by the **5.09.2016**.

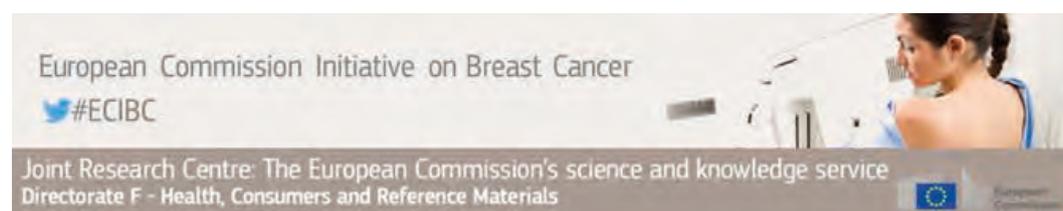
Kindest regards,

Donata LERDA and Zuleika SAZ-PARKINSON
Healthcare Quality/ECIBC Team



European Commission

Directorate General Joint Research Centre
Directorate F – Health, Consumers and Reference Materials
Unit F1 ‘Health in Society’
via E. Fermi, 2749, TP127
I-21027 Ispra (VA), Italy
+39 0332 786201
JRC-CANCER-POLICY-SUPPORT@ec.europa.eu
ecibc.jrc.ec.europa.eu



AND

Fatima Cardoso, MD

EBCC 10 Chair
Director Breast Unit, Champalimaud Clinical Center
Av. De Brasília s/n, 1400-038 Lisbon, Portugal

AND

Susan Knox
Executive Director
Europa Donna – The European Breast Cancer Coalition
Piazza Amendola 3
20149 Milan – Italy

Annex III

Detailed replies from ECIBC National Contacts and ED National Representatives

Original responses were edited by the JRC and approved by the respondents before publication. The original responses will be available upon request.

Countries were coded according to the ISO 3166 standard (reported in *Table 1* of the text and available at: <https://www.iso.org/obp/ui/#search>).

The following tables contain participants' free-text responses to various survey questions. Individual responses have been only slightly modified to minimise grammatical errors. No details or information have been deleted or altered in any way.

Table 1: *Survey Section 2.*

The organisation of healthcare in your country

Questions:

i. **ECIBC:** Geographical responsibility/mandate of your affiliation * National; Regional; Local; Other

ED: Denomination of the country for which you provide the information required in this survey *

ii. **ECIBC:** Please specify if any change in the geographical organisation/responsibility allocation of healthcare occurred since 2012-2013; please indicate NOT APPLICABLE in case your country was not included in that report * YES; NO, NOT APPLICABLE

If YES or NOT APPLICABLE, please fill in the following fields:

- In your country, healthcare and breast cancer care in particular is organised: Nationally; Regionally; Regionally under National coordination; Locally; Locally under Regional/National coordination; Other (If you choose 'Other', please provide a more detailed description)
- In the geographical area under your organisation's responsibility, healthcare and breast cancer care in particular is provided by: A – Public entities exclusively; B – Public entities mainly; C – Private entities mainly; Other
- If you choose 'Other', please provide a more detailed description
- If you choose B, are the public entities also responsible for the initial evaluation and the follow-up quality checks of external services provided by private entities? YES; NO
- If you choose C, Are the private entities supervised by public entities?; Are the private entities initially evaluated by public entities and then followed up for the quality of services provided?; Are the private entities required to be accredited/certified along defined National or European standards?; None of the previous

ED: Please specify if any change in the geographical organisation/responsibility allocation of healthcare occurred since 2012-2013; please indicate NOT APPLICABLE in case your country was not included in that report YES; NO; NOT APPLICABLE

If NO, skip the following two pages and just go to section 4

If YES or NOT APPLICABLE, please fill in the following fields:

- To the best of your knowledge, in your country, healthcare and breast cancer care in particular is organised: Nationally; Regionally; Regionally under National coordination; Locally; Locally under Regional/National coordination; Other; I do not have this information
- If you choose 'Other', please provide a more detailed description
- To the best of your knowledge, in your country, healthcare and breast cancer care in particular is provided by: A–Public entities exclusively; B–Public entities mainly; C–Private entities mainly; Other; I do not have this information
- If you choose 'Other', please provide a more detailed description
- If you choose B, to the best of your knowledge, are public entities also responsible for the initial evaluation and the follow-up quality checks of external services provided by private entities? YES; NO; I do not have this information
- If you choose C: Are the private entities supervised by public entities?; Are the private entities initially evaluated by public entities and then followed up for the quality of services provided?; Are the private entities required to be accredited/certified along defined National or European standards?; None of the previous; I do not have this information.

Country		1. Geographical mandate of ECIBC National Contact (responder to survey)	2.1. Healthcare organisation change since 2012-2013	2.2. If response to question 2.1 is yes, then how is healthcare organised?	2.3. Clarification of 'other' healthcare organisation	2.4. Healthcare and breast cancer care is provided by	2.5. Clarification of 'other' healthcare provider	2.6. If Healthcare provided mainly by public entities, are the same public entities also responsible for the initial evaluation and the follow-up quality checks of external services provided by private entities?
AT	<i>ECIBC National Contacts</i>							
	<i>ED National Representative</i>	Not asked	NO	Regionally under National coordination		Public entities mainly		YES
BE	<i>ECIBC National Contacts</i>	National	NO					
	<i>ED National Representative</i>							
BG	<i>ECIBC National Contacts</i>		NO					
	<i>ED National Representative</i>							
CH	<i>ECIBC National Contacts</i>	National	NOT APPLICABLE	Regionally		Other	Mainly public and publicly subsidised	NO
	<i>ED National Representative</i>		NOT APPLICABLE	Regionally	Switzerland has 26 cantons with 26 different healthcare systems.	Other	Private and public entities, depending on the canton.	I do not have this information.
CY	<i>ECIBC National Contacts</i>	National	NOT APPLICABLE	Nationally		Public entities mainly		NO
	<i>ED National Representative</i>			Nationally		Other	There is no national health system. Health care is both private and public.	

Country		1. Geographical mandate of ECIBC National Contact (responder to survey)	2.1. Healthcare organisation change since 2012-2013	2.2. If response to question 2.1 is yes, then how is healthcare organised?	2.3. Clarification of 'other' healthcare organisation	2.4. Healthcare and breast cancer care is provided by	2.5. Clarification of 'other' healthcare provider	2.6. If Healthcare provided mainly by public entities, are the same public entities also responsible for the initial evaluation and the follow-up quality checks of external services provided by private entities?
CZ	<i>ECIBC National Contacts</i>	National	NOT APPLICABLE	Nationally		Public entities mainly		YES
	<i>ED National Representative</i>		NO					
DE	<i>ECIBC National Contacts</i>	National	NO					
	<i>ED National Representative</i>							
EE	<i>ECIBC National Contacts</i>							
	<i>ED National Representative</i>		NO					
ES	<i>ECIBC National Contacts</i>							
	<i>ED National Representative</i>		NO					
FI	<i>ECIBC National Contacts</i>	Regional	NO	Regionally		Public entities mainly		YES
	<i>ED National Representative</i>							
FR	<i>ECIBC National Contacts</i>	National	NO			Other	In France, healthcare and breast cancer care in particular are provided by both public and private entities.	
	<i>ED National Representative</i>		NO					

Country		1. Geographical mandate of ECIBC National Contact (responder to survey)	2.1. Healthcare organisation change since 2012-2013	2.2. If response to question 2.1 is yes, then how is healthcare organised?	2.3. Clarification of 'other' healthcare organisation	2.4. Healthcare and breast cancer care is provided by	2.5. Clarification of 'other' healthcare provider	2.6. If Healthcare provided mainly by public entities, are the same public entities also responsible for the initial evaluation and the follow-up quality checks of external services provided by private entities?
GR	<i>ECIBC National Contacts</i>	National	NOT APPLICABLE	Nationally		Other	Public breast centres are under the responsibility of the Ministry of Health. Private breast centres are self-managed.	NO
	<i>ED National Representative</i>		NO					
HU	<i>ECIBC National Contacts</i>	National	YES	Nationally		Public entities exclusively	The responsibility of the Office of Chief Medical Officer (CMO) is national providing operating licences for all health care system units nationwide. However, patient care (including breast cancer care) has been organised at regional-local level. Professionally, the National Cancer Institute is in charge.	
	<i>ED National Representative</i>							
IE	<i>ECIBC National Contacts</i>	National	NO	Nationally		Public entities mainly		NO
	<i>ED National Representative</i>		NO	Regionally under National coordination		Public entities mainly		YES

Country		1. Geographical mandate of ECIBC National Contact (responder to survey)	2.1. Healthcare organisation change since 2012-2013	2.2. If response to question 2.1 is yes, then how is healthcare organised?	2.3. Clarification of 'other' healthcare organisation	2.4. Healthcare and breast cancer care is provided by	2.5. Clarification of 'other' healthcare provider	2.6. If Healthcare provided mainly by public entities, are the same public entities also responsible for the initial evaluation and the follow-up quality checks of external services provided by private entities?
IT	ECIBC National Contacts	National	NO					
	ED National Representative		NO					
LT	ECIBC National Contacts	Regional	NO					
	ED National Representative							
LU	ECIBC National Contacts	National	NO					
	ED National Representative		NO					
LV	ECIBC National Contacts	National	NO	Nationally		Public entities mainly		NO
	ED National Representative							
MT	ECIBC National Contacts	National	NO					
	ED National Representative		NO					
NL	ECIBC National Contacts							
	ED National Representative		NO					
NO	ECIBC National Contacts	National	NO					
	ED National Representative			Locally under Regional / National coordination		Public entities exclusively		

Country		1. Geographical mandate of ECIBC National Contact (responder to survey)	2.1. Healthcare organisation change since 2012-2013	2.2. If response to question 2.1 is yes, then how is healthcare organised?	2.3. Clarification of 'other' healthcare organisation	2.4. Healthcare and breast cancer care is provided by	2.5. Clarification of 'other' healthcare provider	2.6. If Healthcare provided mainly by public entities, are the same public entities also responsible for the initial evaluation and the follow-up quality checks of external services provided by private entities?
PL	<i>ECIBC National Contacts</i>	National	NOT APPLICABLE	Locally		Public entities mainly		NO
	<i>ED National Representative</i>							
PT	<i>ECIBC National Contacts</i>	National	NO					
	<i>ED National Representative</i>							
RO	<i>ECIBC National Contacts</i>	National	NO					
	<i>ED National Representative</i>							
RS	<i>ECIBC National Contacts</i>	National	NOT APPLICABLE	Nationally		Public entities mainly		NO
	<i>ED National Representative</i>							
SE	<i>ECIBC National Contacts</i>	National	YES	Locally under Regional / National coordination		Public entities mainly		NO
	<i>ED National Representative</i>		YES	Locally under Regional / National coordination		Public entities mainly		NO
SI	<i>ECIBC National Contacts</i>	National	NO	Regionally under National coordination		Public entities exclusively		
	<i>ED National Representative</i>		NO					

Country		1. Geographical mandate of ECIBC National Contact (responder to survey)	2.1. Healthcare organisation change since 2012-2013	2.2. If response to question 2.1 is yes, then how is healthcare organised?	2.3. Clarification of 'other' healthcare organisation	2.4. Healthcare and breast cancer care is provided by	2.5. Clarification of 'other' healthcare provider	2.6. If Healthcare provided mainly by public entities, are the same public entities also responsible for the initial evaluation and the follow-up quality checks of external services provided by private entities?
SK	ECIBC National Contacts	National	NO					
	ED National Representative							
TR	ECIBC National Contacts							
	ED National Representative		NO					
UK	ECIBC National Contacts	National	YES	Nationally		Public entities mainly		NO
	ED National Representative		NO					

Note to *Table 1*: To Q2.1, several countries did not respond 'YES or NOT APPLICABLE', yet they went on to answer Q2.2. This skipping error has likely introduced a certain degree of response bias to the results as the information that was provided was due to an error on the respondent's part, otherwise, had the respondent followed the instructions correctly, the survey organiser would not have received these data. However, to ensure that all information respondents provided would be covered, the authors of this report decided to incorporate that additional information in *Tables* and *Figures*.

Table 2: *Survey Section 4.*

General questions on Breast Units

Questions:

ECIBC:

1. Are there any Breast Units as defined by the 2006 European Guidelines in the geographical area under your organisation's responsibility? * YES; NO
Comments/Details
2. Are Breast Units required by law in the geographical area under your organisation's responsibility? * YES; NO
Comments/Details
3. Are Breast Units not required by law but just recommended in the geographical area under your organisation's responsibility? * YES, NO
Comments/Details

ED:

- i. Are there any Breast Units as defined by the 2006 European Guidelines in the geographical area under your organisation's responsibility? YES; NO, I do not have this information
Comments/Details
- ii. Are Breast Units required by law in the geographical area under your organisation's responsibility? YES; NO, I do not have this information
Comments/Details
- iii. Are Breast Units not required by law but just recommended in the geographical area under your organisation's responsibility? YES, NO, I do not have this information
Comments/Details

Country		4i. Are there BU in the geographical area under your organisation's responsibility?	4i. Comments	4ii. Are BU required by law?	4ii. Comments	4iii. Are BU not required by law but just recommended?	4iii. Comments
AT	<i>ECIBC National Contacts</i>						
	<i>ED National Representative</i>	YES		NO		YES	
BE	<i>ECIBC National Contacts</i>	YES	Breast clinics (specialised oncology care programmes) are recognised by regional authorities. The recognition criteria are regulated by royal decree, and all aspects do not conform to European Guideline requirements. Regional health authorities, and not the Federal Ministry of Health, are responsible for the recognition of breast units.	NO		YES	
	<i>ED National Representative</i>						
BG	<i>ECIBC National Contacts</i>	YES	There is a breast department at the National Hospital of Oncology, which is equipped for complex treatment of breast cancer.	NO	In Bulgaria, health laws and laws regarding health establishments, regulating the work of the hospitals, are applicable as well.	NO	This is responsibility of the Ministry of Health.
	<i>ED National Representative</i>						
CH	<i>ECIBC National Contacts</i>	NO		NO		YES	They are recommended by professional associations.
	<i>ED National Representative</i>	YES		NO		NO	

Country		4i. Are there BU in the geographical area under your organisation's responsibility?	4i. Comments	4ii. Are BU required by law?	4ii. Comments	4iii. Are BU not required by law but just recommended?	4iii. Comments
CY	<i>ECIBC National Contacts</i>	YES	There has been a breast unit, operating since 2010. The Ministerial Board has recently (19 November 2014) decided to appoint an ad-hoc committee with the mandate to upgrade the breast unit according to the European standards and to prepare a proposal on how this can be achieved. The ad hoc committee has submitted the report to the Ministerial Council. The report included the requirements for further development and operation of the breast centre, according to European Guidelines. The Ministerial Board has approved the development of the centre on 16 February 2016 and appointed a steering committee with the mandate to coordinate the required actions and procedures for the operation of the centre. It is expected that the centre will be fully functional in September 2016.	NO	There is a decision from the Council of Ministers.	YES	
	<i>ED National Representative</i>	NO		NO		NO	
CZ	<i>ECIBC National Contacts</i>	YES		YES		NO	

Country		4i. Are there BU in the geographical area under your organisation's responsibility?	4i. Comments	4ii. Are BU required by law?	4ii. Comments	4iii. Are BU not required by law but just recommended?	4iii. Comments
CZ	<i>ED National Representative</i>	NO		I do not have this information.		I do not have this information.	
DE	<i>ECIBC National Contacts</i>	YES		NO		YES	
	<i>ED National Representative</i>						
EE	<i>ECIBC National Contacts</i>						
	<i>ED National Representative</i>	YES	There are two units without accreditation: one in Tallinn, one in Tartu.	YES	The medical centre is located in northern Estonia.	NO	
ES	<i>ECIBC National Contacts</i>						
	<i>ED National Representative</i>	YES		NO		YES	
FI	<i>ECIBC National Contacts</i>	YES		NO		YES	
	<i>ED National Representative</i>						
FR	<i>ECIBC National Contacts</i>	NO	See comments 4vii on BU concept.	NO	See comments 4vii on BU concept.	NO	See comments 4vii on BU concept.
	<i>ED National Representative</i>	YES		NO		NO	
GR	<i>ECIBC National Contacts</i>	NO	Public breast centres are under the responsibility of the Ministry of Health. Private breast centres are self-managed.	NO		NO	

Country		4i. Are there BU in the geographical area under your organisation's responsibility?	4i. Comments	4ii. Are BU required by law?	4ii. Comments	4iii. Are BU not required by law but just recommended?	4iii. Comments
GR	<i>ED National Representative</i>	YES		NO		NO	
HU	<i>ECIBC National Contacts</i>	YES	Yes, there is one in the National Cancer Institute.	NO		YES	
	<i>ED National Representative</i>						
IE	<i>ECIBC National Contacts</i>	NO	The National Cancer Control Programme and Hospital Group Management are responsible for breast units.	NO		YES	
	<i>ED National Representative</i>	YES		NO		YES	
IT	<i>ECIBC National Contacts</i>	YES		YES	State-regions agreement on breast units networking issued 18 December 2014.	NO	
	<i>ED National Representative</i>	YES		YES		NO	
LT	<i>ECIBC National Contacts</i>	YES	The breast cancer care centre in the NCI was approved as a centre of excellence with SIS accreditation (accreditation in 2014).	NO		YES	
	<i>ED National Representative</i>						

Country		4i. Are there BU in the geographical area under your organisation's responsibility?	4i. Comments	4ii. Are BU required by law?	4ii. Comments	4iii. Are BU not required by law but just recommended?	4iii. Comments
LU	<i>ECIBC National Contacts</i>	NO	The Ministry of Health adapted its first National Cancer Plan for 2014-2018. Breast cancer care is one of the topics.	NO	Luxembourg is a small country, with 5 hospitals, where all cancers are treated. In the framework of the Hospital Plan this might change in the coming years.	NO	
	<i>ED National Representative</i>	NO		NO		NO	
LV	<i>ECIBC National Contacts</i>	NO		NO		NO	
	<i>ED National Representative</i>						
MT	<i>ECIBC National Contacts</i>	NO	One breast care unit is present at the main hospital (Mater Dei Hospital - MDH) but it is not fully in line with the mandatory requirements as stipulated in the 2006 European Guidelines. This unit mainly caters to the diagnosis (patients diagnosed post-referral due to suspicious signs and symptoms), and surgical treatment and follow-up of most patients with breast cancer. Population-based organised mammography screening is carried out in a different set-up and patients diagnosed through the screening programme	NO		NO	The breast unit at MDH was not mandated by law. It has been in operation since 2000.

Country		4i. Are there BU in the geographical area under your organisation's responsibility?	4i. Comments	4ii. Are BU required by law?	4ii. Comments	4iii. Are BU not required by law but just recommended?	4iii. Comments
MT			join the breast care unit after the initial MDT meeting in which their screening diagnosis is discussed and their cancer care pathway is planned. Oncological (chemotherapy, hormone therapy and radiotherapy) treatments and palliative care are managed at the oncology centre.				
	<i>ED National Representative</i>	YES		I do not have this information.		I do not have this information.	
NL	<i>ECIBC National Contacts</i>						
	<i>ED National Representative</i>	YES	Most breast units are part of a general hospital.	NO		YES	
NO	<i>ECIBC National Contacts</i>	YES		NO		YES	
	<i>ED National Representative</i>	NO		NO		YES	
PL	<i>ECIBC National Contacts</i>	YES	There are two 'formal' breast units in Poland.	NO		NO	
	<i>ED National Representative</i>						
PT	<i>ECIBC National Contacts</i>	YES		NO		YES	
	<i>ED National Representative</i>						

Country		4i. Are there BU in the geographical area under your organisation's responsibility?	4i. Comments	4ii. Are BU required by law?	4ii. Comments	4iii. Are BU not required by law but just recommended?	4iii. Comments
RO	<i>ECIBC National Contacts</i>	NO		NO		YES	
	<i>ED National Representative</i>						
RS	<i>ECIBC National Contacts</i>	YES	In line with the regulation concerning the network of healthcare facilities in Serbia, as well as according to the healthcare law there are healthcare facilities established on secondary and tertiary level of healthcare which cover comprehensive cancer care, including breast cancer care as defined by the 2006 European Guidelines.	NO	The Ministry of Health issued a regulation on the network of healthcare facilities in Serbia in charge of oncological healthcare. Those oncology centres are obliged to provide healthcare services for diagnosis and therapy related to breast health. There are six institutions providing BU services: 1. Institute for Oncology and Radiology of Serbia - IORS, 2. Institute for Oncology and Radiology, Vojvodina, Sremska Kamenica, 3. Clinical Centre, Vojvodina, 4. Clinical Centre Niš, 5. Health Centre, Kladovo, 6. Military Hospital VMA, Belgrade.	NO	The healthcare law and regulation of the network of public healthcare facilities in Serbia as well as the law on health insurance are key documents regarding the legal framework concerning the functioning of diagnostic services and therapy for breast malignancies.
	<i>ED National Representative</i>						

Country		4i. Are there BU in the geographical area under your organisation's responsibility?	4i. Comments	4ii. Are BU required by law?	4ii. Comments	4iii. Are BU not required by law but just recommended?	4iii. Comments
SE	<i>ECIBC National Contacts</i>	YES	All of the university hospitals and most hospitals in the country have breast units. A follow up from the National Board of Health and Welfare showed that 70 % of breast units had more than 150 newly diagnosed cases per year (2013).	NO		YES	Recommended in The National Clinical Practice Guidelines for Breast Cancer (2014).
	<i>ED National Representative</i>	YES	The interpretation of the definition given in the 2006 European Guidelines differs. There are no BU according to that definition but for every 250 000 to 300 000 inhabitants. As counties in Sweden are autonomous to the government they also tend to define recommendations/guidelines differently.	NO		YES	National guidelines are inspired to the recommendations from the Swedish Breast Cancer Group, which are continuously updated.
SI	<i>ECIBC National Contacts</i>	YES		NO		YES	See the National Cancer Control Programme.
	<i>ED National Representative</i>	NO		NO		YES	
SK	<i>ECIBC National Contacts</i>	NO		NO		NO	
	<i>ED National Representative</i>						
TR	<i>ECIBC National Contacts</i>						
	<i>ED National Representative</i>	YES		NO		NO	

Country		4i. Are there BU in the geographical area under your organisation's responsibility?	4i. Comments	4ii. Are BU required by law?	4ii. Comments	4iii. Are BU not required by law but just recommended?	4iii. Comments
UK	<i>ECIBC National Contacts</i>	YES	Most breast cancer diagnosis and treatment is performed in units as defined, this has been mandated since the start of the national peer review process in 2000.	NO	No, but hospital breast units have a defined set of peer review standards that have to be met and are measured. Compliance is assessed by visiting teams of external professional peer review assessors.	YES	
	<i>ED National Representative</i>	YES		YES			

Table 3: Survey section 4.

General questions on Breast Units

Questions:

ECIBC:

4. Is there a national accreditation/certification system for Breast Units in the geographical area under your organisation's responsibility? * YES; NO
If YES, please provide details
5. Are there regional/local accreditation/certification systems for Breast Units in the geographical area under your organisation's responsibility? * YES; NO
If YES, please provide details
6. Are these accreditation/certification systems mandatory or voluntary in the geographical area under your organisation's responsibility? * YES, NO
If YES, please provide details
7. If you wish, please add below your comments/considerations on Breast Units organisational concept as defined in the 2006 European Guidelines

ED:

- iv. Is there a national accreditation/certification system for Breast Units in the geographical area under your organisation's responsibility? * YES; NO, I do not have this information
Comments/Details
- v. Are there regional/local accreditation/certification systems for Breast Units in the geographical area under your organisation's responsibility? * YES; NO, I do not have this information
Comments/Details
- vi. Are these accreditation/certification systems mandatory or voluntary in the geographical area under your organisation's responsibility? * YES, NO, I do not have this information
Comments/Details
- vii. If you wish, please add below your comments/considerations on Breast Units organisational concept as defined in the 2006 European Guidelines

Country		4iv. Is there a national accreditation/certification system for BU?	4iv. Comments	4v. Are there regional/local accreditation/certification systems for BU?	4v. Comments	4vi. Are these accreditation/certification systems mandatory or voluntary?	4vi. Comments regarding the question about whether the accreditation/certification systems are mandatory or voluntary
AT	<i>ECIBC National Contacts</i>						
	<i>ED National Representative</i>	YES	Certification system is private and based on professional association, no national responsibility.	NO		Voluntary	
BE	<i>ECIBC National Contacts</i>	NO	Same as 4i comments.	YES	The certification system implies that there is recognition by regional health authorities.		NOT APPLICABLE: hospitals that wish to obtain recognition as a breast unit (in the framework of the hospital law) have to apply to regional health authorities and only obtain it if the criteria in the royal decree are fulfilled.
	<i>ED National Representative</i>						
BG	<i>ECIBC National Contacts</i>	YES	There is a general accreditation system for all hospitals, repeated every 3 to 5 years. It is also applicable to breast departments.	NO		Mandatory	The Ministry of Health requires regular accreditation of all health establishments, depending on their specialisation. The accreditation system of the Ministry of Health; Standards and guidelines for breast cancer treatment; Standards for general surgery; Standards for chemotherapy; Standards for radiotherapy.

Country		4iv. Is there a national accreditation/certification system for BU?	4iv. Comments	4v. Are there regional/local accreditation/certification systems for BU?	4v. Comments	4vi. Are these accreditation/certification systems mandatory or voluntary?	4vi. Comments regarding the question about whether the accreditation/certification systems are mandatory or voluntary
BG	<i>ED National Representative</i>						
CH	<i>ECIBC National Contacts</i>	NO		NO			
	<i>ED National Representative</i>	NO		NO		I do not have this information.	
CY	<i>ECIBC National Contacts</i>	NO	A breast unit was set up at Nicosia General Hospital. Since 2013, it has been part of the EUSOMA network.	NO			NOT APPLICABLE
	<i>ED National Representative</i>	NO		NO		Voluntary	No accreditation
CZ	<i>ECIBC National Contacts</i>	YES	Ministry of Health and the Czech Radiological Society run the system.	NO		Mandatory	Only for the screening programme.
	<i>ED National Representative</i>	I do not have this information.		I do not have this information.		I do not have this information.	
DE	<i>ECIBC National Contacts</i>	YES	General information about the system: http://www.krebsgesellschaft.de/gcs/german-cancer-society/certification.html , Scientific publications and research: https://www.krebsgesellschaft.de/gcs/german-cancer-society/certification/publications_ii.html .	NO		Voluntary	

Country		4iv. Is there a national accreditation/certification system for BU?	4iv. Comments	4v. Are there regional/local accreditation/certification systems for BU?	4v. Comments	4vi. Are these accreditation/certification systems mandatory or voluntary?	4vi. Comments regarding the question about whether the accreditation/certification systems are mandatory or voluntary
DE	<i>ED National Representative</i>						
EE	<i>ECIBC National Contacts</i>						
	<i>ED National Representative</i>	NO		NO		I do not have this information.	
ES	<i>ECIBC National Contacts</i>						
	<i>ED National Representative</i>	YES		NO		Voluntary	
FI	<i>ECIBC National Contacts</i>	NO		NO		Voluntary	
	<i>ED National Representative</i>						
FR	<i>ECIBC National Contacts</i>	NO	See comments 4vii on BU concept.	NO	See comments 4vii on BU concept.	Voluntary	See comments 4vii on BU concept.
	<i>ED National Representative</i>	NO		NO		I do not have this information.	
GR	<i>ECIBC National Contacts</i>	NO		NO			
	<i>ED National Representative</i>	YES		NO		Voluntary	
HU	<i>ECIBC National Contacts</i>	NO		NO		Voluntary	
	<i>ED National Representative</i>						
IE	<i>ECIBC National Contacts</i>	NO		NO		NOT APPLICABLE	

Country		4iv. Is there a national accreditation/certification system for BU?	4iv. Comments	4v. Are there regional/local accreditation/certification systems for BU?	4v. Comments	4vi. Are these accreditation/certification systems mandatory or voluntary?	4vi. Comments regarding the question about whether the accreditation/certification systems are mandatory or voluntary
IE	<i>ED National Representative</i>	YES		YES		I do not have this information.	
IT	<i>ECIBC National Contacts</i>	NO		YES	According to local (regional) initiatives and the state-regions agreement on Breast Units networking (Intesa Conferenza Stato-Regioni) issued 18 December 2014.	Mandatory	The state-regions agreement on breast units networking issued 18 December 2014 provides accreditation criteria and standards according to 2006 European Guidelines.
	<i>ED National Representative</i>	NO	Breast centres can apply for voluntary certification (e.g. EUSOMA).	NO	A regional accreditation system is foreseen but not yet implemented (see document drawn by Italian Ministry of Health, December 2014 Rep. Atti 185/CSR).		According to the document mentioned above the regional accreditation system will become mandatory but at the same time the breast centres can undergo the voluntary certification process (e.g. EUSOMA).
LT	<i>ECIBC National Contacts</i>	NO		NO		Voluntary	
	<i>ED National Representative</i>						
LU	<i>ECIBC National Contacts</i>	NO	In the framework of the Cancer Plan this might become an option.	NO			
	<i>ED National Representative</i>	NO		NO		Voluntary	

Country		4iv. Is there a national accreditation/certification system for BU?	4iv. Comments	4v. Are there regional/local accreditation/certification systems for BU?	4v. Comments	4vi. Are these accreditation/certification systems mandatory or voluntary?	4vi. Comments regarding the question about whether the accreditation/certification systems are mandatory or voluntary
LV	ECIBC National Contacts	NO		NO			
	ED National Representative						
MT	ECIBC National Contacts	NO		NO		Voluntary	
	ED National Representative	NO		NO		I do not have this information.	
NL	ECIBC National Contacts						
	ED National Representative	NO		NO		Voluntary	EUSOMA accreditation was recently obtained by one hospital. More will follow soon.
NO	ECIBC National Contacts	NO		NO		Voluntary	
	ED National Representative	NO		NO			
PL	ECIBC National Contacts	NO		NO			NOT APPLICABLE
	ED National Representative						
PT	ECIBC National Contacts	YES	The accreditation system is starting now (2015).	NO		Voluntary	
	ED National Representative						
RO	ECIBC National Contacts	NO		NO		Voluntary	

Country		4iv. Is there a national accreditation/certification system for BU?	4iv. Comments	4v. Are there regional/local accreditation/certification systems for BU?	4v. Comments	4vi. Are these accreditation/certification systems mandatory or voluntary?	4vi. Comments regarding the question about whether the accreditation/certification systems are mandatory or voluntary
RO	<i>ED National Representative</i>						
RS	<i>ECIBC National Contacts</i>	NO	In the Republic of Serbia there is a national agency for the accreditation of healthcare institutions (AZUS). In order to improve the quality of work of healthcare facilities majority of above listed institutions for oncology care are in the procedure of accreditation.	NO	In the Republic of Serbia there is a national agency for the accreditation of healthcare institutions (AZUS). Accreditation is not obligatory procedure for healthcare institutions in Serbia. Nevertheless, more than 50% of institutions are in the procedure of accreditation or are accredited.	Voluntary	They are not mandatory at the moment.
	<i>ED National Representative</i>						
SE	<i>ECIBC National Contacts</i>	NO		NO		Voluntary	
	<i>ED National Representative</i>	NO	Europa Donna is currently supporting a European quality assurance/accreditation through the European Commission and the JRC.	NO	There is no quality assurance system. Professionals have been looking at EUSOMA criteria, but not even the Swedish Breast Cancer Group has been working on this.	Voluntary	The University Hospital of Lund expressed interest regarding accreditation through EUSOMA. However, costs are high –due to compliance criteria, but also for the accreditation itself. As Swedish university hospitals are public entities, it is not within the policy to pay for a ‘diploma’.

Country		4iv. Is there a national accreditation/certification system for BU?	4iv. Comments	4v. Are there regional/local accreditation/certification systems for BU?	4v. Comments	4vi. Are these accreditation/certification systems mandatory or voluntary?	4vi. Comments regarding the question about whether the accreditation/certification systems are mandatory or voluntary
SI	<i>ECIBC National Contacts</i>	NO		NO			
	<i>ED National Representative</i>	NO		NO		Voluntary	
SK	<i>ECIBC National Contacts</i>	NO		NO			
	<i>ED National Representative</i>						
TR	<i>ECIBC National Contacts</i>						
	<i>ED National Representative</i>	NO		NO		Voluntary	
UK	<i>ECIBC National Contacts</i>	YES	A national peer review process for the symptomatic cancers, with defined criteria for assessment against these, is in place. A well-organised quality assurance programme for screen detected breast cancer is in place. Please see attached peer review documents.	YES	Peer review, which while not providing a certificate, assesses the % compliance and results are publicly available.	Mandatory	There are clear and detailed peer review measures published, each breast unit has to measure itself against these, and compliance is assessed by a visiting group of external peers.
	<i>ED National Representative</i>	YES		YES		YES	

Table 4: Survey section 5.

Breast Units mandatory requirements implementation stage.

Questions:

1. Critical mass

Definition from the 2006 European Guidelines

*A Unit must be of sufficient size to have **more than 150**, newly diagnosed cases of primary breast cancer (at all ages and stages) coming under its care each year.*

Note: these are newly diagnosed breast cancers. They may have been diagnosed elsewhere but if they have received any prior treatment and have been transferred, for example, to receive radiotherapy, they should not be counted.

All primary treatment must be carried out under the direction of the Unit (operation must be in the unit, adjuvant therapies must be directed by the unit but may have been received in other settings e.g. RT and chemotherapy). Follow up should be under the control of the Unit.

The reason for recommending a minimum number is to ensure a caseload sufficient to maintain expertise for each team member and to ensure cost-effective working of the Breast Unit: the establishment of a clinic staffed by experts is expensive and must have a high through-put of patients.

A number of Units will be recognised as teaching centres, nationally or internationally. They may be recognised for teaching over all breast cancer management or special aspects (e.g. screening, reconstruction, pathology).

ECIBC:

1. In the geographical area under your organisation's responsibility is there any kind of requirement that regulates at more than 150 the number of newly diagnosed cases of primary breast cancer cases yearly treated in individual Breast Units? * YES, MANDATORY; YES, VOLUNTARY; NO, BUT PLANNED; NO and NOT PLANNED; I do not know

2. If you replied YES, MANDATORY or VOLUNTARY, please report below the implementation framework of the requirement and the respective year of implementation (more than one answer is possible). Embedded in national/regional legislation; Used as reference for reimbursement from insurances at national/regional level; Institutional licencing requirement at national/regional level; Used in a non-public quality assurance scheme under national/regional governance; Used in a non-public quality assurance scheme; NOT under national/regional governance
3. If you replied YES, please provide a more detailed description: name of legislation/quality assurance scheme, link to the text or reference document
4. Please select the scenario that you think is better representing you country with respect to the critical mass at more than 150 the number of newly diagnosed cases of primary breast cancer cases yearly treated in individual Breast Units *: Virtually all primary breast cancer cases are treated in a centre whose volume is higher than 150 new cases/year; Most primary breast cancer cases are treated in a centre whose volume is higher than 150 new cases/year, but a small amount of cases are treated in centres with a lower volume; Primary breast cancer cases are equally divided in centres with more and less than 150 new cases/year; Even though centres whose volume is higher than 150 new cases/year exist, most cases are treated in low-volume centres; Virtually all primary breast cancer cases are treated in a centre whose volume is lower than 150 new cases/year
5. If you have requirements, but your threshold is different from 150, please provide the number
6. If you wish, please add below your comments/considerations on critical mass mandatory requirement

ED:

1. Is there in your country any kind of requirement that regulates at more than 150 the number of newly diagnosed cases of primary breast cancer cases yearly treated in individual Breast Units? YES; NO; I do not have this information
2. If you wish, please add below your comments/considerations on critical mass mandatory requirement

Country		5.1.1 Is there a requirement that regulates at more than 150 the number of newly diagnosed cases of primary breast cancer cases yearly treated in individual BU? [5.1 for ED Questionnaire]	5.1.2a Implementation framework of the requirement [Not included in ED Questionnaire]	5.1.3 Details [Not included in ED Questionnaire]	5.1.4 Which scenario better represents your country with respect to the critical mass at more than 150 the number of newly diagnosed cases of primary breast cancer cases yearly treated in individual BU? [Not included in ED Questionnaire]	5.1.5 If you have requirements, but your threshold is different from 150, please provide the number [Not included in ED Questionnaire]	5.1.6 Comments [5.1 Comments for ED Questionnaire]
AT	<i>ECIBC National Contacts</i>						
	<i>ED National Representative</i>	NO					The regulations require a minimum 100 primary breast cancer cases in a unit. Indeed, most units have more than 150 patients. The number '100' was chosen due to the geographical (roads are determined by mountains) and political (the 'Länder' having their own hospitals) situation.
BE	<i>ECIBC National Contacts</i>	NO and NOT PLANNED			Even though centres whose volume is higher than 150 new cases per year exist, most cases are treated in low-volume centres.	125	

Country		5.1.1 Is there a requirement that regulates at more than 150 the number of newly diagnosed cases of primary breast cancer cases yearly treated in individual BU? [5.1 for ED Questionnaire]	5.1.2a Implementation framework of the requirement [Not included in ED Questionnaire]	5.1.3 Details [Not included in ED Questionnaire]	5.1.4 Which scenario better represents your country with respect to the critical mass at more than 150 the number of newly diagnosed cases of primary breast cancer cases yearly treated in individual BU? [Not included in ED Questionnaire]	5.1.5 If you have requirements, but your threshold is different from 150, please provide the number [Not included in ED Questionnaire]	5.1.6 Comments [5.1 Comments for ED Questionnaire]
BE	<i>ED National Representative</i>						
BG	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	Institutional licencing requirement at national/regional level. Implemented in 2000. Used in a non-public quality assurance scheme under national/regional governance. Implemented in 2000.		Most primary breast cancer cases are treated in a centre whose volume is higher than 150 new cases per year, but a small number of cases are treated in centres with a lower volume.	120	The requirement of the National Hospital of Oncology is for every surgeon from the Breast Department to have at least 120 patients with primary breast cancer a year
	<i>ED National Representative</i>						
CH	<i>ECIBC National Contacts</i>	NO and NOT PLANNED			Primary breast cancer cases are equally divided in centres with more and less than 150 new cases per year.	125	For a non mandatory certification of Swiss BU's, the requirement is 125 cases. For more details see http://www.krebsliga.ch/de/fachpersonen/qualitaetslabel_fuer_brustzentren/zertifizierte_zentren/ .
	<i>ED National Representative</i>	I do not have this information.					

Country		5.1.1 Is there a requirement that regulates at more than 150 the number of newly diagnosed cases of primary breast cancer cases yearly treated in individual BU? [5.1 for ED Questionnaire]	5.1.2a Implementation framework of the requirement [Not included in ED Questionnaire]	5.1.3 Details [Not included in ED Questionnaire]	5.1.4 Which scenario better represents your country with respect to the critical mass at more than 150 the number of newly diagnosed cases of primary breast cancer cases yearly treated in individual BU? [Not included in ED Questionnaire]	5.1.5 If you have requirements, but your threshold is different from 150, please provide the number [Not included in ED Questionnaire]	5.1.6 Comments [5.1 Comments for ED Questionnaire]
CY	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	Institutional licencing requirement at national/regional level	The Ministry of Health refers to the 2006 European Guidelines. The Public Breast Unit follows the requirements, because there is no legislative framework. Private clinics act voluntarily.	Most primary breast cancer cases are treated in a centre whose volume is higher than 150 new cases per year, but a small number of cases are treated in centres with a lower volume.		Most women who are eligible for public health care services are treated in the centre that meets the above named requirements. The private clinics undergo the rules of free market and therefore the patients chose mainly centres whose volume is higher than 150 new cases per year.
	<i>ED National Representative</i>	NO					
CZ	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	Embedded in national/regional legislation. Implemented in 2010. Used as reference for reimbursement from insurance at national/regional level. Implemented in 2002. Institutional	The legislative framework in the Czech Republic is determined by decree of the Ministry of Health (MoH CR) no. 3/2010 Coll. It determines the content and intervals of preventive	Most primary breast cancer cases are treated in a centre whose volume is higher than 150 new cases per year, but a small number of cases are treated in centres with a lower volume.		Most breast cancer patients are treated in 13 comprehensive oncological centres associated with breast units.

Country		5.1.1 Is there a requirement that regulates at more than 150 the number of newly diagnosed cases of primary breast cancer cases yearly treated in individual BU? [5.1 for ED Questionnaire]	5.1.2a Implementation framework of the requirement [Not included in ED Questionnaire]	5.1.3 Details [Not included in ED Questionnaire]	5.1.4 Which scenario better represents your country with respect to the critical mass at more than 150 the number of newly diagnosed cases of primary breast cancer cases yearly treated in individual BU? [Not included in ED Questionnaire]	5.1.5 If you have requirements, but your threshold is different from 150, please provide the number [Not included in ED Questionnaire]	5.1.6 Comments [5.1 Comments for ED Questionnaire]
CZ	<i>ECIBC National Contacts</i>		licencing requirement at national/regional level. Implemented in 2003. Used in a non-public quality assurance scheme under national/regional governance. Implemented in 2010. Used in a non-public quality assurance scheme NOT under national/regional governance. Implemented in 1970.	examinations and recommended standards. These were published in the Ministry of Health bulletin (April 2010).			
	<i>ED National Representative</i>						
DE	<i>ECIBC National Contacts</i>	NO and NOT PLANNED			Virtually all primary breast cancer cases are treated in a centre whose volume is higher than 150 new cases per year.	100	There are good publications for some tumour sites (colorectal, lung, pancreatic) that show better outcome with higher volume, but this correlation is weak for breast cancer.

Country		5.1.1 Is there a requirement that regulates at more than 150 the number of newly diagnosed cases of primary breast cancer cases yearly treated in individual BU? [5.1 for ED Questionnaire]	5.1.2a Implementation framework of the requirement [Not included in ED Questionnaire]	5.1.3 Details [Not included in ED Questionnaire]	5.1.4 Which scenario better represents your country with respect to the critical mass at more than 150 the number of newly diagnosed cases of primary breast cancer cases yearly treated in individual BU? [Not included in ED Questionnaire]	5.1.5 If you have requirements, but your threshold is different from 150, please provide the number [Not included in ED Questionnaire]	5.1.6 Comments [5.1 Comments for ED Questionnaire]
DE	<i>ECIBC National Contacts</i>						However, from an economic point of view a critical mass can be useful. The median of the number of primary cases (no recurrences, no metastases) in breast cancer centres in Germany is 212 per year. (https://www.krebsgesellschaft.de/gcs/german-cancer-society/certification/documents.html?file=files/dkg/deutsche-krebsgesellschaft/content/pdf/Zertifizierung/Jahresberichte%20mit%20DOI%20und%20ISBN/breast_annual%20report-2016-A3%28160721%29.pdf , page 3).
	<i>ED National Representative</i>						
EE	<i>ECIBC National Contacts</i>						

Country		5.1.1 Is there a requirement that regulates at more than 150 the number of newly diagnosed cases of primary breast cancer cases yearly treated in individual BU? [5.1 for ED Questionnaire]	5.1.2a Implementation framework of the requirement [Not included in ED Questionnaire]	5.1.3 Details [Not included in ED Questionnaire]	5.1.4 Which scenario better represents your country with respect to the critical mass at more than 150 the number of newly diagnosed cases of primary breast cancer cases yearly treated in individual BU? [Not included in ED Questionnaire]	5.1.5 If you have requirements, but your threshold is different from 150, please provide the number [Not included in ED Questionnaire]	5.1.6 Comments [5.1 Comments for ED Questionnaire]
EE	ED National Representative	YES					Estonia is a very little country - population 1,31 million. In Estonia there are two breast units in major hospitals, one for the Northern part of the country, the other for the Southern part. Each year over 700 new breast cancers are diagnosed and treated.
ES	ECIBC National Contacts						
	ED National Representative	NO					
FI	ECIBC National Contacts	NO and NOT PLANNED			Most primary breast cancer cases are treated in a centre whose volume is higher than 150 new cases per year, but a small number of cases are treated in centres with a lower volume.		

Country		5.1.1 Is there a requirement that regulates at more than 150 the number of newly diagnosed cases of primary breast cancer cases yearly treated in individual BU? [5.1 for ED Questionnaire]	5.1.2a Implementation framework of the requirement [Not included in ED Questionnaire]	5.1.3 Details [Not included in ED Questionnaire]	5.1.4 Which scenario better represents your country with respect to the critical mass at more than 150 the number of newly diagnosed cases of primary breast cancer cases yearly treated in individual BU? [Not included in ED Questionnaire]	5.1.5 If you have requirements, but your threshold is different from 150, please provide the number [Not included in ED Questionnaire]	5.1.6 Comments [5.1 Comments for ED Questionnaire]
FI	<i>ED National Representative</i>						
FR	<i>ECIBC National Contacts</i>	NO and NOT PLANNED			Most primary breast cancer cases are treated in a centre whose volume is higher than 150 new cases per year, but a small number of cases are treated in centres with a lower volume.		Question 1.4 is mandatory but doesn't apply to France. See 4vii comments.
	<i>ED National Representative</i>	NO					Thirty cases per year is the minimum requirement for surgeons.
GR	<i>ECIBC National Contacts</i>	NO and NOT PLANNED			Most primary breast cancer cases are treated in a centre whose volume is higher than 150 new cases per year, but a small number of cases are treated in centres with a lower volume.		Unfortunately, in Greece there are no breast centres that meet the 2006 European Guidelines. There is no official position on the threshold of cases even if 150 is the widely applied threshold. To date, there is no national breast cancer registry.

Country		5.1.1 Is there a requirement that regulates at more than 150 the number of newly diagnosed cases of primary breast cancer cases yearly treated in individual BU? [5.1 for ED Questionnaire]	5.1.2a Implementation framework of the requirement [Not included in ED Questionnaire]	5.1.3 Details [Not included in ED Questionnaire]	5.1.4 Which scenario better represents your country with respect to the critical mass at more than 150 the number of newly diagnosed cases of primary breast cancer cases yearly treated in individual BU? [Not included in ED Questionnaire]	5.1.5 If you have requirements, but your threshold is different from 150, please provide the number [Not included in ED Questionnaire]	5.1.6 Comments [5.1 Comments for ED Questionnaire]
GR	<i>ED National Representative</i>	NO					
HU	<i>ECIBC National Contacts</i>	NO, BUT PLANNED			Most primary breast cancer cases are treated in a centre whose volume is higher than 150 new cases per year, but a small number of cases are treated in centres with a lower volume.		
	<i>ED National Representative</i>						
IE	<i>ECIBC National Contacts</i>	YES, VOLUNTARY			Virtually all primary breast cancer cases are treated in a centre whose volume is higher than 150 new cases per year.		There is no mandatory minimum number but there are eight centres. So, all centres treat more than 150 women.
	<i>ED National Representative</i>	YES					
IT	<i>ECIBC National Contacts</i>	YES, MANDATORY	Embedded in national/regional legislation. Implemented in 2014.	State-regions agreement on breast units networking issued	Even though centres whose volume is higher than 150 new cases per		

Country		5.1.1 Is there a requirement that regulates at more than 150 the number of newly diagnosed cases of primary breast cancer cases yearly treated in individual BU? [5.1 for ED Questionnaire]	5.1.2a Implementation framework of the requirement [Not included in ED Questionnaire]	5.1.3 Details [Not included in ED Questionnaire]	5.1.4 Which scenario better represents your country with respect to the critical mass at more than 150 the number of newly diagnosed cases of primary breast cancer cases yearly treated in individual BU? [Not included in ED Questionnaire]	5.1.5 If you have requirements, but your threshold is different from 150, please provide the number [Not included in ED Questionnaire]	5.1.6 Comments [5.1 Comments for ED Questionnaire]
IT	<i>ECIBC National Contacts</i>			the 18 December 2014.	year exist, most cases are treated in low-volume centres.		
	<i>ED National Representative</i>	YES					
LT	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	Used as reference for reimbursement from insurance at national/regional level.	Since 1979, the National Cancer Institute (earlier Institute of Oncology, Vilnius University) has been one of many cancer treatment centres in Lithuania; all public hospitals are reimbursed from State patients funds and the Ministry. There are five main possible cancer treatment hospitals in major cities; three of them provide cancer diagnostics, surgery, radiotherapy and medical oncology; All patients are referred to these centres	Virtually all primary breast cancer cases are treated in a centre whose volume is higher than 150 new cases per year.		1 500 new breast cancer cases are diagnosed in Lithuania per year. There is no requirement on critical mass of breast cancer patients, but there are only three big centres in Lithuania (Vilnius National Cancer Institute, Kaunas and Klaipeda), where comprehensive breast cancer care is possible. In smaller cities as Klaipeda, Siauliai breast surgery and chemotherapy is possible, in Panevezys region only chemotherapy is possible.

Country		5.1.1 Is there a requirement that regulates at more than 150 the number of newly diagnosed cases of primary breast cancer cases yearly treated in individual BU? [5.1 for ED Questionnaire]	5.1.2a Implementation framework of the requirement [Not included in ED Questionnaire]	5.1.3 Details [Not included in ED Questionnaire]	5.1.4 Which scenario better represents your country with respect to the critical mass at more than 150 the number of newly diagnosed cases of primary breast cancer cases yearly treated in individual BU? [Not included in ED Questionnaire]	5.1.5 If you have requirements, but your threshold is different from 150, please provide the number [Not included in ED Questionnaire]	5.1.6 Comments [5.1 Comments for ED Questionnaire]
LT	<i>ED National Representative</i>						
LU	<i>ECIBC National Contacts</i>	YES, VOLUNTARY		No legislation. The requirements for a 'Competence Centre' are defined but not implemented. The year of implementation might be 2017 within the framework of the National Cancer Plan.	Virtually all primary breast cancer cases are treated in a centre whose volume is lower than 150 new cases per year.		Yearly new diagnosed breast cancer cases: approximately 400. For the time being they are treated in five hospitals. The Ministry of Health together with the cancer registry is gathering data regarding all aspects of breast cancer care at national level. This might help policy makers decide whether to have a breast cancer unit in the future. The requirement of 150 new cases a year is a high number; the number of centres should be reduced to 2-3 for the whole country.
	<i>ED National Representative</i>	NO					

Country		5.1.1 Is there a requirement that regulates at more than 150 the number of newly diagnosed cases of primary breast cancer cases yearly treated in individual BU? [5.1 for ED Questionnaire]	5.1.2a Implementation framework of the requirement [Not included in ED Questionnaire]	5.1.3 Details [Not included in ED Questionnaire]	5.1.4 Which scenario better represents your country with respect to the critical mass at more than 150 the number of newly diagnosed cases of primary breast cancer cases yearly treated in individual BU? [Not included in ED Questionnaire]	5.1.5 If you have requirements, but your threshold is different from 150, please provide the number [Not included in ED Questionnaire]	5.1.6 Comments [5.1 Comments for ED Questionnaire]
LV	<i>ECIBC National Contacts</i>	NO and NOT PLANNED			Most primary breast cancer cases are treated in a centre whose volume is higher than 150 new cases per year, but a small number of cases are treated in centres with a lower volume.		
	<i>ED National Representative</i>						
MT	<i>ECIBC National Contacts</i>	NO, BUT PLANNED			Virtually all primary breast cancer cases are treated in a centre whose volume is higher than 150 new cases per year.		
	<i>ED National Representative</i>	YES					
NL	<i>ECIBC National Contacts</i>						
	<i>ED National Representative</i>	NO					For this requirement, the Dutch Breast Cancer Society met a lot of resistance from professionals.

Country		5.1.1 Is there a requirement that regulates at more than 150 the number of newly diagnosed cases of primary breast cancer cases yearly treated in individual BU? [5.1 for ED Questionnaire]	5.1.2a Implementation framework of the requirement [Not included in ED Questionnaire]	5.1.3 Details [Not included in ED Questionnaire]	5.1.4 Which scenario better represents your country with respect to the critical mass at more than 150 the number of newly diagnosed cases of primary breast cancer cases yearly treated in individual BU? [Not included in ED Questionnaire]	5.1.5 If you have requirements, but your threshold is different from 150, please provide the number [Not included in ED Questionnaire]	5.1.6 Comments [5.1 Comments for ED Questionnaire]
NO	<i>ECIBC National Contacts</i>	NO and NOT PLANNED			Most primary breast cancer cases are treated in a centre whose volume is higher than 150 new cases per year, but a small number of cases are treated in centres with a lower volume.		Our health authorities now suggest a minimum of 100 new patients each year at a Breast Cancer Surgery Unit (Report: Cancer Surgery in Norway).
	<i>ED National Representative</i>	NO					
PL	<i>ECIBC National Contacts</i>	NO and NOT PLANNED			Most primary breast cancer cases are treated in a centre whose volume is higher than 150 new cases per year, but a small number of cases are treated in centres with a lower volume.		
	<i>ED National Representative</i>						
PT	<i>ECIBC National Contacts</i>	NO, BUT PLANNED			Most primary breast cancer cases are treated in a centre whose volume is		

Country		5.1.1 Is there a requirement that regulates at more than 150 the number of newly diagnosed cases of primary breast cancer cases yearly treated in individual BU? [5.1 for ED Questionnaire]	5.1.2a Implementation framework of the requirement [Not included in ED Questionnaire]	5.1.3 Details [Not included in ED Questionnaire]	5.1.4 Which scenario better represents your country with respect to the critical mass at more than 150 the number of newly diagnosed cases of primary breast cancer cases yearly treated in individual BU? [Not included in ED Questionnaire]	5.1.5 If you have requirements, but your threshold is different from 150, please provide the number [Not included in ED Questionnaire]	5.1.6 Comments [5.1 Comments for ED Questionnaire]
PT	<i>ECIBC National Contacts</i>				higher than 150 new cases per year, but a small number of cases are treated in centres with a lower volume.		
	<i>ED National Representative</i>						
RO	<i>ECIBC National Contacts</i>	NO and NOT PLANNED			Primary breast cancer cases are equally divided in centres with more and less than 150 new cases per year.		
	<i>ED National Representative</i>						
RS	<i>ECIBC National Contacts</i>	NO and NOT PLANNED			Most primary breast cancer cases are treated in a centre whose volume is higher than 150 new cases per year, but a small number of cases are treated in centres with a lower volume.		The Republic Expert Committee for Oncology is in the process of developing criteria for an oncology accreditation system, including breast cancer management at national level.
	<i>ED National Representative</i>						

Country		5.1.1 Is there a requirement that regulates at more than 150 the number of newly diagnosed cases of primary breast cancer cases yearly treated in individual BU? [5.1 for ED Questionnaire]	5.1.2a Implementation framework of the requirement [Not included in ED Questionnaire]	5.1.3 Details [Not included in ED Questionnaire]	5.1.4 Which scenario better represents your country with respect to the critical mass at more than 150 the number of newly diagnosed cases of primary breast cancer cases yearly treated in individual BU? [Not included in ED Questionnaire]	5.1.5 If you have requirements, but your threshold is different from 150, please provide the number [Not included in ED Questionnaire]	5.1.6 Comments [5.1 Comments for ED Questionnaire]
SE	<i>ECIBC National Contacts</i>	YES, VOLUNTARY		None of the alternatives given in question 1.2 are applicable. There is no formal regulation but most hospitals and county councils are aware of the recommendation, which is also fulfilled in most counties. The majority of hospitals in Sweden had more than 150 newly diagnosed cases of breast cancer per year (result from a follow up from 2013).	Most primary breast cancer cases are treated in a centre whose volume is higher than 150 new cases per year, but a small number of cases are treated in centres with a lower volume.		The National Clinical Practice Guidelines for Breast Cancer (2014) claim that there should be a breast unit per 250 000 inhabitants. The largest units have a population around 500 000 - 800 000 individuals, the smallest one has just 57 000 individuals.
	<i>ED National Representative</i>	I do not have this information.					As a member of the Swedish Breast Cancer Group, who initiates national guidelines/recommendations for the National Board

Country		5.1.1 Is there a requirement that regulates at more than 150 the number of newly diagnosed cases of primary breast cancer cases yearly treated in individual BU? [5.1 for ED Questionnaire]	5.1.2a Implementation framework of the requirement [Not included in ED Questionnaire]	5.1.3 Details [Not included in ED Questionnaire]	5.1.4 Which scenario better represents your country with respect to the critical mass at more than 150 the number of newly diagnosed cases of primary breast cancer cases yearly treated in individual BU? [Not included in ED Questionnaire]	5.1.5 If you have requirements, but your threshold is different from 150, please provide the number [Not included in ED Questionnaire]	5.1.6 Comments [5.1 Comments for ED Questionnaire]
SE	<i>ED National Representative</i>						of Health and Welfare, this has not been under scrutiny during my mandate period.
SI	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	Used in a non-public quality assurance scheme under national/regional governance. Implemented in 2011.	More than 150 per breast unit (there are three in the country) are recommended by The National Cancer Control Programme of the Ministry of Health (http://www.dpor.si/en/).	Most primary breast cancer cases are treated in a centre whose volume is higher than 150 new cases per year, but a small number of cases are treated in centres with a lower volume.		
	<i>ED National Representative</i>	YES					
SK	<i>ECIBC National Contacts</i>	YES, VOLUNTARY			Most primary breast cancer cases are treated in a centre whose volume is higher than 150 new cases per year, but a small number of cases are treated in centres with a lower volume.		

Country		5.1.1 Is there a requirement that regulates at more than 150 the number of newly diagnosed cases of primary breast cancer cases yearly treated in individual BU? [5.1 for ED Questionnaire]	5.1.2a Implementation framework of the requirement [Not included in ED Questionnaire]	5.1.3 Details [Not included in ED Questionnaire]	5.1.4 Which scenario better represents your country with respect to the critical mass at more than 150 the number of newly diagnosed cases of primary breast cancer cases yearly treated in individual BU? [Not included in ED Questionnaire]	5.1.5 If you have requirements, but your threshold is different from 150, please provide the number [Not included in ED Questionnaire]	5.1.6 Comments [5.1 Comments for ED Questionnaire]
SK	<i>ED National Representative</i>						
TR	<i>ECIBC National Contacts</i>						
	<i>ED National Representative</i>						
UK	<i>ECIBC National Contacts</i>	NO and NOT PLANNED	Institutional licencing requirement at national/regional level. Implemented in 2000	Institutional assessment via the national peer review scheme. The vast majority of breast units in England would diagnose more than 150 new breast cancers per year even if the threshold is 100.	Virtually all primary breast cancer cases are treated in a centre whose volume is higher than 150 new cases per year.	100	
	<i>ED National Representative</i>	NO					

Table 5: Survey section 5.

Breast Units mandatory requirements implementation stage.

Questions:

2. Core Team – (a) Composition

Definition from the 2006 European Guidelines

Each member of the core team must have special training in breast cancer; for standards see Chapter 10 (pages 356-365 <http://bookshop.europa.eu/en/european-guidelines-for-quality-assurance-in-breast-cancer-screening-and-diagnosis-pbND7306954/>).

Each member of the breast unit core team must undertake continuing professional education on a regular basis. Breast Unit budgets must include provision for this.

9.5.2.1. *The Breast Unit must have an identified Clinical Director of Breast Services.*

9.5.2.2. *Breast Surgeons (including Gynaecologists performing breast surgery)*

Two or more nominated surgeons specially trained in breast disease, each of whom must personally carry out the primary surgery on at least 50 newly diagnosed cancers per annum and must attend at least one diagnostic clinic per week. For an average sized unit the surgeons will need at least eight identified ca. 4 hr sessions per week in Breast Disease. These sessions will allow for operating time, participation in diagnostic clinics, a follow-up clinic and, where appropriate, screening assessment clinics. A session must be allowed for attendance at a weekly team case management and audit meeting.

A Unit team must provide breast surgical reconstruction when required for those patients not suitable for breast conserving therapy and be able to apply special techniques for patients with extensive local disease. The breast surgeons in the team should be able to undertake basic reconstruction or recontouring and there should be a standard arrangement or joint reconstruction clinic with one or two nominated Plastic Surgeons (non-core team member) who take a special interest in breast reconstructive and recontouring techniques.

9.5.2.3. Breast Radiologists

There must be at least two nominated radiologists, fully trained and with continuing experience in all aspects of breast disease and associated imaging, tissue sampling and localisation procedures under image control. Ideally any radiologist investigating breast patients should participate in the screening programme in countries in which this is established and must participate in a national or regional QA scheme. They must fulfil the volume requirements as laid down for breast assessment in Chapter 5 and the previously published document 'Quality Assurance in the Diagnosis of Breast Disease',²³ reading a minimum of 1 000 mammograms per year (5 000 for those participating in a screening programme).

They must attend multidisciplinary meetings for case management and audit purposes.

They must be present in diagnostic assessment clinics with the surgeon. Each radiologist must attend at least one diagnostic clinic per week for symptomatic patients or screening assessment.

9.5.2.4. Breast Pathologists

A lead pathologist plus usually not more than one other nominated pathologist, specialising in Breast Disease, will be responsible for all breast pathology and cytology.

Pathologists carrying out these roles must have contractual sessions to attend team case management and audit meetings. They must be familiar with national and/or European performance quality standards and guidelines. They must take part in available European, National and Regional quality assurance schemes.

9.5.2.5. Breast Oncologists

(a) A nominated radiation oncologist must arrange the appropriate delivery of radiotherapy.²⁴ He/she must hold advanced disease clinics with other members of the breast team at

23. Perry N, on behalf of EUSOMA Working Party. Quality Assurance in the diagnosis of breast disease. *Eur J Cancer*, 2001, 37, 159-172.

24. Kurtz J, for the EUSOMA Working Party. The curative role of radiotherapy in the treatment of operable breast cancer. *Eur J Cancer*, 2002, 38, 1961-1974.

the Breast Unit and must take part in the case management and audit meetings of the Unit.
*(b) In some countries, Clinical Oncologists carry out both radiation therapy and prescribe the chemotherapy. In centres in which a **Medical Oncologist gives the chemotherapy** he/she should be a member of the core team and take a full part in case management and audit meetings.*

9.5.2.6. Breast Diagnostic Radiographers (Technicians)

***Radiographers** with the necessary expertise and training in mammography are essential members of the team. They must fulfil the training and working practice recommendations as laid down in Chapters 3, 5, and 10. They must be responsible for taking the mammograms, which must not be performed by radiographic or nonradiographic personnel without the above training.*

9.5.2.7. Data Managers

*There must be a system covering audit. **A data manager** must enter data on diagnosis, treatment, pathology and clinical outcomes contemporaneously.*

9.5.2.8. Patient Support staff

*Regular support (advice, counselling, psychological help) is given by Breast Care Nurses in some countries and psychologically professionally trained persons with expertise in Breast Cancer in others. These persons must be members of the core team. They must be available to counsel and offer practical advice and emotional support to newly diagnosed patients at the time the diagnosis is given, so as to further explain treatment plans. They should also be available on demand from patients in the Primary Breast Cancer Follow up clinic and in the Advanced Breast Clinic. Particularly they must be present to support women when the diagnosis is given that the disease has become advanced. **At least two Breast Care Nurses are needed per breast unit.***

ECIBC:

1. Is there, in the geographical area under your organisation's responsibility, any kind of requirement that regulates the composition of the core team as defined in the 2006 European Guidelines? * YES, MANDATORY; YES, VOLUN-

TARY; NO, BUT PLANNED; NO and NOT PLANNED; I do not know

2. If you replied YES, please provide a more detailed description of the team (*i.e.* the clinical and radiation oncologist role, number of radiographers, additional members of the core team, *e.g.* higher numbers and/or additional professional profiles – *e.g.* plastic surgeons – than foreseen in the 2006 European Guidelines)
3. If you replied YES, please report below the implementation framework of the team composition requirements and the respective year of implementation (more than one answer is possible). Embedded in national/regional legislation; Used as reference for reimbursement from insurances at national/regional level; Institutional licencing requirement at national/regional level; Used in a non-public quality assurance scheme under national/regional governance; Used in a non-public quality assurance scheme NOT under national/regional governance
4. If you replied YES, please provide a more detailed description (*i.e.* name of legislation/quality assurance scheme, link to the text or reference document)
5. If you wish, please add below your comments/considerations on core team composition mandatory requirement.

ED:

1. Is there in your country any kind of requirement that regulates the composition of the core team as defined in the 2006 European Guidelines? YES; NO; I do not have this information
2. If you wish, please add below your comments/considerations on core team composition mandatory requirement

Country		2a.1 Is there a requirement that regulates the composition of the core team?	2a.2 Core team detailed description [Not included in ED Questionnaire]	2a.3a Implementation framework of the team composition [Not included in ED Questionnaire]	2a.4 Core team details [Not included in ED Questionnaire]	2a.5 Core team comments [2a.1 Comments for the ED Questionnaire]
AT	<i>ECIBC National Contacts</i>					
	<i>ED National Representative</i>	YES				The catalogue of requirements for breast cancer units 'Anforderungskatalog für Brustgesundheitszentren in Österreich' is based on the 2006 European Guidelines. The composition of the core team is mainly based on those guidelines.
BE	<i>ECIBC National Contacts</i>	YES, MANDATORY	Art. 3 of Royal Decree for specialised oncology care programmes for breast cancer defines: (1) identified clinical director of the breast unit; (2) two breast surgeons (general surgery or gynaecology with experience in breast surgery), who each perform surgery on at least 30 newly diagnosed cases; (3) two radiologists with experience in mammography and breast ultrasonography and in collecting breast tissue samples. They have to read a minimum of 1 000 mammograms per year for diagnostic or screening purposes. One has to have experience in other medical imaging techniques e.g. interventional imaging techniques useful for breast cancer	Embedded in national/ regional legislation. Implemented in 2007.		

Country		2a.1 Is there a requirement that regulates the composition of the core team?	2a.2 Core team detailed description [Not included in ED Questionnaire]	2a.3a Implementation framework of the team composition [Not included in ED Questionnaire]	2a.4 Core team details [Not included in ED Questionnaire]	2a.5 Core team comments [2a.1 Comments for the ED Questionnaire]
BE			<p>and staging or MRI; (4) one pathologist with a minimum of three years' experience in diagnosis of breast pathologies. They have to be available during surgery; (5) one radiation oncologist with a minimum of three years' experience in breast cancer; (6) one oncologist with a minimum of three years' experience in breast cancer treatment; (7) one plastic surgeon with experience in reconstructive surgery. They have to ensure that reconstructive procedures are available in the same surgery, that they are proposed to eligible patients, that waiting times for immediate reconstructive surgery don't delay primary treatment, and must ensure follow-up during hospitalisation and ambulatory care. All these physicians work together in a structured and multidisciplinary way. Additional members of the multidisciplinary team are: breast nurse, psychologist, and data manager.</p>			

Country		2a.1 Is there a requirement that regulates the composition of the core team?	2a.2 Core team detailed description [Not included in ED Questionnaire]	2a.3a Implementation framework of the team composition [Not included in ED Questionnaire]	2a.4 Core team details [Not included in ED Questionnaire]	2a.5 Core team comments [2a.1 Comments for the ED Questionnaire]
BE	<i>ED National Representative</i>					
BG	<i>ECIBC National Contacts</i>	YES, MANDATORY	Pre- and post-surgical clinical conferences, which decide on the treatment plan for each patient, include: 1. Chairman (Director of the Breast Department) 2. Deputy chairman 3. Four surgeons (performing over 150 breast surgeries annually, each) 4. Two radiographers (physicians who read more than 1 000 mammograms annually, each) 5. Two radiotherapists 6. Two chemotherapists 7. One pathologist 8. One psychologist 9. Other specialists when needed - geneticist, cardiologist, endocrinologist, internal disease and plastic surgeon. The meetings are held twice a week.	Used as reference for reimbursement from insurance at national/regional level. Implemented in 2005. Used in a non-public quality assurance scheme under national/regional governance. Implemented in 2005.	Multidisciplinary breast cancer team has been in existence since more than 40 years, regulated by the guidelines of the National Oncology Institute. The guidelines for breast cancer standards are updated every four years. Since 2005, the National Health Insurance Fund introduced adherence to standards as a requirement for reimbursement.	
	<i>ED National Representative</i>					
CH	<i>ECIBC National Contacts</i>	NO and NOT PLANNED				
	<i>ED National Representative</i>	I do not have this information.				

Country		2a.1 Is there a requirement that regulates the composition of the core team?	2a.2 Core team detailed description [Not included in ED Questionnaire]	2a.3a Implementation framework of the team composition [Not included in ED Questionnaire]	2a.4 Core team details [Not included in ED Questionnaire]	2a.5 Core team comments [2a.1 Comments for the ED Questionnaire]
CY	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	The public breast unit includes a surgeon with main interest on breast cancer, a radiologist, a plastic surgeon, a histopathologist, a clinical oncologist. The programme also includes radiographers with special training that have worked in the screening programme since 2010.	Institutional licencing requirement at national/ regional level.		
	<i>ED National Representative</i>	NO				
CZ	<i>ECIBC National Contacts</i>	YES, MANDATORY	Most multidisciplinary teams are complete, but some share, for example, a plastic surgeon or psychologist.	Embedded in national/ regional legislation. Implemented in 2002. Used as reference for reimbursement from insurance at national/ regional level. Implemented in 2002. Institutional licencing requirement at national/ regional level. Implemented in 2002.	The legislative framework for the project in the Czech Republic is determined by decree of the Ministry of Health (MoH CR) no. 3/2010 Coll. It determines the content and intervals of preventive examinations and recommended standards. These were published in the Ministry of Health bulletin (April 2010)	The Commission for the Screening of Breast Cancer at the Ministry of Health (Komda) - is composed by radiologists - breast radiologists, members of professional societies dealing with the diagnosis and treatment of breast diseases, the State Office for Nuclear Safety (SONS), General Health Insurance Company (VZP), the Association of Health Insurance Companies (associates other health insurers) and the Ministry of Health. Commission experts for Breast Radiology (Komda) - are represented mainly by specialists from the Radiological Society JEP, the Association of Non-State Outpatient Radiology and

Country		2a.1 Is there a requirement that regulates the composition of the core team?	2a.2 Core team detailed description [Not included in ED Questionnaire]	2a.3a Implementation framework of the team composition [Not included in ED Questionnaire]	2a.4 Core team details [Not included in ED Questionnaire]	2a.5 Core team comments [2a.1 Comments for the ED Questionnaire]
CZ						the Association of Czech Breast Radiologists (AMA-CZ).
	<i>ED National Representative</i>					
DE	<i>ECIBC National Contacts</i>	YES, MANDATORY	Enclosed in the 'Catalogue of Requirements' are the requirements and quality indicators for certified breast cancer centres in Germany with the definition of the core team and the needed qualification. The requirements 1.1.1/1.1.2 define the partners within the network and in the following chapters the expertise of the partners is described in more detail (1.1.1). Main cooperation partners include: surgeons, gynaecological oncologists, radiologists (with the exception of cooperating radiological facilities that only provide services for the breast cancer centre in conjunction with breast MRIs), pathologists, internal oncologists, radiation therapists and specialists in nuclear medicine. The following points must be regulated in the agreements with the main treatment partners: mandatory participation in tumour	Institutional licencing requirement at national/regional level. Implemented in 2003.	Detailed information in this PowerPoint-presentation: https://www.krebsgesellschaft.de/gcs/german-cancer-society/certification.html?file=files/dkg/deutsche-krebsgesellschaft/content/pdf/Zertifizierung/Materialien%20fuer%20Zentren/160725%20CertificationOfCancerCentres_2016.pdf .	

Country		2a.1 Is there a requirement that regulates the composition of the core team?	2a.2 Core team detailed description [Not included in ED Questionnaire]	2a.3a Implementation framework of the team composition [Not included in ED Questionnaire]	2a.4 Core team details [Not included in ED Questionnaire]	2a.5 Core team comments [2a.1 Comments for the ED Questionnaire]
DE			<p>boards (with the exception of nuclear medicine); Assurance of availability; Description of the treatment processes relevant to the Breast Cancer Centre with a special focus on the interfaces; Obligation to implement established guidelines (S3 Guideline as a basic requirement); Description of the cooperation on the tumour documentation; Declaration of consent to cooperate with internal/external audits; Commitment to adhere to the relevant criteria of the requirements for breast cancer centres and to provide the relevant data annually; Agreement on the part of treatment partners to be publicly named as a part of the breast cancer centre (e.g. on the website); 24h access to the main clinical cooperation partners: surgeons, radiologists (with the exception of MRI), oncologic pharmaceutical therapist (gynaecological and/or internal), radiation therapists (1.1.2). Agreements with other treatment partners: written agreements in which willingness</p>			

Country		2a.1 Is there a requirement that regulates the composition of the core team?	2a.2 Core team detailed description [Not included in ED Questionnaire]	2a.3a Implementation framework of the team composition [Not included in ED Questionnaire]	2a.4 Core team details [Not included in ED Questionnaire]	2a.5 Core team comments [2a.1 Comments for the ED Questionnaire]
DE			engage in cooperation is confirmed are to be signed with treatment partners for the following: Psycho-oncology; Social services; Self-help; Genetic counselling; Gene analysis, family anamnesis (BRCA-1, BRCA-2) and genetic counselling; Physiotherapy; Laboratory (with a round robin test certification); Hospice/palliative medicine; Medical aids supplier; see: 'Catalogue of Requirements': https://www.krebsgesellschaft.de/gcs/german-cancer-society/certification/documents.html?file=files/dkg/german-cancer-society/pdf/Certification/Catalogue%20of%20Req%20breast-H1%201%20%2814%2007%202016%29%20EN.pdf ; 'Indicator Sheet': https://www.krebsgesellschaft.de/gcs/german-cancer-society/certification/documents.html?file=files/dkg/german-cancer-society/pdf/Certification/Indicator%20Sheet%20for%20Breast%20Cancer%20Centres%202017.pdf .			
	ED National Representative					

Country		2a.1 Is there a requirement that regulates the composition of the core team?	2a.2 Core team detailed description [Not included in ED Questionnaire]	2a.3a Implementation framework of the team composition [Not included in ED Questionnaire]	2a.4 Core team details [Not included in ED Questionnaire]	2a.5 Core team comments [2a.1 Comments for the ED Questionnaire]
EE	<i>ECIBC National Contacts</i>					
	<i>ED National Representative</i>	YES				Requirements are defined in the Standards of Cancer Treatment Quality, 2011.
ES	<i>ECIBC National Contacts</i>					
	<i>ED National Representative</i>	NO				
FI	<i>ECIBC National Contacts</i>	YES, MANDATORY	The concept of core teams has been applied in all university hospitals for at least two decades. The university hospital areas (5) take care of treatment of almost all breast cancer cases in the country. This concept is also written in the national guidelines of breast cancer, which are regularly updated by the Finnish Breast Cancer Group. The guidelines are also voluntarily followed in the country.	Used in a non-public quality assurance scheme NOT under national/regional governance.	The concept of core teams has been applied in all university hospitals for at least two decades. The university hospital areas (5 in altogether) take care of treatment of almost all breast cancer cases in the country. This concept is also written in the national guidelines of breast cancer, which are regularly updated by the Finnish Breast Cancer Association. The guidelines are also voluntarily followed in the country.	
	<i>ED National Representative</i>					
FR	<i>ECIBC National Contacts</i>	NO and NOT PLANNED				
	<i>ED National Representative</i>	YES				Core teams are submitted to six quality criteria, as defined in Cancer Plans 1 & 2, and stated by the Cancer National Institute (INCa).

Country		2a.1 Is there a requirement that regulates the composition of the core team?	2a.2 Core team detailed description [Not included in ED Questionnaire]	2a.3a Implementation framework of the team composition [Not included in ED Questionnaire]	2a.4 Core team details [Not included in ED Questionnaire]	2a.5 Core team comments [2a.1 Comments for the ED Questionnaire]
GR	<i>ECIBC National Contacts</i>	NO and NOT PLANNED				<p>The 2006 European Guidelines should become mandatory in everyday practice in all breast centres in Europe. This would be important even for a country that is undergoing severe economic crisis. An example of what was done in 1978 in Strasbourg under the direction of Charles Marie Gros, graduating the first Senologist (Breast Specialist) in Europe should be followed. The distribution of breast centres is unequal in the geographical area of Greece. A population of 10 million needs at least 30 breast centres applying the 2006 European Guidelines, but in Greece the majority of centres are concentrated in Athens with a total of 16 (both public and private). Protocols for diagnosis and management of breast cancer as well as quality control in mammography and in the general functioning of the breast centre are fundamental.</p>
	<i>ED National Representative</i>	NO				

Country		2a.1 Is there a requirement that regulates the composition of the core team?	2a.2 Core team detailed description [Not included in ED Questionnaire]	2a.3a Implementation framework of the team composition [Not included in ED Questionnaire]	2a.4 Core team details [Not included in ED Questionnaire]	2a.5 Core team comments [2a.1 Comments for the ED Questionnaire]
HU	<i>ECIBC National Contacts</i>	NO, BUT PLANNED				In Hungary, there are MDMs, and in between sub-specialised breast MDMs. This consists of surgeons, pathologists, radiotherapists and medical oncologists specialised in BC and sometimes radiologist and psychologist. The "breast nurse" is rarely involved.
	<i>ED National Representative</i>					
IE	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	Each unit in this country has an appropriately trained core team.		This is not embedded in legislation or insurance but it complies with national guidelines that are monitored.	
	<i>ED National Representative</i>	YES				
IT	<i>ECIBC National Contacts</i>	YES, MANDATORY	The members of the Breast Unit Core Team are: - Clinical Director of Breast Services - Breast surgeons (including gynaecologists performing breast surgery): two or more nominated surgeons specially trained in breast disease, each of whom must personally carry out primary surgery on at least 50 newly diagnosed cancers. The breast surgeons in the team should be able to undertake basic reconstruction or re-contouring and	Embedded in national/regional legislation. Implemented in 2014.	State-regions agreement on breast units networking issued 18 December 2014.	

Country		2a.1 Is there a requirement that regulates the composition of the core team?	2a.2 Core team detailed description [Not included in ED Questionnaire]	2a.3a Implementation framework of the team composition [Not included in ED Questionnaire]	2a.4 Core team details [Not included in ED Questionnaire]	2a.5 Core team comments [2a.1 Comments for the ED Questionnaire]
IT			<p>there should be an arrangement with one or two nominated plastic surgeons (non-core team member) specialised in breast reconstructive and re-contouring techniques.</p> <ul style="list-style-type: none"> - Breast radiologists: there must be at least two nominated radiologists, fully trained and with continuing experience in all aspects of breast disease and associated imaging, tissue sampling and localisation procedures under image control. They must read a minimum of 1 000 mammograms per year (5 000 for those participating in a screening programme). - Breast pathologists: a nominated lead pathologist, trained in breast disease and cytology. - A nominated radiation oncologist and / or a clinical oncologists carrying out both radiation therapy and chemotherapy. - Breast diagnostic radiographers (Technicians): fully trained radiographers. - Data manager - Patient support staff: at least two breast care nurses and a psychologist well-trained in psycho-oncology. 			

Country		2a.1 Is there a requirement that regulates the composition of the core team?	2a.2 Core team detailed description [Not included in ED Questionnaire]	2a.3a Implementation framework of the team composition [Not included in ED Questionnaire]	2a.4 Core team details [Not included in ED Questionnaire]	2a.5 Core team comments [2a.1 Comments for the ED Questionnaire]
LT	<i>ED National Representative</i>	YES				
	<i>ECIBC National Contacts</i>	YES, MANDATORY	In our NCI there is a director of breast unit (breast surgeon) as well as 4 breast surgeons, 6 radiologists working in breast screening as well as diagnostics, 10 radiographers trained in mammography, 3 medical oncologists in multidisciplinary team and mostly working with breast cancer patients, 5 radiation oncologists, 14 medical nurses in breast care, psycho-oncologists, a psychologist, 2 pathologists in MDT and consulting breast pathology cases.	Institutional licensing requirement at national/regional level; Used in a non-public quality assurance scheme NOT under national/regional governance.	The team in breast cancer care is defined at National Cancer Institute level, as well as SIS accreditation level. There is no guidance for MDT from Ministry of Health or other institutions.	The Ministry of Health announced the National Cancer Programme on 24 November 2014 with main tasks for 2014-2025 (available on the Ministry of Health website). No accurate description of breast units and implementation guidance are included but there are more general tasks and objectives for cancer care improvement and assurance.
LU	<i>ED National Representative</i>					
	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	According to the Breast Cancer Screening Programme (1992), all radiologists working in screening need an accreditation. All of them are doing assessment. The same for the radiographers. Most oncologists work primarily in breast cancer care, but it's not mandatory. In Luxembourg a National Radiotherapy Centre exists, the radiotherapists			

Country		2a.1 Is there a requirement that regulates the composition of the core team?	2a.2 Core team detailed description [Not included in ED Questionnaire]	2a.3a Implementation framework of the team composition [Not included in ED Questionnaire]	2a.4 Core team details [Not included in ED Questionnaire]	2a.5 Core team comments [2a.1 Comments for the ED Questionnaire]
LU			who are delivering radiotherapy to breastcancer patient are specialised in breast cancer treatment. No requirement for surgeons, or plastic surgeons.			
	<i>ED National Representative</i>	NO				
LV	<i>ECIBC National Contacts</i>	NO and NOT PLANNED				
	<i>ED National Representative</i>					
MT	<i>ECIBC National Contacts</i>	NO, BUT PLANNED				Breast cancer care is mainly carried out by the following: (a) Two nominated surgeons specially trained in breast disease, each of whom carry out the primary surgery on at least 150 newly diagnosed cancers per year and attend three diagnostic clinics per week; (b) Three nominated radiologists, trained and with continuing experience in all aspects of breast disease and associated imaging, tissue sampling and localisation procedures under image control. Each radiologist reads more than 5 000 mammograms per year (these three radiologists are also responsible for the national organised

Country		2a.1 Is there a requirement that regulates the composition of the core team?	2a.2 Core team detailed description [Not included in ED Questionnaire]	2a.3a Implementation framework of the team composition [Not included in ED Questionnaire]	2a.4 Core team details [Not included in ED Questionnaire]	2a.5 Core team comments [2a.1 Comments for the ED Questionnaire]
MT						<p>screening programme). They all attend multidisciplinary meetings for case management and audit purposes; (c) Breast pathologist: the most senior histo-pathologist is responsible for reviewing the majority of breast pathology and cytology. This senior professional is a member of the EWGBSP (European Working Group on Breast Screening Pathology). The pathology laboratories at MDH participate in the UK NEQUAS (National External Quality Assurance Scheme) for Immunohistochemistry; (d) Breast oncologists: Breast cancer referrals are directed to two out of the four clinical oncologists working in Malta. These two oncologists attend breast MDT meetings. To date there is no medical oncologist engaged with health services in Malta; (e) Radiographers: The radiographers working in the Screening Unit are dedicated to the screening service and are trained specifically for this service. A core group are qualified with an MSc in mammo-</p>

Country		2a.1 Is there a requirement that regulates the composition of the core team?	2a.2 Core team detailed description [Not included in ED Questionnaire]	2a.3a Implementation framework of the team composition [Not included in ED Questionnaire]	2a.4 Core team details [Not included in ED Questionnaire]	2a.5 Core team comments [2a.1 Comments for the ED Questionnaire]
MT						graphy; (f) Data manager: BU at MDH does not have the services of a data manager to date. Some data management is performed by one of the breast unit nurses; (g) Patient support staff: presently there are 4.5 FTE (full-time equivalent) nurses working with the BU at MDH.
	<i>ED National Representative</i>	NO				
NL	<i>ECIBC National Contacts</i>					
	<i>ED National Representative</i>	NO				The organisation of breast cancer treatment is covered by the national guidelines. The organisation of breast cancer treatment has implemented some of the requirements of the 2006 European Guidelines, however on a voluntary basis. There is no legal requirement to comply with the National (and 2006 European Guidelines).
NO	<i>ECIBC National Contacts</i>	NO, BUT PLANNED				
	<i>ED National Representative</i>	YES				

Country		2a.1 Is there a requirement that regulates the composition of the core team?	2a.2 Core team detailed description [Not included in ED Questionnaire]	2a.3a Implementation framework of the team composition [Not included in ED Questionnaire]	2a.4 Core team details [Not included in ED Questionnaire]	2a.5 Core team comments [2a.1 Comments for the ED Questionnaire]
PL	<i>ECIBC National Contacts</i>	NO and NOT PLANNED				
	<i>ED National Representative</i>					
PT	<i>ECIBC National Contacts</i>	NO, BUT PLANNED				
	<i>ED National Representative</i>					
RO	<i>ECIBC National Contacts</i>	NO and NOT PLANNED				
	<i>ED National Representative</i>					
RS	<i>ECIBC National Contacts</i>	NO, BUT PLANNED	Breast cancer patient treatment decisions are made by the Breast Cancer Board. Members of the Board include surgeons, radiologists, radiation oncologists, chemotherapists (medical oncologists), pathologists and others, if needed.	Embedded in national/regional legislation. Used as reference for reimbursement from insurances at national/regional level. Implemented in 1980.	Organisation of oncology healthcare since 1980 in Serbia: TQM system improvement. The legal framework consists of: - Regulation on quality system improvement - Regulation on content of healthcare services - Law on Healthcare - Law on Health Insurance	
	<i>ED National Representative</i>					
SE	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	National Guidelines for the Treatment of Breast Cancer (2014) and The National Clinical Practice Guidelines for Breast Cancer (2014) says: The core team should at least consist of breast surgeon, breast cancer oncologist, pathologist, radiologist and breast care nurse.		Question 2.3 is not applicable. There are National Guidelines for the Treatment of Breast Cancer (2014) provided by The National Board of Health and Welfare as well as National Clinical Practice Guidelines for Breast Cancer (2014).	When needed, most units having a specialist plastic surgeon and psycho-social competence available based on the individual needs.

Country		2a.1 Is there a requirement that regulates the composition of the core team?	2a.2 Core team detailed description [Not included in ED Questionnaire]	2a.3a Implementation framework of the team composition [Not included in ED Questionnaire]	2a.4 Core team details [Not included in ED Questionnaire]	2a.5 Core team comments [2a.1 Comments for the ED Questionnaire]
SE	<i>ED National Representative</i>	YES				Sweden has 21 autonomous counties each including a number of hospitals. The requirements are not mandatory; hence, despite National Recommendations/Guidelines issued by the National Board of Health and Welfare, requirements can be set aside locally/regionally for financial or other reasons. This also applies to core teams. The National Guidelines stipulate that within a core team there should be a breast pathologist, breast radiologist, breast surgeon, breast oncologist and a breast care nurse.
	<i>ECIBC National Contacts</i>	NO, BUT PLANNED				
SI	<i>ED National Representative</i>	YES				
	<i>ECIBC National Contacts</i>	NO, BUT PLANNED				
SK	<i>ED National Representative</i>					
	<i>ECIBC National Contacts</i>					
TR	<i>ED National Representative</i>					
	<i>ECIBC National Contacts</i>					

Country		2a.1 Is there a requirement that regulates the composition of the core team?	2a.2 Core team detailed description [Not included in ED Questionnaire]	2a.3a Implementation framework of the team composition [Not included in ED Questionnaire]	2a.4 Core team details [Not included in ED Questionnaire]	2a.5 Core team comments [2a.1 Comments for the ED Questionnaire]
UK	<i>ECIBC National Contacts</i>	YES, MANDATORY	<p>This is the detail of the defined core membership as per the peer review guidelines: There should be a single named lead clinician for the breast MDT who is also a core team member. The lead clinician of the MDT should have agreed the responsibilities of the position with the lead clinician of the host trust (Note: The role of lead clinician of the MDT should not of itself imply chronological seniority, superior experience or superior clinical ability). The MDT should provide the names of core team members for named roles in the team. The core team specific to the breast cancer MDT should include: two designated breast surgeons; a clinical oncologist; a medical oncologist (where the responsibility of chemotherapy is not undertaken by the clinical oncology core member); two imaging specialists; two histopathologists; two breast nurse specialist;</p>	Institutional licencing requirement at national/ regional level. Implemented in 2000.	Compliance is assessed by the national peer review team with local assessment by the hospital cancer team and external verification.	

Country		2a.1 Is there a requirement that regulates the composition of the core team?	2a.2 Core team detailed description [Not included in ED Questionnaire]	2a.3a Implementation framework of the team composition [Not included in ED Questionnaire]	2a.4 Core team details [Not included in ED Questionnaire]	2a.5 Core team comments [2a.1 Comments for the ED Questionnaire]
UK			<p>MDT co-ordinator/secretary; an NHS-employed member of the core or extended team should be nominated as having specific responsibility for users' issues and information for patients and carers; a member of the core team nominated as the person responsible for ensuring that recruitment into clinical trials and other well designed studies is integrated into the function of the MDT.</p> <p>Notes:</p> <ul style="list-style-type: none"> • Each clinical core member should have sessions specified in the job plan for the care of patients with breast cancer and attendance at MDT meetings • Where a medical specialty is referred to, the core team member should be a consultant. Where a medical skill rather than a specialty is referred to, this may be provided by one or more of the core members or by a career grade non-consultant medical staff member. 			

Country		2a.1 Is there a requirement that regulates the composition of the core team?	2a.2 Core team detailed description [Not included in ED Questionnaire]	2a.3a Implementation framework of the team composition [Not included in ED Questionnaire]	2a.4 Core team details [Not included in ED Questionnaire]	2a.5 Core team comments [2a.1 Comments for the ED Questionnaire]
UK			<ul style="list-style-type: none"> • The medically qualified core member(s) depend on the cancer site of the MDT. • The co-ordinator/secretary role needs different amounts of time depending on team workload. See the appendix 2 for an illustration of the responsibilities of this role. <p>The co-ordinator and secretarial role may be filled by two different named individuals or the same one. It does not occupy the whole of an individual's job description.</p> <ul style="list-style-type: none"> • There may be additional core members agreed for the team besides those listed above. 			
	<i>ED National Representative</i>	YES				

Table 6: Survey section 5.

Breast Units mandatory requirements implementation stage.

Questions:

2. Core Team – (b) Training

ECIBC:

1. Is there, in the geographical area under your organisation's responsibility, any kind of requirement that regulates the training standards of the core team as defined in the 2006 European Guidelines? * YES, MANDATORY; YES, VOLUNTARY; NO, BUT PLANNED; NO and NOT PLANNED; I do not know
- 2.
3. If you replied YES, please provide a more detailed description of the training standards, in particular of any deviation from those standards (*e.g.* training in imaging in mammography – both film-screen and digital)
4. If you replied YES, please report below the implementation framework of the team's training standards and the respective year of implementation (more than one answer is possible). Embedded in national/regional legislation; Used as reference for reimbursement from insurances at national/regional level; Institutional licencing requirement at national/regional level; Used in a non-public quality assurance scheme under national/regional governance; Used in a non-public quality assurance scheme NOT under national/regional governance
5. If you replied YES, please provide a more detailed description (*i.e.* name of legislation/quality assurance scheme, link to the text or reference document)
6. If you wish, please add below your comments/considerations on core team's training standards mandatory requirement.

ED:

1. Is there in your country any kind of requirement that regulates the training standards of the core team as defined in the 2006 European Guidelines? YES; NO; I do not have this information.
2. If you wish, please add below your comments/considerations on core team's training standards mandatory requirement.

Country		2b.1 Is there a requirement that regulates the training standards of the core team?	2b.2 Detailed description of training standards [Not included in ED Questionnaire]	2b.3a Implementation framework for the team's training standards [Not included in ED Questionnaire]	2b.4 Training details [Not included in ED Questionnaire]	2b.5 Training comments [2b.1 Comments for ED Questionnaire]
AT	<i>ECIBC National Contacts</i>					
	<i>ED National Representative</i>	YES				Training and qualification for the core team members are defined in the catalogue of the ÖZK.
BE	<i>ECIBC National Contacts</i>	YES, MANDATORY		Embedded in national/regional legislation. Implemented in 2007.		
	<i>ED National Representative</i>					
BG	<i>ECIBC National Contacts</i>	YES, MANDATORY		Embedded in national/regional legislation. Implemented in 1987. Used as reference for reimbursement from insurance at national/regional level. Implemented in 2005.	National expert groups in oncology were established in 1987 following the Order of the Ministry of Health. In 2005, the National Health Insurance Fund introduced additional requirements. The Order of the Ministry of Health about the specialisation of the physicians regulates the mechanism for specialisation in various areas of oncology, including surgery, radiology, and chemotherapy.	
	<i>ED National Representative</i>					
CH	<i>ECIBC National Contacts</i>	NO and NOT PLANNED				
	<i>ED National Representative</i>	I do not have this information.				

Country		2b.1 Is there a requirement that regulates the training standards of the core team?	2b.2 Detailed description of training standards [Not included in ED Questionnaire]	2b.3a Implementation framework for the team's training standards [Not included in ED Questionnaire]	2b.4 Training details [Not included in ED Questionnaire]	2b.5 Training comments [2b.1 Comments for ED Questionnaire]
CY	<i>ECIBC National Contacts</i>	YES, VOLUNTARY				
	<i>ED National Representative</i>	NO				
CZ	<i>ECIBC National Contacts</i>	YES, MANDATORY	Training is supervised by the Czech Radiological Society and concludes with a test.	Embedded in national/regional legislation. Implemented in 2010. Used as reference for reimbursement from insurance at national/regional level. Implemented in 2002. Institutional licencing requirement at national/regional level. Implemented in 2002.	The Commission for the Screening of Breast Cancer at the Ministry of Health (Komda) - is composed by radiologists - breast radiologists, members of professional societies dealing with the diagnosis and treatment of breast diseases, the State Office for Nuclear Safety (SONS), General Health Insurance Company (VZP), the Association of Health Insurance Companies (associates other health insurers) and the Ministry of Health. Commission experts for Breast Radiology (Komda) - are represented mainly by specialists from the Radiological Society JEP, the Association of Non-State Outpatient Radiology and the Association of Czech Breast Radiologists (AMA-CZ).	Training in accordance with EUSOMA and Europa Donna guidelines.
	<i>ED National Representative</i>					

Country		2b.1 Is there a requirement that regulates the training standards of the core team?	2b.2 Detailed description of training standards [Not included in ED Questionnaire]	2b.3a Implementation framework for the team's training standards [Not included in ED Questionnaire]	2b.4 Training details [Not included in ED Questionnaire]	2b.5 Training comments [2b.1 Comments for ED Questionnaire]
DE	<i>ECIBC National Contacts</i>	YES, MANDATORY	For every member of the network we have requirements for qualification (at the beginning of every chapter) and further training (at the end of every chapter). In addition: requirements for attending tumour boards, morbidity-and-mortality-conferences, quality-circles. (see: https://www.krebsgesellschaft.de/gcs/german-cancer-society/certification/documents.html?file=files/dkg/german-cancer-society/pdf/Certification/Catalogue%20of%20Req%20breast-H1%201%20%2814%2007%202016%29%20EN.pdf)	Institutional licencing requirement at national/ regional level. Implemented in 2003.	see 2b.2	
	<i>ED National Representative</i>					
EE	<i>ECIBC National Contacts</i>					
	<i>ED National Representative</i>	YES				Requirements are defined in the Standards of Cancer Treatment Quality, 2011.
ES	<i>ECIBC National Contacts</i>					
	<i>ED National Representative</i>	NO				

Country		2b.1 Is there a requirement that regulates the training standards of the core team?	2b.2 Detailed description of training standards [Not included in ED Questionnaire]	2b.3a Implementation framework for the team's training standards [Not included in ED Questionnaire]	2b.4 Training details [Not included in ED Questionnaire]	2b.5 Training comments [2b.1 Comments for ED Questionnaire]
FI	<i>ECIBC National Contacts</i>	YES, VOLUNTARY		Institutional licencing requirement at national/ regional level.	The person responsible for providing breast services is expected to keep her/his skill up to date and it is also strongly recommended to participate in training (3-10 days each year). However, this is not mandatory.	
	<i>ED National Representative</i>					
FR	<i>ECIBC National Contacts</i>	NO and NOT PLANNED	See 4vii comments			See 4vii comments.
	<i>ED National Representative</i>	YES				Continuous training is foreseen.
GR	<i>ECIBC National Contacts</i>	NO and NOT PLANNED				Each member of the core team of the Breast Centre must have a specialisation and global education in Senology and should follow a continued Senologic education on a regular basis. Breast centres' budgets should include this provision.
	<i>ED National Representative</i>	NO				
HU	<i>ECIBC National Contacts</i>	NO, BUT PLANNED				We consider international guidelines available in BC as core material for team training.
	<i>ED National Representative</i>					

Country		2b.1 Is there a requirement that regulates the training standards of the core team?	2b.2 Detailed description of training standards [Not included in ED Questionnaire]	2b.3a Implementation framework for the team's training standards [Not included in ED Questionnaire]	2b.4 Training details [Not included in ED Questionnaire]	2b.5 Training comments [2b.1 Comments for ED Questionnaire]
IE	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	Training is to a high standard but voluntary.			
	<i>ED National Representative</i>	YES				
IT	<i>ECIBC National Contacts</i>	YES, MANDATORY	Training is expected at a central (regional level) with training targeted to individual job profiles. Multidisciplinary training (when appropriate) is strongly recommended. The training is aimed at achieving the stated standard professional skills as well as non-technical ones.	Embedded in national/regional legislation. Implemented in 2014.	State-regions agreement on breast units networking issued 18 December 2014.	
	<i>ED National Representative</i>	NO				
LT	<i>ECIBC National Contacts</i>	YES, MANDATORY	All standards are common for all medical personal in Lithuania and is regulated by Ministry of Health and the Accreditation Department.	Used as reference for reimbursement from insurance at national/regional level.		
	<i>ED National Representative</i>					
LU	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	The Ministry of Health has to organise continuing medical accreditation for all physicians; but, it is has not been done. The Ministry also responsible for training radiologists and radiographers in digital mammography (films are no longer used), and in other aspects of breast imaging (e.g. MRI).	Embedded in national/regional legislation. Implemented in 2003.	Memorial A, 167, du 19 Novembre 2003: Convention entre l'Etat du Grand Duché de Luxembourg et l'Union des caisses de maladie portant organisation d'un programme permanent de dépistage précoce du cancer du sein par mammographie.	

Country		2b.1 Is there a requirement that regulates the training standards of the core team?	2b.2 Detailed description of training standards [Not included in ED Questionnaire]	2b.3a Implementation framework for the team's training standards [Not included in ED Questionnaire]	2b.4 Training details [Not included in ED Questionnaire]	2b.5 Training comments [2b.1 Comments for ED Questionnaire]
LU	<i>ED National Representative</i>	NO				
LV	<i>ECIBC National Contacts</i>	NO and NOT PLANNED	Board certification is mandatory to practice in Latvia.			Board certification is mandatory to practice in Latvia.
	<i>ED National Representative</i>					
NL	<i>ECIBC National Contacts</i>					
	<i>ED National Representative</i>	YES				
MT	<i>ECIBC National Contacts</i>	NO, BUT PLANNED				
	<i>ED National Representative</i>	NO				
NO	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	Recommended for radiologists: reading 5000 screening exams annually and doing diagnostic mammography.		The radiologist's interpretation scores, recall rate, etc. is continuously monitored and reported.	
	<i>ED National Representative</i>	NO				
PL	<i>ECIBC National Contacts</i>	NO and NOT PLANNED				
	<i>ED National Representative</i>					
PT	<i>ECIBC National Contacts</i>	NO and NOT PLANNED				
	<i>ED National Representative</i>					
RO	<i>ECIBC National Contacts</i>	NO and NOT PLANNED				
	<i>ED National Representative</i>					

Country		2b.1 Is there a requirement that regulates the training standards of the core team?	2b.2 Detailed description of training standards [Not included in ED Questionnaire]	2b.3a Implementation framework for the team's training standards [Not included in ED Questionnaire]	2b.4 Training details [Not included in ED Questionnaire]	2b.5 Training comments [2b.1 Comments for ED Questionnaire]
RS	<i>ECIBC National Contacts</i>	YES, MANDATORY	<p>In the Republic of Serbia, there are official training curricula for educating radiologists (training for future radiologists as defined by universities - medical faculties). In addition, the national screening programme defines standards for additional education of radiologists and radiographers (radiology technicians) for screening mammography. Eighty radiologists and 100 radiographers for screening mammography were trained via an EU-funded project.</p> <p>According to the legal framework of the Republic of Serbia concerning quality improvement, continual medical education for radiologists/radiographers is required for obtaining and renewing licenses. The Serbian Medical Association and Serbian Medical Chamber (for radiologists) as well as the Serbian Chamber of Healthcare professionals (for radiographers) are legally in charge of monitoring and evaluation of this issue.</p>	Embedded in national/ regional legislation; Institutional licencing requirement at national/ regional level.		
	<i>ED National Representative</i>					

Country		2b.1 Is there a requirement that regulates the training standards of the core team?	2b.2 Detailed description of training standards [Not included in ED Questionnaire]	2b.3a Implementation framework for the team's training standards [Not included in ED Questionnaire]	2b.4 Training details [Not included in ED Questionnaire]	2b.5 Training comments [2b.1 Comments for ED Questionnaire]
SE	<i>ECIBC National Contacts</i>	NO and NOT PLANNED				
	<i>ED National Representative</i>	NO				
SI	<i>ECIBC National Contacts</i>	NO, BUT PLANNED				
	<i>ED National Representative</i>	YES				
SK	<i>ECIBC National Contacts</i>	NO, BUT PLANNED				
	<i>ED National Representative</i>					
TR	<i>ECIBC National Contacts</i>					
	<i>ED National Representative</i>					
UK	<i>ECIBC National Contacts</i>	YES, MANDATORY	Most specialties complete a general training e.g. in surgery, oncology, radiology or radiography, but then undertake additional specialist training in breast cancer diagnosis and treatment. For some disciplines this is sub-specialisation at the end of training, but there are also more specific training programmes e.g. the national surgical oncoplastic fellowship scheme, and specific training for breast radiographers.	Institutional licencing requirement at national/regional level. Implemented in 2000.	Assessed in the national peer review process.	

Country		2b.1 Is there a requirement that regulates the training standards of the core team?	2b.2 Detailed description of training standards [Not included in ED Questionnaire]	2b.3a Implementation framework for the team's training standards [Not included in ED Questionnaire]	2b.4 Training details [Not included in ED Questionnaire]	2b.5 Training comments [2b.1 Comments for ED Questionnaire]
UK			Now, doctors and other practitioners would not get appointed to a post in a breast unit without this sub-specialty training.			
<i>ED National Representative</i>	YES					

Table 7: Survey section 5.

Breast Units mandatory requirements implementation stage.

Questions:

A. Core Team – (c) Continuing medical education (CME)

ECIBC:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the CME of the core team as defined in the 2006 European Guidelines? * YES, MANDATORY; YES, VOLUNTARY; NO, BUT PLANNED; NO and NOT PLANNED; I do not know
2. If you replied YES, please provide a more detailed description of the continuing medical education contents/organisation (*e.g.* is CME outsourced to licenced trainers? How is licencing awarded?)
3. If you replied YES, please report below the implementation framework of the team's CME and the respective year of implementation (more than one answer is possible). Embedded in national/regional legislation; Used as reference for reimbursement from insurances at national/regional level; Institutional licencing requirement at national/regional level; Used in a non-public quality assurance scheme under national/regional governance; Used in a non-public quality assurance scheme NOT under national/regional governance
4. If you replied YES, please provide a more detailed description (*i.e.* name of legislation/quality assurance scheme, link to the text or reference document)
5. If you wish, please add below your comments/considerations on core team's CME mandatory requirement

ED:

1. Is there in your country any kind of requirement that regulates the CME of the core team as defined in the 2006 European Guidelines? YES; NO; I do not have this information
2. If you wish, please add below your comments / considerations on core team's CME mandatory requirement

Country		2c.1 Is there a requirement that regulates the CME of the core team?	2c.2 Detailed description of CME contents/ organisation [Not included in ED Questionnaire]	2c.3a Implementation framework of the team's CME [Not included in ED Questionnaire]	2c.4 CME details [Not included in ED Questionnaire]	2c.5 CME comments [2c.1 Comments for ED Questionnaire]
AT	<i>ECIBC National Contacts</i>					
	<i>ED National Representative</i>	YES				The continuing medical education is regulated not only for the core team but for the nursing team, social workers and psycho-oncologist as well.
BE	<i>ECIBC National Contacts</i>	NO and NOT PLANNED				
	<i>ED National Representative</i>					
BG	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	The Bulgarian Society of Physicians has a system for CME. The Department for Specialisation of Medical Doctors regulates the training of specialists.	Embedded in national/ regional legislation. Implemented in 2000.	Regulated by the Bulgarian Association of Physicians.	
	<i>ED National Representative</i>					
CH	<i>ECIBC National Contacts</i>	NO and NOT PLANNED				
	<i>ED National Representative</i>	I do not have this information.				
CY	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	Please see above (continuous training).			
	<i>ED National Representative</i>	NO				

Country		2c.1 Is there a requirement that regulates the CME of the core team?	2c.2 Detailed description of CME contents/ organisation [Not included in ED Questionnaire]	2c.3a Implementation framework of the team's CME [Not included in ED Questionnaire]	2c.4 CME details [Not included in ED Questionnaire]	2c.5 CME comments [2c.1 Comments for ED Questionnaire]
CZ	<i>ECIBC National Contacts</i>	YES, MANDATORY	The condition for practicing medicine in the Czech Republic is to be involved in continuous medical education within the membership in the Czech Medical Chamber.	Embedded in national/ regional legislation. Implemented in 2010. Used as reference for reimbursement from insurance at national/ regional level. Implemented in 2002. Institutional licencing requirement at national/ regional level. Implemented in 2002.	The Czech Medical Chamber gives authorisation to work with a doctor specialising in radiotherapy, chief physician at the breast unit, etc. on the basis of compliance attestation exams and credits for educational courses.	Each specialist must annually complete a specified number of subsidised educational training hours.
	<i>ED National Representative</i>					
DE	<i>ECIBC National Contacts</i>	YES, MANDATORY	In Germany CME is obligatory for every medical doctor having contact with patients. They need a specific number of credit points per year in order to be able to issue invoices.	Embedded in national/ regional legislation	See: German Medical Association: "(Model) Speciality Training Regulations" ; http://www.bundesaerztekammer.de/fileadmin/user_upload/downloads/MFBO2013en.pdf	
	<i>ED National Representative</i>					
EE	<i>ECIBC National Contacts</i>					
	<i>ED National Representative</i>	YES				Requirements are defined in the Standards of Cancer Treatment Quality, 2011.
ES	<i>ECIBC National Contacts</i>					
	<i>ED National Representative</i>	NO				

Country		2c.1 Is there a requirement that regulates the CME of the core team?	2c.2 Detailed description of CME contents/ organisation [Not included in ED Questionnaire]	2c.3a Implementation framework of the team's CME [Not included in ED Questionnaire]	2c.4 CME details [Not included in ED Questionnaire]	2c.5 CME comments [2c.1 Comments for ED Questionnaire]
FI	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	For medical doctors, specialist training in his/her own field (3-10 days per year); Training is strongly recommended by the Finnish Medical Association. So this is a (strong) recommendation, not a requirement.		See above.	Education is recorded on each expert personal education registry, which can be inspected during audits etc., but there is no legal obligation for clinicians. Only for the personnel within mammography screening it is mandatory and in line with the European guideline requirements.
	<i>ED National Representative</i>					
FR	<i>ECIBC National Contacts</i>	NO and NOT PLANNED				
	<i>ED National Representative</i>	YES				Imaging equipment is regularly checked by competent authorities.
GR	<i>ECIBC National Contacts</i>	NO and NOT PLANNED	Each member of the 'core team' takes care of its own CME by attending congresses and seminars (national and international). In the majority of the cases, the registration fees are covered by the individual.			
	<i>ED National Representative</i>	NO				
HU	<i>ECIBC National Contacts</i>	YES, MANDATORY	Regular postgraduate training of various aspects of clinical oncology; not limited to BC teamwork.	Embedded in national/ regional legislation. Implemented in 2005.	250 CME credit should be collected within 5 years' time.	

Country		2c.1 Is there a requirement that regulates the CME of the core team?	2c.2 Detailed description of CME contents/organisation [Not included in ED Questionnaire]	2c.3a Implementation framework of the team's CME [Not included in ED Questionnaire]	2c.4 CME details [Not included in ED Questionnaire]	2c.5 CME comments [2c.1 Comments for ED Questionnaire]
HU	<i>ED National Representative</i>					
IE	<i>ECIBC National Contacts</i>	YES, MANDATORY	Through the sub-specialty college	Embedded in national/regional legislation		
	<i>ED National Representative</i>	YES				
IT	<i>ECIBC National Contacts</i>	YES, MANDATORY	Continuing medical education refers to a more general body of laws: CME is planned and performed on an individual basis by each health operator.	Embedded in national/regional legislation; Institutional licencing requirement at national/regional level.	The National Programme for CME was launched in 2002, according to the Legislative Decree 502/1992 supplemented by Decree 229/1999, which had established the obligation of continuing education for health professionals. The State-Regions agreement of 1 August 2007 defines the reorganisation of the CME programme and establishes the new organisation and rules for its governance. It identifies the National Health Services Agency as the "common home" at national level for the management CME.	
	<i>ED National Representative</i>	NO				CME exists for all specialists.

Country		2c.1 Is there a requirement that regulates the CME of the core team?	2c.2 Detailed description of CME contents/organisation [Not included in ED Questionnaire]	2c.3a Implementation framework of the team's CME [Not included in ED Questionnaire]	2c.4 CME details [Not included in ED Questionnaire]	2c.5 CME comments [2c.1 Comments for ED Questionnaire]
LT	<i>ECIBC National Contacts</i>	NO and NOT PLANNED	There is a regulation for training and skills improvement every 5 years for medical doctors and nurses in Lithuania. CME credits are also possible for this purpose.			
	<i>ED National Representative</i>					
LU	<i>ECIBC National Contacts</i>	NO, BUT PLANNED	In the framework of the cancer plan, a CME would be organised, but there is no handbook planned.			
	<i>ED National Representative</i>	NO				
LV	<i>ECIBC National Contacts</i>	NO and NOT PLANNED				CME is mandatory for board certification and re-certification (takes place every 5 years for medical specialists)
	<i>ED National Representative</i>					
MT	<i>ECIBC National Contacts</i>	NO, BUT PLANNED				
	<i>ED National Representative</i>	NO				
NL	<i>ECIBC National Contacts</i>					
	<i>ED National Representative</i>	YES				
NO	<i>ECIBC National Contacts</i>	NO and NOT PLANNED				
	<i>ED National Representative</i>	NO				

Country		2c.1 Is there a requirement that regulates the CME of the core team?	2c.2 Detailed description of CME contents/ organisation [Not included in ED Questionnaire]	2c.3a Implementation framework of the team's CME [Not included in ED Questionnaire]	2c.4 CME details [Not included in ED Questionnaire]	2c.5 CME comments [2c.1 Comments for ED Questionnaire]
PL	<i>ECIBC National Contacts</i>	YES, MANDATORY	General requirements for CME are implemented by the Medical Board (applies to physicians only). There is no particular organisation responsible. There are a required number of points that are verified by the Medical Board.	Embedded in national/ regional legislation. Implemented in 1997		
	<i>ED National Representative</i>					
PT	<i>ECIBC National Contacts</i>	NO and NOT PLANNED				
	<i>ED National Representative</i>					
RO	<i>ECIBC National Contacts</i>	YES, MANDATORY	Every medical doctor has to acquire 40 CME points per year (200 every 5 years) to renew his professional accreditation. CME points can be obtained through several training programmes, which are all certified as "CME providers" (e.g. European UEMS/ACOE, and US AMA points are recognised). However, this is not specific for oncologists or breast cancer specialists; it is a general requirement for all MDs.	Embedded in national/ regional legislation. Implemented in 1995.		
	<i>ED National Representative</i>					

Country		2c.1 Is there a requirement that regulates the CME of the core team?	2c.2 Detailed description of CME contents/ organisation [Not included in ED Questionnaire]	2c.3a Implementation framework of the team's CME [Not included in ED Questionnaire]	2c.4 CME details [Not included in ED Questionnaire]	2c.5 CME comments [2c.1 Comments for ED Questionnaire]
RS	<i>ECIBC National Contacts</i>	YES, MANDATORY	As described above there is a system of CME in the country for radiologists, oncologists, surgeons and other medical doctors as well as continuing education for healthcare professionals (radiographers). The legal framework in Serbia for CME is as listed below: Law on Healthcare (Official Gazette 107/2005,) Law on Healthcare Chambers (Official Gazette 107/2005 i 99/2010), Regulation on licensing of healthcare professionals (Official Gazette 119/2997, 23/2009, 40/2010).	Embedded in national/ regional legislation.	CME is provided and organized by: - Serbian Medical Society - Serbian Medical Chamber - Medical faculties - Institute for Oncology and Radiology of Serbia - Institute for Oncology of Vojvodina, Sremska Kamenica - Clinical Centre Niš - Clinical Centre Kragujevac Key legal documents: You can find PDF files on the official website of the Cancer Screening Office http://www.skriningsrbija.rs/srl/dokumenta/zakoni/	
	<i>ED National Representative</i>					
SE	<i>ECIBC National Contacts</i>	NO and NOT PLANNED	It is of course very natural that the participants in the care team participate in CME activities, but there are no formal regulations.			
	<i>ED National Representative</i>	NO				

Country		2c.1 Is there a requirement that regulates the CME of the core team?	2c.2 Detailed description of CME contents/organisation [Not included in ED Questionnaire]	2c.3a Implementation framework of the team's CME [Not included in ED Questionnaire]	2c.4 CME details [Not included in ED Questionnaire]	2c.5 CME comments [2c.1 Comments for ED Questionnaire]
SI	<i>ECIBC National Contacts</i>	NO, BUT PLANNED				In general, CME is mandatory for oncologists, but it is not specified for breast cancer.
	<i>ED National Representative</i>	YES				
SK	<i>ECIBC National Contacts</i>	NO, BUT PLANNED				
	<i>ED National Representative</i>					
TR	<i>ECIBC National Contacts</i>					
	<i>ED National Representative</i>					
UK	<i>ECIBC National Contacts</i>	YES, MANDATORY	Each specialty has to complete a defined amount of CME relevant to breast cancer diagnosis and treatment each year and for doctors; this is assessed at the annual appraisal and mandated by the General Medical Council.	Institutional licencing requirement at national/ regional level. Implemented in 1995.	Mandated by the General Medical Council.	
	<i>ED National Representative</i>	YES				

Table 8: *Survey section 6.*

Breast Units non-mandatory requirements implementation stage.

Questions:

A. Equipment (9.6.1)

Definition from the 2006 European Guidelines

9.6.1. The unit must be in possession of all necessary imaging equipment for complete and adequate breast diagnosis.

ECIBC:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the imaging equipment requirement 9.6.1 as defined above? * YES, MANDATORY; YES, VOLUNTARY; NO, BUT PLANNED; NO and NOT PLANNED; I do not know
2. If you replied YES, please provide a more detailed description (*i.e.* name of legislation/quality assurance scheme, link to the text or reference document)
3. If you wish, please add below your comments/considerations on the imaging equipment voluntary requirement

ED:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the imaging equipment requirement 9.6.1 as defined above? YES; NO; I do not have this information
2. If you wish, please add below your comments/considerations on the imaging equipment voluntary requirement

B. Equipment (9.6.2)

Definition from the 2006 European Guidelines

9.6.2. The minimum equipment in a department giving radiotherapy must be two mega-voltage units, a brachytherapy unit, a simulator and a computerised planning system. The department must have a radiotherapeutic quality control programme for breast cases.

ECIBC:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the radiotherapeutic equipment requirement 9.6.2 as defined above? * YES, MANDATORY; YES, VOLUNTARY; NO, BUT PLANNED; NO and NOT PLANNED; I do not know
2. If you replied YES, please provide a more detailed description (*i.e.* name of legislation/quality assurance scheme, link to the text or reference document)
3. If you wish, please add below your comments/considerations on the radiotherapeutic equipment voluntary requirement

ED:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the radiotherapeutic equipment requirement 9.6.2 as defined above? YES; NO; I do not have this information
2. If you wish, please add below your comments/considerations on the radiotherapeutic equipment voluntary requirement

Country		A1. Is there a requirement that regulates the imaging equipment?	A2-A3 Imaging equipment details/ comments	B1. Is there a requirement that regulates radiotherapeutic equipment?	B2-B3 Radiotherapeutic equipment details/comments
AT	<i>ECIBC National Contacts</i>				
	<i>ED National Representative</i>	YES	The ÖZK catalogue defines the imaging equipment required.	YES	The ÖZK catalogue defines the radiotherapeutic equipment required in accordance with the 2006 European Guidelines.
BE	<i>ECIBC National Contacts</i>	YES, MANDATORY	See previous questions, Royal Decree - 26 April 2007	NO and NOT PLANNED	The Hospital Law and Royal Decree on Radiation Oncology Services regulate radiotherapeutic equipment. The minimum technical equipment is specified for radiotherapy services in general, but not specifically for breast cancer. The Royal Decree for Specialised Oncology Care Programmes for Breast Cancer indicates, as recognition criteria for breast units, that there must be the provision of radiotherapy service or an agreement with a hospital that has a radiotherapy service.
	<i>ED National Representative</i>				
BG	<i>ECIBC National Contacts</i>	YES, MANDATORY	Regulation by the Ministry of Health and the National Health Insurance Fund.	YES, MANDATORY	There are Regulations of the Ministry of Health and the National Health Insurance Fund, and accreditation requirements of the National Hospital of Oncology.
	<i>ED National Representative</i>				
CH	<i>ECIBC National Contacts</i>	NO and NOT PLANNED		NO and NOT PLANNED	
	<i>ED National Representative</i>	I do not have this information.		I do not have this information.	
CY	<i>ECIBC National Contacts</i>	YES, MANDATORY	There is a medical devices department that regulates medical equipment in accordance with EU standards (digital mammographers etc.).	YES, MANDATORY	BOCOC (Bank of Cyprus Oncology Centre) is a partner of the Breast Centre Unit. The Centre meets all EU standards and is accredited.

Country		A1. Is there a requirement that regulates the imaging equipment?	A2-A3 Imaging equipment details/ comments	B1. Is there a requirement that regulates radiotherapeutic equipment?	B2-B3 Radiotherapeutic equipment details/comments
CY	<i>ED National Representative</i>	I do not have this information.	There is no breast unit in compliance with the 2006 European Guidelines; however, different centres have the necessary imaging equipment and it is regularly checked.	YES	The Oncology Centre meets all requirements.
CZ	<i>ECIBC National Contacts</i>	YES, MANDATORY	The Ministry of Health Decree no. 221/2010 Col specifies requirements for material and technical equipment of health facilities. The inspection of BU equipment is part of the accreditation process.	YES, MANDATORY	Radiotherapy is an essential part of a Comprehensive Cancer Centre. Checking radiotherapy equipment is part of the accreditation process of the Comprehensive Cancer Centre.
	<i>ED National Representative</i>				
DE	<i>ECIBC National Contacts</i>	YES, MANDATORY	For national mammography screening radiologists, legally mandatory requirements for the imaging equipment are in place. For the voluntary certification of Breast Cancer Centres there are mandatory requirements for imaging equipment: Excerpt from Chapter 3 Breast ultrasound; For breast diagnostics, only ultrasound equipment with a frequency of ≥ 7.5 MHz is to be used; Ultrasound equipment must correspond with DIN EN 61157; Requirement for performing breast ultrasound: Proof of a qualification in breast ultrasound (Fachkunde Mammasonografie [safeguarded], Ultrasound Agreement National Association of Statutory Health Insurance Physicians, DEGUM 1); Standardised documentation of the diagnostic findings according to the S3 guideline (e.g., use of US BI-RADS classification); Stereotaxis; The procedure should be digital and analogue only in exceptional cases; Marking and biopsies must be possible and this option should be employed; MRI: Access to MRI examinations must be ensured. In the event that an MRI cannot be performed directly on the site of the	YES, MANDATORY	The requirements regulating radiotherapeutic equipment are described in Chapter 7 (esp. 7.6) of the Catalogue of Requirements, see: https://www.krebsgesellschaft.de/gcs/german-cancer-society/certification/documents.html?file=files/dkg/german-cancer-society/pdf/Certification/Catalogue%20of%20Req%20breast-H1%201%20%2814%2007%202016%29%20EN.pdf .

Country		A1. Is there a requirement that regulates the imaging equipment?	A2-A3 Imaging equipment details/ comments	B1. Is there a requirement that regulates radiotherapeutic equipment?	B2-B3 Radiotherapeutic equipment details/comments
DE			breast cancer centre, access must be regulated by a cooperation agreement. (see more detailed: https://www.krebsgesellschaft.de/gcs/german-cancer-society/certification/documents.html?file=files/dkg/german-cancer-society/pdf/Certification/Catalogue%20of%20Req%20breast-H1%201%20%2814%2007%202016%29%20EN.pdf)		
	<i>ED National Representative</i>				
EE	<i>ECIBC National Contacts</i>				
	<i>ED National Representative</i>	YES	Requirements are defined in the Standards of Cancer Treatment Quality, 2011.	YES	Requirements are defined in the Standards of Cancer Treatment Quality, 2011.
ES	<i>ECIBC National Contacts</i>				
	<i>ED National Representative</i>	NO		NO	
FI	<i>ECIBC National Contacts</i>	YES, MANDATORY	For breast screening units, the European Guidelines are followed (mandatory).	YES, MANDATORY	The Finnish Radiation and Nuclear Safety Authorisation (STUK) audits and provides requirements for the radiotherapy units. STUK supervises the number of radiotherapy equipment and the number of personnel required per each unit, these numbers are based on the number of patients treated. STUK can withdraw a radiotherapy permit when the unit does not comply with minimal requirements set by law.
	<i>ED National Representative</i>				
FR	<i>ECIBC National Contacts</i>	NO and NOT PLANNED		NO and NOT PLANNED	
	<i>ED National Representative</i>	YES	Imaging equipment is regularly checked by competent authorities.	YES	

Country		A1. Is there a requirement that regulates the imaging equipment?	A2-A3 Imaging equipment details/ comments	B1. Is there a requirement that regulates radiotherapeutic equipment?	B2-B3 Radiotherapeutic equipment details/comments
GR	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	On voluntary basis, a breast centre can be equipped with the following imaging equipment: 1. Mammographer (analog, CR mammographer, digital mammographer or tomosynthesis); 2. 3D U/S; 3. Elastography; 4. Stereotactic localisation of the non-palpable lesions; 5. MRI; A breast centre could have 2, 3 or all of the above types of equipment.	YES, VOLUNTARY	Out of the 13 hospitals that responded to the questionnaire, six reported that they have a radiotherapy department implementing quality control guidelines. In many hospitals radiotherapy equipment is old; an attempt to replace some of it is made through sponsorships from the private sector.
	<i>ED National Representative</i>	NO		NO	
HU	<i>ECIBC National Contacts</i>	YES, MANDATORY		YES, MANDATORY	
	<i>ED National Representative</i>				
IE	<i>ECIBC National Contacts</i>	YES, VOLUNTARY		YES, VOLUNTARY	
	<i>ED National Representative</i>	YES		YES	
IT	<i>ECIBC National Contacts</i>	YES, MANDATORY	State-regions agreement issued 18 December 2014.	YES, MANDATORY	State-regions agreement issued 18 December 2014.
	<i>ED National Representative</i>	YES	See document from the Italian Ministry of Health (18 December 2014 Rep.Atti 185/ CSR).	YES	See document from the Italian Ministry of Health (18 December 2014 Rep.Atti 185/ CSR).
LT	<i>ECIBC National Contacts</i>	YES, MANDATORY	The NCI is following SIS requirements for a dedicated and accredited breast cancer centre as well as equipment. Digital mammography, digital tomosynthesis, stereotactic breast biopsy table, ultrasound units, and breast MRI are available at our institution. At this time we are implementing vacuum assisted US, stereo and MRI guided biopsy.	YES, MANDATORY	Our equipment : Clinac 2100 C/D – 2006; Clinac iX/2100 C/D – 2007; Clinac iX – 2011; Clinac 600 C/D – 2009; Brachytherapy Vari-source 200 – 2002 m.
	<i>ED National Representative</i>				

Country		A1. Is there a requirement that regulates the imaging equipment?	A2-A3 Imaging equipment details/ comments	B1. Is there a requirement that regulates radiotherapeutic equipment?	B2-B3 Radiotherapeutic equipment details/comments
LU	<i>ECIBC National Contacts</i>	NO and NOT PLANNED	The Ministry of Health has a role as consultant. A hospital request for new equipment has to be approved by the health insurance company, but hospitals can also order new equipment with their own budgets. For breast care, all hospitals have the imaging equipment needed; the Ministry of Health controls mammographs.	YES, MANDATORY	The National Radiotherapy Centre fulfils all the international criteria
	<i>ED National Representative</i>	YES		YES	Available in one national centre.
LV	<i>ECIBC National Contacts</i>	NO and NOT PLANNED		NO and NOT PLANNED	
	<i>ED National Representative</i>				
MT	<i>ECIBC National Contacts</i>	NO, BUT PLANNED	The imaging equipment available and planned includes: *two full field digital mammography machines with stereo guided equipment. *ultrasound equipment used for recalls and biopsies is equipped with 2D and 3D probes. *MRI used is a 3 Tesla with dedicated breast software. *currently seeking to acquire a dedicated vacuum assisted MRI stereotactic equipment.	NO, BUT PLANNED	The following is the radiotherapy equipment and capabilities available in Malta to date: *3 Linear Accelerators 2 of which are enabled for IMRT and IGRT (2 x Elekta Versa HD and 1 x Elekta Platform) *Planning Stations – XIO and MONACO systems *1 Large Bore CT Simulator *Patients requiring Brachytherapy are currently referred to a centre in the UK.
	<i>ED National Representative</i>	NO		NO	
NL	<i>ECIBC National Contacts</i>				
	<i>ED National Representative</i>	YES		YES	
NO	<i>ECIBC National Contacts</i>	YES, MANDATORY	Regulated by the Norwegian Radiation Protection Authorities. http://www.nrpa.no/dav/a4e26fdc6c.pdf .	YES, MANDATORY	Regulated by the Norwegian Radiation Protection Authorities.
	<i>ED National Representative</i>	YES		YES	

Country		A1. Is there a requirement that regulates the imaging equipment?	A2-A3 Imaging equipment details/ comments	B1. Is there a requirement that regulates radiotherapeutic equipment?	B2-B3 Radiotherapeutic equipment details/comments
PL	<i>ECIBC National Contacts</i>	YES, MANDATORY	Reference to the European guidelines for quality assurance in breast cancer and diagnosis (4th Edition).	YES, MANDATORY	As specified by the Minister of Health on 26 April 2013 (Journal of Laws pos. 874). The mandatory equipment includes two megavoltage units, a simulator and a computerised planning system and a quality-control programme. Brachytherapy unit is not required.
	<i>ED National Representative</i>				
PT	<i>ECIBC National Contacts</i>	NO, BUT PLANNED		NO, BUT PLANNED	
	<i>ED National Representative</i>				
RO	<i>ECIBC National Contacts</i>	NO and NOT PLANNED		NO and NOT PLANNED	
	<i>ED National Representative</i>				
RS	<i>ECIBC National Contacts</i>	YES, MANDATORY	There is a standard for imaging equipment within departments for radio-diagnostic procedures. The Republic Expert Committee is providing professional recommendations for innovations of technology including equipment concerning breast cancer screening. The Ministry of Health is obliged to provide equipment for public institutions.	NO, BUT PLANNED	There is a standard for the equipment for the departments giving radiotherapy. Departments do have a radio therapeutic quality control programme for breast diseases. A large amount of equipment is out of date, but the Ministry of Health is planning to procure new equipment for radiotherapy at republic level (procurement procedure has been started by Ministry of Health).
	<i>ED National Representative</i>				
SE	<i>ECIBC National Contacts</i>	NO and NOT PLANNED	Laws and regulations for radiation safety are written and governed by The Swedish Radiation Safety Authority.	NO and NOT PLANNED	
	<i>ED National Representative</i>	NO		NO	

Country		A1. Is there a requirement that regulates the imaging equipment?	A2-A3 Imaging equipment details/ comments	B1. Is there a requirement that regulates radiotherapeutic equipment?	B2-B3 Radiotherapeutic equipment details/comments
SI	<i>ECIBC National Contacts</i>	NO, BUT PLANNED	We have no requirement that regulates the imaging equipment requirement, but two breast units have the required equipment.	NO, BUT PLANNED	We have no requirement that regulates the radiotherapeutic equipment requirement, but one breast unit has the required equipment.
	<i>ED National Representative</i>	YES		YES	
SK	<i>ECIBC National Contacts</i>	i do not know		i do not know	
	<i>ED National Representative</i>				
TR	<i>ECIBC National Contacts</i>				
	<i>ED National Representative</i>	YES		YES	
UK	<i>ECIBC National Contacts</i>	YES, MANDATORY	Assessed via the National Health Service Breast Screening Programme Quality Assurance Programme with a three yearly review and check of the equipment.	NO and NOT PLANNED	There are however copious quality control processes around all radiotherapy planning. Most units would have more than the minimum requirements outlined above. There is no regulation regarding department size; although, there are recommendations that a department should have at least two Linacs.
	<i>ED National Representative</i>	YES		YES	

Table 9: Survey section 6.

Breast Units non-mandatory requirements implementation stage.

Questions:

C. Facilities/ Services (9.7.1)

Definition from the 2006 European Guidelines

Clinics (see definition in Section 9.4). Consultations for Breast patients should be held separately, i.e., not as part of general surgery.

New patient clinics

At least one clinic per week for newly referred symptomatic women must be held. A Unit diagnosing 150 new cancers per year must expect over 1500 new referrals of symptomatic women (= approximately 30 per week).

Suggested outcome measures for the waiting times are given in Chapter 5. A suggested good practice is that all newly referred women with breast symptoms should be offered an appointment within 10 working days of receipt of the referral.

Clinics to which patients are referred or self-referred must be staffed by a surgeon, a radiologist and radiographers from the breast care team. Multidisciplinary working must allow all standard investigations for triple assessment (clinical examination and all appropriate imaging and tissue diagnostic procedures) to be completed at one visit. Where possible the finding of no abnormality or a confirmed diagnosis of a benign lesion should be communicated to the patient at that visit.

ECIBC:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the new patient clinics as defined above? *
YES, MANDATORY; YES, VOLUNTARY; NO, BUT PLANNED; NO and NOT PLANNED; I do not know
2. If you replied YES, please provide a more detailed description (*i.e.* name of legislation/quality assurance scheme, link to the text or reference document)
3. If you wish, please add below your comments/considerations on the new patient clinics voluntary requirement

ED:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the new patient clinics as defined above?
YES; NO; I do not have this information
2. If you wish, please add below your comments/considerations on the new patient clinics voluntary requirement

D. Facilities/ Services (9.7.2)

Definition from the 2006 European Guidelines

Communication of the Diagnosis and Treatment Plan

It may not be possible (now that core biopsy is most often used) or may not be considered appropriate by the unit to give the diagnosis of cancer at the initial visit. Women found to have breast cancer should receive that diagnosis within 5 working days. The diagnosis should be ideally communicated personally by the surgeon: if it is communicated by the radiologist, then the surgeon (±) the oncologist must personally advise the patient on treatment. It is recommended that a breast care nurse (or) psychologically trained person (see 9.5.2.8) be present to discuss fully with the patient the options for treatment and to give emotional support.

If a patient has clear advanced breast cancer it may be more appropriate that an oncologist rather than a surgeon gives the diagnosis if the patient's treatment does not involve surgery.

A suitable room with sufficient privacy must be available. In units in which preoperative irradiation or primary medical therapies are used, cases which might be suitable for these should be seen jointly by a surgeon and radiation or medical oncologist before treatment commences.

A diagnosis should not be given to a patient by letter or on the telephone, unless at the specific request of the patient given adequate and full informed choice.

ECIBC:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the communication of the diagnosis and treatment plan as defined above? * YES, MANDATORY; YES, VOLUNTARY; NO, BUT PLANNED; NO and NOT PLANNED; I do not know
2. If you replied YES, please provide a more detailed description (*i.e.* name of legislation/quality assurance scheme, link to the text or reference document)
3. If you wish, please add below your comments/considerations on the communication of the diagnosis and treatment plan voluntary requirement

ED:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the communication of the diagnosis and treatment plan as defined above? YES; NO; I do not have this information
2. If you wish, please add below your comments/considerations on the communication of the diagnosis and treatment plan voluntary requirement

E. Facilities/Services (9.7.3)

Definition from the 2006 European Guidelines

Multidisciplinary Case Management Meetings (MDM's)

All members of the core team must attend the Multidisciplinary Meeting (MDM), which must be held at least weekly.

The following should be discussed:

*cases in which the diagnosis is as yet uncertain e.g., following core biopsy
cases in whom the diagnosis of cancer is confirmed and who may be considered for primary medical therapy
all cases following surgery on receipt of the histopathology for discussion of further care and
cases in follow-up who recently have undergone diagnostic investigations for possible symptoms of recurrent or advanced disease*

It is possibly more convenient to have two MDM's per week:

*one for cases in diagnosis attended by surgeons, radiologists and pathologists and
one for post-operative consideration of prognosis and adjuvant therapies and for cases investigated for disease recurrence (oncologists, surgeons, radiologists and pathologists).*

ECIBC:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the MDMs as defined above? * YES, MANDATORY; YES, VOLUNTARY; NO, BUT PLANNED; NO and NOT PLANNED; I do not know
2. If you replied YES, please provide a more detailed description (*i.e.* name of legislation/quality assurance scheme, link to the text or reference document)
3. If you wish, please add below your comments/considerations on the MDMs voluntary requirement

ED:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the MDMs as defined above? YES; NO; I do not have this information
2. If you wish, please add below your comments/considerations on the MDMs voluntary requirement

Country		C1. Is there a requirement that regulates new patient clinics?	C1-C2 Patient clinics details/comments	D1. Is there a requirement that regulates the communication of the diagnosis and treatment plan?	D2-D3 Communication details/comments	E1. Is there a requirement that regulates Multidisciplinary case management meetings (MDM)?	E2-E3 MDM details/comments
AT	<i>ECIBC National Contacts</i>						
	<i>ED National Representative</i>	YES	The ÖZK catalogue defines all these requirements. The staff and waiting times are also defined and measured.	YES	These requirements are defined in accordance with the 2006 European Guidelines. Usually, times are short. All key figures are continuously measured and benchmarked annually.	YES	The ÖZK catalogue defines the requirements for MDMs in accordance with the 2006 European Guidelines. We call these meetings "boards" or "conferences".
BE	<i>ECIBC National Contacts</i>	NO and NOT PLANNED		YES, MANDATORY	Royal Decree 26 April 2007. The breast unit has to be sufficiently equipped to provide diagnosis within five working days, and the diagnosis must be communicated by the lead physician. A nurse and psychologist have to be available at the time of the communication.	YES, MANDATORY	Royal Decree 26 April 2007. Multidisciplinary meetings are mandatory on a weekly basis.
	<i>ED National Representative</i>						
BG	<i>ECIBC National Contacts</i>	YES, MANDATORY	There are Ministry of Health and National Health Insurance Fund documents as well as accreditation requirements for the National Hospital of Oncology.	YES, MANDATORY	There are Ministry of Health and National Health Insurance Fund documents as well as accreditation requirements for the National Hospital of Oncology	YES, MANDATORY	There are Ministry of Health and National Health Insurance Fund documents as well as accreditation requirements for the National Hospital of Oncology.
	<i>ED National Representative</i>						

Country		C1. Is there a requirement that regulates new patient clinics?	C1-C2 Patient clinics details/comments	D1. Is there a requirement that regulates the communication of the diagnosis and treatment plan?	D2-D3 Communication details/comments	E1. Is there a requirement that regulates Multidisciplinary case management meetings (MDM)?	E2-E3 MDM details/comments
CH	<i>ECIBC National Contacts</i>	NO and NOT PLANNED		NO and NOT PLANNED		NO and NOT PLANNED	
	<i>ED National Representative</i>	I do not have this information.		I do not have this information.		I do not have this information.	
CY	<i>ECIBC National Contacts</i>	YES, MANDATORY	The policy of the MOH is to follow the EU guidelines. Currently, there is no legislative framework. Since November 2014, the Council of Ministers decided the gradual upgrading of the breast unit.	YES, VOLUNTARY	There are regulations regarding communication that are restricted by the capacity of our services.	YES, VOLUNTARY	We are in the process of turning this practice into a mandatory procedure.
	<i>ED National Representative</i>	NO	There are no requirements regulating this; however, the oncology centre's breast department meets all the guideline requirements, including number of cases, waiting times, number of new patients, etc. A breast team meets once a week.	NO	Diagnosis is not received within 5 working days due to histopathology delay. Diagnosis is communicated by surgeon or radiologist. There are no breast nurses.	NO	No requirement but the multidisciplinary team meets once a week to discuss all new cases. This has greatly improved services to women.
CZ	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	New breast units in the Czech Republic are established based on the needs of the regions. Their number restricts the payment of insurance contracts.	YES, VOLUNTARY	Biopsy is communicated to patients within 5 business days individually. The patient may attend multidisciplinary team meetings as well as choose a surgeon and oncologist.	YES, MANDATORY	MDM is held every week. The team solves the indication of treatment for all new patients and patients with recurrence requiring other than oncological treatment. The patient may at-

Country		C1. Is there a requirement that regulates new patient clinics?	C1-C2 Patient clinics details/comments	D1. Is there a requirement that regulates the communication of the diagnosis and treatment plan?	D2-D3 Communication details/comments	E1. Is there a requirement that regulates Multidisciplinary case management meetings (MDM)?	E2-E3 MDM details/comments
CZ							tend multidisciplinary team meetings as well as choose a surgeon and oncologist.
	<i>ED National Representative</i>						
DE	<i>ECIBC National Contacts</i>	YES, MANDATORY	In Germany we don't follow the single entry port concept. The clinics must be held by a consultant. For breast cancer, in nearly all of the centres, it is the gynaecologist's responsibility. All patients must be discussed interdisciplinary as soon as their diagnostic is finished and/or post-operative but not in the clinics. (see: Catalogue of Requirements: Chapter 2, page 17 et seq.)	YES, MANDATORY	The requirements regulating the communication of the diagnosis and treatment plan are described in Chapter 2.1.9, 2.1.10, 1.6.4 and 1.6.5, in addition more requirements in Chapter 1.4 and 1.5 of the Catalogue of Requirements, see: https://www.krebsgesellschaft.de/gcs/german-cancer-society/certification/documents.html?file=files/dkg/german-cancer-society/pdf/Certification/Catalogue%20of%20Req%20breast-H1%201%20%2814%2007%202016%29%20EN.pdf .	YES, MANDATORY	The requirements regulating the MDM are described in Chapter 1.2 of the Catalogue of Requirements, see: https://www.krebsgesellschaft.de/gcs/german-cancer-society/pdf/Certification/Catalogue%20of%20Req%20breast-H1%201%20%2814%2007%202016%29%20EN.pdf .
	<i>ED National Representative</i>						

Country		C1. Is there a requirement that regulates new patient clinics?	C1-C2 Patient clinics details/comments	D1. Is there a requirement that regulates the communication of the diagnosis and treatment plan?	D2-D3 Communication details/comments	E1. Is there a requirement that regulates Multidisciplinary case management meetings (MDM)?	E2-E3 MDM details/comments
EE	<i>ECIBC National Contacts</i>						
	<i>ED National Representative</i>	YES		YES		YES	
ES	<i>ECIBC National Contacts</i>						
	<i>ED National Representative</i>	NO		NO		NO	
FI	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	The organisation of breast services is planned and executed regionally (in five university hospital areas). Organisation and tasks are agreed at upper management level (within the University Hospital's management). Any decision on new breast services will be based on clear requirements and needs.	YES, VOLUNTARY	The over-mentioned recommendations are followed as much as possible, but this is not mandatory.	YES, VOLUNTARY	All breast cancer cases (and in case needed, also recurrences of breast cancers) should be and are being discussed in MDMs. MDMs are recommended in the national treatment guidelines written by the Finnish Breast Cancer Group. As far as I know, the recommendation is followed throughout Finland in all the units where breast cancer is treated.
	<i>ED National Representative</i>						
FR	<i>ECIBC National Contacts</i>	NO and NOT PLANNED		NO and NOT PLANNED	See 4vii comments	NO and NOT PLANNED	
	<i>ED National Representative</i>	NO		YES	An increasing number of public and private hospitals, and anti-cancer centres pro-	YES	MDM are mandatory at least twice a month (French Health Authority, INCa).

Country		C1. Is there a requirement that regulates new patient clinics?	C1-C2 Patient clinics details/comments	D1. Is there a requirement that regulates the communication of the diagnosis and treatment plan?	D2-D3 Communication details/comments	E1. Is there a requirement that regulates Multidisciplinary case management meetings (MDM)?	E2-E3 MDM details/comments
FR					vide diagnosis in one day by the oncologist. Further communication is then given by an oncologic pivot nurse providing the patient with details and answers.		
GR	<i>ECIBC National Contacts</i>	NO and NOT PLANNED		YES, VOLUNTARY	Communication to patients should be given by Senologist (Surgeon or Gynecologist) in a quiet environment.	YES, VOLUNTARY	The 2006 European Guidelines requirement on MDM is implemented in a few breast centres and only on a voluntary basis. Where MDMs exist (Tumour Board), it takes place for the cases where primary (new adjuvant) chemotherapy is given: Always takes place after surgery, the receipt of histopathology report, and after recurrence. The title of the Clinical-Surgical Physician should be adapted to either Senologist or Mastologist. In this way, it can be ensured that only breast cancer-specialised surgeons can operate in breast centres. This would be an important point for

Country		C1. Is there a requirement that regulates new patient clinics?	C1-C2 Patient clinics details/comments	D1. Is there a requirement that regulates the communication of the diagnosis and treatment plan?	D2-D3 Communication details/comments	E1. Is there a requirement that regulates Multidisciplinary case management meetings (MDM)?	E2-E3 MDM details/comments
GR							discussion upon publication of the Survey report. Certainly in the locally advanced breast cancers or in a non-operable one, the priority of the treatment should be taken by a Tumour Board composed of the Senologist (Surgeon or Gynaecologist), Medical Oncologist and Radiotherapist.
	<i>ED National Representative</i>	NO		NO		NO	
HU	<i>ECIBC National Contacts</i>	NO, BUT PLANNED	We are reducing waiting time. We have a national plan for oncological diagnosis in 14 day.	NO, BUT PLANNED	Information and consent are mandatory for all patients, but this in not (always) a task for the MDM.	YES, MANDATORY	MDM for decision of diagnostic issues and treatment is mandatory in Hungary.
	<i>ED National Representative</i>						
IE	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	The new patients with urgent symptoms must be seen within 2 weeks. All other new patients within 12 weeks. Extra clinics have to be organised, if necessary.	NO, BUT PLANNED	There are guidelines about how quickly a patient must be informed.	YES, VOLUNTARY	Minimum 50/ year
	<i>ED National Representative</i>	YES		YES		YES	
IT	<i>ECIBC National Contacts</i>	YES, MANDATORY	State-regions agreement issued the 18 December 2014.	YES, MANDATORY	State-regions agreement issued the 18 December 2014.	YES, MANDATORY	The state-regions agreement issued the 18 December 2014

Country		C1. Is there a requirement that regulates new patient clinics?	C1-C2 Patient clinics details/comments	D1. Is there a requirement that regulates the communication of the diagnosis and treatment plan?	D2-D3 Communication details/comments	E1. Is there a requirement that regulates Multidisciplinary case management meetings (MDM)?	E2-E3 MDM details/comments
IT							mandates MDMs frequency at one per week.
	<i>ED National Representative</i>	YES	See document from the Italian Ministry of Health (18 December 2014 Rep. Atti 185/CSR).	YES	See document from the Italian Ministry of Health (18 December 2014 Rep. Atti 185/CSR).	YES	See document from the Italian Ministry of Health (18 December 2014 Rep. Atti 185/CSR).
LT	<i>ECIBC National Contacts</i>	YES, MANDATORY	We are working in accordance with SIS accreditation standards and guidelines. Annually, we carry out: 23 000 patient consultations with breast pathology; 850 breast cancer patient consultations; 15 000 patients with benign breast diseases; 20 000 diagnostics mammographies; 32 000 screening mammograms (8 000 women for screening per year)	YES, MANDATORY	We have breast cancer diagnosis and treatment standards in Lithuania approved by the Ministry of Health and standards in our Institution	YES, MANDATORY	MDT meetings twice a week.
	<i>ED National Representative</i>						
LU	<i>ECIBC National Contacts</i>	NO, BUT PLANNED	The Ministry of Health will define the requirements for Competence Centres in accordance with the 2006 guidelines.	NO, BUT PLANNED	In the framework of the cancer plan there are no mandatory rules in place, but patients' care is organised together with the surgeon (gynaecologist), the	NO, BUT PLANNED	All clinics organise MDMs, but mostly after surgery, and at different intervals. Some every two weeks, others once every three weeks. The core team includes a sur-

Country		C1. Is there a requirement that regulates new patient clinics?	C1-C2 Patient clinics details/comments	D1. Is there a requirement that regulates the communication of the diagnosis and treatment plan?	D2-D3 Communication details/comments	E1. Is there a requirement that regulates Multidisciplinary case management meetings (MDM)?	E2-E3 MDM details/comments
LU					oncologist and a breast care nurse. Psychological support is also available.		geon, an oncologist, a breast care nurse, a data nurse, occasionally a radiotherapist, and very rarely a pathologist. In recent years, there was a shortage of staff in one national pathology laboratory.
	<i>ED National Representative</i>	NO		NO	No requirement	YES	
LV	<i>ECIBC National Contacts</i>	NO and NOT PLANNED		NO and NOT PLANNED		NO and NOT PLANNED	
	<i>ED National Representative</i>						
MT	<i>ECIBC National Contacts</i>	NO, BUT PLANNED	Just over 300 new cases of breast cancer are seen and followed up at the BU at MDH	NO, BUT PLANNED	Communication of the diagnosis and treatment is done soon after the case discussion during MDT meetings	NO, BUT PLANNED	One MDM is held on a weekly basis. The following cases are discussed: cases in which the diagnosis is as yet uncertain e.g. following core biopsy cases after the triple assessment and all cases having a recall at screening; cases in which the diagnosis of cancer (and staging) is confirmed and may be considered for primary medical therapy; all cases following surgery on receipt of the histopa-

Country		C1. Is there a requirement that regulates new patient clinics?	C1-C2 Patient clinics details/comments	D1. Is there a requirement that regulates the communication of the diagnosis and treatment plan?	D2-D3 Communication details/comments	E1. Is there a requirement that regulates Multidisciplinary case management meetings (MDM)?	E2-E3 MDM details/comments
MT							thology for discussion of further care and; cases in follow-up that have recently undergone diagnostic investigations for possible symptoms of recurrent or advanced disease.
	<i>ED National Representative</i>	NO		NO		NO	
NL	<i>ECIBC National Contacts</i>						
	<i>ED National Representative</i>	NO		NO	In most hospitals, the treatment plan is provided and discussed with the patient even if not mandated by a requirement.	NO	In most cases, even if not mandated, cases are discussed in a multidisciplinary setting at least when treatment is provided. In smaller hospitals, MDMs are held in cooperation with a specialised comprehensive cancer centre or a specialised cancer hospital.
NO	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	According to standardised patient assessment and treatment processes ("package processes") for breast cancer. (Together – against cancer. National Cancer Strategy 2013–2017).	YES, VOLUNTARY	The quality assurance manual for the Norwegian Breast Cancer Screening Programme includes recommendations on communication.	YES, VOLUNTARY	MDM was implemented as a part of the Norwegian Breast Cancer Screening Programme. Most breast units use MDM for all breast cancer patients.

Country		C1. Is there a requirement that regulates new patient clinics?	C1-C2 Patient clinics details/comments	D1. Is there a requirement that regulates the communication of the diagnosis and treatment plan?	D2-D3 Communication details/comments	E1. Is there a requirement that regulates Multidisciplinary case management meetings (MDM)?	E2-E3 MDM details/comments
NO	<i>ED National Representative</i>	YES		YES		YES	
PL	<i>ECIBC National Contacts</i>	NO and NOT PLANNED		NO and NOT PLANNED		YES, MANDATORY	See Polish Parliament Act of 22 July 2014 (Journal of Laws No. 1138) on change of law on healthcare services financed by public resources.
	<i>ED National Representative</i>						
PT	<i>ECIBC National Contacts</i>	NO, BUT PLANNED				NO and NOT PLANNED	
	<i>ED National Representative</i>						
RO	<i>ECIBC National Contacts</i>	NO and NOT PLANNED		NO and NOT PLANNED		YES, VOLUNTARY	Local institutional protocols, such as http://jradonco.ro/upd/display_paper.php?idfile=V19_No2_2013_pp005
	<i>ED National Representative</i>						
RS	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	National good clinical practice guidelines for diagnostics and treatment of breast cancer. Available at: http://www.skriningsrbija.rs/sr/dokumenta/nacionalni-vodici-dobre-klinicke-prakse/	YES, MANDATORY	Law on rights of patient (Official Gazette 45/13), Article 7 The patient has the right to all types of information about the state of his health, of health services and how to use them, as well as all the information on the basis of	YES, MANDATORY	Law on healthcare; National Good Clinical Practice Guideline for Diagnostics and Treatment of Breast Cancer; Healthcare institutions procedures for work (diagnostic services and therapy) as per legal document called Statute of the

Country		C1. Is there a requirement that regulates new patient clinics?	C1-C2 Patient clinics details/comments	D1. Is there a requirement that regulates the communication of the diagnosis and treatment plan?	D2-D3 Communication details/comments	E1. Is there a requirement that regulates Multidisciplinary case management meetings (MDM)?	E2-E3 MDM details/comments
RS					scientific research and technological innovations. A patient has a right to information about the rights of health care insurance and procedures in order to use those rights. A patient has a right for information concerning names and professional status of healthcare workers involved in diagnostics and treatment of the diseases, etc.		Health Institution (specific for each institution).
	<i>ED National Representative</i>						
SE	<i>ECIBC National Contacts</i>	NO, BUT PLANNED	At the moment there is an ongoing investigation whether this process should be regulated in Sweden.	NO, BUT PLANNED	Work is ongoing to organise and standardise care with referring timelines (e.g. waiting time). For breast cancer this will be launched in 2016. Communication of the diagnosis and treatment plan is generally given as stated in the definition above.	YES, VOLUNTARY	The main requirement is that all patients should be discussed at MDM before and after surgery (See National Guidelines for the Treatment of Breast Cancer). Link: http://www.socialstyrelsen.se/Lists/Artikelkatalog/Attachments/19383/2014-4-2.pdf At page 22 it reads (translation): The MDM should include a breast surgeon, a breast oncologist,

Country		C1. Is there a requirement that regulates new patient clinics?	C1-C2 Patient clinics details/comments	D1. Is there a requirement that regulates the communication of the diagnosis and treatment plan?	D2-D3 Communication details/comments	E1. Is there a requirement that regulates Multidisciplinary case management meetings (MDM)?	E2-E3 MDM details/comments
SE							a radiologist, a pathologist and a contact nurses (or breast care nurse). Follow up from 2013 showed that before surgery 97 % had a MDM, and after surgery 98% of patients with newly diagnosed breast cancer.
	<i>ED National Representative</i>	NO	A waiting time according to Chapter 5 (within 10 working days) is not at all applicable in Sweden - nor the communication of outcome at the same visit. Sweden is now planning to adopt the Danish system to reduce waiting time and recently analysed five diagnostic processes. For 2016 another ten are planned, including diagnosis of breast cancer.	NO	See comment in previous question (C1)	YES	As for other requirements, non-harmonised application of guidelines is observed depending on the county, causing unequal care and services throughout Sweden.
SI	<i>ECIBC National Contacts</i>	NO, BUT PLANNED		NO, BUT PLANNED		YES, MANDATORY	The decision of proper diagnostic procedure and therapy is defined at the Multidisciplinary Case Management Meetings.
	<i>ED National Representative</i>	YES	They are available at: http://www.dpor.si/en/	YES		YES	

Country		C1. Is there a requirement that regulates new patient clinics?	C1-C2 Patient clinics details/comments	D1. Is there a requirement that regulates the communication of the diagnosis and treatment plan?	D2-D3 Communication details/comments	E1. Is there a requirement that regulates Multidisciplinary case management meetings (MDM)?	E2-E3 MDM details/comments
SK	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	Only at oncology institutes and university hospitals.	YES, MANDATORY	The National Guidelines for Breast Cancer Diagnosis and Treatment, issued by the Ministry of Health in 2009, and the National Guidelines for Screening Mammography, issued by the Ministry of Health in 2005.	YES, VOLUNTARY	MDM's are only organised in oncology centres and in some university hospitals.
	<i>ED National Representative</i>						
TR	<i>ECIBC National Contacts</i>						
	<i>ED National Representative</i>	YES		YES		YES	
UK	<i>ECIBC National Contacts</i>	YES, MANDATORY	Defined in the national peer review process as per the 2006 European Guidelines definition. It is nationally mandated that all patients with a breast symptom are seen within 14 days (10 working days) of referral.	YES, MANDATORY	There are specific measures stated in the peer review guidelines on patient communication. The MDT should be offering patients the opportunity of a permanent record or summary of at least a consultation between patient and doctor when the following are discussed: diagnosis; treatment options and plan; relevant follow up (discharge) arrangements. The MDT should provide written material	YES, MANDATORY	Mandated via the national peer review measures. There should be an operational policy for the team whereby it is intended that all new cancer patients will be reviewed by a multidisciplinary team for discussion of initial treatment plan. The policy should specify at what other stages in the patient pathway patients are referred back for discussion.

Country		C1. Is there a requirement that regulates new patient clinics?	C1-C2 Patient clinics details/comments	D1. Is there a requirement that regulates the communication of the diagnosis and treatment plan?	D2-D3 Communication details/comments	E1. Is there a requirement that regulates Multidisciplinary case management meetings (MDM)?	E2-E3 MDM details/comments
UK					<p>for patients and carers which includes: information specific to that MDT about local provision of the services offering treatment for that cancer site; information about patient involvement groups and patient self-help groups; information about the services offering psychological, social and spiritual/ cultural support, if available; information specific to the MDT's cancer site or group of cancers about the disease and its treatment options (including names and functions/roles of the team treating them); information about services available to support the effects of living with cancer and dealing with its emotional effects. The core MDT, at their regular meetings should agree and</p>		

Country		C1. Is there a requirement that regulates new patient clinics?	C1-C2 Patient clinics details/comments	D1. Is there a requirement that regulates the communication of the diagnosis and treatment plan?	D2-D3 Communication details/comments	E1. Is there a requirement that regulates Multidisciplinary case management meetings (MDM)?	E2-E3 MDM details/comments
UK					record individual patient's treatment plans which includes: the identity of patients discussed; the multidisciplinary treatment planning decision (i.e. to which modality(s) of treatment - surgery, radiotherapy, chemotherapy, hormone therapy or supportive care or combinations of the same, that are to be referred for consideration).		
	<i>ED National Representative</i>	YES		YES		YES	

Table 10: *Survey section 6.*

Breast Units non-mandatory requirements implementation stage.

Questions:

F. Facilities/ Services (9.7.4)

Definition from the 2006 European Guidelines

Physiotherapy

Physiotherapy must be available for the post-operative recovery period to ensure good shoulder mobility, etc.

ECIBC:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the provision of physiotherapy as defined above? * YES, MANDATORY; YES, VOLUNTARY; NO, BUT PLANNED; NO and NOT PLANNED; I do not know
2. If you replied YES, please provide a more detailed description (*i.e.* name of legislation/quality assurance scheme, link to the text or reference document)
3. If you wish, please add below your comments/considerations on the provision of physiotherapy voluntary requirement

ED:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the provision of physiotherapy as defined above? YES; NO; I do not have this information
2. If you wish, please add below your comments/considerations on the provision of physiotherapy voluntary requirement

G. Facilities/ Services (9.7.5)

Definition from the 2006 European Guidelines

Adjuvant therapies

The multidisciplinary team (MDT) must decide on the appropriate adjuvant therapies in light of the pathology of the surgical specimen.

Radiotherapy may be delivered within the same hospital or patients may have to travel to a Radiotherapy Unit in another Hospital (at which the core team radiation oncologist must be able to supervise their treatment).

The administration of cytotoxic therapy as adjuvant therapy or for advanced disease must be by an accredited oncologist (member of the core team) with proper facilities. Cytotoxic therapies may be given in another hospital but the decisions regarding their application must be made by the MDT of the Unit.

ECIBC:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the provision of adjuvant therapies as defined above? * YES, MANDATORY; YES, VOLUNTARY; NO, BUT PLANNED; NO and NOT PLANNED; I do not know
2. If you replied YES, please provide a more detailed description (*i.e.* name of legislation/quality assurance scheme, link to the text or reference document)
3. If you wish, please add below your comments/considerations on the provision of adjuvant therapies voluntary requirement

ED:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the provision of adjuvant therapies as defined above? YES; NO; I do not have this information
2. If you wish, please add below your comments/considerations on the provision of adjuvant therapies voluntary requirement

H. Facilities / Services (9.7.6)

Definition from the 2006 European Guidelines

Advanced and recurrent Breast Cancer

There must be one Advanced Breast Cancer Clinic at least every 2 weeks at the Breast Unit, separate from the general oncology clinics (although sometimes combined with gynaecological oncology) and attended by the Clinical Oncologist ± Medical Oncologist (see 9.5.2.5 b). The surgeon must be available if required for consultation and must be in full attendance if the breast surgeons supervise the endocrine therapies. Patients with distant metastases locally advanced primary breast cancer and local or regional recurrence, must be managed in this clinic according to protocols agreed by the multidisciplinary team.

Patients who have received radiotherapy or chemotherapy at another Cancer Centre should normally be referred back to the Breast Team at their Breast Unit for further follow-up and decision making in the Advanced Breast Cancer Clinic.

A palliative care/pain control service must be easily accessible.

ECIBC:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the management of advanced and recurrent breast cancer as defined above? * YES, MANDATORY; YES, VOLUNTARY; NO, BUT PLANNED; NO and NOT PLANNED; I do not know
2. If you replied YES, please provide a more detailed description (*i.e.* name of legislation/quality assurance scheme, link to the text or reference document)
3. If you wish, please add below your comments/considerations on the management of advanced and recurrent breast cancer voluntary requirement

ED:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the management of advanced and recurrent breast cancer as defined above? YES; NO; I do not have this information
2. If you wish, please add below your comments/considerations on the management of advanced and recurrent breast cancer voluntary requirement

Country		F1. Is there a requirement that regulates physiotherapy?	F2-F3 Physiotherapy details/comments	G1. Is there a requirement that regulates provision of adjuvant therapies?	G2-G3 Adjuvant therapy details/comments	H1. Is there a requirement that regulates management of advanced and recurrent breast cancer?	H2-H3 Advanced and recurrent breast cancer details/comments
AT	<i>ECIBC National Contacts</i>						
	<i>ED National Representative</i>	YES	Every certified breast cancer unit has a physiotherapist and lymphologist specialised in treating breast cancer patients.	YES	The decisions are made during MDMs. Each unit has one or more radiotherapy and oncology departments. In special cases, the gynaeco-oncologists are responsible for chemotherapy.	YES	There are regular clinics for these patients with two core team members: radiotherapist and oncologist. For every patient, a responsible in charge of care is identified within the unit. Still manageable patients are discussed during the MDM. Otherwise, palliation and pain control are provided in the units.
BE	<i>ECIBC National Contacts</i>	YES, MANDATORY	Physiotherapy is included in the Royal Decree 26 April 2007 as a requirement for a breast unit.	YES, MANDATORY	It is a mandatory requirement included in the Royal Decree 26 April 2007, for recognition of a breast unit.	NO and NOT PLANNED	
	<i>ED National Representative</i>						
BG	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	Accreditation requirements of the National Hospital of Oncology	YES, MANDATORY	There are Ministry of Health and National Health Insurance Fund documents as well as accreditation requirements for the National Hospital of Oncology.	YES, MANDATORY	There are Ministry of Health and National Health Insurance Fund documents as well as accreditation requirements for the National Hospital of Oncology.
	<i>ED National Representative</i>						

Country		F1. Is there a requirement that regulates physiotherapy?	F2-F3 Physiotherapy details/comments	G1. Is there a requirement that regulates provision of adjuvant therapies?	G2-G3 Adjuvant therapy details/comments	H1. Is there a requirement that regulates management of advanced and recurrent breast cancer?	H2-H3 Advanced and recurrent breast cancer details/comments
CH	<i>ECIBC National Contacts</i>	NO and NOT PLANNED		NO and NOT PLANNED		NO and NOT PLANNED	
	<i>ED National Representative</i>	I do not have this information.		I do not have this information.		I do not have this information.	
CY	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	Physiotherapy is regularly provide , though it is not regulated yet as a mandatory practice.	YES, VOLUNTARY	No legislative framework yet.	YES, VOLUNTARY	There is a breast cancer clinic operating once a week.
	<i>ED National Representative</i>	NO		YES		NO	
CZ	<i>ECIBC National Contacts</i>	YES, MANDATORY	Physiotherapy will begin after surgery. Physiotherapy is part of comprehensive cancer treatment, with emphasis on drainage to prevent lymphedema.	YES, MANDATORY	Adjuvant therapy is indicated under Czech standards of cancer care, the so-called "Blue Book", based on the recommendations of ASCO, ESMO, NCCN.	YES, VOLUNTARY	Oncological therapy of advanced breast cancer is indicated under Czech standards of cancer care, the so-called blue book, based on the recommendations of ASCO, ESMO, NCCN.
	<i>ED National Representative</i>						
DE	<i>ECIBC National Contacts</i>	YES, MANDATORY	Agreements with other treatment partners: Written agreements in which willingness to engage in cooperation is confirmed are to be signed with treatment partners for the following: Psycho-oncology; Social services; Self-help; Genetic counselling; Gene analysis, family	YES, MANDATORY	The requirements regulating the provision of adjuvant therapies are laid down in Chapter 6.2 (pages 29 et seq.) and 7 (pages 33 et seq.) of the Catalogue of Requirements, see: https://www.krebsgesellschaft.de/gcs/german-cancer-society/certifi-	YES, MANDATORY	The requirements regulating the management of advanced and recurrent breast cancer are described in Chapter 1.2.4 and Chapter 9 of the Catalogue of Requirements, see: https://www.krebsgesellschaft.de/gcs/german-cancer-society/certifi-

Country		F1. Is there a requirement that regulates physiotherapy?	F2-F3 Physiotherapy details/comments	G1. Is there a requirement that regulates provision of adjuvant therapies?	G2-G3 Adjuvant therapy details/ comments	H1. Is there a requirement that regulates management of advanced and recurrent breast cancer?	H2-H3 Advanced and recurrent breast cancer details/ comments
DE			anamnesis (BRCA-1, BRCA-2) and genetic counselling; Physiotherapy; Laboratory (with a round robin test certification); Hospice/palliative medicine; Medical aids supplier; The following points can, for example, be regulated in the agreements with the treatment partners: Cooperation on further training measures and public relations work; Description of the cooperation and interfaces; Type of communication between the two parties; Confidentiality; (see Catalogue of Requirements, Chapter 1.1.2)		cation/documents. html?file=files/dkg/german-cancer-society/pdf/Certification/Catalogue%20of%20Req%20breast-H1%201%20%2814%2007%202016%29%20EN.pdf.		cation/documents. html?file=files/dkg/german-cancer-society/pdf/Certification/Catalogue%20of%20Req%20breast-H1%201%20%2814%2007%202016%29%20EN.pdf.
	<i>ED National Representative</i>						
EE	<i>ECIBC National Contacts</i>						
	<i>ED National Representative</i>	YES		YES		YES	
ES	<i>ECIBC National Contacts</i>						
	<i>ED National Representative</i>	NO		NO		NO	
FI	<i>ECIBC National Contacts</i>	YES, MANDATORY	Physiotherapist should be available based on	YES, VOLUNTARY	The adjuvant therapy is decided during the	YES, VOLUNTARY	The recurrent breast cancer cases are

Country		F1. Is there a requirement that regulates physiotherapy?	F2-F3 Physiotherapy details/comments	G1. Is there a requirement that regulates provision of adjuvant therapies?	G2-G3 Adjuvant therapy details/comments	H1. Is there a requirement that regulates management of advanced and recurrent breast cancer?	H2-H3 Advanced and recurrent breast cancer details/comments
FI			patients' needs. Every patient receives personal guidance on how to reach normal mobility of the shoulder by a physiotherapist during their hospital stay for the primary surgical treatment.		MDM, and the primary oncologist (or her/his substitute) responsible for breast cancer will be the person ultimately deciding the treatment. The Finnish Breast Cancer Group (FBCG) consists of breast cancer specialists from all university areas in Finland; the FBCG also writes the national guidelines. Thus, people responsible of the breast cancer treatment in each region are also involved in writing the guidelines.		discussed during the MDM (if needed) or in a meeting with several expert oncologists within the clinic. Otherwise, the person responsible for breast cancer treatment is at least consulted. National guidelines are followed similarly as in the case of adjuvant treatment (please see above).
	<i>ED National Representative</i>						
FR	<i>ECIBC National Contacts</i>	NO and NOT PLANNED	See 4vii comments	NO and NOT PLANNED		NO and NOT PLANNED	See 4vii comments
	<i>ED National Representative</i>	NO	Support care is given by a number of hospitals (generally public). Some associations do offer it for free.	YES	As required by INCa and the French Health Authority.	I do not have this information.	Normally are managed during MDMs.
GR	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	Out of the 13 breast centres that answered the questionnaire, only two responded that they have Physiotherapy section but they are not specialised	YES, VOLUNTARY	Regarding Radiotherapy: six out of the 13 hospital consulted for this questionnaire stated to have a Radiotherapeutic Department which is under	NO, BUT PLANNED	It is correct to distinguish the breast cancer clinic with metastatic breast cancer or locally advanced from local regional recurrence. The new

Country		F1. Is there a requirement that regulates physiotherapy?	F2-F3 Physiotherapy details/comments	G1. Is there a requirement that regulates provision of adjuvant therapies?	G2-G3 Adjuvant therapy details/ comments	H1. Is there a requirement that regulates management of advanced and recurrent breast cancer?	H2-H3 Advanced and recurrent breast cancer details/ comments
GR			in lymphoedema treatment. I totally agree with the 2006 European Guidelines requirement.		“Quality Control” guidelines. Regarding the Cytotoxic Therapy: ten out of 13 hospitals have Cytotoxic Therapy Department. The majority of them follow St. Gallen consensus meetings and/ or ASCO guidelines.		case should be treated separately but such a procedure is not applied in breast centres. Furthermore, medical oncologists usually keep the patients that they treat in the same department, given that patients generally do not come back to the breast centre. The same attitude occurs with radiotherapists. There is no palliative care/pain service that is easily accessible in every hospital.
	<i>ED National Representative</i>	NO		NO		NO	
HU	<i>ECIBC National Contacts</i>	NO, BUT PLANNED		YES, MANDATORY	See as above on MDM decisions.	YES, MANDATORY	All changes in systemic or local therapies should be discussed during the MDM session
	<i>ED National Representative</i>						
IE	<i>ECIBC National Contacts</i>	YES, VOLUNTARY		YES, VOLUNTARY	There are guidelines with regard the waiting times for medical oncology.	NO and NOT PLANNED	
	<i>ED National Representative</i>	YES		YES		YES	

Country		F1. Is there a requirement that regulates physiotherapy?	F2-F3 Physiotherapy details/comments	G1. Is there a requirement that regulates provision of adjuvant therapies?	G2-G3 Adjuvant therapy details/comments	H1. Is there a requirement that regulates management of advanced and recurrent breast cancer?	H2-H3 Advanced and recurrent breast cancer details/comments
IT	<i>ECIBC National Contacts</i>	YES, MANDATORY	The state-regions agreement issued 18 December 2014 considers physiotherapy as a component of general psycho-physical rehabilitation.	YES, MANDATORY	State-regions agreement issued 18 December 2014.	YES, VOLUNTARY	State-regions agreement issued 18 December 2014.
	<i>ED National Representative</i>	YES	See document from the Italian Ministry of Health (18 December 2014 Rep. Atti 185/ CSR).	YES	See document from the Italian Ministry of Health (18 December 2014 Rep. Atti 185/ CSR).	YES	See document from the Italian Ministry of Health (18 December 2014 Rep. Atti 185/ CSR).
LT	<i>ECIBC National Contacts</i>	YES, MANDATORY	Regulated by breast cancer diagnosis and treatment standards in Lithuania and the NCI.	YES, MANDATORY	Every time approved during the MDT meeting (surgeons, radiologists, radiotherapy oncologists, medical oncologists, pathologists, and geneticist). Regulated by breast cancer diagnosis and treatment standards in Lithuania and the NCI. In some cases an individual approach to the case is possible.	YES, MANDATORY	Cases of advanced or recurrent disease are discussed either in the Department of Conservative Treatment (medical oncology and radiotherapy - 1 time a week) or during the MDT as mentioned above.
	<i>ED National Representative</i>						
LU	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	Physiotherapists are well trained, but no one is doing only breast cancer treatment due to low volume.	NO, BUT PLANNED	Will be adopted in the framework of the cancer plan guidelines on breast cancer management. Almost all breast cancer patients are treated at the National Radiotherapy	NO, BUT PLANNED	Will be adopted in the framework of the cancer plan guidelines on breast cancer management.

Country		F1. Is there a requirement that regulates physiotherapy?	F2-F3 Physiotherapy details/comments	G1. Is there a requirement that regulates provision of adjuvant therapies?	G2-G3 Adjuvant therapy details/ comments	H1. Is there a requirement that regulates management of advanced and recurrent breast cancer?	H2-H3 Advanced and recurrent breast cancer details/ comments
LU					Centre or in Germany (cross border- because the location is closer to the residence of the patients). All adjuvant treatments are delivered at the five hospitals. The health insurance company covers 100% of the costs.		
	<i>ED National Representative</i>	NO	There is no requirement but ED Luxembourg has coordinated the training of 200 physiotherapists to manual treatment of lymphoedema. Their addresses are published on the ED Luxembourg website.	NO		NO	
LV	<i>ECIBC National Contacts</i>	NO and NOT PLANNED		NO and NOT PLANNED		NO and NOT PLANNED	
	<i>ED National Representative</i>						
MT	<i>ECIBC National Contacts</i>	NO, BUT PLANNED	Post-operative physiotherapy support is available at the acute hospital (MDH). A dedicated breast care team assess all patients prior to surgery and supports post-operatively. Cases are continually followed for any secondary mobility complications	NO, BUT PLANNED	Adjuvant therapies (radiotherapy and cytotoxic therapy) are given at the Oncology Department. This department presently resides in another hospital outside MDH. The Oncology Department is migrating to a new purposely built Oncology Centre (which is	NO, BUT PLANNED	Patients with advanced and recurrent breast cancer are seen and managed at the BU in MDH as well as at the Oncology Department. These cases are also discussed during MDT meetings. Patients who finished treatment and are 'disease free' are seen

Country		F1. Is there a requirement that regulates physiotherapy?	F2-F3 Physiotherapy details/comments	G1. Is there a requirement that regulates provision of adjuvant therapies?	G2-G3 Adjuvant therapy details/comments	H1. Is there a requirement that regulates management of advanced and recurrent breast cancer?	H2-H3 Advanced and recurrent breast cancer details/comments
MT			either at out-patient level within the acute hospital or at the Oncology Hospital.		located adjacent to MDH), the Sir Anthony Mammo-Oncology Centre, which became fully operational in the summer of 2015. The new Centre has upgraded radiotherapy facilities.		at minimum 6-month intervals (alternating between appointments at the breast unit and the Oncology Department).
	<i>ED National Representative</i>	NO		NO		YES	
NL	<i>ECIBC National Contacts</i>						
	<i>ED National Representative</i>	YES		YES		YES	
NO	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	There is a national action programme with guidelines for diagnostics, treatment and follow up of patients with breast cancer (Norwegian Breast Cancer Group): http://www.helsebiblioteket.no/retningslinjer/brystkreft/forord;jsessionid=658DCBE4660D8DoFEo8364EFEE27CBEE?hideme=true . Standardised patient assessment and treatment processes ("package processes") for breast cancer.	YES, MANDATORY	The national action programme includes guidelines for diagnostics, treatment, and follow up of patients with breast cancer (Norwegian Breast Cancer Group). It standardised patient assessment and treatment processes ("package processes") for breast cancer.	YES, MANDATORY	The national action programme includes guidelines for diagnostics, treatment, and follow up of patients with breast cancer (Norwegian Breast Cancer Group). It standardised patient assessment and treatment processes ("package processes") for breast cancer.
	<i>ED National Representative</i>	YES		YES		YES	

Country		F1. Is there a requirement that regulates physiotherapy?	F2-F3 Physiotherapy details/comments	G1. Is there a requirement that regulates provision of adjuvant therapies?	G2-G3 Adjuvant therapy details/comments	H1. Is there a requirement that regulates management of advanced and recurrent breast cancer?	H2-H3 Advanced and recurrent breast cancer details/comments
PL	<i>ECIBC National Contacts</i>	i do not know		YES, MANDATORY	See Polish Parliament Act of 22 July 2014 (Journal of Laws No. 1138) on change of law on healthcare services financed by public resources.	NO and NOT PLANNED	
	<i>ED National Representative</i>						
PT	<i>ECIBC National Contacts</i>	NO, BUT PLANNED		NO, BUT PLANNED		NO, BUT PLANNED	
	<i>ED National Representative</i>						
RO	<i>ECIBC National Contacts</i>	NO and NOT PLANNED		YES, VOLUNTARY	http://jradonco.ro/upd/display_paper.php?id-file=V19_No2_2013_pp005 .	NO and NOT PLANNED	
	<i>ED National Representative</i>						
RS	<i>ECIBC National Contacts</i>	NO, BUT PLANNED	Some centres have a specialist for physiotherapy and physiotherapists, while the others refer their patients to specialised healthcare institutions for physiotherapy.	YES, MANDATORY	The MDT team is in charge of deciding the appropriate adjuvant therapies. Each institution is in charge of organising the work of the MDT. Usually there are more than one MDT in one institution. In our country, in institutions that provide oncology healthcare, the 2006 European Guidelines recommendation for composition of MDT is strictly followed.	NO and NOT PLANNED	All breast cancer patients in all stages are treated and monitored in the same units. There is no Advanced Breast Cancer Clinics in Serbia defined as formally independent clinics.

Country		F1. Is there a requirement that regulates physiotherapy?	F2-F3 Physiotherapy details/comments	G1. Is there a requirement that regulates provision of adjuvant therapies?	G2-G3 Adjuvant therapy details/comments	H1. Is there a requirement that regulates management of advanced and recurrent breast cancer?	H2-H3 Advanced and recurrent breast cancer details/comments
RS					All specialised oncology institutions have MDTs. Independent MDTs: IORS Serbia, Institute for Oncology of Vojvodina, Sremska Kamenica, Clinical Center Serbia, Clinical Center Niš, Clinical Center Kragujevac, Military Medical Academy. Not fully independent MDTs with visiting experts from previously listed institutions: Hospital Bežanijska Kosa (KBC), general hospitals (Valjevo, Bor, Šabac, Cacak, Kladovo, Loznica, and Užice).		
	<i>ED National Representative</i>						
SE	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	F2-F3 Physiotherapy details/comments: Physiotherapy is available at most breast units. Prophylactic programmes and educational sessions are also available at these units.	YES, VOLUNTARY	All radiotherapy is delivered at dedicated radiation units, often nearby most of the breast units. At a few of the smaller hospitals, chemotherapy is mostly delivered by oncologist from nearby bigger breast units.	YES, VOLUNTARY	At the major units patients with advanced and recurrent breast cancer are managed on weekdays by oncologists.
	<i>ED National Representative</i>	YES	Depends on the country. In some of them patients have to find	YES	Depends on the country. Radiotherapy is mainly available at	YES	Depends on the country. Patients with a recurrence, ABC or

Country		F1. Is there a requirement that regulates physiotherapy?	F2-F3 Physiotherapy details/comments	G1. Is there a requirement that regulates provision of adjuvant therapies?	G2-G3 Adjuvant therapy details/ comments	H1. Is there a requirement that regulates management of advanced and recurrent breast cancer?	H2-H3 Advanced and recurrent breast cancer details/ comments
SE			assistance within the private care.		university hospitals and at other radiotherapy units. Chemotherapy is delivered at university hospitals and at other hospitals - either linked to a university hospital where a "movable" oncology unit is present or available one to few days per week.		MBC are generally treated at the university clinics or related smaller units.
SI	ECIBC National Contacts	YES, VOLUNTARY	Post-operative physiotherapy is offered to all operated patients.	YES, MANDATORY	The decision of proper adjuvant therapy is defined at the Multidisciplinary Case Management Meetings.	YES, MANDATORY	The decision of proper management of advanced and recurrent breast cancer is determined at the Multidisciplinary Case Management Meetings.
	ED National Representative	NO		YES		NO	
SK	ECIBC National Contacts	YES, VOLUNTARY	In oncology centres and university (teaching) hospitals.	YES, MANDATORY	The majority of patients are treated in special oncologic centres (adjuvant chemotherapy and radiotherapy).	i do not know	
	ED National Representative						
TR	ECIBC National Contacts						
	ED National Representative	YES		YES		YES	

Country		F1. Is there a requirement that regulates physiotherapy?	F2-F3 Physiotherapy details/comments	G1. Is there a requirement that regulates provision of adjuvant therapies?	G2-G3 Adjuvant therapy details/comments	H1. Is there a requirement that regulates management of advanced and recurrent breast cancer?	H2-H3 Advanced and recurrent breast cancer details/comments
UK	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	The physiotherapist is considered to be a member of the extended multi-disciplinary team and is governed by the measure as outlined below: The MDT should provide the names of members of the extended team for named roles in the team if they are not already offered as core team members. The named extended team for the breast MDT should include: • a core member of the specialist palliative care team; • breast radiographer; • psychiatrist or clinical psychologist; • plastic/reconstructive surgeon; • clinical geneticist/genetics counsellor; • physiotherapist/lymphoedema/practitioner.	YES, MANDATORY	Mandated via the national peer review process, each region (network) of England has to have specific network wide guidelines for treatment, and all patients are discussed at a multi-disciplinary team meeting to decide adjuvant treatment. The Network Site Specific Group (NSSG) should agree network-wide clinical guidelines (how a given patient should be clinically managed), usually at the level of which modality of treatment is indicated. The NSSG, in consultation with the Network Chemotherapy Group (NCG) should agree a list of acceptable chemotherapy treatment algorithms. It should be updated bi-annually than detailed regimens or surgical techniques).	YES, VOLUNTARY	This would be a broad recommendation and would be the standard of care in most breast units, although this is not mandated or included as a measure in the peer review guidance.
	<i>ED National Representative</i>	YES		YES		YES	

Table 11: Survey section 6.

Breast Units non-mandatory requirements implementation stage.

Questions:

I. Facilities / Services (9.7.7)

Definition from the 2006 European Guidelines

Follow-up of primary breast cancer

All patients with primary breast cancer must be followed-up in a Clinic directly supervised by one of the surgeons. Any necessary imaging or other investigations should be carried out at the same visit.

Although the patient may have to visit a separate Hospital to receive radiotherapy or specialised chemotherapy, the decisions on the case management and the subsequent follow-up should be by the team members of her Breast Unit. The skills of the diagnostic breast team are then available for the detection and investigation of a possible recurrence.

ECIBC:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the follow-up of primary breast cancer as defined above? * YES, MANDATORY; YES, VOLUNTARY; NO, BUT PLANNED; NO and NOT PLANNED; I do not know
2. If you replied YES, please provide a more detailed description (*i.e.* name of legislation/quality assurance scheme, link to the text or reference document)
3. If you wish, please add below your comments/considerations on the follow-up of primary breast cancer voluntary requirement

ED:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the follow-up of primary breast cancer as defined above? YES; NO; I do not have this information
2. If you wish, please add below your comments/considerations on the follow-up of primary breast cancer voluntary requirement

J. Facilities/ Services (9.7.8)

Definition from the 2006 European Guidelines

Benign disease

The Breast Unit must also advise and where necessary treat women with benign disease (e.g. cysts, fibroadenoma, mastalgia, inflammatory conditions, mammillary fistula and phyllodes tumour).

ECIBC:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the management of benign disease as defined above? * YES, MANDATORY; YES, VOLUNTARY; NO, BUT PLANNED; NO and NOT PLANNED; I do not know
2. If you replied YES, please provide a more detailed description (*i.e.* name of legislation/quality assurance scheme, link to the text or reference document)
3. If you wish, please add below your comments/considerations on the management of benign disease voluntary requirement

ED:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the management of benign disease as defined above? YES; NO; I do not have this information
2. If you wish, please add below your comments/considerations on the management of benign disease voluntary requirement

K. Facilities/ Services (9.7.9)

Definition from the 2006 European Guidelines

Family History/genetics

Advice is best given in a multidisciplinary clinic, the specialists involved are a clinical geneticist and from the team a breast surgeon with reconstructive skills, radiologist and psy-

chiatrist or clinical psychologist. Gene probing must be available when required and ideally a molecular geneticist should be accessible for consultation by the specialists in the clinic.

ECIBC:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the management of family history/genetics as defined above? * YES, MANDATORY; YES, VOLUNTARY; NO, BUT PLANNED; NO and NOT PLANNED; I do not know
2. If you replied YES, please provide a more detailed description (*i.e.* name of legislation/quality assurance scheme, link to the text or reference document)
3. If you wish, please add below your comments/considerations on the management of family history/genetics voluntary requirement

ED:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the management of family history/genetics as defined above? YES; NO; I do not have this information
2. If you wish, please add below your comments / considerations on the management of family history/genetics voluntary requirement

Country		I1. Is there a requirement that regulates the follow-up of primary breast cancer?	I2-I3 Primary breast cancer details/ comments	J1. Is there a requirement that regulates the management of benign disease?	J2-J3 Benign disease details/comments	K1. Is there a requirement that regulates the management of family history/genetics?	K2-K3 Family history/genetics details/comments
AT	<i>ECIBC National Contacts</i>						
	<i>ED National Representative</i>	YES	The follow up of each patient is secured in the units. One discipline, usually the surgeon / gynaecologist, is responsible, sometimes together with radiotherapist and / or oncologist.	YES	All breast units are able to treat women with benign disease as the surgeons and gynaecologists are not only responsible for cancer patients but for all patients with breast diseases.	YES	The ÖZK catalogue defines the requirements for family history/genetics in accordance with the 2006 European Guidelines.
BE	<i>ECIBC National Contacts</i>	YES, MANDATORY		NO and NOT PLANNED		YES, MANDATORY	The Royal Decree of 26 April 2007 specifies that breast units must have an agreement with a centre for human genetics to provide genetic counselling.
	<i>ED National Representative</i>						
BG	<i>ECIBC National Contacts</i>	YES, MANDATORY	There are Ministry of Health and National Health Insurance Fund documents as well as accreditation requirements for the National Hospital of Oncology.	YES, MANDATORY	There are Ministry of Health and National Health Insurance Fund documents as well as accreditation requirements for the National Hospital of Oncology.	YES, VOLUNTARY	There are Ministry of Health and National Health Insurance Fund documents as well as accreditation requirements for the National Hospital of Oncology.
	<i>ED National Representative</i>						
CH	<i>ECIBC National Contacts</i>	NO and NOT PLANNED		NO and NOT PLANNED		NO and NOT PLANNED	
	<i>ED National Representative</i>	I do not have this information.		I do not have this information.		I do not have this information.	

Country		I1. Is there a requirement that regulates the follow-up of primary breast cancer?	I2-I3 Primary breast cancer details/comments	J1. Is there a requirement that regulates the management of benign disease?	J2-J3 Benign disease details/comments	K1. Is there a requirement that regulates the management of family history/genetics?	K2-K3 Family history/genetics details/comments
CY	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	The patients undergo follow up at regular intervals (e.g. monthly, every 3 months, 6 months, yearly).	YES, VOLUNTARY	See above.	YES, VOLUNTARY	The Institute of Neurology and Genetics is an associated partner and offers genetic counselling and gene probing services.
	<i>ED National Representative</i>	NO					
CZ	<i>ECIBC National Contacts</i>	YES, MANDATORY	Follow up of our breast cancer patients is governed by uniform rules of the Czech Oncological Society.	YES, VOLUNTARY	Patients with benign breast disease are followed in breast surgery clinics or in the department of gynaecology.	YES, MANDATORY	Genetic testing of patients is carried out under recommended conditions (ESMO). Carriers of genetic mutations and syndromes are observed in secondary prevention clinics in comprehensive centres.
	<i>ED National Representative</i>						
DE	<i>ECIBC National Contacts</i>	NO and NOT PLANNED	The Follow-up of primary breast cancer is described in Chapter 10 of the Catalogue of Requirements: https://www.krebsgesellschaft.de/gcs/german-cancer-society/certification/documents.html?file=files/dkg/german-cancer-society/pdf/Certification/Catalogue%20of%20Req%20breast-H1%201%20%2814%20	YES, MANDATORY	The requirements regulating the management of benign disease are described in Chapter 2.1.3 of the Catalogue of Requirements, see: https://www.krebsgesellschaft.de/gcs/german-cancer-society/certification/documents.html?file=files/dkg/german-cancer-society/pdf/Certification/Catalogue%20of%20	YES, MANDATORY	The requirements regulating the management of family history/genetics are described in Chapter 2.1.4 and Chapter 1.1.2 of the Catalogue of Requirements, see: https://www.krebsgesellschaft.de/gcs/german-cancer-society/certification/documents.html?file=files/dkg/german-cancer-society/pdf/Certification/

Country		I1. Is there a requirement that regulates the follow-up of primary breast cancer?	I2-I3 Primary breast cancer details/ comments	J1. Is there a requirement that regulates the management of benign disease?	J2-J3 Benign disease details/comments	K1. Is there a requirement that regulates the management of family history/genetics?	K2-K3 Family history/genetics details/comments
DE			07%202016%29%20 EN.pdf. This definition only focuses on the hospital (i.e. breast unit). In Germany, most therapies and follow-up of patients are performed through office-based doctors. They must be part of the certified network, must attend and present patients at the MDM.		Req%20breast-H1%201%20%2814%2007%202016%29%20 EN.pdf.		Catalogue%20of%20Req%20breast-H1%201%20%2814%2007%202016%29%20 EN.pdf. The questionnaire must be used for patients in order to detect a hereditary carcinomas is available at: https://www.krebsgesellschaft.de/deutsche-krebsgesellschaft-wtrl/deutsche-krebsgesellschaft/zertifizierung/erhebungsboegen/dokumente-im-ueberblick.html?file=-files/dkg/deutsche-krebsgesellschaft/content/pdf/Zertifizierung/Checklisten%20und%20Algorithmen/checkliste_erbliche_belastung_brust-a5-160330.xlsx (in German).
	<i>ED National Representative</i>						
EE	<i>ECIBC National Contacts</i>						
	<i>ED National Representative</i>	YES		YES		YES	

Country		I1. Is there a requirement that regulates the follow-up of primary breast cancer?	I2-I3 Primary breast cancer details/comments	J1. Is there a requirement that regulates the management of benign disease?	J2-J3 Benign disease details/comments	K1. Is there a requirement that regulates the management of family history/genetics?	K2-K3 Family history/genetics details/comments
ES	<i>ECIBC National Contacts</i>						
	<i>ED National Representative</i>	NO		NO		NO	
FI	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	Each hospital area has own follow-up guidelines. In the majority of hospital areas, follow-up (up to 5 years) is organised in the oncological clinics; otherwise, it is organised in surgical units. The FBCG has included in the national guidelines the minimum requirements for follow-up.	NO and NOT PLANNED	Benign breast lesions are investigated in collaboration with the radiologist, surgeon and pathologist; the oncologist is also consulted. Unclear cases may be discussed at the MDM, if needed.	YES, VOLUNTARY	In case of strong family history (or other reason), the patient can be referred to a geneticist, available in all hospitals, by the doctor (family doctor, surgeon, oncologist, etc.). There is also a system organised by the Cancer Society of Finland, in which the healthy relatives of patients with strong family history can get genetic counselling and referral to a university hospital for genetic testing consideration. The FBCG has recommended clear criteria for family history for referring patients to genetic counselling
	<i>ED National Representative</i>						
FR	<i>ECIBC National Contacts</i>	NO and NOT PLANNED	See 4vii comments	NO and NOT PLANNED	See 4vii comments	NO and NOT PLANNED	See 4vii comments
	<i>ED National Representative</i>	YES	It is supervised by surgeon or medical oncologist on a regular basis.	YES		YES	

Country		I1. Is there a requirement that regulates the follow-up of primary breast cancer?	I2-I3 Primary breast cancer details/ comments	J1. Is there a requirement that regulates the management of benign disease?	J2-J3 Benign disease details/comments	K1. Is there a requirement that regulates the management of family history/genetics?	K2-K3 Family history/genetics details/com-ments
GR	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	On voluntary basis the breast centre counts on the fact that the patient will remain in the same breast centre. A major problem arises with patients who are residents in counties far from Athens or other major cities like Thessaloniki or Ioannina where most of the breast centres are located. During their follow-up, patients may decide to be monitored by doctors who are near-by their home.	YES, VOLUNTARY	Usually patients visit at least two or three different doctors to receive other opinions regarding their case.	YES, VOLUNTARY	Six hospitals out of 13 reported to have a geneticist as a collaborator. Since the cost of a genetic laboratory is very high, a possible alternative would be to have a counselling geneticist or a skilled nurse specialised on hereditary breast cancer within every breast centre.
	<i>ED National Representative</i>	NO		NO		NO	
HU	<i>ECIBC National Contacts</i>	YES, VOLUNTARY		NO and NOT PLANNED		NO, BUT PLANNED	In case of familiarity, it is recommended to screen for genetic background.
	<i>ED National Representative</i>						
IE	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	Follow-up for 5 years followed by annual mammography.	YES, VOLUNTARY	Patients seen within 12 weeks and imaged as appropriate.	YES, VOLUNTARY	There are national guidelines.
	<i>ED National Representative</i>	YES	Follow up includes where possible imaging and other investigations.	I do not have this information.		YES	

Country		I1. Is there a requirement that regulates the follow-up of primary breast cancer?	I2-I3 Primary breast cancer details/comments	J1. Is there a requirement that regulates the management of benign disease?	J2-J3 Benign disease details/comments	K1. Is there a requirement that regulates the management of family history/genetics?	K2-K3 Family history/genetics details/comments
IT	<i>ECIBC National Contacts</i>	YES, MANDATORY	State-regions agreement issued 18 December 2014.	NO and NOT PLANNED	The state-regions Agreement issued 18 December 2014 does not cover treatment of benign diseases which is left to local management. The Italian screening guidelines do not recommend treatment of benign lesions.	YES, MANDATORY	State-regions agreement issued 18 December 2014.
	<i>ED National Representative</i>	YES	See document from the Italian Ministry of Health (18 December 2014 Rep. Atti 185/CSR).	YES	See document from the Italian Ministry of Health (18 December 2014 Rep. Atti 185/CSR).	YES	See document from the Italian Ministry of Health (18 December 2014 Rep. Atti 185/CSR).
LT	<i>ECIBC National Contacts</i>	YES, MANDATORY	Patients for follow-up are supervised by medical oncologists or surgeons.	YES, MANDATORY	The NCI has separate recommendations for registration and waiting times as well as follow-up recommendations for different benign breast pathology cases.	YES, MANDATORY	Patients are referred to genetics consultation by medical oncologists, surgeons or MDT. All women with known BRCA 1-2 mutations are offered breast MRI for surveillance.
	<i>ED National Representative</i>						
LU	<i>ECIBC National Contacts</i>	NO, BUT PLANNED	Will be adopted in the framework of the cancer plan guidelines on breast cancer management.	NO and NOT PLANNED		NO, BUT PLANNED	Will be implemented for high risk women in the framework of the cancer plan guidelines on breast cancer management.
	<i>ED National Representative</i>	NO		NO		NO	Working groups discussing this topic are in place.

Country		I1. Is there a requirement that regulates the follow-up of primary breast cancer?	I2-I3 Primary breast cancer details/ comments	J1. Is there a requirement that regulates the management of benign disease?	J2-J3 Benign disease details/comments	K1. Is there a requirement that regulates the management of family history/genetics?	K2-K3 Family history/genetics details/com-ments
LV	<i>ECIBC National Contacts</i>	NO and NOT PLANNED		NO and NOT PLANNED		NO and NOT PLANNED	
	<i>ED National Representative</i>						
MT	<i>ECIBC National Contacts</i>	NO, BUT PLANNED	Patients who finished treatment and are 'disease free' are seen at least at 6-month intervals (alternating between appointments at the Breast Unit and the Oncology Department).	NO, BUT PLANNED	Patients with benign breast disease are seen and managed at the BU in MDH	NO, BUT PLANNED	The BU at MDH has started a family history/genetics clinic which is led by a clinical geneticist. Patients are referred by surgeons to the geneticist who sees these cases during genetics clinic sessions.
	<i>ED National Representative</i>	YES		YES		YES	
NL	<i>ECIBC National Contacts</i>						
	<i>ED National Representative</i>	YES		YES		NO	In case of family history patients are normally referred to specialised centres for genetic testing, even if not mandated.
NO	<i>ECIBC National Contacts</i>	YES, MANDATORY	The national action programme includes guidelines for diagnostics, treatment, and follow up of patients with breast cancer (Norwegian Breast Cancer Group).	YES, MANDATORY	The national action programme includes guidelines for diagnostics, treatment, and follow up of patients with breast cancer (Norwegian Breast Cancer Group).	YES, MANDATORY	The national action programme includes guidelines for diagnostics, treatment, and follow up of patients with breast cancer (Norwegian Breast Cancer Group).
	<i>ED National Representative</i>	YES		YES		YES	

Country		I1. Is there a requirement that regulates the follow-up of primary breast cancer?	I2-I3 Primary breast cancer details/comments	J1. Is there a requirement that regulates the management of benign disease?	J2-J3 Benign disease details/comments	K1. Is there a requirement that regulates the management of family history/genetics?	K2-K3 Family history/genetics details/comments
PL	<i>ECIBC National Contacts</i>	NO and NOT PLANNED		NO and NOT PLANNED		NO and NOT PLANNED	
	<i>ED National Representative</i>						
PT	<i>ECIBC National Contacts</i>	NO, BUT PLANNED		NO, BUT PLANNED		YES, MANDATORY	Portuguese law regulates genetic clinics, how they work, how they store the data and the need for clinical geneticists.
	<i>ED National Representative</i>						
RO	<i>ECIBC National Contacts</i>	NO and NOT PLANNED		NO and NOT PLANNED		NO and NOT PLANNED	
	<i>ED National Representative</i>						
RS	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	Depending on the type of cancer, a patient is monitored by experts. Usually it is the same doctor that diagnosed the disease. Decisions regarding therapy are made by the MDT. Individual follow-up of the patient is done by one doctor - by the radiologist or by the oncologist or sometimes by the surgeon or more than one, if needed.	YES, VOLUNTARY	Legislation defines the same rights for patients for the treatment of benign diseases and malignant diseases (according to the legal framework in Serbia and in line with patients' rights). In the guideline document developed by the experts (approved by MoH), there is a protocol/scheme for the treatment of benign diseases. It is used by experts on daily basis, but not mandatory by law.	YES, VOLUNTARY	Equipment for genetic analysis is available at the Institute for Oncology and Radiology of Serbia. This institution also provides genetic counselling for patients and their families.

Country		I1. Is there a requirement that regulates the follow-up of primary breast cancer?	I2-I3 Primary breast cancer details/ comments	J1. Is there a requirement that regulates the management of benign disease?	J2-J3 Benign disease details/comments	K1. Is there a requirement that regulates the management of family history/genetics?	K2-K3 Family history/genetics details/comments
RS	<i>ED National Representative</i>						
SE	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	The follow up in Sweden is usually managed by the oncologist or by breast care nurses. In some units this is performed by a breast surgeon.	YES, VOLUNTARY	It is managed by the breast surgeon at the breast units.	YES, VOLUNTARY	At university hospitals, there are specific family history clinics which have separate MDMs with participation of clinical geneticists, breast surgeons, plastic surgeons, oncologists and psychologists.
	<i>ED National Representative</i>	YES	Depends on the county. Follow-up is in most counties not in accordance with 2006 European Guidelines. The follow-up could sometimes be constituted by a letter from the health care provider.	YES	Depends on the county and even in BUs is not always implemented.	YES	At university hospitals, family history clinics/genetic/hereditary investigators are available.
SI	<i>ECIBC National Contacts</i>	YES, MANDATORY	Follow-up is part of breast cancer management guidelines	YES, MANDATORY	Management of benign disease is part of breast cancer guidelines.	YES, MANDATORY	Genetic consultation is offered to all patients along the criteria described in breast cancer management guidelines in genetic clinic, which is present in one unit.
	<i>ED National Representative</i>	YES		YES		YES	
SK	<i>ECIBC National Contacts</i>	YES, MANDATORY	The majority of patients will be followed-up in specialised oncology centres	YES, VOLUNTARY	The national guidelines for breast cancer diagnosis and treatment given by Ministry	YES, VOLUNTARY	In oncology centres and some university hospitals.

Country		I1. Is there a requirement that regulates the follow-up of primary breast cancer?	I2-I3 Primary breast cancer details/ comments	J1. Is there a requirement that regulates the management of benign disease?	J2-J3 Benign disease details/comments	K1. Is there a requirement that regulates the management of family history/genetics?	K2-K3 Family history/genetics details/com-ments
SK			and/or in specialised departments of some university hospitals.		of Health defines specialists (specialised gynaecologists and /or surgeons) for treatment of breast diseases.		
	<i>ED National Representative</i>						
TR	<i>ECIBC National Contacts</i>						
	<i>ED National Representative</i>	YES		YES		I do not have this information.	
UK	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	The amount of clinical follow up is decreasing in England with a recommendation that patients should be discharged after 3 years of follow up (NICE guidance).	YES, VOLUNTARY	Not mandated but all breast units see the full range of benign disease which they diagnose and manage; most units would see approximately 20 patients with benign disease for every breast cancer diagnosed.	YES, VOLUNTARY	The family history provision is more mixed across the country with different patterns in different places - see NICE family history guidance. For those at moderate risk these are commonly managed within the breast unit by the breast team, often an advanced nurse practitioner. Screening mammography for this group is performed within the local breast unit. Those at high risk are referred to the regional genetics service

Country		I1. Is there a requirement that regulates the follow-up of primary breast cancer?	I2-I3 Primary breast cancer details/ comments	J1. Is there a requirement that regulates the management of benign disease?	J2-J3 Benign disease details/comments	K1. Is there a requirement that regulates the management of family history/genetics?	K2-K3 Family history/genetics details/com-ments
UK							for counselling and genetic testing, and for possible consider-ation of risk reducing mastectomy for those who are gene positive. For those at high risk surveillance mam-mography and MRI are organised through the National Health Service Breast Screen-ing Programme.
	<i>ED National Representative</i>	YES		YES		YES	

Table 12: *Survey section 6.*

Breast Units non-mandatory requirements implementation stage.

Questions:

L. Facilities/ Services (9.7.11)

Definition from the 2006 European Guidelines

Breast Screening

Ideally breast screening centres should be a part of Breast Units and the same radiologists should be members of the Unit team and work in screen detection and the diagnosis of symptomatic disease. Assessment centres should be placed in Breast Units.

ECIBC:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the breast screening management as defined above? * YES, MANDATORY; YES, VOLUNTARY; NO, BUT PLANNED; NO and NOT PLANNED; I do not know
2. If you replied YES, please provide a more detailed description (*i.e.* name of legislation/ quality assurance scheme, link to the text or reference document)
3. If you wish, please add below your comments/considerations on the breast screening management voluntary requirement

ED:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the breast screening management as defined above? YES; NO; I do not have this information
2. If you wish, please add below your comments/considerations on the breast screening management voluntary requirement

M. Facilities/ Services (9.7.12)

Definition from the 2006 European Guidelines

Patient information

Women must be offered clear written and oral information regarding their diagnosis and/or treatment options. The Breast Unit should also provide written information concerning local out-patient support groups and advocacy organisations and should also respect the patients rights as outlined in the Breast Cancer Resolution of the European Parliament (OJ C 68 E (18.03.2004), p. 611). Patients should be provided with a list of their rights as outlined in the breast cancer resolution.

ECIBC:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the patient information as defined above? *
YES, MANDATORY; YES, VOLUNTARY; NO, BUT PLANNED; NO and NOT PLANNED; I do not know
2. If you replied YES, please provide a more detailed description (*i.e.* name of legislation/quality assurance scheme, link to the text or reference document)
3. If you wish, please add below your comments/considerations on the patient information voluntary requirement

ED:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the patient information as defined above?
YES; NO; I do not have this information
2. If you wish, please add below your comments/considerations on the patient information voluntary requirement

Country		L1. Is there a requirement that regulates breast screening management?	L2-L3 Breast screening management details/comments	M1. Is there a requirement that regulates the patient information?	M2-M3 Patient information details/comments
AT	<i>ECIBC National Contacts</i>				
	<i>ED National Representative</i>	NO	In Austria, only some of the screening and assessment centres are part of certified breast cancer units.	YES	All patients get information during the continuous process of informed consent.
BE	<i>ECIBC National Contacts</i>	NO and NOT PLANNED		YES, MANDATORY	Royal Decree on 26 April 2007. Breast units must have an agreement with patient organisations.
	<i>ED National Representative</i>				
BG	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	There are Ministry of Health and National Health Insurance Fund documents as well as accreditation requirements for the National Hospital of Oncology	YES, MANDATORY	There are Ministry of Health and National Health Insurance Fund documents as well as accreditation requirements for the National Hospital of Oncology, and the Breast Department.
	<i>ED National Representative</i>				
CH	<i>ECIBC National Contacts</i>	YES		YES	
	<i>ED National Representative</i>	I do not have this information.		I do not have this information.	
CY	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	Mammography centres are satellites of the breast unit.	YES, VOLUNTARY	Oral information is provided.
	<i>ED National Representative</i>	NO	We do not have a breast unit but have a national screening programme in accordance with the 2006 European Guidelines.	NO	Written information provided by NGOs.
CZ	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	There is an integrated screening unit in the comprehensive cancer centre.	YES, MANDATORY	All therapeutic and diagnostic interventions are conditional upon signing an informed consent, which has a unified format.
	<i>ED National Representative</i>				

Country		L1. Is there a requirement that regulates breast screening management?	L2-L3 Breast screening management details/comments	M1. Is there a requirement that regulates the patient information?	M2-M3 Patient information details/comments
DE	<i>ECIBC National Contacts</i>	YES, MANDATORY	The requirements regulating breast screening management are described in Chapter 2.1.3 of the Catalogue of Requirements, see: https://www.krebsgesellschaft.de/gcs/german-cancer-society/certification/documents.html?file=files/dkg/german-cancer-society/pdf/Certification/Catalogue%20of%20Req%20breast-H1%201%20%2814%2007%202016%29%20EN.pdf .	YES, MANDATORY	The requirements regulating the patient information are described in Chapter 2.1.1 and Chapter 1.6.3 et seq. of the Catalogue of Requirements, see: https://www.krebsgesellschaft.de/gcs/german-cancer-society/certification/documents.html?file=files/dkg/german-cancer-society/pdf/Certification/Catalogue%20of%20Req%20breast-H1%201%20%2814%2007%202016%29%20EN.pdf . Patient information and shared decision making is mandatory but not with regard to the Resolution of the European Parliament.
	<i>ED National Representative</i>				
EE	<i>ECIBC National Contacts</i>				
	<i>ED National Representative</i>	YES	Mammography screening is organised, nationwide, age group 50-62, interval 2 years.	YES	
ES	<i>ECIBC National Contacts</i>				
	<i>ED National Representative</i>	NO		NO	
FI	<i>ECIBC National Contacts</i>	YES, MANDATORY	ISO standards are followed across Finland.	YES, MANDATORY	Both the doctors and nurses provide verbal and written information on all the topics previously mentioned.
	<i>ED National Representative</i>		Which ISO?		
FR	<i>ECIBC National Contacts</i>	NO and NOT PLANNED	As noted previously, in France the organisation for screening and diagnostics is distinct from the organisation of treatments. Screening and diagnostics are mainly performed in private radiology units for individual as well as organised mammography. The French organised breast cancer	NO and NOT PLANNED	

Country		L1. Is there a requirement that regulates breast screening management?	L2-L3 Breast screening management details/comments	M1. Is there a requirement that regulates the patient information?	M2-M3 Patient information details/comments
FR			screening programme is established at national level and implemented at departmental level under the responsibility of regional health agencies (26). Agencies finance and control screening management structures in charge of the invitation of the target population, training, communication, evaluation of the programme etc. In case of positive screening, the screening structure shares information about the woman with the GP who will be in charge of her follow up in coordination with the oncology team.		
	<i>ED National Representative</i>	YES	France applies the 2006 European Guidelines but for age range. Screening is provided from women aged 50 to 74 every two years. The possibility to start screening at age 40 or 45 is now under evaluation.	YES	Usually (but not often) patients receive written information on diagnosis and treatment either directly from the hospital or through their medical doctor. To fully understand the discussions about treatment, the patient has to be educated on the topic. There is no rule foreseeing that patients have to be informed about NGOs (e.g. on advocacy). However, nurses provide this information when available.
GR	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	It is very important for breast centres to have a separate section for a breast screening but in countries like Greece with a lot of islands and remote villages a national breast screening programme with mobile mammography units would be more appropriate.	NO and NOT PLANNED	The patient must receive full information regarding her diagnosis in writing and advice regarding her therapeutic treatment so to avoid any misunderstanding. Recently, some non-profit, non-governmental organisations have been involved with patient advocacy.
	<i>ED National Representative</i>	NO		NO	
HU	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	This requirement is applied only by complex screening units to have proper diagnostic and therapeutic background.	NO, BUT PLANNED	
	<i>ED National Representative</i>				

Country		L1. Is there a requirement that regulates breast screening management?	L2-L3 Breast screening management details/comments	M1. Is there a requirement that regulates the patient information?	M2-M3 Patient information details/comments
IE	<i>ECIBC National Contacts</i>	YES, VOLUNTARY		YES, VOLUNTARY	
	<i>ED National Representative</i>	YES		NO	
IT	<i>ECIBC National Contacts</i>	YES, MANDATORY	Mammographic screening has been a Basic Healthcare Parameter (LEA) since 2001. Guidelines are provided by the Minister of Health - Department of Prevention in agreement with regional governments according to the state-regions Agreement on breast units networking issued 18 December 2014.	YES, MANDATORY	State-regions agreement on breast units networking issued 18 December 2014.
	<i>ED National Representative</i>	YES	See document from the Italian Ministry of Health (18 December 2014 Rep. Atti 185/ CSR).	YES	See document from the Italian Ministry of Health (18 December 2014 Rep. Atti 185/ CSR).
LT	<i>ECIBC National Contacts</i>	YES, MANDATORY	All radiologists interpreting diagnostic mammograms also work in breast screening in the same NCI or outside the NCI in other screening units.	NO, BUT PLANNED	Oral information is given after every MDT meeting. Written information is mandatory before surgery, medical oncology, radiotherapy or interventional radiology procedures. There are separate information documents regarding different procedures or treatment modalities. There is no single document concerning all information about the disease, its type and all treatment possibilities. But usually the woman is offered information along international guidelines.
	<i>ED National Representative</i>				
LU	<i>ECIBC National Contacts</i>	YES, MANDATORY	The screening method is based on the 2006 EU guidelines. It is explained in the Guide des Bonnes Pratiques http://www.sante.public.lu/fr/catalogue-publications/rester-bonne-sante/cancer-prevention-depistage/guide-bonnes-pratiques-programme-mammographie-2014/index.html and in the	YES, VOLUNTARY	Legislation: loi du 24 juillet 2014, droits et obligations des patients, Memorial A num 140, 31 juillet 2014. Every physician should provide written information concerning diagnosis and treatment. All hospitals have for the time being their own printed material or distribute what developed by the Cancer Foundation and/or Europa Donna Luxembourg.

Country		L1. Is there a requirement that regulates breast screening management?	L2-L3 Breast screening management details/comments	M1. Is there a requirement that regulates the patient information?	M2-M3 Patient information details/comments
LU			Memorial A, num 167, 19 November 2003. All radiologists working in screening need an accreditation. All radiologists do assessment. Every radiologist is allowed to do breast imaging, and some of them know only some technics. All radiologists are working inside a hospital. Breast cancer screening and diagnosis activities are done in a general radiology centre because no breast unit with dedicated radiologists exists.		
	<i>ED National Representative</i>	YES		NO	
LV	<i>ECIBC National Contacts</i>	NO and NOT PLANNED		NO and NOT PLANNED	
	<i>ED National Representative</i>				
MT	<i>ECIBC National Contacts</i>	NO, BUT PLANNED	Mammography screening is performed at a National Screening Unit which is located outside the MDH precincts. The radiologists working in the screening programme also perform the diagnosis of symptomatic diseases and are members of the multi-disciplinary team.	NO, BUT PLANNED	A breast cancer treatment booklet has been developed and tailored for both local women and men who are starting or having treatment for breast cancer. The aim is to provide patients with the appropriate information at an adequate point in the breast care pathway (i.e. at the initial point of contact prior to commencement of treatment). Such information is now available at the breast unit, Department of Oncology and Gozo General Hospital. Since it helps to know what to expect and where patients can get further support after diagnosis, this booklet has included relevant information about the various treatment options for breast cancer and other relevant information which the patient/relatives may find useful in their cancer journey. The information in this booklet focuses on early stage breast cancer. This booklet is available in both Maltese and English languages.

Country		L1. Is there a requirement that regulates breast screening management?	L2-L3 Breast screening management details/comments	M1. Is there a requirement that regulates the patient information?	M2-M3 Patient information details/comments
MT					Advanced (metastatic) breast cancer treatment information is also available; the latter was written on behalf of Europa Donna France and translated into English by a member of Europa Donna Malta. This booklet is also being translated into the Maltese language. Breast screening information leaflets are also available at breast screening units. Moreover, the breast units are also developing information at the diagnostic stage of the pathway.
	<i>ED National Representative</i>	YES		NO	
NL	<i>ECIBC National Contacts</i>				
	<i>ED National Representative</i>	NO	In The Netherlands, a wide screening programme has been in place since 1990. It is not part of breast cancer units but organised separately. The quality of the breast cancer screening programme is assured by regular control of the Dutch Reference Centre for screening which also checks equipment, organisation and education of professionals involved.	NO	Almost every hospital has written information about diagnosis, treatment, and patient groups, even if not mandated.
NO	<i>ECIBC National Contacts</i>	YES, MANDATORY	The Norwegian Breast Cancer Screening Programme foresees coverage of women aged 50-69.	YES, VOLUNTARY	The national action programme includes guidelines for diagnostics, treatment, and follow up of patients with breast cancer.
	<i>ED National Representative</i>	YES		YES	
PL	<i>ECIBC National Contacts</i>	NO and NOT PLANNED		NO and NOT PLANNED	
	<i>ED National Representative</i>				
PT	<i>ECIBC National Contacts</i>	NO and NOT PLANNED		YES, MANDATORY	Informed consent is mandatory by law for all patients. There is not a specific law for breast cancer patients.

Country		L1. Is there a requirement that regulates breast screening management?	L2-L3 Breast screening management details/comments	M1. Is there a requirement that regulates the patient information?	M2-M3 Patient information details/comments
PT	<i>ED National Representative</i>				
RO	<i>ECIBC National Contacts</i>	NO, BUT PLANNED		NO and NOT PLANNED	
	<i>ED National Representative</i>				
RS	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	Organisation of breast cancer screening is defined by the Regulation on breast cancer screening in Serbia (Official Gazette 73/2013). In the implementation of organised screening, institutions from all three levels of healthcare are included. Specialised institutions only read mammography images as part of the screening programme, including additional diagnostic services and breast cancer therapy.	YES, MANDATORY	Law on patient rights - Written information provided by breast units/hospitals as well as by non-governmental organisations.
	<i>ED National Representative</i>				
SE	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	National population-based screening in place since 1986 is recommended by The National Board of Health and Welfare from age 40-74, with screening intervals of 18-24 months. All County Councils offer this. The screening units in rural areas are managed by mobile teams, while in urban areas it is often in collaboration with the clinical mammography unit and breast unit. There are also special screening units (sub-contracted) in urbanised areas which refer patients to the breast units.	YES, VOLUNTARY	Written information is sent in advance before mammography screening. Individual breast units have information about bio-banking. Oral information is given at most surgery clinics. Some oncology units have written information about chemotherapy and radiotherapy. Leaflets (e.g. information about patient support groups/organisations) are available at most breast units. Patient support groups/organisations have in most cases excellent contact with the breast units. Frequently, education sessions are arranged between breast units and patient support groups/organisations.
	<i>ED National Representative</i>	YES	Population-based screening programmes have been in place since mid-1980s and the general recommendations are that all	YES	Depends on the county. Written information is given in connection with mammography screening. Should a patient be diagnosed

Country		L1. Is there a requirement that regulates breast screening management?	L2-L3 Breast screening management details/comments	M1. Is there a requirement that regulates the patient information?	M2-M3 Patient information details/comments
SE			women between the ages of 40 - 74 are invited at intervals of 18 - 24 months. In remote areas, mobile screening units are available. There are recommendations about personnel competence, not always upheld as these services are sometimes contracted.		with breast cancer it is normally the breast surgeon - sometimes together with a breast care nurse - that informs the patient of the cancer diagnosis. If the patient is referred by a general practitioner in a primary ward - this could be done by letter. Written information about the process through surgery, radiotherapy to chemotherapy is given in quite a few clinics/hospitals. Patient support groups are working in some of the hospitals on a voluntary basis providing brochures and other information leaflets produced by the National Breast Cancer Association.
	<i>ECIBC National Contacts</i>	YES, MANDATORY	Defined in national breast screening programme - (DORA)	YES, VOLUNTARY	The patients are informed by the treating oncologist, information leaflets and the Cancer Patients' Association of Slovenia.
SI	<i>ED National Representative</i>	YES	Available only in some parts of Slovenia.	NO	
	<i>ECIBC National Contacts</i>	NO, BUT PLANNED		NO, BUT PLANNED	
SK	<i>ED National Representative</i>				
	<i>ECIBC National Contacts</i>				
TR	<i>ED National Representative</i>	YES		YES	
	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	It is recommended that breast units should be combined symptomatic and screening units, and most are, although this is not mandated.	YES, MANDATORY	Mandated via the National Peer Review Measures, see response to D2-D3.
UK	<i>ED National Representative</i>	YES		YES	

Table 13: Survey section 6.

Breast Units non-mandatory requirements implementation stage.

Questions:

N. S. Associated Services and non-core personnel (9.8.1)

Definition from the 2006 European Guidelines

These are services for which it cannot be expected that staff will spend the majority of their time on breast disease.

Extra Psychological Support

If the patient is experiencing psychological morbidity that cannot be dealt with effectively by members (usually breast care nurse or psycho-oncologist) of the Unit team, she should be referred to a psychiatrist with whom there are particular arrangements to see breast patients for the Breast Unit (non-core team member).

ECIBC:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the extra psychological support as defined above? * YES, MANDATORY; YES, VOLUNTARY; NO, BUT PLANNED; NO and NOT PLANNED; I do not know
2. If you replied YES, please provide a more detailed description (*i.e.* name of legislation/quality assurance scheme, link to the text or reference document)
3. If you wish, please add below your comments/considerations on the extra psychological support voluntary requirement

ED:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the extra psychological support as defined above? YES; NO; I do not have this information
2. If you wish, please add below your comments/considerations on the extra psychological support voluntary requirement

O. S. Associated Services and non-core personnel (9.8.2)

Definition from the 2006 European Guidelines

Plastic Surgeon

The Breast Unit should make arrangement with one or two nominated plastic surgeons with a special interest in breast reconstructive and recontouring techniques.

ECIBC:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the plastic surgery as defined above? * YES, MANDATORY; YES, VOLUNTARY; NO, BUT PLANNED; NO and NOT PLANNED; I do not know
2. If you replied YES, please provide a more detailed description (*i.e.* name of legislation/quality assurance scheme, link to the text or reference document)
3. If you wish, please add below your comments/considerations on the plastic surgery voluntary requirement

ED:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the plastic surgery as defined above? YES; NO; I do not have this information
2. If you wish, please add below your comments/considerations on the plastic surgery voluntary requirement

P. S. Associated Services and non-core personnel (9.8.3)

Definition from the 2006 European Guidelines

Geneticists

Women seeking advice with regard to risk, e.g., family history, must be able to receive advice from the Breast team, which must include a clinical geneticist with a specialist interest in breast cancer (see 9.7.9).

ECIBC:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the genetist advice as defined above? * YES, MANDATORY; YES, VOLUNTARY; NO, BUT PLANNED; NO and NOT PLANNED; I do not know
2. If you replied YES, please provide a more detailed description (*i.e.* name of legislation/quality assurance scheme, link to the text or reference document)
3. If you wish, please add below your comments/considerations the genetist advice voluntary requirement

ED:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the genetist advice as defined above? YES; NO; I do not have this information
2. If you wish, please add below your comments/considerations on the genetist advice voluntary requirement

Country		N1. Is there a requirement that regulates the extra psychological support?	N2-N3 Extra psychological support details/comments	O1. Is there a requirement that regulates plastic surgery?	O2-O3 Plastic surgery details/comments	P1. Is there a requirement that regulates geneticist advice?	P2-P3 Geneticist advice details/comments
AT	<i>ECIBC National Contacts</i>						
	<i>ED National Representative</i>	YES	Every patient is offered psycho-oncological support. The psycho-oncologist is a member of the breast team; 10-50% of patients get support at least once during illness, some of them more.	YES	Every breast unit has at least one nominated plastic surgeon.	YES	Every unit has a nominated clinical geneticist.
BE	<i>ECIBC National Contacts</i>	YES, MANDATORY	Royal Decree on 26 April 2007. One of the recognition criteria for a breast unit is ensuring sufficient psychological support and follow-up of patients. A psychologist is included in the multidisciplinary team.	YES, MANDATORY	See previous questions on medical requirements.	YES, VOLUNTARY	The geneticist is not included in the breast unit team, but breast units must have a written agreement with a centre for human genetics to provide genetic counselling.
	<i>ED National Representative</i>						
BG	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	There are Ministry of Health and National Health Insurance Fund documents as well as accreditation requirements for the National Hospital of Oncology. Patients are sent to a specialised psychological support centre.	YES, VOLUNTARY	There are Ministry of Health and National Health Insurance Fund documents as well as accreditation requirements for the National Hospital of Oncology. A plastic surgeon is included in the multidisciplinary team when necessary.	YES, VOLUNTARY	There are Ministry of Health and National Health Insurance Fund documents as well as accreditation requirements for the National Hospital of Oncology, and also requirements of the Breast Department

Country		N1. Is there a requirement that regulates the extra psychological support?	N2-N3 Extra psychological support details/comments	O1. Is there a requirement that regulates plastic surgery?	O2-O3 Plastic surgery details/comments	P1. Is there a requirement that regulates geneticist advice?	P2-P3 Geneticist advice details/comments
BG	<i>ED National Representative</i>						
CH	<i>ECIBC National Contacts</i>	NO and NOT PLANNED		NO and NOT PLANNED		NO and NOT PLANNED	
	<i>ED National Representative</i>	I do not have this information.		I do not have this information.		I do not have this information.	
CY	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	Psychiatric help is provided but is not legally regulated.	YES, VOLUNTARY		YES, VOLUNTARY	
	<i>ED National Representative</i>	NO	Psychological support is offered through NGOs and a psychologist at the Oncology Centre.	NO		NO	
CZ	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	The psychologist is part of the multidisciplinary team or on call.	YES, VOLUNTARY	Each unit is connected to one or more of the clinics of plastic surgery.	YES, MANDATORY	Each unit has the opportunity to send patients to genetic testing and counselling.
	<i>ED National Representative</i>						
DE	<i>ECIBC National Contacts</i>	NO and NOT PLANNED	The psycho-oncologist is mandatory within the certification system and the psycho-oncologist could be a psychologist or a psychiatrist. (see Chapter 1.4.1, https://www.krebsgesellschaft.de/gcs/german-cancer-society/certification/documents).	YES, MANDATORY	The requirements regulating plastic surgery are described in Chapter 5.2.21 et seq. and Chapter 1.1.1 / 1.1.2 of the Catalogue of Requirements, see: https://www.krebsgesellschaft.de/gcs/german-cancer-society/certification/documents.html?file=files/dkg/	YES, MANDATORY	The requirements regulating geneticist advice are described in Chapter 2.1.4 and Chapter 1.1.2 of the Catalogue of Requirements, see: https://www.krebsgesellschaft.de/gcs/german-cancer-society/certification/documents.html?file=files/dkg/german-cancer-soci-

Country		N1. Is there a requirement that regulates the extra psychological support?	N2-N3 Extra psychological support details/comments	O1. Is there a requirement that regulates plastic surgery?	O2-O3 Plastic surgery details/comments	P1. Is there a requirement that regulates geneticist advice?	P2-P3 Geneticist advice details/comments
DE			<p>html?file=files/dkg/german-cancer-society/pdf/Certification/Catalogue%20of%20Req%20breast-H1%201%20%2814%2007%2016%29%20EN.pdf)</p> <p>Why should there be an obligatory psychiatrist? Is there evidence that shows more psychiatric diseases in cancer patients than in normal population?</p>		<p>german-cancer-society/pdf/Certification/Catalogue%20of%20Req%20breast-H1%201%20%2814%2007%202016%29%20EN.pdf.</p>		<p>ety/pdf/Certification/Catalogue%20of%20Req%20breast-H1%201%20%2814%2007%202016%29%20EN.pdf.</p>
	<i>ED National Representative</i>						
EE	<i>ECIBC National Contacts</i>						
	<i>ED National Representative</i>	YES	There are psychologists available for cancer patients (non-core team members).	YES		YES	
ES	<i>ECIBC National Contacts</i>						
	<i>ED National Representative</i>	NO		NO		NO	
FI	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	All hospitals have psychosocial units that can be consulted. In addition, dedicated nurses with psychotherapy (or equivalent) education are available.	YES, VOLUNTARY	The FBCG recommends that each patient should be offered discussion about the timing of breast reconstruction (imminent or delayed). Plastic surgeons are taking part to the MDMs.	YES, VOLUNTARY	Referral to geneticist will be organised when needed. All university hospital areas have them in place. The FBCG recommendations are followed.

Country		N1. Is there a requirement that regulates the extra psychological support?	N2-N3 Extra psychological support details/comments	O1. Is there a requirement that regulates plastic surgery?	O2-O3 Plastic surgery details/ comments	P1. Is there a requirement that regulates geneticist advice?	P2-P3 Geneticist advice details/ comments
FI	<i>ED National Representative</i>						
FR	<i>ECIBC National Contacts</i>	NO and NOT PLANNED		NO and NOT PLANNED		NO and NOT PLANNED	
	<i>ED National Representative</i>	NO	Extra psychological support is given by most of public entities. It's mandatory in palliative care units. The Cancer Plan insists on giving this support to all patients, as needed.	YES	Provided for free in public hospitals and anti-cancer centres.	YES	
GR	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	In 2002, the Hellenic Senologic Society founded and operates the Centre for Psychosocial Support for women with breast cancer "Ellie Lambeti". The Centre provides free of charge personalised services to women with breast cancer and to the members of their families. The existence of such centres is vital to patients' wellbeing.	YES, VOLUNTARY	On voluntary basis, private hospitals cooperate with a plastic surgeon with special interest in breast reconstructive and re-contouring techniques. It is very important for the patient to know that a plastic surgeon is on her side. The hope that she could have a breast reconstruction facilitates the decision when mastectomy is proposed, raises their morale, and revives hope.	YES, VOLUNTARY	It is very important for women who wish to be informed about the risk to address to the specialised doctor to get a clear picture of their risk.
	<i>ED National Representative</i>	NO		NO		NO	

Country		N1. Is there a requirement that regulates the extra psychological support?	N2-N3 Extra psychological support details/comments	O1. Is there a requirement that regulates plastic surgery?	O2-O3 Plastic surgery details/comments	P1. Is there a requirement that regulates geneticist advice?	P2-P3 Geneticist advice details/comments
HU	<i>ECIBC National Contacts</i>	NO and NOT PLANNED		NO, BUT PLANNED	Patient should make own arrangements for plastic surgery.	NO and NOT PLANNED	
	<i>ED National Representative</i>						
IE	<i>ECIBC National Contacts</i>	YES, VOLUNTARY		YES, VOLUNTARY		YES, VOLUNTARY	There is a national service separate from the breast units but they work together.
	<i>ED National Representative</i>						
IT	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	State-regions agreement on breast units networking issued 18 December 2014.	YES, MANDATORY	State-regions agreement on breast units networking issued 18 December 2014.	YES, MANDATORY	State-regions agreement on breast units networking issued 18 December 2014.
	<i>ED National Representative</i>	YES	See document from the Italian Ministry of Health (18 December 2014 Rep. Atti 185/CSR).	YES	See document from the Italian Ministry of Health (18 December 2014 Rep. Atti 185/CSR).	YES	See document from the Italian Ministry of Health (18 December 2014 Rep. Atti 185/CSR).
LT	<i>ECIBC National Contacts</i>	YES, MANDATORY	The patient can be referred to psychologist by the MDT, medical oncologists, or surgeon.	YES, MANDATORY		YES, MANDATORY	Patient is referred to genetics by the MDT, medical oncologist, or surgeon. Geneticist could refer for further testing, if needed.
	<i>ED National Representative</i>						
LU	<i>ECIBC National Contacts</i>	NO, BUT PLANNED	Will be adopted in the framework of the Cancer Plan guidelines on breast cancer management.	NO, BUT PLANNED	Will be adopted in the framework of the Cancer Plan guidelines on breast cancer management.	NO, BUT PLANNED	The Social Security allows a genetic advice in some conditions described in: Memorial A , numb. 46, 31 mars 2014.

Country		N1. Is there a requirement that regulates the extra psychological support?	N2-N3 Extra psychological support details/comments	O1. Is there a requirement that regulates plastic surgery?	O2-O3 Plastic surgery details/comments	P1. Is there a requirement that regulates geneticist advice?	P2-P3 Geneticist advice details/comments
LU	<i>ED National Representative</i>	NO	A law is being issued to regulate psycho-therapist in extra hospital areas.	NO		NO	Working groups discussing this topic are in place.
LV	<i>ECIBC National Contacts</i>	NO and NOT PLANNED		NO and NOT PLANNED		NO and NOT PLANNED	
	<i>ED National Representative</i>						
MT	<i>ECIBC National Contacts</i>	NO, BUT PLANNED	Due to lack of psychology professionals the presence of a psychologist whenever breast cancer patients are being given the bad news cannot be guaranteed. This situation is currently being evaluated. Plans are in place to provide for a psychologist both at the National Screening Unit and at the Breast Unit at MDH. More psychology professionals need to be employed within oncology, to be able to meet this need, as well as the needs pertaining to patients with other forms of cancer. Patient befriending and support is also provided by patient support groups. There are 2	NO, BUT PLANNED	Breast care surgeons have started to perform both oncoplastic surgery as well as immediate reconstruction procedures. Patients requiring delayed reconstruction are referred and managed by a plastic surgeon.	NO, BUT PLANNED	The BU at MDH has started a family history/ genetics clinic which is led by a clinical geneticist. Patients are referred by the surgeons to the geneticist who sees these cases during the genetics clinic sessions.

Country		N1. Is there a requirement that regulates the extra psychological support?	N2-N3 Extra psychological support details/comments	O1. Is there a requirement that regulates plastic surgery?	O2-O3 Plastic surgery details/comments	P1. Is there a requirement that regulates geneticist advice?	P2-P3 Geneticist advice details/comments
MT			non-governmental organisations providing these services: Europa Donna (Malta) and Action for Breast Cancer Foundation.				
	<i>ED National Representative</i>	NO		NO		NO	
NL	<i>ECIBC National Contacts</i>						
	<i>ED National Representative</i>	NO	Extra psychological support is always available if needed. As in the Netherlands psychological support is partly a health insurance issue and partly a municipal obligation, reimbursement may be complex.	NO	Not every hospital has a plastic surgeon with the required skills. The capacity of plastic surgeons specialised in this kind of surgery is a problem.	NO	See N, there are specialised genetic clinics so you are referred to that clinic, most are part of university hospitals
NO	<i>ECIBC National Contacts</i>	NO and NOT PLANNED		YES, VOLUNTARY	The national action programme includes guidelines for diagnostics, treatment, and follow up of patients with breast cancer.	YES, VOLUNTARY	The national action programme includes guidelines for diagnostics, treatment, and follow up of patients with breast cancer.
	<i>ED National Representative</i>	YES		YES		YES	
PL	<i>ECIBC National Contacts</i>	NO and NOT PLANNED		NO and NOT PLANNED		NO and NOT PLANNED	
	<i>ED National Representative</i>						
PT	<i>ECIBC National Contacts</i>	NO, BUT PLANNED		NO, BUT PLANNED		NO, BUT PLANNED	

Country		N1. Is there a requirement that regulates the extra psychological support?	N2-N3 Extra psychological support details/comments	O1. Is there a requirement that regulates plastic surgery?	O2-O3 Plastic surgery details/ comments	P1. Is there a requirement that regulates geneticist advice?	P2-P3 Geneticist advice details/ comments
PT	<i>ED National Representative</i>						
RO	<i>ECIBC National Contacts</i>	NO and NOT PLANNED		YES, VOLUNTARY	Recently (two years ago [2013]) , reconstructive surgery following interventions for breast cancer have been included in the reimbursement scheme. Voluntary arrangements have been made to create surgery teams that include plastic surgeons to allow patients to benefit from reconstruction techniques.	NO and NOT PLANNED	
	<i>ED National Representative</i>						
RS	<i>ECIBC National Contacts</i>	YES, MANDATORY	Law on healthcare: Provide all necessary support to patients including psychological counselling and if needed to referral to psychiatrist.	YES, VOLUNTARY	Available at large centres as the Institute for Oncology and Radiology and the military medical academy.	YES, VOLUNTARY	
	<i>ED National Representative</i>						
SE	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	At some breast units, psychological support is available.	YES, VOLUNTARY	Plastic surgeons are available at all university hospitals and at other hospitals with breast units. The other units refer patients to these breast units or to a university hospital.	YES, VOLUNTARY	Please, see answer question K2 (on family history and genetics). At university hospitals there are specific family history clinics which have separate MDMs that include

Country		N1. Is there a requirement that regulates the extra psychological support?	N2-N3 Extra psychological support details/comments	O1. Is there a requirement that regulates plastic surgery?	O2-O3 Plastic surgery details/comments	P1. Is there a requirement that regulates geneticist advice?	P2-P3 Geneticist advice details/comments
SE							clinical geneticists, breast surgeons, plastic surgeons, oncologists and psychologists.
	<i>ED National Representative</i>	YES	Depending on the county and according to recommendations from the Swedish Breast Cancer Group (which form the basis for the National Guidelines issued by the National Board of Health and Welfare). In most hospitals, including the university ones, this is not commonly at hand. Often, the patient has to ask for this service and not even then this is given.	YES	It is included in the National Guidelines, but mostly not fulfilled; it depends on the county. University hospitals have plastic surgeons. In addition, onco-plastic surgery is now performed at some university hospitals. Patients' rights or possibilities to reconstruction and access to direct-reconstruction is being debated.	YES	It is included in the National Guidelines on Breast Cancer Treatment and available at university hospitals.
SI	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	Psycho-oncology support is available in the frame of Department for Psycho-oncology (in one unit).	YES, MANDATORY	Plastic surgery is part of breast cancer management guidelines and is available for all breast cancer patients who need it.	YES, MANDATORY	Genetic consultation is offered to all patients in accordance with the criteria described in breast cancer management guidelines at our genetics clinic.
	<i>ED National Representative</i>	NO		YES		YES	
SK	<i>ECIBC National Contacts</i>	i do not know		YES, VOLUNTARY	In oncology centres and university hospitals.	YES, VOLUNTARY	In oncology centres and university hospitals.
	<i>ED National Representative</i>						

Country		N1. Is there a requirement that regulates the extra psychological support?	N2-N3 Extra psychological support details/comments	O1. Is there a requirement that regulates plastic surgery?	O2-O3 Plastic surgery details/ comments	P1. Is there a requirement that regulates geneticist advice?	P2-P3 Geneticist advice details/ comments
TR	<i>ECIBC National Contacts</i>						
	<i>ED National Representative</i>	NO		YES		I do not have this information.	
UK	<i>ECIBC National Contacts</i>	YES, MANDATORY	Mandated via national peer review as a member of the extended multi-disciplinary team, (See response to F2-F3).	YES, MANDATORY	Mandated in the NICE guidance on early and locally advanced breast cancer (see below) and assessed via the national peer review measures; that the diagnosing and treating surgeon can either: offer breast reconstruction and re-contouring techniques or that there is a clear pathway defined for referral to a plastic surgeon who can offer immediate breast reconstruction. In practise many breast surgeons in England are trained in onco-plastic surgery and are able to offer immediate and delayed breast reconstruction. From the Early and locally advanced NICE guidance: 1.5.1 Discuss immediate breast reconstruction with all	YES, VOLUNTARY	Those at moderate risk are usually assessed within the breast unit and counselled appropriately; those at high risk are referred to the regional genetics service.

Country		N1. Is there a requirement that regulates the extra psychological support?	N2-N3 Extra psychological support details/comments	O1. Is there a requirement that regulates plastic surgery?	O2-O3 Plastic surgery details/comments	P1. Is there a requirement that regulates geneticist advice?	P2-P3 Geneticist advice details/comments
UK					patients who are being advised to have a mastectomy, and offer it except where significant comorbidity or (the need for) adjuvant therapy may preclude this option. All appropriate breast reconstruction options should be offered and discussed with patients, irrespective of whether they are all available locally.		
	<i>ED National Representative</i>	YES		YES		YES	

Table 14: *Survey section 6.*

Breast Units non-mandatory requirements implementation stage.

Questions:

Q. S. Associated Services and non-core personnel (9.8.4)

Definition from the 2006 European Guidelines

Palliative Care

A specialist palliative care service must be available for the referral of patients with advanced breast cancer. A close working relationship must be established between members of the Breast Unit (especially the breast care nurse) and the palliative care service to ensure that breakdowns in continuity of care do not occur and also with the local network for home assistance.

ECIBC:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the provision of palliative care as defined above? * YES, MANDATORY; YES, VOLUNTARY; NO, BUT PLANNED; NO and NOT PLANNED; I do not know
2. If you replied YES, please provide a more detailed description (*i.e.* name of legislation/quality assurance scheme, link to the text or reference document)
3. If you wish, please add below your comments/considerations on the provision of palliative care voluntary requirement

ED:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the provision of palliative care as defined above? YES; NO; I do not have this information
2. If you wish, please add below your comments/considerations on the provision of palliative care voluntary requirement

R. S. Associated Services and non-core personnel (9.8.5)

Definition from the 2006 European Guidelines

Prosthesis

There must be provision for a Prosthesis fitting service within the unit.

ECIBC:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the provision of prosthesis as defined above?
* YES, MANDATORY; YES, VOLUNTARY; NO, BUT PLANNED; NO and NOT PLANNED; I do not know
2. If you replied YES, please provide a more detailed description (*i.e.* name of legislation/quality assurance scheme, link to the text or reference document)
3. If you wish, please add below your comments/considerations on the provision of prosthesis voluntary requirement

ED:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the provision of prosthesis as defined above?
YES; NO; I do not have this information
2. If you wish, please add below your comments/considerations on the provision of prosthesis voluntary requirement

S. S. Associated Services and non-core personnel (9.8.6)

Definition from the 2006 European Guidelines

Physiotherapy and Lymphoedema

An identified Physiotherapist or a Breast Care Nurse for the treatment of lymphoedema and late sequelae.

ECIBC:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the provision of physiotherapy and lymphoedema treatment as defined above? * YES, MANDATORY; YES, VOLUNTARY; NO, BUT PLANNED; NO and NOT PLANNED; I do not know
2. If you replied YES, please provide a more detailed description (*i.e.* name of legislation/quality assurance scheme, link to the text or reference document)
3. If you wish, please add below your comments/considerations the provision of physiotherapy and lymphoedema treatment voluntary requirement

ED:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the provision of physiotherapy and lymphoedema treatment as defined above? YES; NO; I do not have this information
2. If you wish, please add below your comments/considerations on the provision of physiotherapy and lymphoedema treatment voluntary requirement

Country		Q1. Is there a requirement that regulates the provision of palliative care?	Q2-Q3 Palliative care details/comments	R1. Is there a requirement that regulates provision of prosthesis?	R2-R3 Prosthesis details/comments	S1. Is there a requirement that regulates the provision of physiotherapy and lymphoedema treatment?	S2-S3 Physiotherapy and lymphoedema treatment details/comments
AT	<i>ECIBC National Contacts</i>						
	<i>ED National Representative</i>	YES	Each unit has a nominated palliative care inpatient and outpatient service.	YES	Breast care nurse and prosthesis companies are part of the units.	YES	They are part of every breast unit team.
BE	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	This is not specifically required in the Royal Decree on Breast Units, but a breast unit has to be part of an oncology care programme, and in this context there is a specific link with palliative care teams.	NO and NOT PLANNED		YES, MANDATORY	In the Royal Decree of 26 April 2007, specific attention is given to treatment of lymphoedema
	<i>ED National Representative</i>						
BG	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	There are Ministry of Health and National Health Insurance Fund documents as well as accreditation requirements for the National Hospital of Oncology. There is a service for pain control.	YES, MANDATORY	There are Ministry of Health and National Health Insurance Fund documents as well as accreditation requirements for the National Hospital of Oncology.	YES, VOLUNTARY	There are Ministry of Health and National Health Insurance Fund documents as well as accreditation requirements for the National Hospital of Oncology.
	<i>ED National Representative</i>						
CH	<i>ECIBC National Contacts</i>	NO and NOT PLANNED		NO and NOT PLANNED		NO and NOT PLANNED	
	<i>ED National Representative</i>	I do not have this information.		I do not have this information.		I do not have this information.	

Country		Q1. Is there a requirement that regulates the provision of palliative care?	Q2-Q3 Palliative care details/comments	R1. Is there a requirement that regulates provision of prosthesis?	R2-R3 Prosthesis details/comments	S1. Is there a requirement that regulates the provision of physiotherapy and lymphoedema treatment?	S2-S3 Physiotherapy and lymphoedema treatment details/comments
CY	<i>ECIBC National Contacts</i>	YES, VOLUNTARY		YES, VOLUNTARY		YES, VOLUNTARY	
	<i>ED National Representative</i>	NO		NO	Prosthesis provided by EUROPA DONNA Cyprus.	NO	
CZ	<i>ECIBC National Contacts</i>	YES, MANDATORY	Each comprehensive cancer centre is usually associated with inpatient palliative care, hospice care, and mobile home hospice.	YES, MANDATORY	Patients' breast units have the ability to get breast prostheses covered by insurance in the hospital shop or nearby.	YES, VOLUNTARY	Each BU is connected to a rehabilitation centre with the option of manual and instrumental lymph drainage, under the supervision of a lymphologist.
	<i>ED National Representative</i>						
DE	<i>ECIBC National Contacts</i>	YES, MANDATORY	The requirements regulating the provision of palliative care are described in Chapter 9 and Chapter 1.2.4 of the Catalogue of Requirements, see: https://www.krebsgesellschaft.de/gcs/german-cancer-society/certification/documents.html?file=files/dkg/german-cancer-society/pdf/Certification/Catalogue%20of%20Req%20breast-H1%201%20%2814%2007%202016%29%20EN.pdf .	YES, MANDATORY	The requirements regulating the provision of prosthesis are described in Chapter 1.1.2 and 5.2.25 of the Catalogue of Requirements, see: https://www.krebsgesellschaft.de/gcs/german-cancer-society/certification/documents.html?file=files/dkg/german-cancer-society/pdf/Certification/Catalogue%20of%20Req%20breast-H1%201%20%2814%2007%202016%29%20EN.pdf .	YES, MANDATORY	The requirements regulating the provision of physiotherapy and lymphoedema treatment are described in Chapter 1.1.2 of the Catalogue of Requirements, see: https://www.krebsgesellschaft.de/gcs/german-cancer-society/certification/documents.html?file=files/dkg/german-cancer-society/pdf/Certification/Catalogue%20of%20Req%20breast-H1%201%20%2814%2007%202016%29%20EN.pdf .

Country		Q1. Is there a requirement that regulates the provision of palliative care?	Q2-Q3 Palliative care details/comments	R1. Is there a requirement that regulates provision of prosthesis?	R2-R3 Prosthesis details/comments	S1. Is there a requirement that regulates the provision of physiotherapy and lymphoedema treatment?	S2-S3 Physiotherapy and lymphoedema treatment details/comments
DE	<i>ED National Representative</i>						
EE	<i>ECIBC National Contacts</i>	YES		NO		YES	
	<i>ED National Representative</i>						
ES	<i>ECIBC National Contacts</i>						
	<i>ED National Representative</i>	NO		NO		NO	
FI	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	EAPC guidelines for palliative care are followed. There is a three-level organisation of palliative care as recommended in the Cancer Control Plan.	YES, MANDATORY	This is outsourced in most cases to external service providers. All patients get referral and prosthesis free of charge. There is a law on prosthesis and other medical equipment.	YES, VOLUNTARY	Physiotherapy should be given according to patient need. Lymphotherapy as well, but the public service may be limited due to limited resources. However, it is partially reimbursed for BC patients by the Finnish government, so patients may also use private sector services.
	<i>ED National Representative</i>						
FR	<i>ECIBC National Contacts</i>	NO and NOT PLANNED		NO and NOT PLANNED		NO and NOT PLANNED	
	<i>ED National Representative</i>	NO		NO	Patients are informed by surgeons about the prosthesis	NO	It is provided differently across hospitals.

Country		Q1. Is there a requirement that regulates the provision of palliative care?	Q2-Q3 Palliative care details/comments	R1. Is there a requirement that regulates provision of prosthesis?	R2-R3 Prosthesis details/comments	S1. Is there a requirement that regulates the provision of physiotherapy and lymphoedema treatment?	S2-S3 Physiotherapy and lymphoedema treatment details/comments
GR	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	Six out of the 13 hospitals that have answered, declare that they have protocols for palliative care service. There is a non-profit Centre of palliative care, called "Tzeni Karezi", which provides its services to a certain number of patients.	NO and NOT PLANNED	Currently, none of the 13 hospitals can provide the patient with a prosthesis fitting service within the breast centre; although, such a service would be very helpful to patients.	YES, VOLUNTARY	Only two out of the 13 breast units responded that they have a physiotherapy section but they are not specialised in lymphoedema. In the past, physiotherapy was very important as the axillary dissection of lymph nodes provoked more often lymphoedema. Nowadays, biopsy of the sentinel lymph node during the operation, in case that it is negative- limits the cases of lymphoedema and consequently the need of physiotherapy.
	<i>ED National Representative</i>	NO		NO		NO	
HU	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	Pain and palliative symptom control is managed on a case-by-case basis; hence, it is treated as a voluntary requirement.	NO and NOT PLANNED		YES, VOLUNTARY	
	<i>ED National Representative</i>						
IE	<i>ECIBC National Contacts</i>	YES, VOLUNTARY		YES, VOLUNTARY		NO, BUT PLANNED	

Country		Q1. Is there a requirement that regulates the provision of palliative care?	Q2-Q3 Palliative care details/comments	R1. Is there a requirement that regulates provision of prosthesis?	R2-R3 Prosthesis details/comments	S1. Is there a requirement that regulates the provision of physiotherapy and lymphoedema treatment?	S2-S3 Physiotherapy and lymphoedema treatment details/comments
IE	<i>ED National Representative</i>	YES		YES		NO	All cancer or DCIS patients get post-operative physiotherapy. It is not foreseen for benign disease.
	<i>ECIBC National Contacts</i>	YES, MANDATORY	State-regions agreement on breast units networking issued the 18 December 2014.	YES, MANDATORY	State-regions agreement on breast units networking issued the 18 December 2014.	YES, MANDATORY	State-regions agreement on breast units networking issued the 18 December 2014.
IT	<i>ED National Representative</i>	YES	See document from the Italian Ministry of Health (18 December 2014 Rep. Atti 185/CSR).	YES	See document from the Italian Ministry of Health (18 December 2014 Rep. Atti 185/CSR).	YES	See document from the Italian Ministry of Health (18 December 2014 Rep. Atti 185/CSR).
	<i>ECIBC National Contacts</i>	YES, MANDATORY	Patients are usually referred by the medical oncologist or other MDT members	NO, BUT PLANNED	Reimbursement of outer prosthesis is regulated by the Lithuanian Ministry of Health, but there is no rule for reimbursement of implants after breast cancer surgery.	YES, MANDATORY	Regulated by breast cancer diagnosis and treatment standards in Lithuania and the NCI.
LT	<i>ED National Representative</i>						
LU	<i>ECIBC National Contacts</i>	YES, MANDATORY	Luxembourg has a law which regulates access to palliative care and to euthanasia: Memorial A , numb. 46, 16 mars 2009. Explanations available on: http://www.sante.public.lu/fr/actualites/2009/06/guide-soins-palliatifs/index.html	NO and NOT PLANNED	Some nurses are trained to provide explanations about the breast prosthesis during patient's hospitalisation.	NO, BUT PLANNED	Will be adopted in the framework of the Cancer Plan guidelines on breast cancer management.
	<i>ED National Representative</i>						

Country		Q1. Is there a requirement that regulates the provision of palliative care?	Q2-Q3 Palliative care details/comments	R1. Is there a requirement that regulates provision of prosthesis?	R2-R3 Prosthesis details/comments	S1. Is there a requirement that regulates the provision of physiotherapy and lymphoedema treatment?	S2-S3 Physiotherapy and lymphoedema treatment details/comments
LU	<i>ED National Representative</i>	NO		NO		NO	There is no requirement but ED Luxembourg has coordinated the training of 200 physiotherapists for manual treatment of lymphoedema. Their addresses are published on the ED Luxembourg website.
	<i>ECIBC National Contacts</i>	NO and NOT PLANNED		NO and NOT PLANNED		NO and NOT PLANNED	
	<i>ED National Representative</i>						
MT	<i>ECIBC National Contacts</i>	NO, BUT PLANNED	A specialist palliative care service and unit is located within the oncology department and it will also be migrating to the new oncology hospital within the MDH precincts. Referrals to the specialist palliative care services come from several sources that include the breast unit teams at MDH, other MDH departments, the oncology department, the rehabilitation hospital, long-term care residences, and family practice. Initial assessment is carried	NO, BUT PLANNED	The fitting and provision of prosthesis is performed at the BU at MDH and is led by the breast care nurses. This service is also supported by a breast cancer patients support group (a non-governmental organisation called Action for Breast Cancer Foundation).	NO, BUT PLANNED	A dedicated lymphoedema clinic, within the physiotherapy services at the oncology hospital has been supporting post-operative patients with secondary lymphoedema since 2003. Clinicians within the clinic are specifically trained in post-operative lymphoedema management observing current UK and European set modalities and practices.

Country		Q1. Is there a requirement that regulates the provision of palliative care?	Q2-Q3 Palliative care details/comments	R1. Is there a requirement that regulates provision of prosthesis?	R2-R3 Prosthesis details/comments	S1. Is there a requirement that regulates the provision of physiotherapy and lymphoedema treatment?	S2-S3 Physiotherapy and lymphoedema treatment details/comments
MT			<p>out by palliative care specialist at palliative care out-patients or at MDH for in-patients. Patients and their families are than referred to other team members as deemed necessary; occupational therapy, physiotherapy, psychology, social work, spiritual director, tissue viability unit and Hospice Malta (a non-governmental organisation). The latter also provide home care and loan of equipment. Patients continue attending outpatients follow ups until they are less well. This is complemented with visits by the hospice doctor at home as necessary. Patients are admitted to palliative in-patient unit for symptom control, palliative radiotherapy or end-of-life care as indicated and required.</p>				
	<i>ED National Representative</i>	NO		YES		YES	The national guidelines have a para-

Country		Q1. Is there a requirement that regulates the provision of palliative care?	Q2-Q3 Palliative care details/comments	R1. Is there a requirement that regulates provision of prosthesis?	R2-R3 Prosthesis details/comments	S1. Is there a requirement that regulates the provision of physiotherapy and lymphoedema treatment?	S2-S3 Physiotherapy and lymphoedema treatment details/comments
MT							graph physiotherapy and lymphoedema (voluntary).
NL	<i>ECIBC National Contacts</i>						
	<i>ED National Representative</i>	YES		NO		NO	
NO	<i>ECIBC National Contacts</i>	YES, MANDATORY	The national action programme includes guidelines for diagnostics, treatment, and follow up of patients with breast cancer.	YES, VOLUNTARY		NO and NOT PLANNED	
	<i>ED National Representative</i>	NO		YES		YES	
PL	<i>ECIBC National Contacts</i>	NO and NOT PLANNED		NO and NOT PLANNED		NO and NOT PLANNED	
	<i>ED National Representative</i>						
PT	<i>ECIBC National Contacts</i>	NO, BUT PLANNED		YES, MANDATORY	Portuguese law states that the responsibility for prosthesis is on the treating hospital.	NO, BUT PLANNED	
	<i>ED National Representative</i>						
RO	<i>ECIBC National Contacts</i>	NO and NOT PLANNED		NO and NOT PLANNED		NO and NOT PLANNED	
	<i>ED National Representative</i>						

Country		Q1. Is there a requirement that regulates the provision of palliative care?	Q2-Q3 Palliative care details/comments	R1. Is there a requirement that regulates provision of prosthesis?	R2-R3 Prosthesis details/comments	S1. Is there a requirement that regulates the provision of physiotherapy and lymphoedema treatment?	S2-S3 Physiotherapy and lymphoedema treatment details/comments
RS	<i>ECIBC National Contacts</i>	YES, MANDATORY	Strategy of palliative care in Serbia. - Law on healthcare. -Plan for healthcare from 2015 this includes plan for provision of palliative healthcare in the Republic of Serbia financed by Health Insurance Fund and free of charge for users. -Now, the Ministry of Health has formed the network of hospitals within the public healthcare sector with hospital beds for palliative care. Thirty hospitals have capacities for palliative care.	YES, MANDATORY	Patients must attend the Institute for Oncology and Radiology of Serbia, the Military Medical Academy and the Institute of Oncology of Vojvodina, or Sremska Kamenica. They provide the prosthesis fitting services within their departments.	YES, MANDATORY	Physiotherapy and lymphoedema treatment is provided in Institute for Oncology and Radiology of Serbia, the Military Medical Academy and Institute of Oncology of Vojvodina, Sremska Kamenica. Patients from other healthcare institutions are referred to above mentioned institutions.
	<i>ED National Representative</i>						
SE	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	The management of palliative care various throughout Sweden. Palliative Care is arranged by multiple institutions/units, and by both County Councils and Municipalities.	YES, VOLUNTARY	All patients with mastectomy and primary reconstruction can request a prosthesis. Single breast units have a very high rate of reconstructions.	YES, VOLUNTARY	Individuals who developed lymphoedema should be managed by a physiotherapist (according to the National Guidelines and the National Clinical Practice Guidelines for Breast Cancer); however, not all units have personnel that

Country		Q1. Is there a requirement that regulates the provision of palliative care?	Q2-Q3 Palliative care details/comments	R1. Is there a requirement that regulates provision of prosthesis?	R2-R3 Prosthesis details/comments	S1. Is there a requirement that regulates the provision of physiotherapy and lymphoedema treatment?	S2-S3 Physiotherapy and lymphoedema treatment details/comments
SE							are educated in the treatment of lymphoedema. It should be emphasised that during the last decade, single units have reduced the problem with lymphoedema by the use of sentinel node and better use of surgery with or without radiotherapy.
	<i>ED National Representative</i>	YES	Even if recommended by the National Guidelines, palliative care organisation differs depending on whether it is in the domain of the county council or municipality.	YES	Depends on the county. Generally a patient treated with a mastectomy will have access to a prosthesis.	NO	Depends on the county, but due to lack of lymphoedema therapists, it is rarely provided.
SI	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	Palliative care is offered to all patients who need it (not separately for breast cancer patients only).	NO, BUT PLANNED	Prosthesis fitting service is currently located outside breast units; however, it is offered to all breast cancer patients.	NO, BUT PLANNED	
	<i>ED National Representative</i>	YES		YES		NO	
SK	<i>ECIBC National Contacts</i>	NO, BUT PLANNED		YES, MANDATORY	In oncology centres and in some university hospitals.	YES, MANDATORY	In oncology centres and in some university hospitals.

Country		Q1. Is there a requirement that regulates the provision of palliative care?	Q2-Q3 Palliative care details/comments	R1. Is there a requirement that regulates provision of prosthesis?	R2-R3 Prosthesis details/comments	S1. Is there a requirement that regulates the provision of physiotherapy and lymphoedema treatment?	S2-S3 Physiotherapy and lymphoedema treatment details/comments
SK	ED National Representative						
TR	ECIBC National Contacts						
	ED National Representative	NO		YES		YES	
UK	ECIBC National Contacts	YES, MANDATORY	Defined by and mandated by the NICE Guidance on advanced disease, see below: Healthcare professionals involved in the care of patients with advanced breast cancer should ensure that the organisation and provision of supportive care services comply with advanced breast cancer (update) NICE clinical guideline 81. The recommendations made in Improving outcomes in breast cancer: manual update (NICE) cancer service guidance [2002] and Improving supportive and palliative care for adults with cancer (NICE cancer service guidance [2004]), in particular	YES, VOLUNTARY	This is provided as standard by the breast care nurses in every breast unit in England.	YES, MANDATORY	Mandated through the national peer review measures and defined as one of the members of the extended MDT, which includes: a core member of the specialist palliative care team; breast radiographer; psychiatrist or clinical psychologist; plastic/reconstructive surgeon; clinical geneticist/genetics counsellor; physiotherapist/lymphoedema/practitioner There is also advice and guidance on the management of lymphoedema in the NICE Advanced Breast Cancer Guidelines 2009, updated in 2014 as indicated: 1.5.1 Discuss with people who have or

Country		Q1. Is there a requirement that regulates the provision of palliative care?	Q2-Q3 Palliative care details/comments	R1. Is there a requirement that regulates provision of prosthesis?	R2-R3 Prosthesis details/comments	S1. Is there a requirement that regulates the provision of physiotherapy and lymphoedema treatment?	S2-S3 Physiotherapy and lymphoedema treatment details/comments
UK			<p>the following two recommendations: 'Assessment and discussion of patients' needs for physical, psychological, social, spiritual and financial support should be undertaken at key points (such as diagnosis; at commencement, during, and at the end of treatment; at relapse; and when death is approaching).'</p> <p>'Mechanisms should be developed to promote continuity of care, which might include the nomination of a person to take on the role of "key worker" for individual patients.' [2009].</p>				<p>who are at risk of breast-cancer-related lymphoedema that there is no indication that exercise prevents, causes or worsens lymphoedema. [new 2014]</p> <p>1.5.2 Discuss with people who have or who are at risk of breast cancer-related lymphoedema that exercise may improve their quality of life. [new 2014]</p> <p>1.5.3 Assess patients with lymphoedema for treatable underlying factors before starting any lymphoedema management programme. [2009]</p> <p>1.5.4 Offer all patients with lymphoedema complex decongestive therapy (CDT) as the first stage of lymphoedema management. [2009]</p> <p>1.5.5 Consider using multilayer lymphoedema bandaging (MLLB) for volume reduction as a</p>

Country		Q1. Is there a requirement that regulates the provision of palliative care?	Q2-Q3 Palliative care details/comments	R1. Is there a requirement that regulates provision of prosthesis?	R2-R3 Prosthesis details/comments	S1. Is there a requirement that regulates the provision of physiotherapy and lymphoedema treatment?	S2-S3 Physiotherapy and lymphoedema treatment details/comments
UK							<p>first treatment option before compression hosiery. [2009] 1.5.6 Provide patients with lymphoedema with at least two suitable compression garments. These should be of the appropriate class and size, and a choice of fabrics and colours should be available. [2009]</p> <p>1.5.7 Provide patients with lymphoedema clear, written information and the contact details of local and national lymphoedema support groups [2009].</p>
	ED National Representative	YES		YES		YES	

Table 15: Survey section 6.

Breast Units non-mandatory requirements implementation stage.

Questions:

T. Research (9.9)

Definition from the 2006 European Guidelines

Research is one of the essential parts of training of specialists. As part of Audit Units must record numbers of patients entered into clinical trials and details of all other research. Units should be encouraged to provide research opportunities and this must be taken into account when assessing units for their suitability for accepting trainees.

ECIBC:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the management of research as defined above? * YES, MANDATORY; YES, VOLUNTARY; NO, BUT PLANNED; NO and NOT PLANNED; I do not know
2. If you replied YES, please provide a more detailed description (*i.e.* name of legislation/quality assurance scheme, link to the text or reference document)
3. If you wish, please add below your comments/considerations on the management of research voluntary requirement

ED:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the management of research as defined above? YES; NO; I do not have this information
2. If you wish, please add below your comments/considerations on the management of research voluntary requirement

U. Teaching (9.10)

Definition from the 2006 European Guidelines

The Unit must provide teaching, whether simply for junior staff or for students or on a national or international basis. Some units may particularly concentrate on certain areas (e.g. Reconstruction, Screening, Pathology, etc.).

ECIBC:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the management of teaching provision as defined above? * YES, MANDATORY; YES, VOLUNTARY; NO, BUT PLANNED; NO and NOT PLANNED; I do not know
2. If you replied YES, please provide a more detailed description (*i.e.* name of legislation/quality assurance scheme, link to the text or reference document)
3. If you wish, please add below your comments/considerations on the management of teaching provision voluntary requirement

ED:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the management of teaching provision as defined above? YES; NO; I do not have this information
2. If you wish, please add below your comments/considerations on the management of teaching provision voluntary requirement

V. Additional point (9.11)

Definition from the 2006 European Guidelines

The implementation of the suggested structure of Breast Units requires a reorganisation of time in each discipline, so that as a consultant spends more time in breast disease, his or her colleagues no longer treat breast cancer and specialise in other areas. Rationalisation of work patterns, in this way would provide sufficient staff for the Breast Units. Such a move would coincide with changes that are already occurring within all disciplines, for example, from General Surgery the emergence of specialist surgeons for urology, microinvasive techniques, vascular surgery, upper GI, hepatic and colon.

All work must be carried out or directly supervised by specialists specifically trained in breast disease. A service provided by a trained specialist is more efficient and more cost

effective – diagnostic decisions are made earlier whereas junior staff are more likely to call a patient back several times unnecessarily and to carry out unnecessary investigations; operating by consultants gives better results for technical reasons; the interpretation of imaging techniques and the reading of histology is much more likely to produce definitive opinions if carried out by experts.

We [the guidelines authors] estimate that for a 10 million total population base 30-40 Breast Units are required for the ideal service and that reorganisation in this way will provide considerable financial savings. This could easily be achieved and should be attractive to many countries.

ECIBC:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the additional points as defined above? * YES, MANDATORY; YES, VOLUNTARY; NO, BUT PLANNED; NO and NOT PLANNED; I do not know
2. If you replied YES, please provide a more detailed description (*i.e.* name of legislation/quality assurance scheme, link to the text or reference document)
3. If you wish, please add below your comments/considerations the additional points voluntary requirement

ED:

1. In the geographical area under your organisation's responsibility, is there any kind of requirement that regulates the additional points as defined above? YES; NO; I do not have this information
2. If you wish, please add below your comments/considerations on the additional points voluntary requirement

Country		T1. Is there a requirement that regulates the management of research?	T2-T3 Research details/comments	U1. Is there a requirement that regulates the management of teaching provision?	U2-U3 Teaching provision details/comments	V1. Is there a requirement that regulates additional points?	V2-V3 Additional points details/comments
AT	<i>ECIBC National Contacts</i>						
	<i>ED National Representative</i>	YES	Every unit must take part in clinical studies for at least 10% of patients.	NO	There are no "musts", but most of the units provide teaching.	YES	In 2014, nearly 80% of all breast cancer patients were treated in certified breast cancer units.
BE	<i>ECIBC National Contacts</i>	YES, VOLUNTARY		NO and NOT PLANNED		YES, MANDATORY	See Royal Decree 26 April 2007.
	<i>ED National Representative</i>						
BG	<i>ECIBC National Contacts</i>	YES, MANDATORY	There are Ministry of Health and National Health Insurance Fund documents as well as accreditation requirements for the National Hospital of Oncology.	YES, VOLUNTARY	There are Ministry of Health and National Health Insurance Fund documents as well as accreditation requirements for the National Hospital of Oncology. The training is according to the yearly plan for specialisations in the National Hospital of Oncology	YES, VOLUNTARY	There are Ministry of Health and National Health Insurance Fund documents as well as accreditation requirements from the National Hospital of Oncology. If they wish, general surgeons can be trained in breast cancer according to the yearly plan of the Breast Department.
	<i>ED National Representative</i>						
CH	<i>ECIBC National Contacts</i>	NO and NOT PLANNED		NO and NOT PLANNED		NO and NOT PLANNED	
	<i>ED National Representative</i>	I do not have this information.		I do not have this information.		I do not have this information.	
CY	<i>ECIBC National Contacts</i>	YES, VOLUNTARY		YES, VOLUNTARY		YES, VOLUNTARY	

Country		T1. Is there a requirement that regulates the management of research?	T2-T3 Research details/comments	U1. Is there a requirement that regulates the management of teaching provision?	U2-U3 Teaching provision details/comments	V1. Is there a requirement that regulates additional points?	V2-V3 Additional points details/comments
CY	<i>ED National Representative</i>						
CZ	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	In comprehensive oncological centres undergoing clinical studies (usually phase II and III), on the issue of breast cancer	YES, VOLUNTARY	Breast units provide training to postgraduate students, medics, and middle medical staff.	YES, VOLUNTARY	The Medical Chamber, professional societies, and insurance companies.
	<i>ED National Representative</i>						
DE	<i>ECIBC National Contacts</i>	YES, MANDATORY	The requirements regulating the management of research are described in Chapter 1.7 of the Catalogue of Requirements, see: https://www.krebsgesellschaft.de/gcs/german-cancer-society/certification/documents.html?file=files/dkg/german-cancer-society/pdf/Certification/Catalogue%20of%20Req%20breast-H1%201%20%2814%2007%202016%29%20EN.pdf .	YES, MANDATORY	Training of new breast surgeons: The training of one breast surgeon must be organised for each location and for every 100 primary cases. Breast surgeons in training must provide evidence of at least 20 operations per year (not as a second surgeon). (see: Catalogue of Requirements, Chapter 5.2.8) Advanced training for every discipline/staff member: example: page 22 (3.16): "Further/additional training: A qualification plan for physicians and other staff members (radiological technicians) must be submitted in which the qualification measures for the	Quality of scintigraphic marking/detection of the sentinel node (see Chapter 4.3 et seq.) Guideline-based quality indicators (e.g. Chapter 1.2.8 et seq.) Criteria for nursing care (see Chapter 1.8) Criteria for social workers (see Chapter 1.5) Self-help groups (see Chapter 1.6.8) (<a 156="" 814"="" 854="" 868="" data-label="Page-Footer" href="https://www.krebsgesellschaft.de/gcs/german-cancer-society/certification/docu-</td> <td></td> </tr> </tbody> </table> </div> <div data-bbox="> <p>Annex III Detailed replies from ECIBC National Contacts and ED National Representatives 367</p> 	

Country		T1. Is there a requirement that regulates the management of research?	T2-T3 Research details/comments	U1. Is there a requirement that regulates the management of teaching provision?	U2-U3 Teaching provision details/comments	V1. Is there a requirement that regulates additional points?	V2-V3 Additional points details/comments
DE					coming year are described." Always at end of each Chapter of the Catalogue of Requirements). https://www.krebsgesellschaft.de/gcs/german-cancer-society/certification/documents.html?file=files/dkg/german-cancer-society/pdf/Certification/Catalogue%20of%20Req%20breast-H1%201%20%2814%2007%202016%29%20EN.pdf . Teaching for students is performed through the university hospitals but they are only a small part of all certified Breast Cancer Centres.	ments.html?file=files/dkg/german-cancer-society/pdf/Certification/Catalogue%20of%20Req%20breast-H1%201%20%2814%2007%202016%29%20EN.pdf)	
	<i>ED National Representative</i>						
EE	<i>ECIBC National Contacts</i>						
	<i>ED National Representative</i>	NO		YES		YES	
ES	<i>ECIBC National Contacts</i>						
	<i>ED National Representative</i>	NO		NO		NO	

Country		T1. Is there a requirement that regulates the management of research?	T2-T3 Research details/comments	U1. Is there a requirement that regulates the management of teaching provision?	U2-U3 Teaching provision details/comments	V1. Is there a requirement that regulates additional points?	V2-V3 Additional points details/comments
FI	<i>ECIBC National Contacts</i>	NO and NOT PLANNED		YES, VOLUNTARY	Teaching is provided in all university hospitals. MD specialisation is being carried out as well and specialising doctors follow the curriculum they have been given. The Board of Oncology professors in the Finnish Oncology Foundation yearly defines requirements for the oncology education.	NO and NOT PLANNED	Every university hospital has dedicated breast cancer specialists; in smaller central hospitals oncologists consult breast cancer specialists at university hospitals, when needed. According to Finnish law, patients have the freedom to choose their place of treatment inside Finland.
	<i>ED National Representative</i>						
FR	<i>ECIBC National Contacts</i>	NO and NOT PLANNED		NO and NOT PLANNED		NO and NOT PLANNED	
	<i>ED National Representative</i>	YES		I do not have this information.		I do not have this information.	Breast units are not officially recognised, but rather it is based on the hospital initiative. Outpatient surgery is becoming more available, mostly in public hospitals and anti-cancer centres. The Cancer Plan insists on quality of life and high quality care affordable for all patients.
GR	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	Unfortunately, as we do not have a National Cancer Registry, each doctor arranges his/her participation in	YES, VOLUNTARY	Since 2009, the Hellenic Senologic Society operates under the auspices of the Senologic International	NO and NOT PLANNED	In Greece, the majority (16) of breast centres are in Athens; they are both public and private.

Country		T1. Is there a requirement that regulates the management of research?	T2-T3 Research details/comments	U1. Is there a requirement that regulates the management of teaching provision?	U2-U3 Teaching provision details/comments	V1. Is there a requirement that regulates additional points?	V2-V3 Additional points details/comments
GR			research on personal basis. There is no organised participation in research.		Society (SIS) and the Hellenic Ministry of Health. It is dedicated to physicians who wish to work in the breast disease area. The school covers all relevant topics. At the end doctors undergo written exams based on 100 multiple choice questions.		
	<i>ED National Representative</i>	NO		NO		NO	
HU	<i>ECIBC National Contacts</i>	YES, VOLUNTARY		YES, MANDATORY	Just in teaching hospitals.	YES, VOLUNTARY	
	<i>ED National Representative</i>						
IE	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	Some research is carried out.	YES, VOLUNTARY		YES, VOLUNTARY	There are national guidelines encompassing all the previous questions. They are monitored centrally and reviewed annually.
	<i>ED National Representative</i>	YES		YES		YES	
IT	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	The state-regions agreement on breast units networking issued 18 December 2014 highlights the importance of the research and recommends BUs to join research programmes.	YES, VOLUNTARY	State-regions agreement on breast units networking issued 18 December 2014.	YES, MANDATORY	State-regions agreement on breast units networking issued 18 December 2014.

Country		T1. Is there a requirement that regulates the management of research?	T2-T3 Research details/comments	U1. Is there a requirement that regulates the management of teaching provision?	U2-U3 Teaching provision details/comments	V1. Is there a requirement that regulates additional points?	V2-V3 Additional points details/comments
IT	<i>ED National Representative</i>	YES	See document from the Italian Ministry of Health (18 December 2014 Rep.Atti 185/CSR).	YES	See document from the Italian Ministry of Health (18 December 2014 Rep.Atti 185/CSR).	YES	See document from the Italian Ministry of Health (18 December 2014 Rep.Atti 185/CSR).
LT	<i>ECIBC National Contacts</i>	YES, MANDATORY	In case breast cancer clinical trials are ongoing, medical oncologists, surgeons, or MDT members can refer patients to the principal investigator for information and possible participation in clinical trials.	YES, MANDATORY	Most MDT members are also personnel of Vilnius University, delivering lectures and workshops for students, residents, and other doctors.	NO and NOT PLANNED	Lithuania's population is 3 million people; therefore, 10 breast units could be recommended for our country. Now, there is a possibility to get breast care in 5 units, some diagnostic procedures and breast cancer screening is available in more than 30 sites.
	<i>ED National Representative</i>						
LU	<i>ECIBC National Contacts</i>	NO, BUT PLANNED	In the framework of the Cancer Plan and through the National Cancer Institute.	NO and NOT PLANNED		NO and NOT PLANNED	
	<i>ED National Representative</i>	I do not have this information.		I do not have this information.		NO	In Luxembourg, working groups are in place to tackle all above points. Requirements will be included in the hospital and cancer plans.
LV	<i>ECIBC National Contacts</i>	NO and NOT PLANNED		NO and NOT PLANNED		NO and NOT PLANNED	
	<i>ED National Representative</i>						

Country		T1. Is there a requirement that regulates the management of research?	T2-T3 Research details/comments	U1. Is there a requirement that regulates the management of teaching provision?	U2-U3 Teaching provision details/comments	V1. Is there a requirement that regulates additional points?	V2-V3 Additional points details/comments
MT	<i>ECIBC National Contacts</i>	NO, BUT PLANNED	At the organisational level, research and audits are currently focusing on understanding the needs of cancer patients and their families, identify any service gaps that could be improved and to map out the holistic care pathway in various cancer sites, including breast cancer. A new director's post on cancer care pathways was included in 2014. Internal audits are frequently performed by the surgical firms engaged in the BU at MDH. The Oncology Department participates in and manages patients involved in clinical trials particularly with regards to chemotherapy.	NO, BUT PLANNED	Teaching of junior staff is conducted internally by all the clinicians involved. Identified new expertise required is developed by supporting and sponsoring specialist medical trainees and young resident specialists to specialise and obtain new expertise in identified centres abroad. One recent example was the attainment of new local expertise in onco-plastic surgery.	NO and NOT PLANNED	Malta has one breast unit (which follows most of the requirements included in the 2006 Guidelines) for a population of just over 420,000 (2012 Demographic Review - National Statistics Office).
	<i>ED National Representative</i>	NO		NO		NO	
NL	<i>ECIBC National Contacts</i>						
	<i>ED National Representative</i>	I do not have this information.		I do not have this information.		I do not have this information.	I do not know whether there are additional requirements as stated above.

Country		T1. Is there a requirement that regulates the management of research?	T2-T3 Research details/comments	U1. Is there a requirement that regulates the management of teaching provision?	U2-U3 Teaching provision details/comments	V1. Is there a requirement that regulates additional points?	V2-V3 Additional points details/comments
NO	<i>ECIBC National Contacts</i>	YES, MANDATORY	National Breast Cancer Registry.	YES, VOLUNTARY	Specialist training for doctors.	YES, MANDATORY	Specialist structure for doctors (i.e. breast and endocrine surgery).
	<i>ED National Representative</i>	YES		YES		YES	
PL	<i>ECIBC National Contacts</i>	NO and NOT PLANNED		NO and NOT PLANNED		NO and NOT PLANNED	
	<i>ED National Representative</i>						
PT	<i>ECIBC National Contacts</i>	NO, BUT PLANNED		NO, BUT PLANNED		NO, BUT PLANNED	
	<i>ED National Representative</i>						
RO	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	Several centres participate in clinical research through international multi-centric clinical trials, including breast cancer trials. However, this is rather 'tolerated' than regulated; there is no regulation, voluntary or not, to support clinical research.	YES, VOLUNTARY	Larger centres, usually in connection with the university, provide training for students, residents, and also postgraduate courses for cancer specialists, covering different theoretic and practical subjects.	NO and NOT PLANNED	
	<i>ED National Representative</i>						
RS	<i>ECIBC National Contacts</i>	YES, MANDATORY	Healthcare law defines obligation of tertiary healthcare institutions within the public healthcare system to conduct research in	YES, MANDATORY	On the basis of the Law on education, all healthcare institutions that are part of the university teaching centres are included	i do not know	Experts from oncology centres in Serbia are within their departments already directed/ focused on particular types of tumours

Country		T1. Is there a requirement that regulates the management of research?	T2-T3 Research details/comments	U1. Is there a requirement that regulates the management of teaching provision?	U2-U3 Teaching provision details/comments	V1. Is there a requirement that regulates additional points?	V2-V3 Additional points details/comments
RS			order to improve quality of healthcare.		in the process of teaching: - undergraduate studies - postgraduate studies - continual medical education		(e. g. breast cancer department within surgery, radiotherapy or medical oncology). Experts from those departments are collaborating through multidisciplinary meetings and making final treatment decisions. List of participants in the survey prof. dr Radan Dzodic, : kabinet@ncrc.ac.rs, radan@ncrc.ac.rs prof. dr Zorica Milosevic, pipao11@ptt.rs, mr.sc Ana Jovicevic, anajovicevic@ncrc.ac.rs dr Verica Jovanovic, MSc , verica_jovanovic@batut.org.rs prof.dr Dragan Ilic, kabinet@batut.org.rs
	<i>ED National Representative</i>						
SE	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	All university hospitals have research activities. Other breast units are involved in research activities at different levels and interests.	YES, VOLUNTARY	At all university hospitals there are associated medical schools providing education of medical students. in addition there are many hospitals	NO, BUT PLANNED	Please, see answers to question 1.6, C.2 and vii. At the moment there is an ongoing investigation whether this process [new patient

Country		T1. Is there a requirement that regulates the management of research?	T2-T3 Research details/comments	U1. Is there a requirement that regulates the management of teaching provision?	U2-U3 Teaching provision details/comments	V1. Is there a requirement that regulates additional points?	V2-V3 Additional points details/comments
SE			The National Guidelines set as target that more than 25 per cent of the patients at the breast unit should be included in research (studies). The National Board have not done any follow up yet.		associated with nurse training schools. There are national education and training courses for a variety of subjects, e.g. breast cancer surgeon, oncology with focus on breast cancer. Pathology and radiology normally have separate education programmes.		clinics] should be regulated in Sweden.
	<i>ED National Representative</i>	NO	There should be mandatory criteria when staff are employed that research is part of the "job-description" in a breast unit. So far is being discussed, but not yet put in place.	YES	All university hospitals are associated with the medical schools and part of the training takes place at a university hospital (voluntary).	NO	
SI	<i>ECIBC National Contacts</i>	YES, VOLUNTARY	Clinical trials in breast cancer are the important part of work of breast cancer specialists and are carried out according to GCP standards, the Declaration of Helsinki on biomedical research and the Directives and Recommendations of the European Commission (http://ec.europa.eu/health/documents/eudralex/vol-10/).	YES, MANDATORY	Two breast cancer units are part of teaching hospitals. These units carry out postgraduate education and specialisation of the profession such as medical oncology, surgery, radiotherapy, radiology and others.	NO, BUT PLANNED	

Country		T1. Is there a requirement that regulates the management of research?	T2-T3 Research details/comments	U1. Is there a requirement that regulates the management of teaching provision?	U2-U3 Teaching provision details/comments	V1. Is there a requirement that regulates additional points?	V2-V3 Additional points details/comments
SI	<i>ED National Representative</i>	YES		YES		NO	
SK	<i>ECIBC National Contacts</i>	YES, MANDATORY	In specialised oncology centres (e.g. National Cancer Institute, etc.).	YES, MANDATORY	In university hospitals and in some teaching departments of specialised oncology centres.	NO, BUT PLANNED	
	<i>ED National Representative</i>						
TR	<i>ECIBC National Contacts</i>						
	<i>ED National Representative</i>	I do not have this information.		YES		I do not have this information.	
UK	<i>ECIBC National Contacts</i>	YES, MANDATORY	Mandated by the National Peer Review Measures and assessed by them, and the regional network site-specific group, see below: The NSSG should discuss at least annually, the report on clinical trials from each of its MDTs (see relevant MDT measures). The following should be present at the discussion: the Chair of the NSSG or a nominated ED National Representative; the NSSG research lead; the lead clinician of	YES, VOLUNTARY	Each breast unit would have attached junior staff, at the very least, which would be taught within the unit.	YES, VOLUNTARY	While this is not mandatory this has largely been implemented in England, with most clinicians and staff involved in the diagnosis and treatment of breast cancer doing only this, or the majority of their practise being in the diagnosis and treatment of breast cancer. The population of England is 53 million and there are approximately 180 breast units, which fit with the figures above and allows the necessary degree of specialisation.

Country		T1. Is there a requirement that regulates the management of research?	T2-T3 Research details/comments	U1. Is there a requirement that regulates the management of teaching provision?	U2-U3 Teaching provision details/comments	V1. Is there a requirement that regulates additional points?	V2-V3 Additional points details/comments
UK			<p>the MDT or nominated ED National Representative from that MDT; the clinical lead of the research network or a nominated ED National Representative from the research network.</p> <p>A programme for improvement for clinical trial entry for the MDT should be agreed at the discussion.</p> <p>The MDT should produce a report at least annually on clinical trials, for discussion with the NSSG. The report should include.</p> <p>Details of the MDT's trials portfolio including the extent of local provision of the national portfolio.</p> <p>The MDT's recruitment to the portfolio, including the extent of delivery against the locally agreed timescales and targets.</p>				

Country		T1. Is there a requirement that regulates the management of research?	T2-T3 Research details/comments	U1. Is there a requirement that regulates the management of teaching provision?	U2-U3 Teaching provision details/comments	V1. Is there a requirement that regulates additional points?	V2-V3 Additional points details/comments
UK			The MDT's programme for improvement for the above, as proposed to the NSSG. The MDT should agree a final programme for improvement at the NSSG discussion meeting.				
	<i>ED National Representative</i>	YES		YES		YES	

Europe Direct is a service to help you find answers to your questions about the European Union
Free phone number (*): 00 800 6 7 8 9 10 11

(*): Certain mobile telephone operators do not allow access to 00 800 numbers or these calls may be billed.

A great deal of additional information on the European Union is available on the Internet.
It can be accessed through the Europa server <http://europa.eu>

How to obtain EU publications

Our publications are available from EU Bookshop (http://publications.europa.eu/howto/index_en.htm),
where you can place an order with the sales agent of your choice.

The Publications Office has a worldwide network of sales agents.
You can obtain their contact details by sending a fax to (352) 29 29-42758.

JRC Mission

As the science and knowledge service of the European Commission, the Joint Research Centre's mission is to support EU policies with independent evidence throughout the whole policy cycle.



EU Science Hub
ec.europa.eu/jrc



@EU_ScienceHub



EU Science Hub - Joint Research Centre



Joint Research Centre



EU Science Hub

