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Report of a **European survey** on the organisation of **breast cancer care** services

Supporting information for the European Commission initiative on breast cancer

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Foreword

by Krzysztof Maruszewski

Director, *JRC Institute for Health and Consumer Protection*

In 1987, the European Commission initiated the Europe against cancer programme. The programme was instrumental in funding the actions to develop the *European guidelines for quality assurance in breast cancer screening and diagnosis*.

In 2003, the European Council issued a recommendation to the Member States to offer evidence-based cancer screening through a systematic population-based approach with quality assurance at all appropriate levels and in accordance with the *European guidelines for quality assurance in breast cancer screening and diagnosis* (now in their fourth edition since 2006). This was followed by the Council's conclusions in 2008 which invited the European Commission to explore the potential for developing a European pilot accreditation scheme for breast cancer screening and follow-up, based on the *New European guidelines for quality assurance in breast cancer screening and diagnosis* and on other evidence-based guidelines for the other stages of care.

The European Commission assigned the Joint Research Centre (JRC) the task of steering and coordinating a dual European Commission initiative including the development of a *European quality assurance scheme* underpinned by accreditation and by a platform of evidence-based guidelines, including the *New European guidelines for quality assurance in breast cancer screening and diagnosis*.

Developing a single European quality assurance scheme is very complex. In order to take into account different organisational settings of healthcare systems within each country, it was necessary to obtain a map of the organisation and current status of breast cancer services providing screening and care in Europe. Consequently, a survey was organised in 2012 involving 28 Member States plus Iceland and Norway. Outcomes from the survey are reported in this document.

I encourage the readers to consider this EUR report, being based on the information provided by European countries on many correlated healthcare topics, as a reference for subsequent stages of the European Commission initiative on breast cancer and for other projects in the field.

It is in my opinion one of the first contributions that the JRC's Institute for Health and Consumer Protection (JRC-IHCP), in its

coordination role for this initiative, is giving to the continuous effort of Europe towards the improvement of quality of the health-care provided to all European citizens.

Therefore, I invite all the stakeholders to carefully read the report and to provide their feed-back on the impact and potential use of it, but to also report any additional information not covered by this survey as the JRC will, if necessary, for this initiative on breast cancer and for the general interest of European health authorities, organise further surveys.

Last but not least, I wish to express my gratitude to all national contacts who contributed to the survey and count on their collaboration in future surveys.

Executive summary

The JRC, the European Commission's in-house science service, was assigned in December 2012 with the tasks of (i) developing a new edition of the *European guidelines for quality assurance in breast cancer screening and diagnosis* and of (ii) developing a *European quality assurance (QA) scheme* for breast cancer services based on the European legislative framework on accreditation (defined in Regulation (EC) No 765/2008). Those tasks are part, together with other activities, of the European Commission initiative on breast cancer (ECIBC).

Both with the scope of building up the knowledge base for the ECIBC, and in view of designing a flexible QA scheme adaptable to different organisational settings, a survey was conducted targeting Member States, Norway and Iceland. The survey was set-up for providing information on several aspects of healthcare, like the organisational settings of breast cancer services, cancer screening programmes, competence requirements for professionals, patient's safety and QA. Contact persons for each country were identified with the support of the European Commission's Directorate-General (DG) for Health and Consumers and of the network of Representatives of Member States and Participating Countries for the European Partnership for Action Against Cancer (EPAAC).

Twenty-five out of 30 contacted countries provided the information requested, corresponding to a response rate of 83%. Survey responses highlighted the diversity of organisational settings for breast cancer care between countries. The primary findings are:

- In 88% of responding countries, healthcare is provided exclusively or mainly by public authorities, reflecting the European tradition of universal public coverage in healthcare.
- Alternative medicine as a complementary therapy for cancer patients is provided in a supervised and organised manner in 40% of countries; where it is provided on a voluntary basis, it is not monitored by the public healthcare system.
- When considering the requirements of healthcare professionals, control on the entry level qualifications is usually high, but decreasing from physicians to nurses to paramedical staff. For breast cancer care in particular, standardised education paths are available only in 64% of countries for physicians and less than 50% for nurses and paramedical staff.
- In 22 countries, breast cancer screening programmes are operational. Among them, 20 are organised and 18 are population-based. Among the three countries not having screening programmes, two reported ongoing or planned pilot projects. However, despite wide agreement in Europe on aspects targeted by the *Council Recommendations*, the target age range and the screening interval, there are still differences in the way screening programmes are organised and how they perform.

- Fourteen countries have ongoing screening programmes for colorectal cancer and another five countries are in a transition phase toward an organised programme. Eighteen countries have screening programmes for cervical cancer and one country is converting its current opportunistic activity into a population-based programme.
- With respect to organisation of breast cancer services, the survey has foreseen a choice between different given scenarios. Countries were asked to define which one better represented the situation in their country/region. Four countries have breast cancer services covering all the stages of breast cancer care and 13 countries have breast cancer services co-operating together to cover all stages. In two countries, delivery partners are contracted for some parts of the breast cancer care process, while six countries reported that none of the proposed scenarios (nor any combination) described their organisation of breast cancer care.
- Evidence-based procedures and reporting systems in the patient safety area are mandatory in nine countries (and recommended in 11). In two countries, a mixed situation was reported and in another country clinical risk management systems are not yet established. Periodic verification of these procedures is obligatory in 16 countries.
- Eighteen out of 25 countries declared that quality management systems were in place for breast cancer care in their country. When considering the characteristics of the systems in place, accreditation according to ISO 15189:2012, ISO/IEC 17040:2005 or certification according to ISO 9001:2008 was reported. With regard to QA systems not falling under the legal framework of accreditation, 15 public schemes and 11 private ones were reported by individual countries.

In conclusion, healthcare systems are diverse across Europe and different QA schemes for breast cancer care are in place, covering less than 50% of European countries. In order to grant equal quality of care to women, the European Commission supports the development of a European, modular, flexible and evidence-based QA scheme.

This report covers all of the information obtained from the survey. This information will be applied for the development of the scheme and is also, via the publication of this report, made available to interested stakeholders.

1. Introduction to the European Commission initiative on breast cancer

This initiative, underway at Joint Research Centre's Institute for Health and Consumer Protection (JRC-IHCP), is aimed at setting up a single system for defining, establishing and auditing/monitoring a minimum set of quality requirements for breast cancer care across Europe. The project has two main pillars:

1. Development and publication of the *New European guidelines for QA in breast cancer screening and diagnosis*.
2. Development of a *European QA scheme* for breast cancer services (BCSs), underpinned by the European Union's (EU) legal framework of accreditation[1] and by a set of evidence-based guidelines.

This initiative is in response to the Council *Conclusions on reducing the burden of cancer*[2] and it aims to mitigate the risks connected to inadequate prevention and quality of care.

Its concept foresees that all aspects of breast cancer prevention and care, screening, diagnosis, treatment, survivorship–support–palliative care, and management of recurrence (follow-up) are covered. It also foresees that the requirement of a multi-disciplinary approach will be ensured and focuses on putting women at the centre of the process.

The processes involved in the development of the *European QA scheme* will rely on information gathered through the survey of European health systems, and seeks, as far as possible, not to duplicate existing national and private schemes. *The European QA scheme* will be based on the *New European guidelines for QA in breast cancer screening and diagnosis* (and, if necessary, on the selection of existing guidelines recommendations for other stages and aspects of care not covered in the *New European guidelines for QA in breast cancer screening and diagnosis*).

A more detailed description of the European Commission initiative on breast cancer (EC-IBC) is available in the *Concept Document*,[3] which takes into account the feed-back received by stakeholders and participants of two workshops organised in 2013. It should be considered a 'living' document.

The present document, prepared by the Healthcare Quality Team within the Public Health Policy Support Unit of JRC-IHCP, replaces the deliverable *D.B.4_1_13 Working Groups Proceedings Year 1 of the Administrative Arrangement SANCO/2012/C–17.030600/12 //SI2.635313* between the DG Health and Consumers and the JRC.

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

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

3. Concept document–2013 version.

2. Scope of the survey

In 2012, in collaboration with DG Health and Consumers and the network of Representatives of Member States and Participating Countries of the EPAAC, a designate contact person responsible for coordinating responses at country level for each of the 28 Member States plus Iceland and Norway was identified. The survey included a data protection form and a questionnaire covering several aspects of healthcare, like organisational models, cancer screening, patients' safety, existing QA schemes and competence requirements for professionals.

The survey was organised primarily to map out and understand the organisation of breast cancer care and screening across Europe. The information requested was considered as crucial for setting-up a QA scheme flexible enough to respect and take into account different contexts.

It should be highlighted that the ECIBC aims to encourage application of evidence-based guidelines and harmonised operating procedures. If well-designed, the *European QA scheme* will strengthen the impact of evidence-based healthcare and outcomes of women affected by breast cancer.

3. Survey organisation

3.1. Method

The Adobe tool *LiveCycle Designer*® was used to design, distribute and manage the information provided (using the *distribute form* and *collect answers* tools). This tool allows the creation of interactive forms with automatic submission (*e.g.* via e-mail), with the flexibility of a multiple user interface. Communication with designate contacts occurred via a functional mail-box (jrc-cancer-policy-support@ec.europa.eu) accessible to all group members. In this way, full-time assistance and support could be provided to all participants.

Participants in the survey received two PDF documents: the questionnaire and the data protection form. Both documents are included in *Annex I*.

The questionnaire form was divided into six sections:

1. Administrative details
   - Contact details
   - Geographical responsibility
2. The healthcare organisation
   - Provider of healthcare in the country (private/public, details)
   - Brief description of healthcare organisation
   - Alternative medicine for cancer patients
   - Requirements for competence of health professionals (physicians, nursing staff, paramedical staff)
3. Breast cancer screening
   - Screening programmes in the country (organisation, coordination)
   - Details on breast cancer screening (organised programmes)
   - Opportunistic breast cancer screening
4. Breast cancer services organisation
   - List of different scenarios
   - Relationship between breast cancer services and screening programmes
   - Additional activities provided by breast cancer services
5. Quality requirements for breast cancer services
   - Evidence-based procedures for patient safety and reporting systems
   - Quality management systems for breast cancer services
6. Certification/accreditation schemes
   - Certification schemes for breast cancer services in the country.

Twelve of the 30 questions were mandatory (marked with an asterisk and controlled by the software used) and the remaining 18 were considered as optional. However, countries were encouraged to report optional information whenever possible. The whole of *Section 6* was optional due to the complex nature of the questions.

Once all of the data was entered into the database, a manual data cleaning procedure was performed and inconsistencies and/or missing data were reported for each particip-

ating country. *Section 4* and *Section 6* were the sections with more inconsistences; therefore, a questionnaire supplement with the list of points for clarification was sent to participating countries as well. The questionnaire supplement is included in *Annex I*.

The data protection form included a privacy statement and asked for consent to use the data provided in this survey for the development of the accreditation protocol and for research purposes. As this report will be publicly available, a *Request of Consent for Publication* was sent to all participating countries which provided information (see *e-mail* in *Annex II*).

Countries were coded according to the International Organisation of Standardisation (ISO) 3166 standard (reported in *Table 1* and available at: https://www.iso.org/obp/ui/#search). The abbreviations used in the text are listed in *Table 2*.

Table 1. *ISO codes of countries*

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

Table 2. *Abbreviations used in text*

Abbr.	Meaning	Abbr.	Meaning	Abbr.	Meaning
BCS	Breast Cancer Service	EPAAC	European Partnership for Action Against Cancer	IARC	International Agency for Research on Cancer
CAM	Complementary and Alternative Medicine	EU	European Union	ISO	International Organisation for Standardisation
DP	Delivery Partners	EUSOMA	European Society of Breast Cancer Care Professionals	NAB	National Accreditation Body
ECIBC	European Commission Initiative on Breast Cancer	EUNICE	European Network for Information on Cancer	QA	Quality Assurance
ECN	European Cancer Network	HiT	Health Systems in Transition	WHO	World Health Organization

3.2. Timeframe

JRC proposed to DG Health and Consumers that the network of Representatives of Member States and Participating Countries of EPAAC be consulted for identifying the national contacts responsible for providing information.

DG Health and Consumers informed EPAAC Representatives of Member States and Participating Countries on the 29 June 2012 (see *e-mail* in *Annex II*) of the survey launch and that the EPAAC network was asked to nominate a person responsible for it. In the case of no nomination, the EPAAC network member was considered the national contact responsible for the survey. *Annex III* contains a list of the EPAAC network members (in June 2012) and the list of national contacts responsible for the survey in each country. All nominated persons were contacted by e-mail via the functional mail-box.

1. The survey was launched on 24 July 2012 and the deadline for completion was 15 October 2012.
2. On 29 August 2012, participants were individually contacted by JRC team members to offer assistance to those who required clarification or support in completing the questionnaire.
3. On 2 October 2012, a reminder regarding the approaching deadline was sent.
4. By the deadline, 12 countries had sent back a completed questionnaire. For all the others, an individual follow-up e-mail was sent on 22 October 2012.
5. After an intense period of follow-up, the last questionnaire was received on 19 November 2012.
6. During the two *Workshops on the proposal for a voluntary EU accreditation scheme for breast cancer services and the further development of the European breast cancer guidelines* organised by the JRC-IHCP Cancer Policy Support Group 21 to 22 February 2013 and 13 to 14 March 2013, a presentation of preliminary data from the survey was done. Both presentations are available online: link to first presentation; link to second presentation.
7. A request for clarifications (in particular, regarding *Section 6*) and data integration was sent out on 17 June 2013.
8. After an intense follow-up, the last clarifications were received on 16 August 2013. Two countries (CZ and HR) did not respond and HU provided only partial information.
9. On 26 August 2013 respondents were asked to confirm and approve the proposal of JRC for summary tables of individual data, as they appear in the present document (*Annex IV*).
10. On 30 September 2013, the last confirmation was received. Five countries (CZ, FR, LV, SK, RO) did not respond.
11. On 15 November 2013, participating countries were asked to provide their consent for publication of the data. Furthermore, participants were told that in the absence of a reply before 22 November, the 'Silence gives consent' rule (consent is assumed when there is no evidence of disagreement) would be applied and it would have been recorded as a consent.

12. Four (CZ, FR, LV, RO) of the five countries from which a data confirmation was not received, eventually confirmed. Therefore, only data from SK should be considered as provisional.

3.3. Participants

In *Table 3*, the 25 countries responding and the nominated responsible who completed the questionnaires are listed. For two countries (IE, NO), the person responsible for the questionnaire was replaced between the first questionnaire in 2012 and the update in 2013.

Table 3. *List of participants*

Country	Survey Respondents	Other collaborators	Affiliations
AT	Alexandra RAMSSL-SAUER	Magdalena ARROUAS Alexandra FEICHTER Alexander GOLLMER Eva KERNSTOCK	ARS: Gesundheit Österreich GmbH, Vienna MA, AF, AG, EK: Austrian Federal Ministry of Health, Vienna
BE	Saskia VAN DEN BOGAERT	–	Federal Public Service of Public Health, Brussels
BG	Constanta TIMCHEVA	Nadia DIMITROVA	CT: Chemotherapy Clinic to the Specialised Hospital for Active Treatment in Oncology, Sofia ND: National Cancer Registry, Sofia
CY	Myrto AZINA-CHRONIDES	Maria ATHANASIADOU	Ministry of Health, Nicosia
CZ	Ladislav DUSEK	Ondřej MÁJEK	Masaryk University, Institute of Biostatistics and Analyses, Brno
DE	Karen BUDEWIG	Vanessa KÄAEB-SANYAL Simone WESSELMANN	KB: Federal Ministry of Health, Bonn VKS: Kooperationsgemeinschaft Mammographie GbR; Berlin SW: Bereichsleiterin Zertifizierung – Deutsche Krebsgesellschaft e.V., Berlin
EE	Inna VABAMÄE	–	Ministry of Social Affairs, Tallinn
ES	Isabel PEÑA-REY	Yolanda AGRA VARELA Inés PALANCA SÁNCHEZ Vicenta LABRADOR CAÑADAS Vicenta LIZARBE ALONSO Pilar SOLER CRESPO	IPR and PSC: Area of Strategies in Health, Madrid YAV: Area of Safety and Quality, Madrid IPS: Area of Accreditation, Madrid VLC and VLA: Area of Prevention, Madrid
FI	Liisa PYLKKÄNEN	Nea MALILA Tytti SARKEALA	LP: Cancer Society of Finland, Helsinki NM: Finnish Cancer Registry/Cancer Society of Finland, Helsinki TS: Mass Screening Registry/Cancer Society of Finland, Helsinki

Table 3. *(cont.)*

Country	Survey Respondents	Other collaborators	Affiliations
FR	Rosemary ANCELLE-PARK	–	Department of Health, Ministry of Health, Paris
HR	Ariana ZNAOR	–	Croatian National Cancer Registry, Croatian National Institute of Public Health, Zagreb
HU	Zoltán MÁTRAI András BUDAI	–	ZM: National Institute of Oncology, Dept. Breast and Sarcoma Surgery, Budapest AB: National Public Health and Medical Officer Service, Budapest
IE	Mary JACKSON (2012) Michael CONROY (2013)	Keith COMISKEY Fiona CONROY	Department of Health, Dublin
IT	Antonio FEDERICI Alessandro GHIRARDINI	–	Ministry of Health, Roma
LT	Arvydas GABRILAVICIUS	Inga CECHANOVIČIENĖ	General Medical Care Division, Vilnius
LU	Astrid SCHARPANTGEN	Roger CONSBRUCK	Ministère de la Santé, Luxembourg
LV	Mara EPERMANE	–	Diagnostic Radiology Center, Riga East University Hospital, Riga
MT	Miriam DALMAS	Stephen BRINCAT Gordon CARUANA DINGLI Joseph DEBONO Nadine DELICATA Doreen PACE Joe PSAILA	MD: Office of the Chief Medical Officer, Ministry for Health, Valletta SB: Sir Paul Boffa Hospital, Floriana ND and JP: National Screening Unit, Valletta GCD and JD: Mater Dei Hospital, Msida DP: Sir Paul Boffa Hospital, Floriana
NL	Annemarieke RENDERING	Nynke DE JONG	AR: Ministry of Health, Welfare and Sport, The Hague NDJ: National Institute for Public Health and the Environment (RIVM), Bilthoven
NO	Leif NORDBOTTEN (2012) Solveig HOFVIND (2013)	–	LN: Norwegian Directorate of Health, Oslo SH: Cancer Registry of Norway, Oslo
RO	Florian Alexandru NICULA	Carmen LISENCU	'Prof. Dr. Ion Chiricuta' Institute of Oncology, Cluj-Napoca
SE	Karin LEIFLAND	–	Unilabs AB, Sweden, Stockholm
SI	Blanka MIKL MEŽNAR	–	Ministry of Health, Republic of Slovenia, Ljubljana
SK	Alena KÁLLAYOVÁ	–	Slovak Republic, Bratislava
UK*	Jane ALLBERRY	Tim ELLIOTT	Department of Health, London

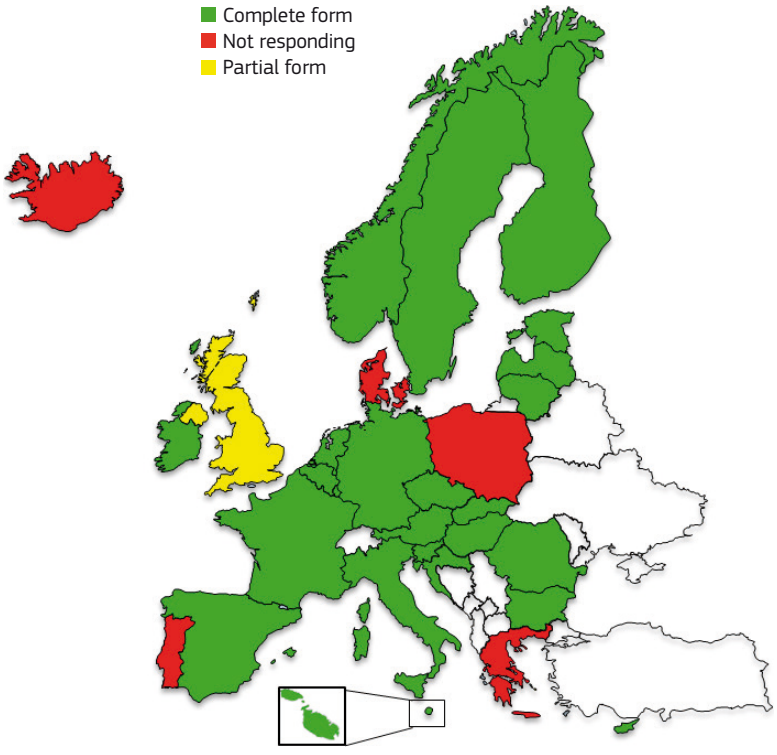
UK* data refer to England only.

4. Survey results

In all tables, countries not responding were not included, but they are visible on every map and reported in *Annex III* along with the names of EPAAC contacts.

In all descriptions, with the sole exception of breast cancer screening indicators, rates are expressed considering that the 25 countries responding represent the 100% of respondents (so, for instance, 88% of the countries reported a mainly public-based health system, means that this was the response of 22 countries out of 25).

Figure 1. *Country participation map*



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

General overview

Twenty-five out of the 30 countries which were asked to participate responded, corresponding to a response rate of 83%. One hundred per cent of those responding provided their consent for data publication. DK, GR, IS, PL and PT did not respond to the survey; therefore, no information is available for these countries. An overview of participating countries is reported in *Figure 1*.

Data submitted for UK refer to England only and are accurate up to 31 March 2013, after which a major reform of the healthcare system took place – which is not reflected in this report. For those reasons, hereinafter UK will be referred to as UK*.

Even if the results of this survey do not cover all of the invited countries, a response rate of 83% can be considered quite satisfactory and can draw a reliable picture of the current European situation in terms of the organisation of breast cancer care.

4.1. Section 1: *Contact details and area of competence*

All participants provided the mandatory information. As regards the area of competence, 24 out of the 25 contributors had a national mandate, with the sole exception of UK, where the respondent covered only England. Many of them (44%) were em-

ployed by their National Ministry of Health. Other organisations responding were research centres, cancer registries and screening programmes. In all cases, due to the procedure applied for identifying respondents, they were responsible for the information provided for their own country.

The fact that most of the people responsible for the questionnaire compilation came from their respective health ministries and in some cases also from cancer registries and screening programmes, assures a high level of competence for professional profiles reporting information. The high number of people further involved in the questionnaire compilation as contributors in addition to the original respondent (*i.e.* 28 more collaborators) also reflects the level of commitment by countries and the broad spectrum of competences and professional profiles contributing to the survey.

4.2. Section 2: *Healthcare organisation*

In this section participants were asked to report about organisational settings of their healthcare system (a mandatory response), with additional questions in particular about competence requirements for healthcare professionals. In fact, any QA scheme for BCSs should be flexible enough to be applicable in any kind of organisation setting; in addition the healthcare service nature (*i.e.* public or private) providing breast cancer care, can affect the application of QA schemes.

General healthcare organisation This section was meant to define whether the healthcare, and the breast cancer care in particular, is provided by public and/or private entities and whether public entities are involved in the initial evaluation and/or quality checks of private entities.

Twenty-two countries (88%) reported that healthcare is provided by public health authorities, for 18 (72%) mainly and for four (16%) exclusively. Of the 20 countries reporting participation of private entities in the healthcare system, eight stated that those outsourced services are not checked by public authorities.

Participants were also asked to report additional details on the healthcare system in their own country following the *World Health Organization (WHO) Health Systems in Transition (HiT)* report template: http://www.euro.who.int/en/who-we-are/partners/observatory/health-systems-in-transition-hit-series.

Therefore, organisational structure of the healthcare system, health delivery system, financing and coverage and financial resource allocation were addressed as well. Even if a HiT report is available on the WHO web for each European country, including all countries participating into this JRC survey, this point was included in this survey to ensure that an updated and short description would be provided. Thus, 22 out of the 25 responding countries (88%) also reported further information and/or a résumé of the HiT report. With regard to this section, in order to improve readability of the tables and to

focus the information on the main points, in *Annex IV*, *Table 1*, a shortened version of the original text is provided. The original response is available upon request.

Aggregated information on general health system characteristics is described in *Figure 2a* and corresponding map (*Figure 2b*).

Figure 2a. *Health system characteristics (aggregated data)*

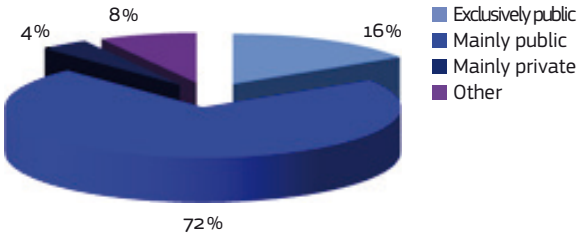
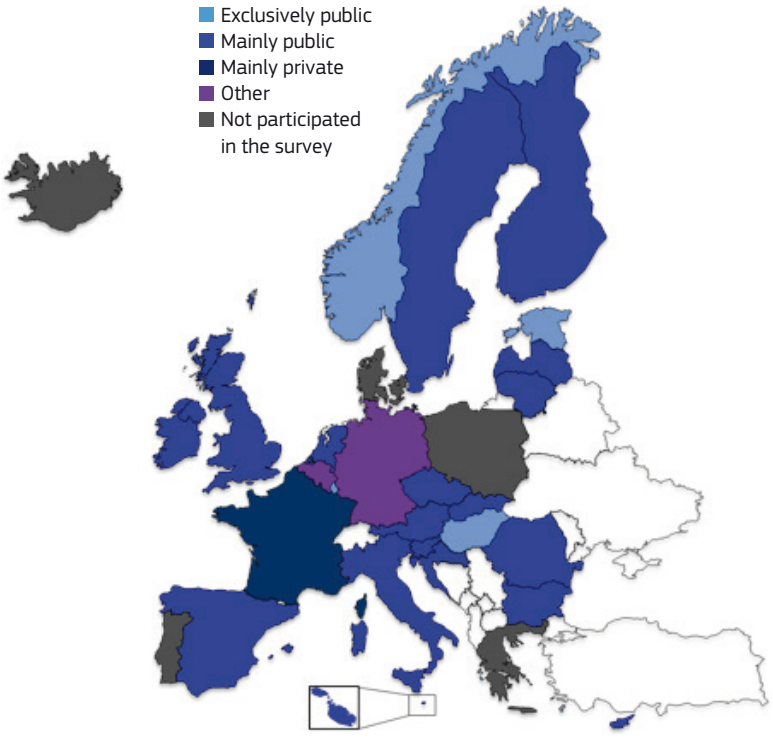


Figure 2b. *Health system characteristics map (per country)*



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

The fact that the majority of countries reported a mainly or totally public system was an expected result when considering the European tradition of universal coverage via a public control of healthcare services. State regulation provides for universal health insurance or service coverage for healthcare through compulsory schemes.[4,5] However, the fact that some countries preferred not to choose a pre-defined category, due to the complexity of the relationship between private and public in their system, reflects the increased synergy and overlapping of public and private systems that has emerged in the recent years[6] and that must be taken into account when defining the structure of the *European QA scheme*.

Additional information – Alternative medicine

In the same section where organisational settings were to be reported, participants were also asked to report whether alternative medicine is provided for cancer patients and, if yes, at which stage of care. Complementary medicine refers to practices that have known efficiency and are used along with conventional methods, whereas alternative medicine is promoted as a substitute for conventional medicine and have not been scientifically proven, sometimes even been disapproved (Deng, 2009). In a survey conducted by the European Oncology Nursing Society among cancer patients in 15 Euro-

4. http://www.europarl.europa.eu/workingpapers/saco/pdf/101_en.pdf.

5. http://www.who.int/whr/2010/en/index.html.

6. http://www.euro.who.int/__data/assets/pdf_file/0009/98307/E92469.pdf.

pean countries, use of complementary and alternative medicine was reported by 36% of the patients surveyed and varied greatly between the participating countries (Molassiotis, 2005). Common reasons for cancer patients to seek alternative treatments were the expectation of a therapeutic response and improving physical and emotional well-being (Wanchai, 2010). This questionnaire was not designed with the intention to fully describe this issue and a unique definition of complementary and alternative medicine (CAM) was not provided to respondents.

Even if the question was not mandatory, all participants responded. In 10 countries (40% of respondents) alternative medicine is offered, mainly in the area of palliative care and managing side effects. For some countries (AT, MT, NL, SI) alternative medicine, when present, is not provided by the public healthcare system and/or is covered only by certain insurance policies/companies.

Details on individual responses and on descriptions provided by participants are reported in *Annex IV*, *Table 2*. Aggregated information on alternative medicine for cancer patients is described in *Figure 3a* and corresponding map (*Figure 3b*).

These data show that European situation is heterogeneous on this subject. While in 40% of countries this kind of complementary assistance is provided in a supervised and organised manner, in countries where it is provided on a voluntary basis, it is not supervised by the public healthcare system. Since it has been reported (Deng, 2009) that patients supported with guidance on CAM are less likely to pursue potentially dangerous alternative therapies and more likely to adhere to the conventional therapy, the future *European QA scheme* should include guidelines for breast cancer care that take into account the tendencies and preferences of patients on this topic and provide evidence-based recommendations.

Figure 3a. *Use of alternative medicine for cancer patients (aggregated data)*

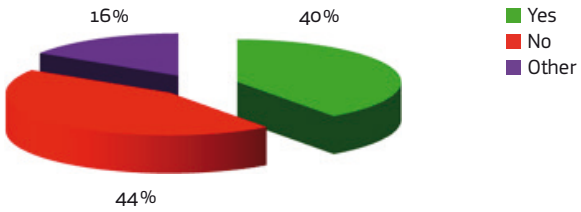
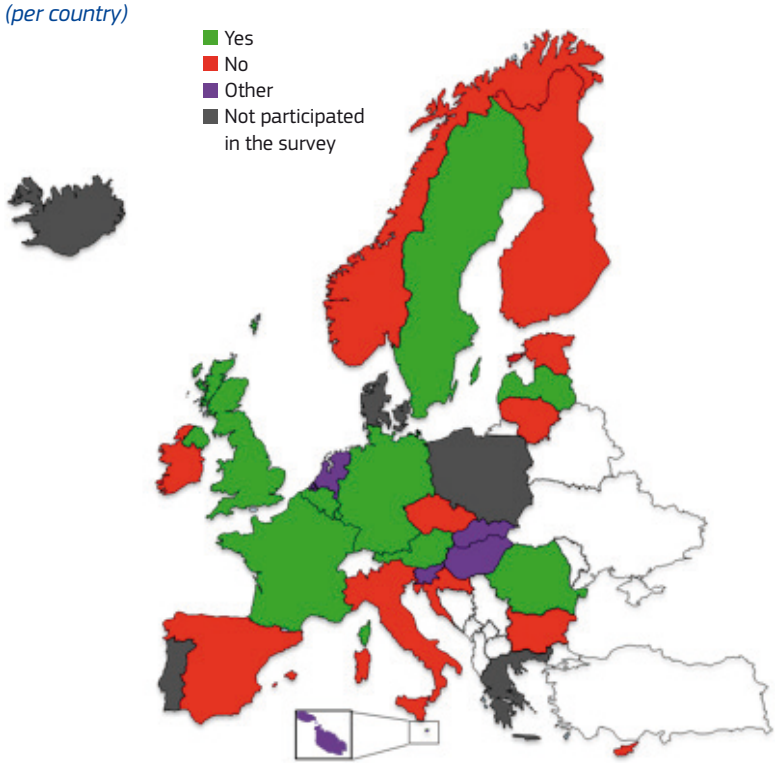


Figure 3b. *Use of alternative medicine for cancer patients (per country)*



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

Additional information – Requirements for competence of health professionals In the same section where organisational setting details were to be reported, participants were asked to report for physicians, nursing staff and paramedical staff requirements in the country. Choice was given among (i) mandatory entry level qualifications, (ii) a registration-licensing system, (iii) requirements for training/competence updating and (iv) specific training for breast cancer (physician and nurses only). In fact, since Article 3(1)(c) of the Treaty[7] states the right of EU citizens to work in Member States other than the one in which they obtained their qualification, many efforts have been undertaken in the European landscape in order to harmonise the professional profiles, in particular in the healthcare field. Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005[8] seeks to overcome obstacles caused by different requirements from Member States by organising the reciprocal recognition of professional qualifications. Application of the Cross-border Health Directive (Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011)[9] will increase the need for uniform qualifications even more. Therefore, from the perspective of the harmonisation of breast cancer care in Europe, a description of the individual countries professional pathways will be necessary. Furthermore, requirements for staff qualifications and skills are a cornerstone of most quality management systems (from the ISO standards to the hospital accreditation systems to the breast cancer QA schemes – see *Section 6*).

As regards to physicians, most countries reported that mandatory steps for entering the profession, for registration and for competence updating are in place. In 16 of 25 countries (64%), specific training for breast cancer care exists as well. This training is provided by different entities across countries: through an accreditation system (AT), a specialised degree (DE, SI), a Master's degree (ES), training in specialist centres (CZ), training by medical associations (FI), training provided by screening programmes (NL, SI) or a mix of different actors (IT, UK*). On the other hand, such specific training for nursing staff is present in only nine countries (36%), whilst for paramedical staff, several countries reported partial or no qualification (40%), registration (44%) and competence updating (64%), in particular for chiropractors and osteopaths.

Details of individual responses and descriptions provided by participants are reported in *Annex IV*, *Table 3*, *Table 4* and *Table 5*. Aggregated information is described in *Figures 4-6*. Bold numbers on bars correspond to the number of positive responses.

The data show that the level of control on the entry qualifications is usually high, but decreasing from physicians to nurses to paramedical staff. The level of control is reduced also when considering registration/licensing and competence updating. If we consider

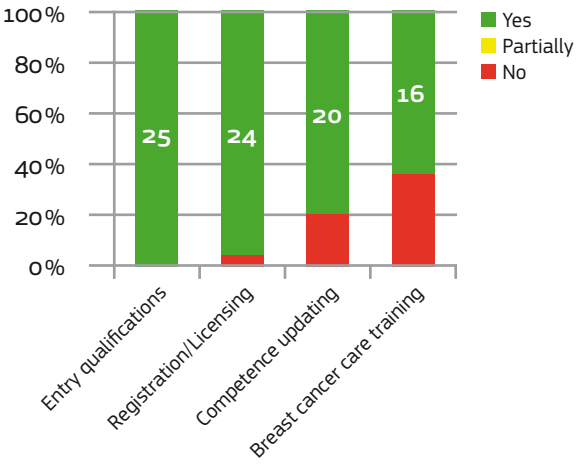
7. OJ C 325, 24.12.2002, pp. 40-41.

8. OJ L 255, 30.9.2005, p. 22.

9. OJ L 88, 4.4.2011, p. 45.

breast cancer care in particular, standardised education patterns are available only in 64% of the countries for physicians and less than 50% for nurses and paramedical staff, which reflect a lack of consistency also within countries. It is worth mentioning that guidelines for training of staff involved in breast cancer screening are included in the *European guidelines for QA in breast cancer screening and diagnosis* (hereinafter those guidelines will be referred to as *European QA guidelines*) and a position paper on the *Guidelines on the standards for the training of specialised health professionals dealing with breast cancer* was published on behalf of the European Society of Breast Cancer Care Professionals (EUSOMA) in 2007 (Cataliotti, 2007). *Boosting Innovation and Cooperation in European Cancer Control – The key findings*[10] published within the EPAAC project also defined the importance of harmonisation and improvement of healthcare staff training.

Figure 4. *Requirements for competence for physicians (aggregated data – positive responses in bold)*



10. http://www.epaac.eu/images/OF_Ljubljana/Cancer_book_web_version.pdf.

Figure 5. *Requirements for competence for nursing staff (aggregated data – positive responses in bold)*

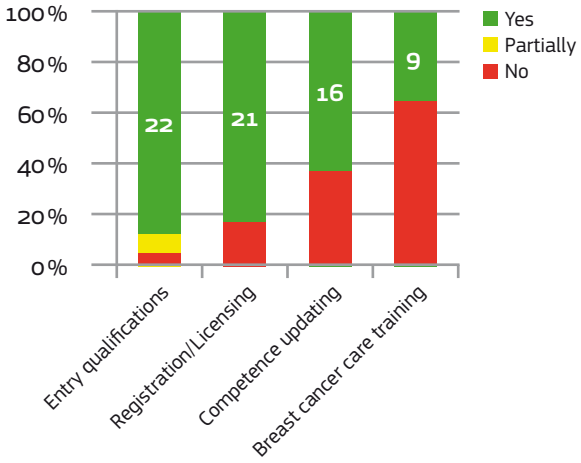
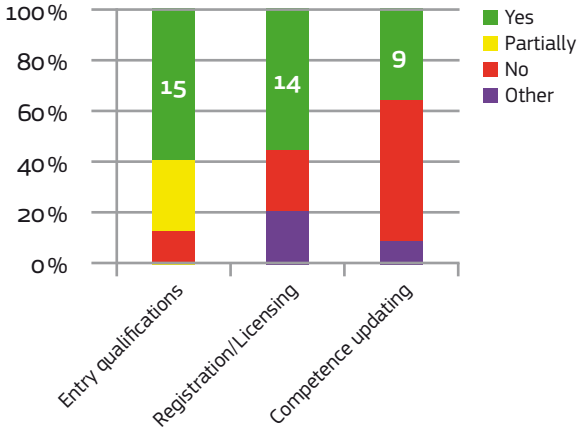


Figure 6. *Requirements for competence for paramedical staff (aggregated data – positive responses in bold)*



4.3. Section 3: *Cancer screening*

The screening step targets a healthy population and usually is a women's only point of contact with BCS. In cases where cancer is detected, it is the point of access for diagnosis confirmation and subsequent treatment. Moreover, there is substantial consensus between the Member States and

the Council of the EU in promoting breast cancer screening based on mammography as a public health policy: the Council Recommendation of 2 December 2003 on cancer screening 2003/878/EC[11] (hereinafter referred to as the *Council Recommendations*) suggests implementation of breast cancer screening programmes with a mammogram every other year for women aged 50 to 69 years in accordance with the *European QA guidelines* with an organised, population-based approach. In 2008, the *Report on the implementation of the Council Recommendation on cancer screening* (hereinafter this report is referred to as the *Implementation Report*), based on a written survey of the 27 Member States conducted by DG Health and Consumers in the second half of 2007 and supplemented by information obtained through the European Cancer Network (ECN) and European Network for Information on Cancer (EUNICE) projects, described the situation of breast, cervix and colorectal cancer screening programmes in Europe up to 2007, four years after the Recommendation's adoption. Mammographic screening data by the EUNICE survey about programme characteristics, coverage and participation up to 2007 were also recently published (Giordano, 2012). From the perspective of inclusion in the *European QA scheme* of essential key performance indicators and requirements for the screening, and missing an updated description of the EU Member States implementation of breast cancer screening programmes at the time of the preparation of the questionnaire, the aim of this section was to investigate the presence of those screening programmes and to focus on some performance indicators. Additional questions on colorectal and cervical cancer programmes were added in order to update the European picture with respect to the other two cancer sites targeted by the *Council Recommendations* on some general aspects.

General European screening scenario This section recorded the presence of screening programmes and defined their level of organisation in terms of the complexity of the degree of public responsibility, organisation and supervision and the centralised or delocalised level of coordination (mandatory responses).

The definitions of the screening organisation (*Table 4a*) are extracted from the *Implementation Report* (see also *Annex I*).

When considering the national or regional level of coordination, the following definitions were provided as per *Table 4b*.

The questionnaire was not designed for retrieving information about the country implementation status, *i.e.* planning phase, pilot phase, ongoing rollout, or rollout completion, as defined in the *Implementation Report*.

Additional information was sought mainly on the performance indicators of breast cancer screening programmes.

All 25 responding countries provided information for this section.

11. OJ L 327, 16.12.2003, pp. 34-37.

Table 4a. *Definitions of the screening organisations*

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

Table 4b. *Definitions of the screening organisations*

National screening programme	A screening programme which is run with the same modalities and criteria (*e.g.* for selection of screening centres, for the modality of calling the target women, etc.) in the whole country.
Regional screening programme, nationally coordinated	A screening programme which is run independently by different regions of the same country, not necessarily applying the same modalities and criteria, however, at national level a coordination observatory is in place.
Regional screening programme	A screening programme which is run with the same criteria (*e.g.* for selection of screening centres, for the modality of calling the target women, etc.) in the whole region.
Local screening programme, regional/national coordinated	A screening programme which is run independently by different areas of the same region or country, not necessarily applying the same modalities and criteria, however, at regional and/or national level a coordination observatory is in place.
Local screening programme	A screening programme which is run with the same criteria (*e.g.* for selection of screening centres, for the modality of calling the target women, etc.) in the whole area (province, town, etc.).

Breast cancer screening

Twenty-two countries (88%) have screening programmes for breast cancer, among which 20 (80% of the total) are organised, according to the definitions given. In fact, AT is piloting an organised population-based programme and, currently, there is non-organised screening coordinated at national level; in SI, an organised programme is present only in certain areas of the country. All three countries (12%) not having screening programmes reported on-going projects.

Eighteen organised programmes (including SI, even if operating only in certain areas) have a national coordination and they are all population-based with the exception of

CZ and LT. Two countries have a population-based programme with regional coordination (BE and ES) and one country (SE) reported a population-based programme with national, regional or local coordination depending on the area. The pilot project in AT is population-based, regional with national coordination.

Table 5. *Breast cancer screening programmes*

Country	Organised programme	Population-based programme	Coordination
AT	Pilot	Some of the regional projects are population-based	Pilot
BE	YES	YES	Regional
BG	NO	–	–
CY	YES	YES	National
CZ	YES	NO	National
DE	YES	YES	National
EE	YES	YES	National
ES	YES	YES	Regional
FI	YES	YES	National
FR	YES	YES	National
HR	YES	YES	National
HU	YES	YES	National
IE	YES	YES	National
IT	YES	YES	National
LT	YES	NO	National
LU	YES	YES	National
LV	YES	YES	National
MT	YES	YES	National
NL	YES	YES	National
NO	YES	YES	National
RO	NO	NO	–
SE	YES	YES	National/Regional/Local depending on the area

Table 5. *(cont.)*

Country	Organised programme	Population-based programme	Coordination
SI	YES (in certain areas)	YES (in certain areas)	National, but operating only in certain areas
SK	NO	NO	–
UK*	YES	YES	National

UK* data refer to England only.

Details of individual responses and descriptions provided by participants are reported in *Annex IV*, *Table 6*. Aggregated information is described in *Figure 7a* and corresponding map (*Figure 7b*). AT (pilot) and SI (operating only in certain areas) are reported as 'Other'.

If we compare this data with the corresponding figure in the *Implementation Report*, some countries included in the former are not in the current document (DK, GR, PO, PT, UK-Scotland and UK-Northern Ireland) and vice versa (HR, NO). However, considering that in 2007 a population-based programme rollout was ongoing or complete in DK, PO, PT, UK-Scotland and UK-Northern Ireland and that those countries not reporting a population-based programme in 2007, like LV and LT, had a national one in place in 2012, an increase in compliance to the *Council Recommendations* can be inferred. Updated information is still missing for GR, a country where a population-based programme was not in place nor planned in 2007.

Figure 7a. *Presence of an organised screening programme for breast cancer (aggregated data)*

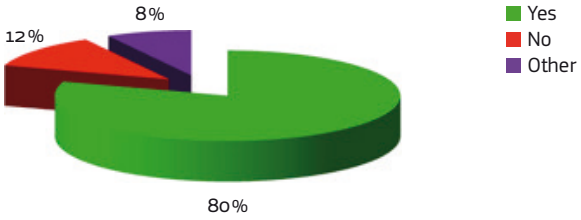


Figure 7b. *Presence of an organised screening programme for breast cancer (per country)*

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

Colorectal cancer screening

Fourteen out of 25 countries (56%) have ongoing screening programmes for colorectal cancer and another five countries (20%) (CY only for certain regions) are in a transition phase toward an organised programme. In fact, DE is converting its current opportunistic activity into a population-based programme, FI and NO are currently engaged in a pilot phase, NL is starting programme roll-out in 2014. RO and BG are in the process of planning a programme. The organised established programmes have national coordination in 12 countries (48%) and regional coordination in two (8%, BE and ES). In two of the nationally coordinated countries (8%, HU and LT), the programme is regionally organised. One country (CY) reported having a nationally coordinated programme, but it is only active in certain areas. In the questionnaire, a question on whether the programme is population-based or not was not included for colorectal cancer screening.

Figure 8a. *Presence of an organised screening for colorectal cancer (aggregated data)*

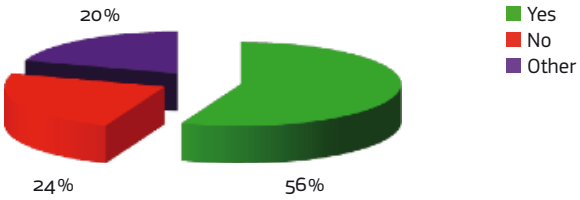
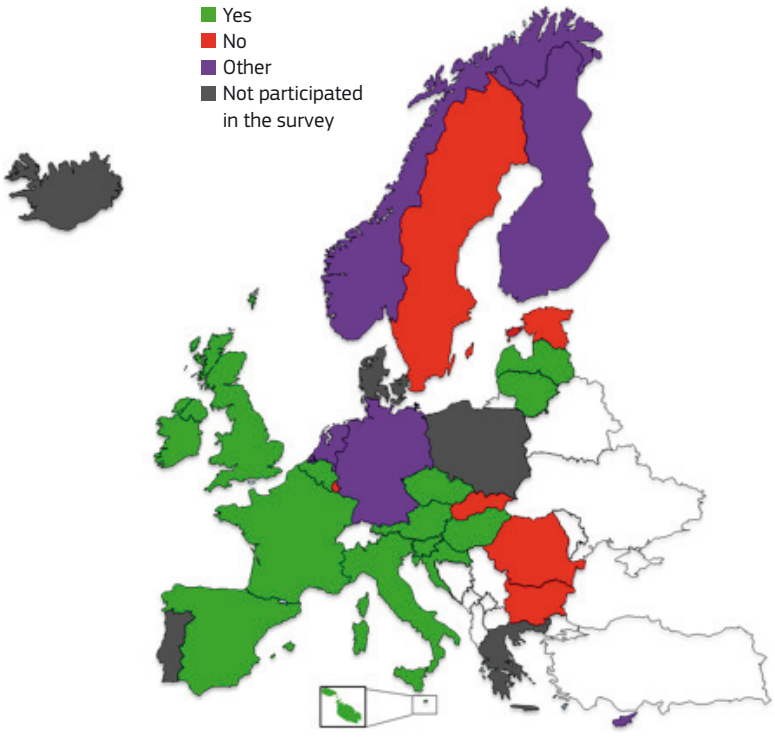


Figure 8b. *Presence of an organised screening for colorectal cancer (per country)*



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

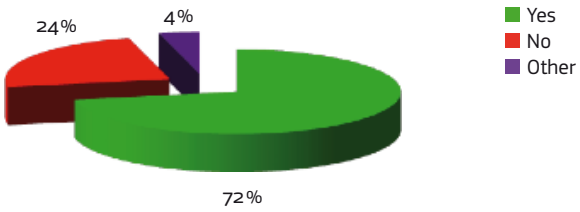
Details of individual responses and descriptions provided by participants are reported in *Annex IV*, *Table 6*. Aggregated information is described in *Figure 8a* and corresponding map (*Figure 8b*). Countries with programmes which are only active in certain regions (CY), in pilot (FI, NO), in roll-out (NL) and transition (DE) phases are reported as 'Other'.

Cervical cancer screening

Eighteen out of 25 countries (72%) have screening programmes for cervical cancer and one (4%, DE) is converting its current opportunistic activity into a population-based, quality-assured programme. BG is in the process of planning a programme. The organised programmes were reported as national in 15 countries (60%), regional in one (4%, BE) and regional or local with national coordination in two (8%, FR and RO).

Details of individual responses and descriptions provided by participants are reported in *Annex IV*, *Table 6*. Aggregated information is described in *Figure 9a* and corresponding map (*Figure 9b*). DE is reported as 'Other'.

Figure 9a. *Presence of an organised screening for cervical cancer (aggregated data)*



Additional information – European breast cancer screening programmes This section provides further information about breast cancer screening programmes. Every country which reported to have a breast cancer screening programme in place (n=22) provided, at the very least, information about its main characteristics (age range, type of test, etc.). In some cases, data are specific for a single screening programme within the country or a single region: corresponding codes are reported in *Table 6*.

Table 6. *Codes for regions*

Code	Name
ATa	Vienna-Voralber-Salzburg
ATb	Burgenland
ATc	Tirol
BEa	Brussels
BEb	Flemish
BEc	Walloon
ESa	different Spanish regions
ESb	different Spanish regions
ITa	different Italian regions
ITb	different Italian regions
UK*	England

UK* data refer to England only.

Figure 9b. *Presence of an organised screening for cervical cancer (per country)*

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

Most screening programmes started in the first decade of this century, with the exception of older programmes (FI in 1987, UK* in 1988, SE in 1989, NL in 1990, LU in 1992, NO in 1996) and more recent ones (2011 in EE and the pilot ongoing in AT); programmes in ES started in different years from 1990 to 2011 (see *Annex IV*, *Table 7*).

Years for which data were available and reported ranged from 2008 to 2012, with the majority of information pertaining to 2010 and 2011.

The method most often used is mammography alone, with the exception of FR which implements mammography plus clinical breast examination. A specific question about analogic vs. digital mammography was not included in the questionnaire and the corresponding figure was voluntarily reported by some countries (see *Annex IV*, *Table 7*).

With regard to the age range, most countries/programmes covered the 50-69 range suggested by the *Council Recommendations*. The extension to age 74 is reported for FR, ITb, NL and SE; the extension under age 50 is reported by ATb (40), ATc (40), SE (40), CZ (44), ESb (45), ITb (45). EE, IE and MT do not cover the age range and screening stops at age 62, 64 and 60 respectively. CZ did not report a maximum age limit. Detailed information on age range is reported in *Figure 10* (CZ is reported in a different colour due to the absence of an upper age limit).

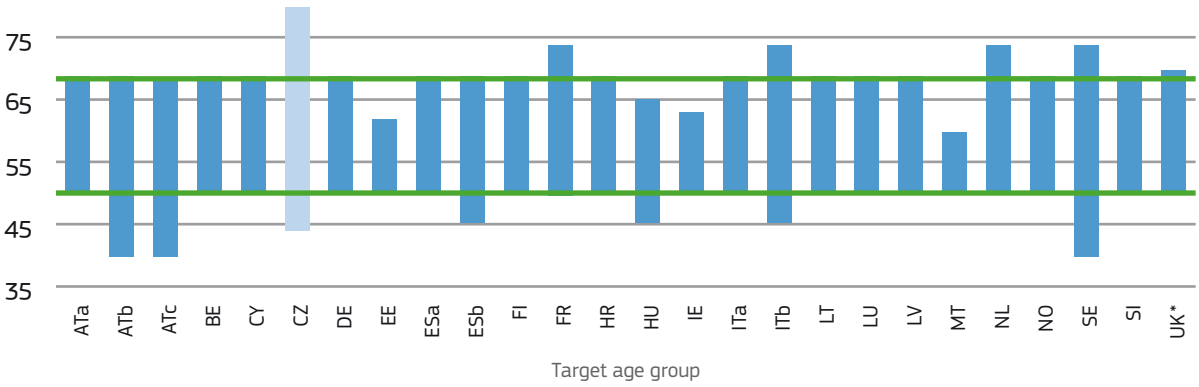
With regard to the screening interval, most countries/programmes use the 24-month interval suggested by the *Council Recommendations* with the exception of AT (12 to 24 months depending on pilot project, age or *Breast Imaging-Reporting and Data System* category), MT and UK* (36 months), SE (18-21-24 months according to age and area).

Details of descriptions provided by each participating country are summarised in *Annex IV*, *Table 7*.

Each country which reported to have a mammography screening programme in place could report detailed information about key programme indicators, *i.e.* number of invitations per year, invitation rate per round, participation rate, recall rate, detection rate, positive predictive value, even if in some cases one or more indicators were not reported.

A clear description of numerators and denominators for each indicator was not provided within the questionnaire; therefore further clarifications were necessary during

Figure 10. *Age range*



UK* data refer to England only.

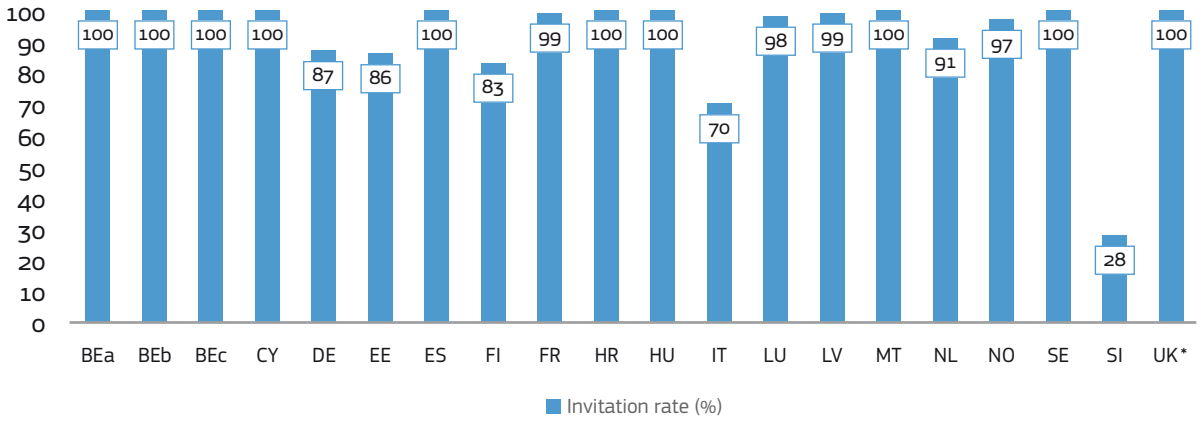
the data check follow-up phase. Notwithstanding this additional effort, it is not possible to ensure that data have been consistently interpreted and reported by countries. Thus, the following figures are mainly indicative trends and cannot constitute a source for comparison between countries. Details of descriptions provided by each participating country are reported in *Annex IV*, *Table 8*.

The number of people invited per year depended mostly on the country population and the programmes' coverage – ranged from 13 000 (MT) to 4 801 000 (DE).

With regard to the invitation rate per round, defined in the questionnaire as 'the percentage of the invited women over the target group', most countries reported a percentage higher than 90 %. Lower percentages are reported for DE (87 %), EE (86 %), FI (83 %), IT (70 %) and SI (28 %). The invitation rate can approximate the coverage by invitation, which is defined by the *European QA guidelines* as 'the extent to which the screening programme covers the eligible population by invitation' and can be calculated as 'the ratio between the number of invitations during a period equal to the screening interval and the number of women in the eligible population'. Detailed information on invitation rate is reported in *Figure 11*.

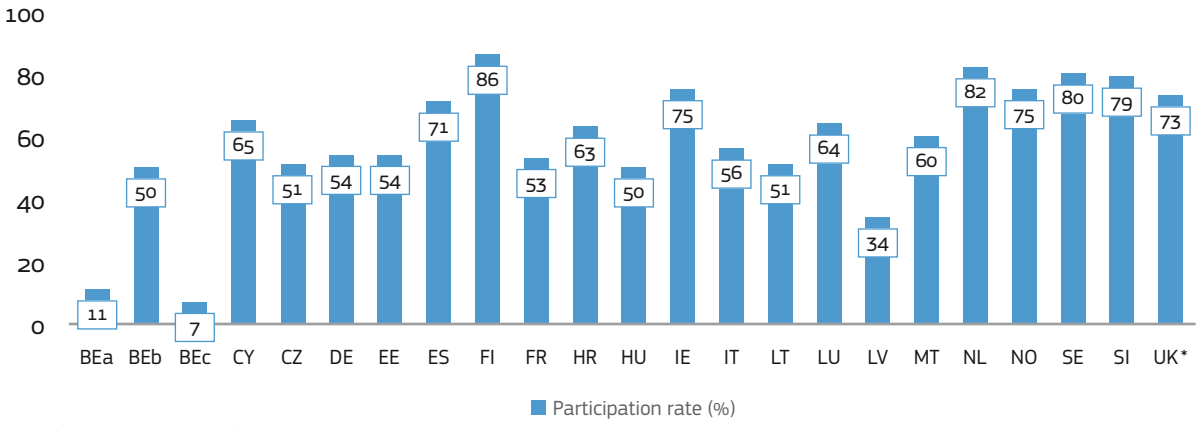
As regards the participation rate per round (defined in the questionnaire as the percentage of women screened to the number invited), four countries (FI, NL, SE and SI) reported a percentage higher than 75 %, which was the desirable threshold for the corresponding indicator in the *European QA guidelines* whose definition was 'the number of women who have a screening test as a proportion of all women who are invited to attend for screening', and other four (ES, IE, NO and UK*) higher than 70 %, which was the acceptable level. Detailed information on participation rate is reported in *Figure 12*.

Figure 11. *Invitation rate (%)*



UK* data refer to England only.

Figure 12. *Participation rate (%)*



UK* data refer to England only.

The recall rate was defined in the questionnaire as '% of women recalled for further assessment over all women who had a screening examination' without a separate question for first screening round and subsequent rounds. Since many countries reported the indicator split per round, in the data check step, it was required that other countries report the indicator in this way as well. Thus, in *Figure 13a* and *Figure 13b*, two different versions of the indicators are reported. For first screening rounds four countries (IE, IT, LU and MT) had a recall rate higher than the maximum acceptable level of 7% of the corresponding indicator (in the *European QA guidelines* definition was 'the number of women recalled for further assessment as a proportion of all women who had a screening examination') and five countries performed below the desirable level of 5% (CZ, NL, NO, SE and SI). For subsequent screening rounds, no country had a recall rate higher than the maximum acceptable level of 5% and most countries performed below the desirable level of 3%.

Figure 13a. *Recall rate (%)*

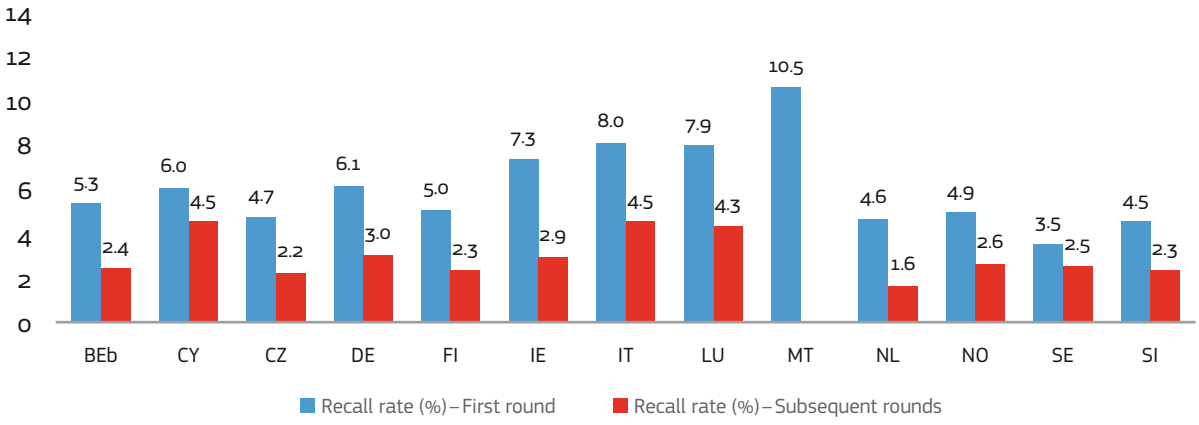
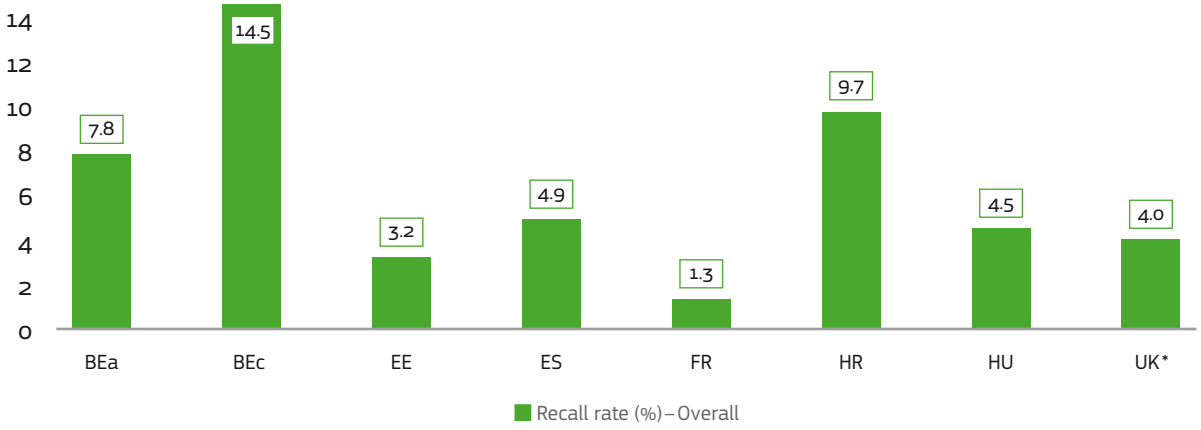


Figure 13b. *Recall rate (%) – overall*

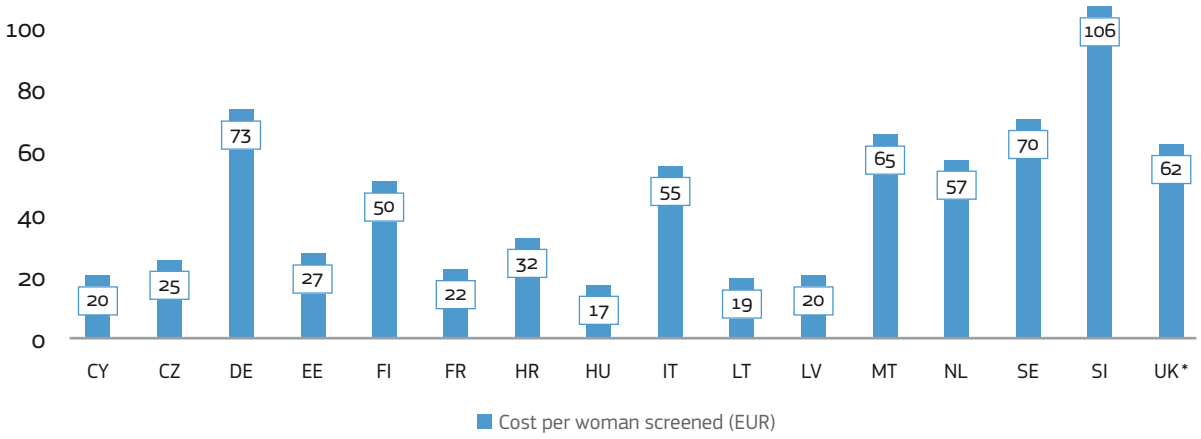


UK* data refer to England only.

For detection rate and positive predictive value, even after an intense follow up, a consistency in the definition of rates across countries cannot be ensured; therefore it was preferred not to propose graphics comparing countries. Instead, individual data is reported in *Annex IV*, *Table 8* and *Table 9*.

The participants were finally asked to report the estimated cost of a woman screened in their local currency. The corresponding figures converted in euros on 23 April 2013 are reported in *Figure 14* and ranged from EUR 17 (HU) to EUR 73 (DE). Further details about operational costs to be included in the mammography's estimate were not provided and reported costs were not normalised according to cost of life. Therefore, this figure is merely indicative of a trend.

Figure 14. *Cost per woman screened (EUR)*



As already reported in previous documents (Giordano, 2012), the results presented show that, despite wide agreement in Europe on aspects targeted by the *Council Recommendations* such as the screening test (mammography), the target age range (50-69 years) and the screening interval (two years), there are still differences in the way screening programmes are organised. These differences can be due to different policy priorities in the individual countries, but also to the need for an updated set of European recommendations with respect to some criteria (*e.g.* the age). Furthermore, differences between countries in terms of performance indicators were observed, not only with respect to the indicator's outcome, but also when considering the ability to collect the information and to deliver it consistently. Therefore, the future *European QA scheme* should aim to improve the dissemination of evidence-based European breast cancer screening recommendations and to support the collection and benchmarking of programme indicators.

Additional information – Opportunistic screening This additional section provided information regarding the extent of opportunistic breast cancer screening, whose definition in an International Agency for Research on Cancer (IARC) reference document[12] is 'Screening outside an organised or population-based screening programme, as a result of *e.g.* a recommendation made during a routine medical consultation, consultation for an unrelated condition, on the basis of a possibly increased risk for developing breast cancer (family history or other known risk factor) or by self-referral'.

The extent of the phenomenon was approximated in the questionnaire asking countries whether there are activities outside of the organised screening programme that account for more than 10% of the total number of mammograms performed for asymptomatic, average-risk women. In fact, the *European QA scheme* will also take those activities into account.

Twenty-two countries provided information – where activities outside the organised screening programmes accounting for more than 10% of the total activity, were reported in nine countries (36%), and below 10% in eight countries (32%). In five countries, the situation was unknown (20%).

NL noted that according to the *Population Screening Act*, a permit is needed to screen cancer and this act limits opportunistic breast cancer screening to a small percentage. In SI, a non-programme screening (see *Table 4a* for definition) had been active for more than 10 years based on healthcare structures and private practices. In other countries, such activity is mainly based on private practice (BE, CY, FI and FR).

Aggregated information is described in *Figure 15a* and corresponding map (*Figure 15b*). Details of individual responses and descriptions provided by participants are reported in *Annex IV*, *Table 10*.

12. World Health Organization – International Agency for Research on Cancer: *IARC Handbooks of Cancer Prevention, Volume 7: Breast Cancer Screening* (Lyon, France: IARC Press, 2002).

With cutbacks being implemented across a wide range of health services in Europe, it is a priority to focus prevention activities which are evidence-based and cost-effective. Poorly designed programmes, and uncoordinated early detection services waste considerable financial, material and human resources (Martin-Moreno, 2013). Furthermore, due to concerns about the amount of over-diagnosis in breast cancer screening (Paci, 2012; Independent UK Panel on Breast Cancer Screening, 2012), an additional effort to reduce unnecessary testing and to strictly monitor every step of the screening pathway is a priority. The level of control of the key epidemiologic indicators of screening programmes that will be required by the *European QA scheme* will help to reach the aforementioned goals and will require an improvement of the level of organisation and supervision of screening activity in countries.

4.4. Section 4: *Breast cancer care organisation*

In order to develop a QA scheme for breast cancer care which would be flexible enough to be applied in every geographical and political context, it is necessary to check how the Member States have organised the whole pathway of breast cancer care in terms of the presence and responsibility allocated to an entity supervising the single actors which provide the different stages of service, from screening to treatment to end-of-life care. Information about breast cancer screening organisation (*Section 3*) is closely embedded with the organisation model discussed in *Section 4*. Thus, participants were asked to report about organisational settings of breast cancer care in their countries (mandatory response), with additional questions about the relation between BCSs and screening programmes and the provision of services like cultural mediation, palliative care, caregivers' support, etc. The questionnaire adopted a general operational definition of 'breast cancer service' (BCS), intended as any health-

Figure 15a. *Opportunistic screening (aggregated data)*

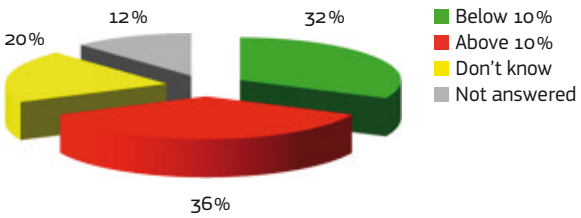
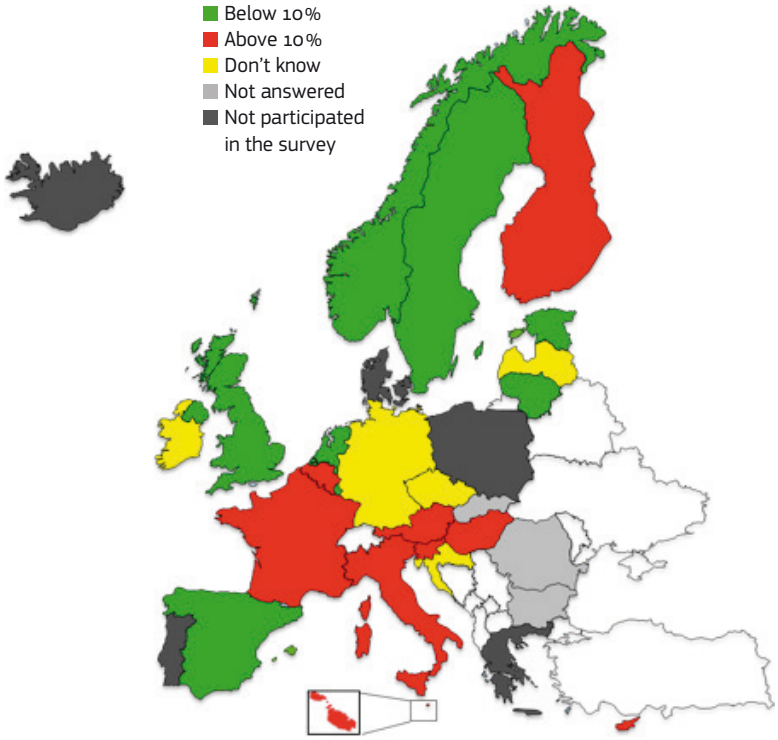


Figure 15b. *Opportunistic screening (per country)*



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

care provider treating or providing services to breast cancer patients at every stage of the disease, including early diagnosis in a screening context. In fact, the European Parliament resolution on breast cancer in the European Union[13] and the European Parliament resolution on breast cancer in the enlarged European Union[14] that asked the European countries to 'establish a network of certified multidisciplinary breast centres' and to 'ensure nationwide provision of interdisciplinary breast units in accordance with the EU guidelines' were applied by countries in different ways and up to now the definition of 'breast unit' has not been univocally interpreted in Europe (Costa, 2009).

Breast cancer services scenario In this section, countries were given nine different scenarios for breast cancer care organisation and they were asked to define which one better represented the situation in their country/region. Participants were also asked to briefly describe their BCSs organisation and define the main differences from the chosen scenario. The proposed scenarios could be grouped in three different families: those in which there is only one BCS (1a and 1b), those in which two or more BCSs are collaborating in a more or less coordinated way (2a and 2b) and those in which there is one BCS responsible for the process and delivery partners are contracted in (3a and 3b) or out (4a and 4b).

13. (2002/2279(INI)). P5_TA(2003) 0270.

14. (RE/636089EN.doc). B6-0528/2006.

After the first review of the data and respondents' comments, it emerged that a scenario in which two or more BCSs collaborate and are supervised by more than one entity was missing. Thus, an additional scenario called 2c (see *Annex II*) was sent out 17 June 2013 together with requests for clarifications (in particular regarding *Section 6*) and data integration. Nine countries switched from their original answers to scenario 2c. Most notably, DE proposed a further modification to scenario 2c, in which one entity is responsible for the screening phase and two different certification schemes cover the treatment phase.

All 25 responding countries provided information for this section. Nineteen countries (76%) could define their system with one of the scenarios given, whilst six countries (24%) reported that the organisation of breast cancer care in their area could not be described by any one or any combination of the given scenarios (scenario 6).

Four countries (16%) have a single BCS covering all the stages of breast cancer care. This can happen when a BCS is responsible for the whole process of breast cancer care and provides all stages of the breast cancer care, like in the case of CY (scenario 1a):

Figure 16a. *Scenario 1a*

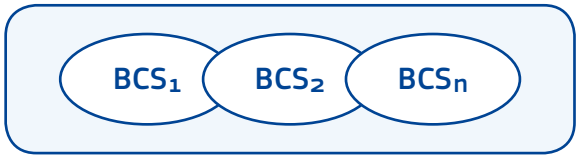
or when a BCS which is not responsible for the whole process of breast cancer care, provides all stages of breast cancer care and it is supervised by an external entity (*e.g.* the

Regional Health Authority) for the organisation and quality of breast cancer care, like in BE, HU and NO (scenario 1b):

Figure 16b. *Scenario 1b*

Thirteen countries (52%) have more than one BCSs co-operating together to cover all stages. In one country (BG) two or more BCSs are co-operating and equally responsible for the whole process of breast cancer care and they cover all stages together (scenario 2a):

Figure 17a. *Scenario 2a*

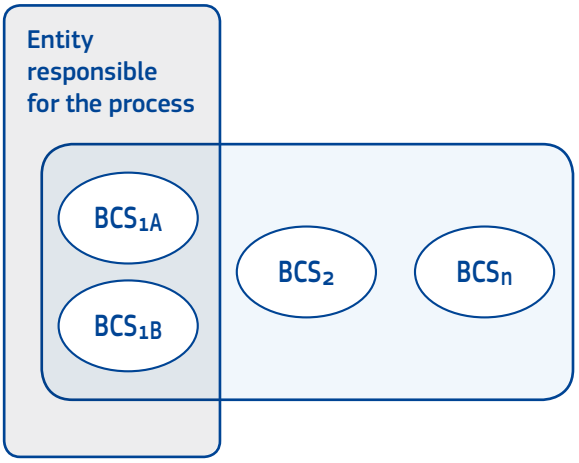


In two countries (LT and MT), two or more BCSs are co-operating, but they are not responsible for the whole breast cancer care process; however, together they cover all stages of breast cancer care. They are coordinated and supervised by an external entity (e.g. the Regional Health Authority) for the organisation and quality of the whole breast cancer care process (scenario 2b):

Figure 17b. *Scenario 2b*

Ten countries (40%) chose scenario 2c, which was proposed as an additional choice after the collation and evaluation of initial survey responses. In this scenario, two or more co-operating BCSs cover breast cancer care and are supervised by an external entity for only a part of the process:

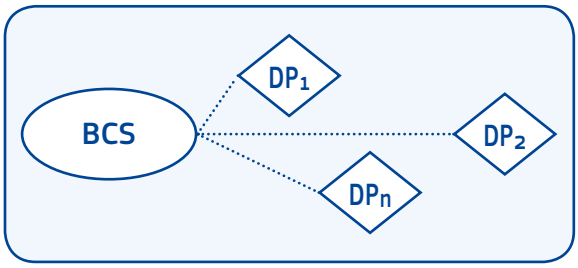
Figure 17c. *Scenario 2c*



DE proposed a modification to scenario 2c, which is reported in *Annex V*, where more than one entity is responsible for the coordination.

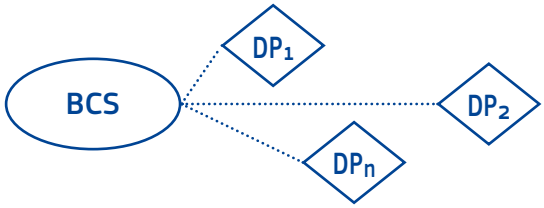
BCSs of SE and UK* contracts delivery partners (DPs) for some stages. In SE, the BCS is responsible for the entire breast cancer care process but relies on DPs for some services at all stages of the breast cancer care process; the BCS contracts these services in and thereby fall under its direct responsibility (scenario 3a):

Figure 18. *Scenario 3a*



For the UK*, the BCS subcontracts DPs out and the DPs have to confirm to the BCS that the quality requirements have been fulfilled (scenario 4a):

Figure 19. *Scenario 4a*



Scenarios 3b and 4b, where BCS subcontracts DPs and they are all under the supervision of an external authority, were not chosen by any of the respondents.

In conclusion, seven different scenarios were chosen to represent the current situation of breast cancer care in the countries participating in the survey, and nearly 25% of the countries could not identify a suitable scenario. Even if the proposed organisation settings could have been interpreted in different ways by the questionnaire participants, the picture that emerged is one of important heterogeneity between countries. Sixteen percent of countries (BE, CY, HU, NO) reported a simpler scenario, at least on a theoretical point of view, which corresponded to the scenario with only one BCS. It is worth noting that none of the larger European countries belong to this group, which means that more complex models may be necessary when flexible solutions with respect to the population size and geographical conditions are required.

Details on individual responses and descriptions provided by participants are reported in *Annex IV*, *Table 11*. Aggregated information is described in *Figure 20a* and corresponding map (*Figure 20b*). DE is reported as scenario 2c.

Additional information: relationship between breast cancer services and screening programmes Because of the importance of the screening programmes in the organisation of breast cancer care processes in European countries, in order to better understand the relationship between the programmes and the entities addressing care, the questionnaire enclosed two additional questions for this section, about the responsibility in the organisation of screening and in the execution of screening mammograms.

Twenty-one out of 25 participating countries (84%) responded to the first question: the organisation of the programme is carried out by BCSs only in six countries (24% of the total).

Fifteen out of 25 participating countries (60%) responded to the second question: mammograms for screening programmes are carried out by the BCSs in thirteen countries (52% of the total and 87% of the responding countries).

Even if from a general perspective screening programmes and hospital centres treating breast cancer should be closely connected, due to the different organisational settings, it is not always the case. Data from the present questionnaire show how in the case of a BCS which is also responsible for screening programmes happens in one out of four countries, whereas the case of BCSs performing mammograms is far more frequent (even if the response rate to this question was low). This reflects the health services organisation in most countries, in which screening programmes are under the responsibility of a regional or national authority, which is different from the responsibility of the clinical centre dealing with women after breast cancer diagnosis and coordinating the care. This figure corresponds closely to scenario 2c, which was selected by many countries. It is worth noting that in a recent position paper by EUSOMA (Wilson, 2013), a requirement states that 'It is recommended that where possible population-based breast screening programmes be based within or be closely associated with a Breast Centre […]'.

Figure 20a. *Organisation of breast cancer care services (aggregated data)*

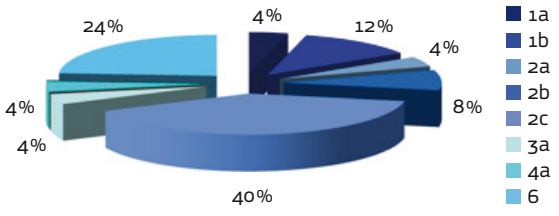
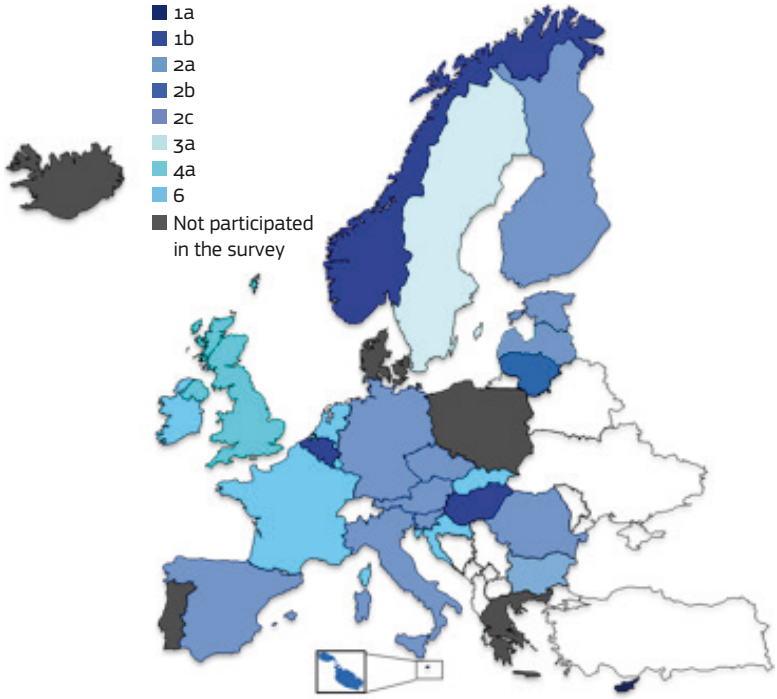


Figure 20b. *Organisation of breast cancer care services (per country)*



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

Additional information – Further services provided Medical advances, early detection and increasing life expectancy have markedly increased cancer survivorship (Ries, 2007). In cancer types with longer survival rates such as breast cancer, therapy costs for survivors in the continuing care phase tends to be the largest proportion of the total cancer expenditures (Mariotto, 2011). Care in survivorship covers a broad range of issues beyond the diagnosis and treatment phases, including but not limited to follow-up treatment, quality of life and caregivers.

Palliative care is an essential part of this type of care, and its main goal is to improve the quality of life of the patients and their fami-

lies. Palliative care includes symptoms management, psychological support for the patient and the family, as well as guidance for decision making. Rehabilitation, which is crucial when cancer therapy results in physical impairment or disability, aims to help the patient remain independent and gain control over their life. To appreciate the differences in healthcare values is critical for comprehension between people of different cultural backgrounds and for patients to make informed decisions. With the transposition of the Directive 2011/24/EU,[15] cultural mediation to assist the patient both for translation and for de-coding cultural issues related to the present distress will gain even more importance. These additional aspects need to be carefully evaluated for their inclusion in the *European QA scheme*. Thus, this section was meant for collecting information about the provision of additional services for breast cancer (and other kinds of neoplasms) like the abovementioned cultural mediation, palliative care, and caregivers' support.

Seventeen out of 25 participating countries (68%) reported data for this additional question.

The majority of the responding countries reported providing palliative care (AT, BG, CY, CZ, DE, ES, FI, FR, IE, LT, MT, UK*) and rehabilitation (BG, FI, FR, HR, LT, NL, SI, UK*) but only a minority specified that services are systematically organised: in fact, in some countries, one or more of these services are included as part of routine cancer care (CY, CZ, DE, ES, FI, FR, IE, LT, UK*), in other countries those services rely on voluntary providers. Although palliative care and rehabilitation is provided in most countries, some services are provided by only a minority of the countries such as cultural mediation (CY) and psychosocial support (CY, ES, FI, LT). DE reported that the provision of palliative care is a certification criterion for cancer centres and for sites other than breast. The data highlight the differences between the participating countries and the need for further efforts to harmonise additional services which are provided. Details on the additional information given by the countries can be found in *Annex IV*, *Table 11*.

4.5. Section 5: *Safety and quality*

The aim of *Section 5* and *Section 6* was to investigate countries' policies in terms of patient safety and the presence and characteristics of quality management systems related to BCSs. In fact, these items will be cornerstones in the *European QA scheme*. Furthermore, the Directive 2011/24/EU[16] seeks to ensure safety and quality in healthcare across different countries; Member States are obliged to inform the patients on the safety and quality standards in place and to cooperate with other Member States on standards and guidelines related to these issues.

In the original layout of the questionnaire, *Section 5* included a part called 'The quality system'. However, in the present report the presentation of data was reordered to provide

15. See note 9, p. 12.

16. See note 9, p. 12.

a better description of breast cancer quality management schemes according to the Regulation (EC) No 765/2008[17] (therein referred as the EC Regulation) and all of the information regarding quality management systems is included in *Section 6*.

Although *Section 5* included non-compulsory information, all 25 countries provided information.

Clinical risk management Clinical risk can be defined as the chance of an adverse outcome resulting from clinical investigation, treatment or patient care.[18] Clinical risk management is a systematic approach of identifying the risk of harm and taking action to prevent or control the risk.[19] Reporting near-misses and incidents of harm helps identify strategies to provide patient safety.

As reported in the Council Recommendations of June 2009,[20] Member States are in different levels in the development and implementation of effective and comprehensive patient safety strategies, therefore the Member States are recommended to establish efficient and transparent patient safety programmes and set up comprehensive reporting systems to analyse the extent and the causes of the incidents in order to develop efficient solutions and interventions. In addition, DG Health and Consumers is promoting a Joint Action[21] on patient safety in order to provide Member States with support and tools to implement those Council Recommendations.

This section collected information regarding countries' policies about evidence-based procedures for clinical risk management and corresponding reporting systems. If procedures and/or reporting systems were present, information about their periodical verification was also requested.

All participants provided the information requested even if the section was optional. Evidence-based procedures and reporting systems are mandatory in nine countries (36%) and recommended in 11 (44%). On the other hand, in AT and SI, evidence-based procedures are mandatory but reporting is not, whilst in the UK* evidence-based procedures are recommended only and reporting is mandatory. In one country (SK), clinical risk management systems are not established and, therefore, no reporting system is in place.

Periodic verification of these procedures is obligatory in 15 countries (60%). The verification process is handled by the Ministry of Health in CY and IT, by the National Health Fund and the National Public Health and Medical Officer Service in HU, and by the National Cancer Peer Review Programme in the UK*. The verification period shows great differences among countries, ranging between once a month (ES, HU) and once in three years (IT, UK*).

17. See note 1, p. 1.

18. http://www.nrls.npsa.nhs.uk/resources/?entryid45=59825&q=0%c2%ac0555%c2%ac.

19. http://www.nrls.npsa.nhs.uk/resources/?entryid45=59825&q=0%c2%ac0555%c2%ac.

20. OJ C 151, 3.7.2009, p. 1.

21. http://ec.europa.eu/health/patient_safety/policy/index_en.htm.

Figure 21a. *Regulations on evidence-based procedures and reporting systems (aggregated data)*

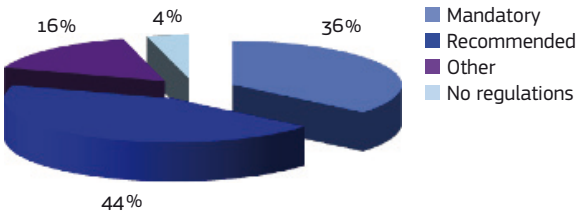
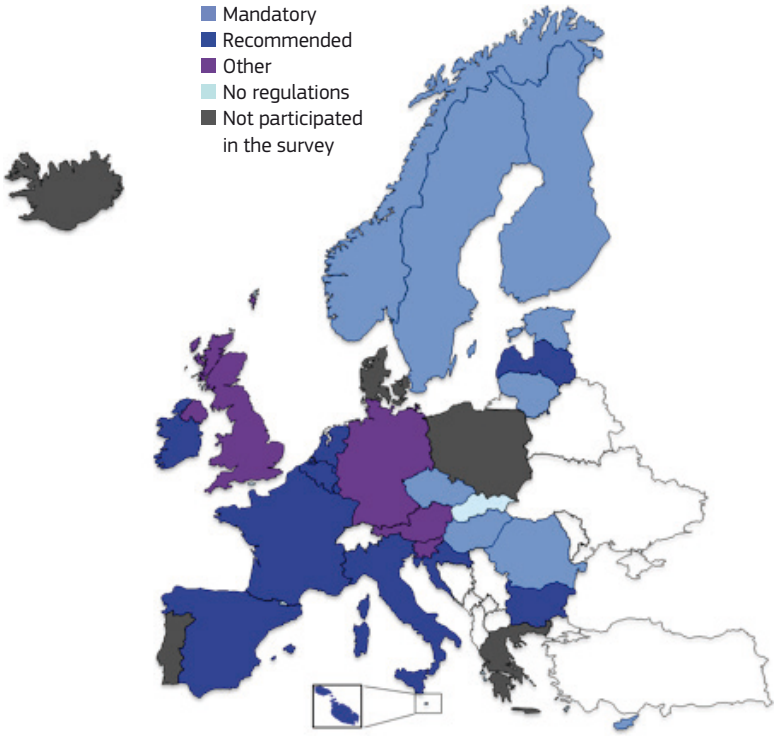
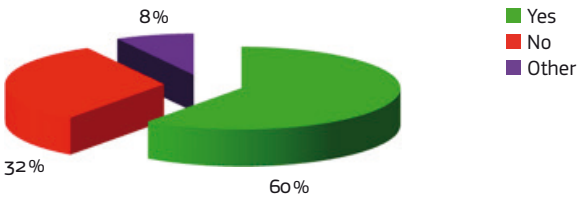


Figure 21b. *Regulations on evidence-based procedures and reporting systems (per country)*



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

Figure 22. *Presence of mandatory verification systems*



Details on individual responses and descriptions provided by participants are reported in *Annex IV*, *Table 12*. Aggregate and country information is presented in *Figures 21a-b and 22*.

Differences in patient safety policies and reporting systems between the participating countries show the need for supporting those policies and the need for maintaining comprehensive blame-free reporting systems.

4.6. Section 6: *Accreditation and certification schemes*

As reported in *Section 5*, information included under 'The quality system' is reported together with information collected in *Section 6*. Due to the different definitions of the term 'accreditation' and the various models of quality management in a healthcare context, information in this section was reordered. This issue is of key importance for the design and the implementation of the *European QA scheme* that will need to be compatible with the existing quality improvement programmes. In fact, the term 'accreditation' can mean different things according to the context (*e.g.* professional bodies, consortia of clinician and managers, ISO) (*Table 7*) (Shaw, 2000).

As regards different models of quality management in healthcare, the principal peer review techniques in Europe, which focus on whole hospitals or services, were identified by the *External Peer Review Techniques project (ExPeRT)* (Heaton, 2000) as: certification according to the ISO standards, professional peer review, health service accredi-

Table 7. *Definition of 'accreditation'*

Used by	Intended meaning	Since
Professional bodies	Recognition of specialty training	19th Century
Consortia of clinicians and managers	Recognition of service delivery	about 1920
International Organisation of Standardisation	Recognition of agency competent to certificate healthcare providers	1946

Adapted from Shaw, 2000.

tation and assessment against the European Framework for Quality Management (Shaw, 2010), plus the regulatory and government-based system which have grown in the last 10 years (Shaw, 2006).

Thus, the heterogeneity of answers from the different countries reflected the plurality of models existing in Europe, even if, as reported in previous publications, those different models are going towards comprehensive standards for organisation, management and clinical performance. For example, the *Methods of Assessing Response to Quality Improvement Strategies (MARQuIS)* project (Vallejo, 2009), had already reported that individual accreditation programmes in each country differ considerably in their respective standards, assessment procedures and thresholds for award. Moreover, the *EC Regulation* sets out a comprehensive legal framework for accreditation in the European environment for the first time. The *EC Regulation* sets out a number of requirements for accreditation, namely one single national accreditation body acting as the public authority. Accreditation is to be performed as a non-commercial, non-competitive activity and the national accreditation bodies (NABs) have to undergo peer evaluation to ensure the continuous quality of their work. Furthermore, NABs have to be members of the European co-operation for Accreditation (EA) which organises the peer evaluation process and which may be requested by the EC to develop and implement specific schemes. Therefore, due to the fact that a voluntary European scheme for BCSs underpinned by accreditation would adopt the definition of accreditation as defined in the *EC Regulation*, the present report will classify the reported QA schemes for BCSs according to their definition of accreditation. A deeper analysis of the individual schemes content, plus a survey directed to the NABs, will be published in a JRC report entitled *Comparison of quality assurance schemes for breast cancer services in Europe*.

The quality system, accreditation and certification schemes Thus, participating countries were asked to approve the new structure of the data over the follow up phase that took place in August 2013. Only 23 countries reacted to this request. Therefore, for those countries not providing data at this stage

(CZ and HR), data as reported in the following paragraphs must be considered as provisional.

Eighteen out of 25 countries (72%) declared that quality management systems were in place for breast cancer care in their country. LV reported that only quality indicators were collected and MT reported that a quality management system was present for only oncology and screening. When considering the characteristics of the systems in place, three countries (DE, EE, LT) mentioned accreditation according to ISO 15189:2012,[22] one country mentioned conformity assessment according to ISO/IEC 17040:2005[23] (NL) and nine countries (AT, CZ, DE, FI, HU, IT LT, NL, RO) mentioned certification according to ISO 9001:2008.[24] The Swedish Board for Accreditation and Conformity Assessment (SWEDAC) is performing accreditation and certification in healthcare according to different standards, which are mentioned on their website: http://www.swedac.se/en/What-does-Swedac-do/What-is-accreditation/Standards/. However, which standards are currently applied to breast cancer care is not declared. Main characteristics of the above-mentioned standards and their possible application to healthcare are:

ISO 15189:2012 – Medical laboratories: Accreditation of medical laboratories bodies to perform screening, medical testing and examinations based on procedures and guidelines (*e.g.* mammography, histopathology tests, etc.).

EN ISO 15224:2012 – Health care services – Quality management systems – Requirements based on EN ISO 9001:2008. Accreditation of certification bodies for certifying management systems by national accreditation bodies based on ISO standards.

ISO/IEC 17065:2012: Accreditation of certification bodies for certifying products, processes and services against both the requirements of and any additional measures prescribed by the scheme owner in regulations, operating manuals, directives and guidelines. Audit of management system including also a check of medical specifications (*e.g.* based on guidelines for the treatment of breast cancer).

ISO/IEC 17040:2005: Conformity assessment – General requirements for peer assessment for conformity assessment bodies and accreditation bodies.

With regard to QA systems not falling under the *EC Regulation*, different public or private systems were reported by the countries. Those schemes are summarised in *Tables 8a-b*. The data refer to information reported by countries solely and not to any other information retrievable via the schemes' owners.

22. http://www.iso.org/iso/catalogue_detail?csnumber=56115.

23. http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=31815.

24. http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=46486.

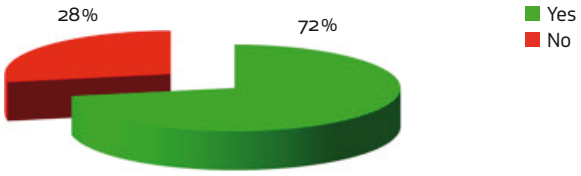
Table 8a. *Public certification schemes in countries*

Public scheme	Country
Royal Decree for Accreditation of Breast Cancer Care Programmes	BE
Certification process of the Andalusian Health Quality Agency (Agencia de Calidad Sanitaria de Andalucía)	ES
Cancer Treatment Authorisation	FR
National breast cancer care protocol	HU
National Quality Review of Symptomatic Breast Disease Services	IE
Emilia Romagna Region system	IT
Lombardy Region system	IT
Screening National Observatory (pilot)	IT
Veneto Region system	IT
External review for screening	MT
Regional Undersoknigsregister Mammografi Halsokontroll	SE
Nationella Arbetsgruppen for Mammografi	SE
Stockholm/Gotland quality system	SE
National Cancer Peer Reviewed Programme	UK*
National Health Service Breast Screening Programme (NHSBSP) quality assurance for breast cancer screening	UK*

Table 8b. *Private certification schemes in countries*

Private scheme	Country
Doc-Cert	AT
European Society of Breast Cancer Specialists (EUSOMA)	AT, HU, IT
Kooperation für Transparenz und Qualität im Gesundheitswesen (KTQ)	AT, DE
ProCumCert	AT
AKZert	DE
European Foundation for Quality Management (EFQM)	DE
Kooperationsgemeinschaft Mammographie	DE
OncoZert	DE
Joint Commission International	DE
Voluntary national certification scheme for breast cancer care of the Spanish Society for Senology and Pathology of the Breast (Sociedad Española de Senología y Patología de la Mama)	ES
Organisation of European Cancer Institutes (OECI)	HU

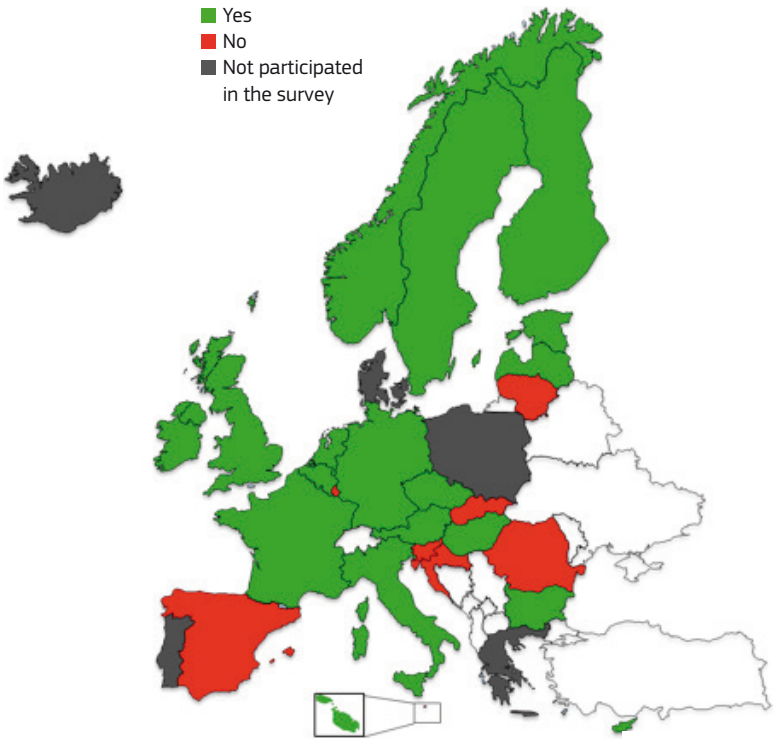
Figure 23a. *Presence of quality management (aggregated data)*



Details of individual responses and descriptions provided by the participants are reported in *Annex IV*, *Table 13*. Aggregate and country information is reported in *Figures 23a-b* and *24*.

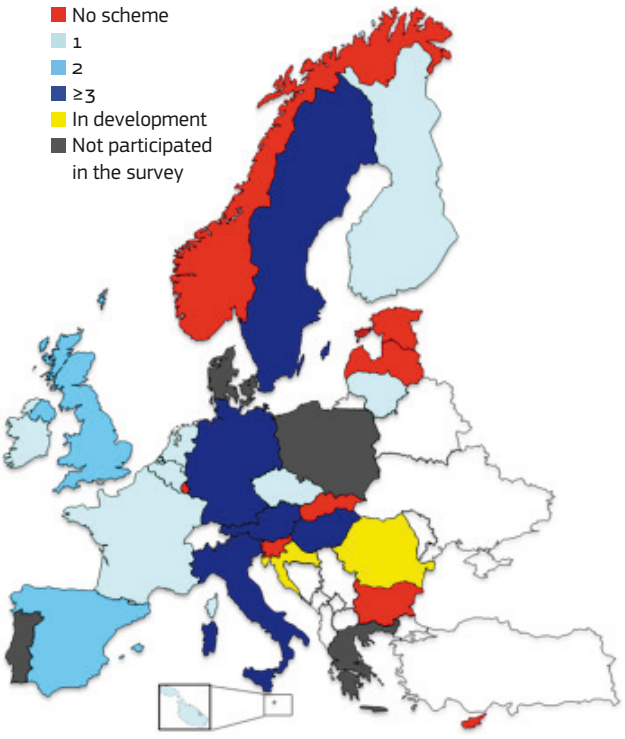
As expected by the diversity of healthcare quality and breast cancer care, a number of schemes are present – with some countries hosting more than one scheme and other countries without any scheme. A description of the contents of the schemes goes beyond the scope of the present report, and it will be included in the JRC report *Comparison of quality assurance schemes for breast cancer services in Europe* (forthcoming).

Figure 23b. *Presence of quality management (per country)*



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

Figure 24. *Number of quality schemes*



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

5. Conclusions

Although the results of this survey do not cover 100% of the invited countries, a response rate of 83% can be considered quite satisfactory and can paint a reliable picture of the current European situation in terms of the organisation of breast cancer care. Most of those who were responsible for the completion of the questionnaire came from their respective health ministries and, in some cases, from cancer registries and screening programmes – assuring a high level of competence for those providing and reporting information.

Very important information was collected with this survey with respect to the design of the *European QA scheme*. In addition, a general overview was obtained on the status of implementation of several European directives, recommendations and conclusions, even if the survey was not designed for this purpose.

In fact, other survey activities (recently concluded or ongoing) will help to draw a better picture of the European situation with respect to some issues addressed in the present report.

A survey on social inequalities and participation in cancer screening programmes was launched by the cancer and public health research group from the Fundación para el Fomento de la Investigación Sanitaria y Biomédica (FISABIO, Valencia, Spain) in 2013 in the context of the activity of the *EPAAC Work Package 6 (Screening and Early Diagnosis)*.[25] This survey included also figures on the presence and organisation of breast cancer screening programmes, age range of target population and participation rate, which were also covered by the JRC survey. Due to differences in contact points, participating countries, screening programmes included in the analysis, and definitions given, some discrepancies between the results of the two surveys were detected and a follow-up action was jointly planned with FISABIO to address this issue.

A survey on the implementation of the *Council Recommendation on Patient Safety*[26] is ongoing and more detailed information on this aspect for the *European QA scheme* will be derived from *The Commission's Second Report to the Council on the implementation of Council Recommendation 2009/C 151/01 on patient safety, including the prevention and control of healthcare associated infections* to complement the information received from the JRC survey in the section dedicated to quality and safety aspects.

Finally, within *EPAAC Work Package 7 (Healthcare)*, a survey was conducted on complementary and alternative medicine for cancer patients. The report on this survey will,

25. http://www.epaac.eu/images/OF_Ljubljana/Presentations/27.11/EPAAC_Open_Forum_Ljubljana_Ana_Molina.pdf.

26. See note 20, p. 31.

as well as the previously mentioned ones, constitute an additional source of information, complementing the section of the JRC survey dedicated to alternative medicine.
In conclusion, the following can be derived from the results of the survey:

- Eighty percent of responding countries have an organised breast cancer screening programme in place. The level of implementation of the *Council Recommendations* has slightly improved when compared with the *Implementation Report*, issued in 2007; however, there are no similarities between the methods and the target countries of the current and past report. Therefore, this result should be considered with caution.
- Notable differences in breast cancer screening indicators across countries were detected; developing the *New European guidelines for QA in breast cancer screening and diagnosis* is urgently needed in order to steer the direction of the programmes with respect to important issues (*e.g.* age range for screening).
- Opportunistic screening represents a significant number of mammograms done in some countries; in a period in which budget cuts can jeopardise the provision of evidence-based and cost-effective interventions, opportunistic ones, when existing, should shift towards a more controlled organisation and comply with the European recommendations.
- When considering the relationship between screening programmes and BCSs, different scenarios can be applied. The most frequently reported one (40% of responding countries) corresponds to an organisation in which the organised screening is owned and/or supervised by an entity which is different from the one supervising the other step(s) of the care. This should be taken into account when designing the *European QA scheme* and additional efforts should be dedicated for smoothing the interface between screening and treatment and for improving traceability.
- Care provided after or as a co-lateral activity with respect to the main surgical or medical treatment is provided in a different way across Europe. A harmonised approach to alternative medicine, palliative care and to other support activities should be envisaged.
- Qualifications of professionals dealing with breast cancer do not meet a unique set of standards. European trainings and certifications should be available for physicians, nurses and other healthcare professionals.
- QA systems are frequently designed to respond to the abovementioned issues, at a national or international level and are publicly or privately driven. However, a plethora of schemes is present and a common set of standards is neither available nor applied. A specific analysis of each scheme's content, plus a survey targeting the NABs, will be published in a future JRC report entitled *Comparison of quality assurance schemes for breast cancer services in Europe*.

To conclude, a European-wide scheme could address all the above mentioned points and can help harmonise the situation in Europe and ensure that European citizens can receive the same quality of care at least for the essential aspects regardless of where they live. However, the diversity of organisational settings of breast cancer care in countries is posing a challenge to the future scheme: nine countries reported having a public system in place and so it will be necessary to identify modalities of cooperation/integration in order to allow the same level of quality of care provided by BCSs all over Europe. The ECIBC can help to create a frame, which, in turn, could help to enhance implementation of evidence-based breast cancer care practices, (already present in some European countries), with a goal of improving the quality of breast cancer care for European women.

6. Acknowledgments

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Most of all, we would like to express our gratitude to all those responding to the survey and for the extremely valuable information they provided.

7. Bibliography

Cataliotti L., De Wolf C., Holland R., Marotti L., Perry N., Redmond K., Rosselli Del Turco M., Rijken H., Kearney N., Ellis I.O., Di Leo A., Orecchia R., Noel A., Andersson M., Audretsch W., Bjurstam N., Blamey R.W., Blichert-Toft M., Bosmans H., Burch A., Bussolati G., Christiaens M.R., Colleoni M., Cserni G., Cufer T., Cush S., Damilakis J., Drijkoningen M., Ellis P., Foubert J., Gambaccini M., Gentile E., Guedea F., Hendriks J., Jakesz R., Jassem J., Jereczek-Fossa B.A., Laird O., Lartigau E., Mattheiem W., O'higgins N., Pennery E., Rainsbury D., Rutgers E., Smola M., Van Limbergen E., von Smitten K., Wells C., Wilson R., EUSOMA: 'Guidelines on the Standards for the Training of Specialised Health Professionals Dealing with Breast Cancer', *Eur J Cancer*, Vol. 43, 2007, pp. 660-675.

Costa S.D.: 'Certify it! Breast Cancer Units in Europe', *Breast Care*, Vol. 4, 2009, pp. 213-217.

Deng G.E., Frenkel M., Cohen L., Cassileth B.R., Abrams D.I., Capodice J.L., Courneya K.S., Dryden T., Hanser S., Kumar N., Labriola D., Wardell D.W., Sagar S., Society for Integrative Oncology: 'Evidence-Based Clinical Practice Guidelines for Integrative Oncology: Complementary Therapies and Botanicals', *Journal of the Society for Integrative Oncology*, Vol. 7, 2009, pp. 85-120.

Giordano L., von Karsa L., Tomatis M., Majek O., de Wolf C., Lancucki L., Hofvind S., Nyström L., Segnan N., Ponti A., Eunice Working Group: 'Mammographic Screening Programmes in Europe: Organization, Coverage and Participation', *J Med Screen*, Vol. 19, Suppl 1:7, 2012, pp. 2-82.

Heaton C.: 'External Peer Review in Europe: an Overview from the ExPeRT Project. External Peer Review Techniques', *Int J Qual Health Care*, Vol. 12, 2000, pp. 177-182.

Independent UK Panel on Breast Cancer Screening: 'The Benefits and Harms of Breast Cancer Screening: an Independent Review', *Lancet*, Vol. 380, 2012, pp. 1778-1786.

Lerda D., Deandrea S., Freeman C., Nicholl C., Nicholson N., Zupan J.: *A Voluntary Accreditation Scheme for Breast Cancer Services & the Further Development of European Breast Cancer Guidelines. Project Workshops Report*, Luxembourg: Publications Office of the European Union, 2013.

Mariotto A.B., Yabroff K.R., Shao Y., Feuer E.J., Brown M.L.: 'Projections of the Cost of Cancer Care in the United States: 2010-2020', *J Natl Cancer Inst*, Vol. 103, 2010, pp. 117-128.

Martín-Moreno J.M., Anttila A., von Karsa L., Alfonso-Sánchez J.L., Gorgojo L.: 'Cancer Screening and Health System Re-

silience: Keys to Protecting and Bolstering Preventive Services During a Financial Crisis', *Eur J Cancer*, Vol. 48, 2012, pp. 2212-2218.

Molassiotis A., Fernández-Ortega P., Pud D., Ozden G., Scott J.A., Panteli V., Margulies A., Browall M., Magri M., Selvekerova S., Madsen E., Milovics L., Bruyns I., Gudmundsdottir G., Hummerston S., Ahmad A.M., Platin N., Kearney N., Patiraki E.: 'Use of Complementary and Alternative Medicine in Cancer Patients: a European Survey', *Ann Oncol*, Vol. 16, 2005, pp. 655-663.

Paci E., EUROSCREEN working group: 'Summary of the Evidence of Breast Cancer Service Screening Outcomes in Europe and First Estimate of the Benefit and Harm Balance Sheet', *J Med Screen*, Vol. 19, Suppl. 1, 2012, pp. 5-13.

Perry N., Broeders M., de Wolf C., Törnberg S., Holland R., von Karsa L. (eds.): *European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis*, 4th ed., Luxembourg: Office for Official Publications of the European Communities, 2006.

Ries L., Melbert D., Krapcho M., Mariotto A., Miller B., Feuer E., Clegg L., Horner M., Howlader L., Eisner M., Reichman M., Edwards B. (eds.): *SEER Cancer Statistics Review 1975-2004*, National Cancer Institute, 2007, http://seer.cancer.gov/archive/csr/1975_2004/ [accessed 6 June 2007].

Shaw C.D.: 'Accreditation in European health care', *Jt Comm J Qual Patient Saf*, Vol. 32, 2006, pp. 266-275.

Shaw C.D.: 'External Quality Mechanisms for Health Care: Summary of the ExPeRT Project on Visitatie, Accreditation, EFQM and ISO Assessment in the European Union Countries', *Int J Qual Health Care*, Vol. 12, 2000, pp. 169-175.

Shaw C., Groene O., Mora N., Suñol R.: 'Accreditation and ISO Certification: Do They Explain Differences in Quality Management in European Hospitals?, *Int J Qual Health Care*, Vol. 22, 2010, pp. 445-451.

Vallejo P., Suñol R.: 'MARQUiS: Quality Improvement Strategies for European Cross-border Healthcare', *Qual Saf Health Care*, Vol. 18, 2009, pp. i1-i2.

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: Office for Official Publications of the European Communities, 2008.

Wanchai A., Armer J.M., Stewart B.R.: 'Complementary and Alternative Medicine Use Among Women with Breast Cancer: A Systematic Review', *Clin J Oncol Nurs*, Vol. 14, 2010, pp. E45-E55.

Wilson A.R., Marotti L., Bianchi S., Biganzoli L., Claassen S., Decker T., Frigerio A., Goldhirsch A., Gustafsson E.G., Mansel R.E., Orecchia R., Ponti A., Poortmans P., Regitnig P., Rosselli Del Turco M., Rutgers E.J., van Asperen C., Wells C.A., Wengström Y., Cataliotti L.: 'The Requirements of a Specialist Breast Centre', *Eur J Cancer*, Vol. 49, 2013, pp. 3579-3587.

8. Annexes

The tables in *Annex IV* and *Annex V* present the responses to the questionnaire as submitted by the contributing countries.

8.1. Annex I: *Data protection form and questionnaire*

Survey on the organisation of breast cancer services

PRIVACY STATEMENT – TREATMENT OF PERSONAL DATA

1. Description.

The survey on the organisation of Breast Cancer Services launched by the Joint Research Centre (JRC) is for the purpose of mapping the situation in Europe regarding the general organisation of National Health Systems and of Breast Cancer Services. It addresses in particular the implementation of quality systems and the organisation and management of cancer screening.

Personal data of respondents to the questionnaire, hereafter called 'users', and contact persons identified for each of the concerned countries (EU Member States, EEA members plus Switzerland), hereafter called 'contact persons', will be collected and further processed for the purpose detailed hereafter under point 2.

This processing of personal data has been notified at JRC corporate level (DPO-1924) and is under the responsibility of the Head of Unit Internal and external communication at the JRC, acting as Controller. The specific e-Service is under the supervision of the Cancer Policy Support team leader at the JRC's Institute for Health and Consumer Protection (IHCP).

Intended under the processing process is the collection, collation, and storage of personal data. In terms of such operations, Regulation (EC) 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 Community institutions and bodies and on the free movement of such data, is applicable.

2. What personal information do we collect, what is the legal basis, for what purpose will it be used and through which technical means?

Personal data held on the users and the contact persons are: name, affiliation and address of the affiliation, and contact details (telephone number and e-mail address).

The Legal Basis of processing is:
- The Commission Implementing Decision of 1 December 2011 (2011/C 358/06)
- The fact that participation of users and contact persons is on a voluntary basis.

The contact persons have informed the respective users about the collection of their personal data and have received their consent for the current processing purpose.

The purpose of the processing of personal data of users will be exclusively for collation and storage of the data obtained from the questionnaire. In case of publication of data obtained from specific (i.e. non-aggregated) survey responses, the contact persons and the users will be contacted personally for their consent.

The technical means of collecting the data of users and contact persons will be via e-mail. Data will be stored in password protected accounts on the servers of the JRC.

3. Who has access to your information and to whom is it disclosed?

Access to the questionnaire responses will be restricted to members of the JRC specifically working on the dossier relating to the EU accreditation scheme for breast cancer services.

No personal data will be transmitted to parties outside the recipients and the legal framework mentioned.

4. How do we protect and safeguard your information?

The information will be stored on password protected accounts on the JRC data servers.

5. How can you verify, modify or delete your information?

Users are able to update their personal information or to cancel their registration by sending an e-mail to the survey helpdesk (jrc-ihcp-cancer-policy@ec.europa.eu).

6. How long do we keep your data?

The use of the personal data will be held for a maximum of ten years.

7. Contact Information

Queries concerning the processing can be directed to the survey helpdesk (jrc-ihcp-cancer-policy@ec.europa.eu).

Questions relating to the protection of personal data can be directed to:
- JRC's Data Protection Co-ordinator: jrc-data-protection-coordinator@ec.europa.eu
- European Commission's Data Protection Officer: data-protection-officer@ec.europa.eu

8. Recourse

In the event of a dispute, complaints can be directed to:
- the European Data Protection Supervisor: edps@edps.europa.eu

CONSENT ON INFORMATION PROVIDED

The information provided in this survey will be used solely by the European Commission's Joint Research Centre in the development of a European accreditation protocol for voluntary accreditation of breast cancer services.

Information provided in the survey will however be useful for performing research studies and eventual publication of the results.

I have read the disclaimer and I agree to JRC using data provided in this survey for the development of the accreditation protocol and, prior agreement, for research purposes:

YES	NO
○	○

Please send this FORM back to us by clicking the button below:

Submit by Email

Survey on the organisation of Breast Cancer Care Services

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

The survey is in part response to the European Council's invitation to the Commission to explore the possibility of developing a voluntary accreditation scheme for breast cancer screening and care. The main purpose of this questionnaire is to map the different set-ups of breast cancer services in the participating countries to ensure the optimum flexibility in the design of the accreditation protocol. However, you will also be asked to provide some additional information concerning general aspects of the health system as well as some information on the two other cancer sites covered by European guidelines for the quality assurance of screening (colorectal and cervical).

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 and the survey has been designed in such a way to make this easy. We would wish to stress the importance of receiving as many comprehensive responses as possible in order to ensure the accreditation protocol is designed with the necessary flexibility to adapt to the situation in your country (and associated regions).

All information requested is important, however the questionnaire is organised such that it is possible *to skip some sections/questions* if they are not relevant to your situation.

The questionnaire is structured around the following sections:

1. **Administrative details**
2. **The health care organisation**
3. **Breast cancer screening**
4. **Breast cancer services organisation**
5. **Quality requirements for breast cancer services**
6. **Certification/accreditation schemes**

For any information or help concerning the survey, please contact the survey helpdesk:

Name	**Telephone**
Donata LERDA	0039-0332-786201
Ciarán NICHOLL	0039-0332-789523
Silvia DEANDREA	0039-0332-786333
Crystal FREEMAN	0039-0332-789131

E-mail: jrc-ihcp-cancer-policy@ec.europa.eu

>> Read carefully before filling-in the FORM <<

1. This FORM has to be filled in using Adobe Acrobat Reader and submitted electronically. Data entered in the fields can be saved to disc and retrieved later or forwarded to others to complete.
2. Once you have completed the form, please send it back to us: you will find at the end of the questionnaire a button for sending the created FORM Submit by Email.

*The fields marked with a * are mandatory: you will not be able to send the FORM if you have not filled in all the mandatory fields.*

PLEASE SEND BACK THIS FORM BEFORE THE 15/10/2012

Session 1 – Contact and affiliation details

Contact details

Title	
Name*	
Surname*	
Affiliation*	
Address*	
Postal Code*	
Town*	
Country*	
Telephone*	
Fax	
E-mail*	

Geographical responsibility/mandate of your affiliation*

National	Regional	Local	Other
○	○	○	○

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

Denomination of the geographical area (please also provide the approximate population figure)*

2

Session 2 – The Health Care organisation

Mandatory questions

1.m - Is the health care, and the breast cancer care in particular, in the geographical area under your organisation's responsibility 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
○	○	○	○

If you choose "None of the previous", please provide a more detailed description

3

2.m - Please provide a brief description of your health care organisation in the geographical area of its operation, with reference to possible specificities for breast cancer care.*

With reference to the HiT reports Link to WHO-European Observatory of Health Systems and Policies the description should address the following points:
Organisational structure of the Health Care System
Health Delivery System
Financing and coverage
Financial Resource Allocation (e.g. hospital inpatient care, domiciliary services, outpatient care, drugs and other medical devices and appliances)

4

Additional points
(please refer to the geographical area under your organisation's responsibility)

1.a - Is alternative medicine offered for cancer patients?

YES	**NO**	**Other**
○	○	○

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

If you choose **YES,** it is offered in the field of:

Prevention	Health quality	Treatment integration	Side effects of treatments	Palliative care	None of the previous
○	○	○	○	○	○

If you choose "None of the previous", please provide a more detailed description

2.a - Requirements for competence of health professionals

Physicians
Are there mandatory entry-level qualifications?

YES	**Partially** mandatory requirements in place *(e.g. there is a system of concourses for accession to a certain level of responsibility)*	**Other**
○	○	○

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

Is there any mandatory registration - licensing system?

YES	NO	Other
○	○	○

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

Are there any mandatory requirements for training / competence updating (e.g. continuous medical education, on-the-job training, etc)?

YES	NO	Other
○	○	○

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

Does any specific training exist in your country in the field of breast cancer care? (e.g. degree, master, post-degree, private school, etc)

YES	NO
○	○

If you choose **YES**, please provide a more detailed description

6

Nursing staff
Are there mandatory entry-level qualifications?

YES	**Partially** mandatory requirements in place *(e.g. there is a system of concourses for accession to a certain level of responsibility)*	**Other**
○	○	○

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

Is there any mandatory registration - licensing system?

YES	**NO**	**Other**
○	○	○

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

Are there any mandatory requirements for training / competence updating (e.g. continuous medical education, on-the-job training, etc)?

YES	**NO**	**Other**
○	○	○

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

7

Does any specific training exist in your country in the field of breast cancer care? (e.g. degree, master, post-degree, private school, etc)

YES	NO
○	○

If you choose **YES**, please provide a more detailed description

Paramedical staff (e.g. such as chiropractors, osteopaths, physiotherapists, etc) Are there mandatory entry-level qualifications?

YES	Partially	NO
○	○	○

If you choose **Partially**, please provide a more detailed description

Is there any mandatory registration - licensing system?

YES	NO	Other
○	○	○

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

Are there any mandatory requirements for training / competence updating (e.g. continuous medical education, on-the-job training, etc)?

YES	NO	Other
○	○	○

8

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

3.a - Please add additional information if available (e.g. links to relevant legislation, Health Institutions, portals of breast cancer services for the geographical area under your organisation's responsibility)

9

Session 3 –Cancer Screening

For this section, please refer to the following definitions, based on the EU Report on cancer screening implementation Link to EU Report.

"non-programme screening" (commonly referred also as opportunistic screening): examinations for early detection of breast cancer performed in a diagnostic or clinical setting, independent from the public screening policy (if existing).

"programme screening": examinations financed by public sources performed in the context of a public screening policy documented in a law, or an official regulation, decision, directive or recommendation, and where the policy defines, at minimum: the screening test, the examination intervals, group of persons eligible to be screened.

"organised screening": programme screening where other procedures (e.g. standard operating procedures) are specified and where a team at national or regional level is responsible for implementing the policy, i.e. for coordinating the delivery of screening services, maintaining requisite quality, reporting on performances and results.

"population-based screening": programme screening where in each round of the screening the persons in the eligible target in the area served by the programme are individually identified and personally invited.

Mandatory questions

3.m - Is there a screening programme for cancer in your geographical area of concern?*

	Breast	Colon-rectal	Cervical
YES National[1]	☐	☐	☐
YES Regional[2] *(Nationally co-ordinated)*	☐	☐	☐
YES Regional[3]	☐	☐	☐
YES Local[4] *(Reg/Nat co-ordinated)*	☐	☐	☐
YES Local[5]	☐	☐	☐
NO	☐	☐	☐
Other[#]	☐	☐	☐

(1) A "National screening programme", is a screening which is run with the same modalities and criteria (e.g. for selection of screening centres, for the modality of calling the target women, etc) in the whole country

10

(2) A "Regional screening programme, nationally co-ordinated", is a screening which is run independently by different regions of the same country, not necessarily applying the same modalities and criteria, however at national level a coordination observatory is in place

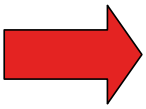
(3) As "Regional screening programme", a programme which is run with the same criteria (e.g. for selection of screening centres, for the modality of calling the target women, etc) in the whole region

(4) A "Local screening programme, Reg/Nat co-ordinated", is a screening which is run independently by different areas of the same region or nation, not necessarily applying the same modalities and criteria, however at regional and/or national level a coordination observatory is in place

(5) As "Local screening programme", a programme which is run with the same criteria (e.g. for selection of screening centres, for the modality of calling the target women, etc) in the whole area (province, town, etc)

Other[#]:
If you choose this option, please provide a more detailed description

If no breast screening is in place, you can skip the rest of this section by CTRL+clicking this button



Otherwise, please continue with the next set of mandatory questions (FOR BREAST SCREENING ONLY AND WITH REFERENCE TO THE LAST YEAR WHEN A REPORT IS AVAILABLE):

4.m - Please report the year of the last report to which the information reported in the following refer to* *(format YYYY)*:

5.m - Is the Screening Programme organised?* *(see definitions above)*

YES	NO	Other
○	○	○

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

6.m - Is it population-based?* *(see definition above)*

YES	NO	Other
○	○	○

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

7.m - Target age group range:*

50-69	Other
○	○

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

12

Additional points

Please report as comprehensively as possible on the following information about the screening programme in place in your geographical area of concern (AGAIN REFERRING TO LAST YEAR REPORTED)

4.a - Invitation rate *(% of invited women over the target group)*:	
5.a - Year of initial implementation *(yyyy)*:	
6.a - Screening method *(e.g. mammography)*:	
7.a - Screening interval *(**months** between rounds)*:	
8.a - Annual number of invitations:	
9.a - Annual participation rate *(% of women screened to the number invited)*:	
10.a - Annual cancer detection rate:	
11.a - Annual recall rate *(% of women recalled for further assessment over all women who had a screening examination):*	
12.a - Annual positive predictive value *(PPV: the ratio of lesions that are truly positive to those test positive):*	
13.a - Cost per screened woman ***(local currency)***:	

14.a - Please describe how the detection rate is calculated:

Not normalised by age	Normalised by age	Other
○	○	○

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

13

15.a - Does the number reported in 10.a also include positives confirmed at a later stage?

YES	NO	Other
○	○	○

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

16.a - Website of the screening programme for further information:

17.a - Do the following entities (or any other activities outside of the organised screening programs) together account for >10% of the total mammographies performed for asymptomatic average-risk women?

Charities
Health care structures independent from the organised screening programme
Private insurances
Employers for their employee
Private specialists

YES	NO	Don't know
○	○	○

If you choose **YES**, please provide a more details *(e.g. the prevalent activity(ies) among the ones listed above)*

Session 4 – Breast Cancer Services Organisation

Legend and key information:

BCS1, BCS2:	Breast Cancer Services (e.g. Diagnosis laboratory with mammography, Hospital department)
DP:	Delivery Partner (e.g. post-screen counselling)
BCC:	Breast Cancer Care

Breast Cancer Care (BCC) stages are considered to be:

1. Screening
2. Diagnosis
3. Treatment (surgery, chemotherapy / hormontherapy, radiotherapy)
4. Post Treatment Surveillance and Management of recurrence (including palliative care and associated support to patients and their carers)
5. Re-habilitation and other activities for improving the quality of life (e.g. psycho-oncology, involvement in social groups, etc)

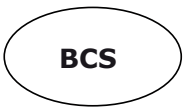
Mandatory questions

8.m - Please choose, using the radio buttons below, from the scenarios the **ONE** which better represents the situation in your country / region. Then you are asked to provide a brief description of your system and report the main differences from the chosen scenario.*

Scenarios		**Scenarios**	
1a	○	**1b**	○
2a	○	**2b**	○
3a	○	**3b**	○
4a	○	**4b**	○
5	○	**6**	○

Scenario 1a

The BCS is responsible for the whole process of BCC and provides all stages of the BCC.



Short description and main differences from the scenario **1a**

Is the BCS also responsible for organizing the screening programme?

YES	**NO**
○	○

If you choose **NO**, please describe the entity responsible for the screening and the functional link with the BCS (in case of a single entity, please provide contact details)

Does the BCS carry out mammographies for the screening programme?

YES	**NO**
○	○

Scenario 1b

The BCS is <u>not responsible for the whole process</u> of BCC; however, it provides all stages of the BCC. It is supervised by an external entity (e.g. the Regional Health Authority) for the organization and quality of the whole BCC.

16

Please describe the entity responsible for the process and the functional link with the BCS (in case of a single entity, please provide contact details)

Short description and main differences from the scenario **1b**

Does the BCS also organise the screening programme?

YES	**NO**
○	○

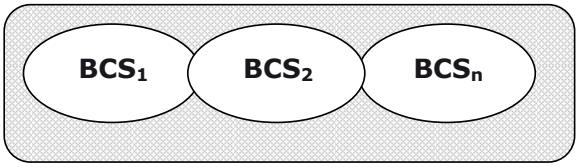
If you choose **NO**, please describe the entity responsible for organising the screening and the functional link with the BCS (in case of a single entity, please provide contact details)

Does the BCS carry out mammographies for the screening programme?

YES	**NO**
○	○

Scenario 2a

Two or more BCSs are co-operating and equally responsible for the whole process of BCC and together they cover all stages of BCC.



Short description and main differences from scenario **2a**

Are the BCSs also responsible for organising the screening programme?

YES	**NO**
○	○

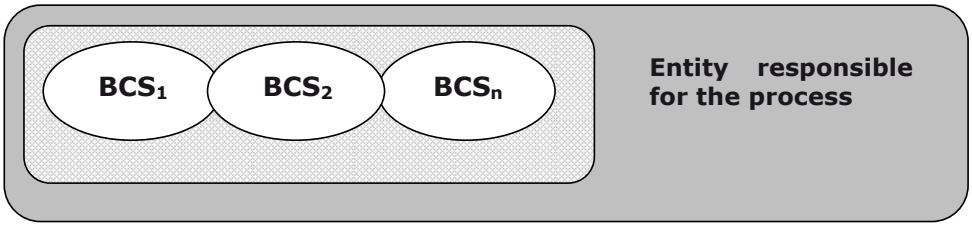
If you choose **NO**, please describe the entity responsible for the screening and the functional link with the BCSs. In the case of a single entity, please provide contact details

Do the BCSs, or one of them, carry out mammographies for the screening programme?

YES	**NO**
○	○

Scenario 2b

Two or more BCSs are co-operating but they are not responsible for the whole process of BCC; however, together they cover all stages of the BCC. They are coordinated and supervised by an external entity (e.g. the Regional Health Authority) for the organization and quality of the whole BCC.



Please describe the entity responsible for the process and the functional link with the BCSs (in case of a single entity, please provide contact details)

Short description and main differences from scenario **2b**

Do the BCSs also organise the screening programme?

YES	**NO**
○	○

If you choose **NO**, please describe the entity responsible for the screening and the functional link with the BCSs. In the case of a single entity, please provide contact details.

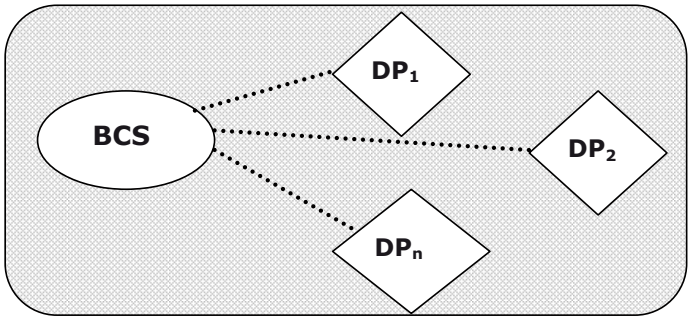
19

Do the BCSs, or at least one of them, carry out mammographies for the screening programme?

YES	NO
○	○

Scenario 3a

The BCS is responsible for the whole process of BCC but relies on delivery partners (DPs) for some services for delivering all BCC stages; the BCS contracts these services **in** and they thereby fall under its direct responsibility.



Short description and main differences from the scenario **3a**

20

Is the BCS also responsible for organising the screening programme?

YES	NO
○	○

If you choose **NO**, please describe the entity responsible for the screening and the functional link with the BCS (in case of a single entity, please provide contact details)

Does the BCS carry out mammographies for the screening programme?

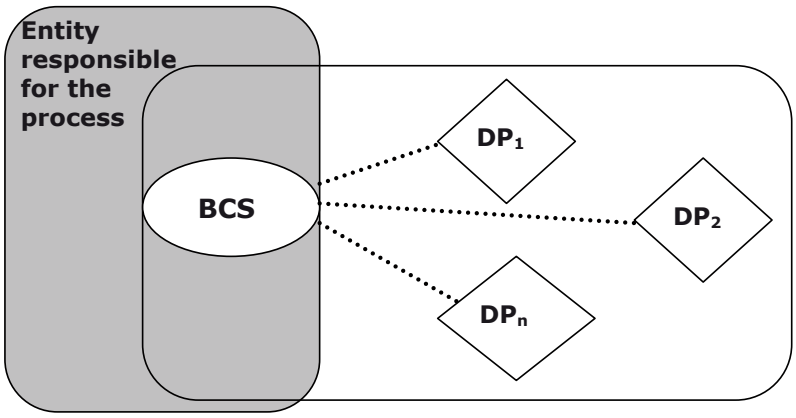
YES	NO
○	○

Does at least one of the DPs carry out mammographies for the screening programme?

YES	NO
○	○

Scenario 3b

The BCS is <u>not responsible for the whole process</u> of BCC and also depends on some services from delivery partners (DPs) for delivering all BCC stages; the BCS <u>contracts these services **in**</u> and they thereby fall under its direct responsibility. The BCS is supervised by an external entity (e.g. the Regional Health Authority) for the organization and quality of the whole BCC.



21

Please describe the entity responsible for the process and the functional link with the BCS. In case of a single entity, please provide contact details.

Short description and main differences from scenario **3b**

Does the BCS also organise the screening programme?

YES	**NO**
○	○

If you choose **NO**, please describe the entity responsible for the screening and the functional link with the BCS. In case of a single entity, please provide contact details.

Does the BCS carry out mammographies for the screening programme?

YES	**NO**
○	○

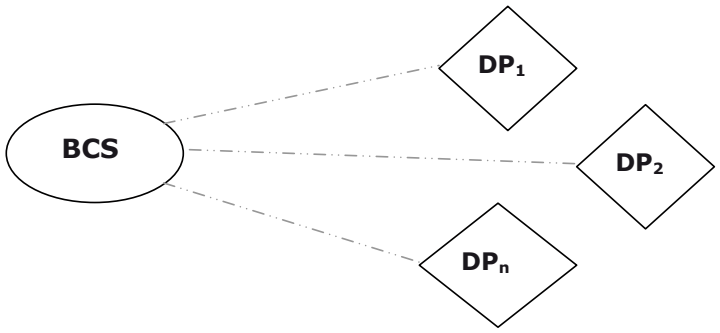
22

Does at least one of the DPs carry out mammographies for the screening programme?

YES	NO
○	○

Scenario 4a

The BCS is responsible for the whole process of BCC but depends for some services on delivery partners (DPs) for delivering all BCC stages. The BCS sub-contracts these services **out** and the DPs have to confirm to the BCS that the quality requirements are fulfilled.



Short description and main differences from the scenario **4a**

Is the BCS also responsible for organising the screening programme?

YES	NO
○	○

If you choose **NO**, please describe the entity responsible for the screening and the functional link with the BCS. In the case of a single entity, please provide contact details.

Does the BCS carry out mammographies for the screening programme?

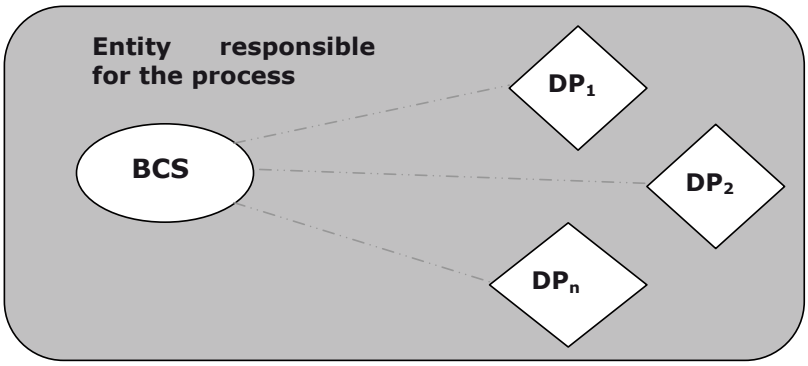
YES	**NO**
○	○

Does at least one of the DPs carry out mammographies for the screening programme?

YES	**NO**
○	○

Scenario 4b

The BCS is <u>not responsible for the whole process</u> of BCC but depends on some services from delivery partners (DPs) for delivering all BCC stages. The BCS sub-<u>contracts these services **out**</u>. The BCS and the DPs are independently supervised by an external entity (e.g. the Regional Health Authority) for the organization and quality of the whole BCC.



Please describe the entity responsible for the process and the functional link with the BCS. In the case of a single entity, please provide contact details.

Short description and main differences from scenario **4b**

Does the BCS also organise the screening programme?

YES	**NO**
○	○

If you choose **NO**, please describe the entity responsible for the screening and the functional link with the BCS (in case of a single entity, please provide contact details)

Does the BCS carry out mammographies for the screening programme?

YES	**NO**
○	○

Does at least one of the DPs carry out mammographies for the screening programme?

YES	NO
○	○

Scenario 5

The organisation of BCC in your geographical area of concern can be described by a mix of the scenarios described above. Please list the scenario types involved and provide an overview on how BCC is provided

Does the BCS also organise the screening programme?

YES	NO
○	○

If you choose **NO**, please describe the entity responsible for the screening and the functional link with the BCS. In the case of a single entity, please provide contact details.

26

Scenario 6

The organisation of BCC in your geographical area of concern cannot be described by any one or any mix of the scenarios described. Please provide an overview of how BCC is provided

Does the BCS also organise the screening programme?

YES	**NO**
○	○

If you choose **NO**, please describe the entity responsible for the screening and the functional link with the BCS. In the case of a single entity, please provide contact details.

Additional points

18.a - Please also specify below whether additional services, which might be relevant for this specific cancer but also for other cancers, are provided (e.g. translator, cultural mediator, palliative care, patients' carers support, etc)

28

Session 5 – Safety and Quality

The clinical risk management

For answers to this section, please refer to Council recommendations
Link to Council Recommendations, in particular as concerns the following points:

- updated safety standards and/or best practices, in particular for medication-related events, healthcare associated infections, complication during or after surgical interventions
- monitoring system for errors, adverse events and near misses
- prevention and control programme for healthcare associated infections

9.m - In your geographical area of concern evidence-based procedures and reporting systems are:*

1 - Mandatory	2 - Not mandatory but **recommended**	**Other**
○	○	○

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

10.m - If you responded positively to either option 1 or option 2, please specify whether the above described procedures are periodically verified*

YES	**NO**	**Other**
○	○	○

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

If you choose **YES**, please specify periodicity, verifier identity, actions taken if verification detects non-compliances

The quality system

11.m - In your geographical area of concern, do breast cancer services have quality management systems?*

YES	NO
○	○

If YES, do they have to be:

1 - Accredited	2 - Certified	No requirement	Other
○	○	○	○

If you choose option **1**, please provide the reference standard(s) (e.g. according to ISO 15189)

If you choose option **2**, please provide the reference standard(s) (e.g. according to ISO 9001)

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

30

12.m - As regards the BCC stages (screening, diagnosis, treatment/therapy, and post treatment), in your geographical area of concern:*

1 - Mandatory requirements	**2 – Mandatory** requirements for some of the BCC stages	**NO** Mandatory requirements	**Other**
○	○	○	○

Legend:
1 - it might, e.g., consist of a list of best practices for all the stages of BCC, including the pre-examination (e.g. call and registration of patients) and the post-examination (e.g. the dialog with the patient, the link with the following stages)

If you choose option **2**, please report the BCC stages covered by those requirements *(see Session 4 at page 15 for a possible list)*

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

Session 6 – Accreditation and Certification schemes[i]

To acquire the information on the actual situation of accreditation and certification schemes, we aim, with your support, to map out the existing schemes providing certification, designation, qualification, etc according to a predefined set of requirements.

In your geographical area of concern, are there any certification schemes either implemented or in development for BCSs?

YES	In development	NO
○	○	○

If **YES**, then please describe (e.g. Is it a national scheme? Is it mandatory? Are there more than one scheme from which to choose (and how many)? Is it performed by a public or private entity? Is it only for breast or also for other cancers (please specify)? How many BCSs are certified in your geographical area of concern?)

And also, if **YES**, please provide contact details

Name of the scheme(s)

[i] In this session "certification" is not used with its correct meaning in the accreditation environment (Regulation (EC) No 765/2008), but to indicate private associations providing a certificate according to a selected set of requirements. The word "accreditation" instead, is used according to its legal definition.

Link to scheme(s) webpage(s)

e-mail address(es) of provider(s)

Name and surname of the your contact person(s) plus e-mail(s) and phone number(s)

*You have now concluded the survey: **THANKS** again for the time you dedicated to filling-in the questionnaire.*
The information you provide to us will be used to design the protocol and scheme of accreditation for Breast Cancer Services, and this will allow optimising the adhesion to such a voluntary scheme.

PLEASE SEND BACK THIS FORM BEFORE THE 15/10/2012

Once you filled-in the form, use the email button and submit the filled-in form to us via e-mail. You may also save it to your computer.

Submit by Email

ACCREDITATION AND CERTIFICATION

Accreditation, certification and conformity assessment fall under Regulation EC 765/2008 and are managed by the network of European Cooperation for Accreditation and National Accreditation Bodies. Other quality assessment systems available in EU for breast cancer services are neither accreditation nor certification in this legislation framework. For this reason, we will create a new Survey table in order to include the information related to the breast cancer schemes cited in the survey forms received (e.g. "certification" by professional societies of clinical practices, national quality assurance systems, etc.).

Definitions

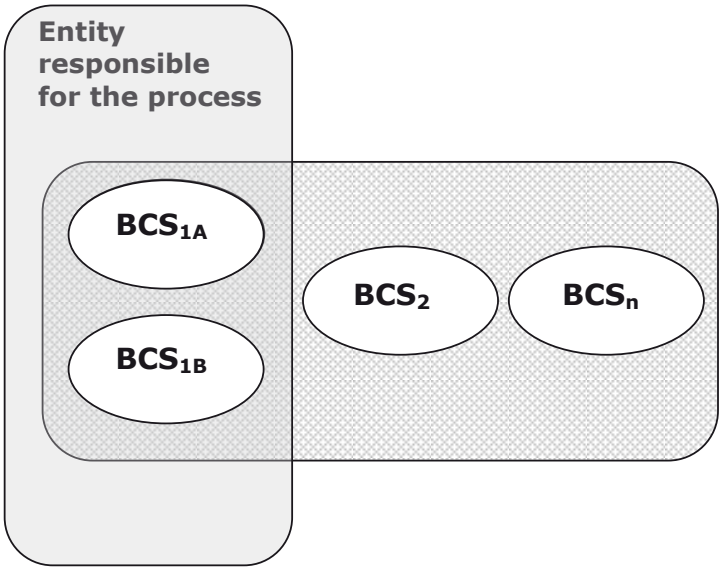
ACCREDITATION: "Third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks" (ISO/IEC 17000 definition).
Examples of accreditation are ISO 15189 and ISO 17025 for laboratories and ISO 17043 for providers of proficiency tests.
It does NOT include "institutional accreditation" like licensing of healthcare providers by health authority, nor professional accreditation.

CERTIFICATION: "Third-party attestation related to products, processes, managements systems or persons" (ISO/IEC 17000 definition).
Examples of certification are ISO 9001 for quality management systems.
It does NOT include different quality assurance systems (e.g. "certification" by professional societies).

CONFORMITY ASSESSMENT: "the process demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled" (Regulation EC 765/2008 definition).

SCENARIO 2c

Two or more BCSs are co-operating but they are not responsible for the whole process of BCC; however, together they cover all stages of the BCC. A supervision for the organization and quality by an external entity (e.g. the Regional Health Authority) of is present only for a part of the BCC process (e.g. screening supervised and coordinated, treatment and follow up not)



8.2. Annex II: *E-mail communications*

From: SANCO C2 HEALTH INFORMATION
Sent: Friday, June 29, 2012 3:45 PM
Subject: Invitation to audio/video meeting on 19 July 2012 to discuss a proposal for a joint action 2013

Dear EPAAC Member States' representatives,

1) We would like to invite you to a special audio/video meeting **on 19 July 2012 at 11.00 to 13.00** in order to discuss the proposal for the joint action that DG SANCO intends to suggest under 2013 work plan, namely **joint action "Development of European guidelines on quality assurance in comprehensive and personalised cancer care"**.

The work plan 2013 has not yet been approved by the Health Programme Committee and also the Commission Decision has to be adopted before the joint action is officially proposed. Therefore, for the moment we can only discuss the potential action.

But in order to save the valuable preparation time we would like to engage you in preparations already at this stage. Please find attached a non-paper describing some key elements that we would see in the new joint action, but please feel free to make any suggestions. In particular we would like to invite you to consider the role of your country, of competent institutes/agencies/bodies in this joint action and please signal any specific interest that you have, if possible already during or prior to the meeting.

2) In addition, we would like to use the opportunity to brief you on the state of play of 2 actions that have been initiated under the leadership of the Joint Research Centre: Institute for Health and Consumer Protection (JRC-IHCP) in Ispra. These are the Establishment of the first EU voluntary accreditation scheme for breast cancer services and support in the cancer information area (please find a summary document attached). We feel that this may be useful after the discussion on the European Cancer Information System that was held during the last Open Forum in Rome.

Please note that in relation to the project on Establishment of the first EU voluntary accreditation scheme for breast cancer services JRC-IHCP will shortly launch a survey in the Member States. In order to coordinate the whole process, we kindly ask you to inform us by **Thursday 5th July** who is the **nominated contact point from your individual countries** who will act as the interface with the JRC-IHCP. If we do not receive your response the questionnaire will be sent to you.

3) For our IT colleagues to organise this meeting, we would need to know who will be connecting via audio and who will connect via video. In this regard, **kindly let us know (marie-louise.galea@ec.europa.eu) at your earliest how you plan to connect (via audio or via video connection)** to this special meeting on 19 July at 11.00 to 13.00.

- Participants who will **connect via audio need to send us the telephone number** on which we would be able to call you from our conferencing system.

- **Participants connecting via video need to provide the following technical details** of the site from which you will connect;
  - IT/Technical Contact + their e-mail address & telephone number (our IT colleagues will contact them to try out the connection before the meeting)
  - Equipment technical details
  - ISDN & IP addresses

Once we have everyone's responses our IT department who will be responsible for connecting everyone will provide us with all the necessary information which we will forward to you at once.

Sent on behalf of Stefan Schreck, Head of Health Information Unit

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From: JRC CANCER POLICY SUPPORT
Sent: Tuesday, July 24, 2012 4:08 PM
Subject: Ares(2012)900743: Survey on the organisation of Breast Cancer Care Services

Ares(2012)900743

Dear Madam, dear Sir,

Your contact details have been passed on to us by our colleagues in DG SANCO and this communication concerns the European survey on the organisation of Breast Cancer Services which the European Commission's Joint Research Centre is now launching.

You have been identified as the person responsible for co-ordinating the survey in your country. If this is not correct, please could we ask you to inform us immediately?

Please note that the deadline for submission of survey responses is **15/10/2012**.

The survey is enclosed (first attachment) in this mail and the second attachment is the data privacy statement.

Please read the privacy statement and the agreement of consent of use.

Check the appropriate box and then click on the button: Submit by Email – this will send the form automatically back to us (Please always use the option "Desktop Email application"). Note that you can change/revoke your choice at any time. All you need to do is to send us an e-mail informing us of your change and we will reply with confirmation.

Please note the following important points concerning the survey:

1) The survey can be saved at any stage of the process. It does not therefore need to be completed in one go.

2) The survey can be partially completed and then sent to someone else for further completion. The form will automatically save all the answers.

3) Once the form is completed, it can be submitted by clicking on the button: Submit by Email – this will send the survey response directly to us. Note however that this operation will not succeed if any of the mandatory questions have been left unanswered.

4) If you need to send survey copies to regional/local offices, please provide us with a list of the associated contact points (including: **name, e-mail and phone number**). This will help us verify the response rate and afterwards we will forward the questionnaires we receive from your network to you, so you will be fully kept in the loop.

If you need any further information, please do not hesitate to contact us at this e-mail box or via the phone numbers listed in the questionnaire.

We would like to thank you and your collaborators in advance for dedicating your time to completing this questionnaire. Since the information you provide will be important to design the accreditation scheme that must be implementable in all EU Member States and in the other participating countries, we kindly ask you to provide as complete a response as possible.

Best regards,

Sent on behalf of Donata LERDA, Public Health Policy Support Unit

From: JRC CANCER POLICY SUPPORT
Sent: Monday, June 17, 2013 10:43 AM
Subject: Follow up on the 2012 Survey for the EU voluntary accreditation scheme for Breast Cancer Services

Dear Sir/Madam,

as announced in the e-mail that we sent last week, we are contacting you with regards to the survey on Breast Cancer Services we conducted last year.

We are grateful for the time and competence in providing the information on the various aspects of Breast Cancer Care organization tackled by the questionnaire. To be able to complete the survey report, correct compilation of your responses in tables is needed. Therefore, we are coming back to you in order to verify some information included in the questionnaire.

In the attached file you will find a form reporting the number of question in the survey, the answer you provided and our question and/or suggested change.

In particular, we have found the question related to "accreditation" and "certification" very challenging due to the lack of harmonization of definitions/concepts in this area. Moreover, an additional breast cancer scenario is now available for the description of breast cancer care in your country. You can find as attachments a common definition of accreditation and certification and the description of the new scenario: they could help you to reformulate your answers, if it is the case.

We would be grateful if you could send back to us the required integration/clarifications possibly **by 28/06/2013**.

In case you should need support or further information on this request, please do not hesitate contacting us at the e-mail address jrc-cancer-policy-support@ec.europa.eu. I am the contact point for this survey and you can also reach me by phone or e-mail for any kind of clarification.

With grateful greetings by the JRC team on Healthcare Quality,

Sent on behalf Silvia DEANDREA, Public Health Policy Support Unit

From: JRC CANCER POLICY SUPPORT
Sent: Thursday, August 22, 2013 2:42 PM
Subject: Data checking for the "Report for the Survey on the organisation of breast cancer services in Europe"

Dear Ms Sir/Madam,

Thanks to the efforts and cooperation of you and the other survey participants, we are finalising the "Report for the Survey on the organisation of breast cancer services in Europe" and we envisage having it published by the end of the year.

In the file enclosed you can find the data that you have provided as they were reported in the original questionnaire (attached), with the exceptions of:

1. the changes due to the clarifications that we have asked for in June, and

2. the full description of: your health organisation, cancer screening, and quality and safety.

With regards to this second issue, to improve readability of the tables and to focus the information you provided on the main points, we would like to propose a shortened version of your original text down to 50-200 words. For this reason, we would like you to check with particular attention those paragraphs, which are highlighted in yellow, in order to verify that the original meaning of your description has been preserved.

We would like to highlight that, your original answer will be very useful for the future development of the project and will be made available upon request to all report readers.

In order to make this data available to European citizens and stakeholders as soon as possible, we would ask to provide an answer by **September 1st**. As for the previous step of the survey, we are fully available for any support or clarification needed.

We would like to thank you again for the time you dedicated for contributing to such an important collection of information and to the final document derived.

With grateful greetings by the JRC team on Healthcare Quality,

Sent on behalf Silvia DEANDREA, Public Health Policy Support Unit

From: JRC CANCER POLICY SUPPORT
Sent: Friday, November 15, 2013 6:37 PM
Subject: Publication of the "Report for the Survey on the organisation of breast cancer services in Europe"

Dear Sir/Madam,

Thanks to the efforts and cooperation of you and other survey participants, we are now finalising the "Report for the Survey on the organisation of breast cancer services in Europe" and we envisage having it published within few weeks.

We are coming back to you in order to ask your consent for the publication of the data that you provided last year and that you confirmed with your last e-mail on DD/MM/YYYY: this can be done by simply replying YES to this e-mail. If we do not hear from you by 22/1½013, we will apply the rule "Silence gives consent" (consensus is assumed when there's no evidence of disagreement).

With kindest regards,

Sent on behalf Donata LERDA, Public Health Policy Support Unit

8.3. Annex III: *EPAAC contacts (June 2012)*

Annex III, Table 1. *List of EPAAC contacts and person nominated as responsible for the survey*

Country	EPAAC contact (June 2012)	Survey nominated contact	Affiliation
AT	Magdalena ARROUAS	Alexandra RAMSSL-SAUER	MA: Ministry of Health ARS: Gesundheit Österreich GmbH
BE	Saskia VAN DEN BOGAERT	Saskia VAN DEN BOGAERT	Federal Public Service of Public Health
BG	Constanta TIMCHEVA	Constanta TIMCHEVA	Chemotherapy Clinic to the Specialised Hospital for Active Treatment in Oncology
CY	Myrto AZINA- CHRONIDES	Myrto AZINA- CHRONIDES	Ministry of Health
CZ	Bohuslav MELICHAR	Bohuslav MELICHAR	Steering Committee of Czech Society for Oncology
DE	Antonius HELOU	Hiltrud KASTENHOLZ	HK: Federal Ministry of Health, Institute for Quality and Efficiency in Health
EE	Meeli MATSALU	Inna VABAMÄE	Ministry of Social Affairs
ES	Isabel SAIZ	Inés PALANCA	Ministry of Health
DK	Mie RASBECH	Mie RASBECH	Ministry of Health
FI	Liisa PYLKKÄNEN	Liisa PYLKKÄNEN	Cancer Society of Finland, Helsinki
FR	Rosemary ANCELLE-PARK	Rosemary ANCELLE-PARK	Department of Health, Ministry of Health
GR	Evangelia (Lia) TZALA	Evangelia (Lia) TZALA	Hellenic Centre for Disease Control and Prevention
HR	HOIC David	Ariana ZNAOR	HD: Mission of the Republic of Croatia to the European Union and to the European Atomic Energy Community AZ: Croatian National Cancer Registry, Croatian National Institute of Public Health
HU	Brigitta GYEBNAR	Krisztina BICSAK	BG: Ministry of Health KB: Public Health Department
IE	Fiona CONROY	Lilian FINUCANE	FC: Ministry of Health LF: Cancer & Blood Policy Unit, Department of Health

Rows corresponding to those countries not returning the filled-in questionnaire are grey-shaded.

Annex III, Table 1. *(cont.)*

Country	EPAAC contact (June 2012)	Survey nominated contact	Affiliation
IS	Gudrun SIGURJONSDOTTIR	Gudrun SIGURJONSDOTTIR	Ministry of Health
IT	Fabrizio OLEARI	Antonio FEDERICI	Ministry of Health
LT	Audrone MAZURKIENE	Arvydas GABRILAVICIUS	AM: Ministry of Health AG: General Medical Care Division
LU	Astrid SCHARPANTGEN	Astrid SCHARPANTGEN	Ministère de la Santé
LV	Anita MAURINA	Mara EPERMANE	AM: Centre for Disease Prevention and Control of Latvia ME: Diagnostic Radiology Center, Riga East University Hospital
MT	Miriam DALMAS	Miriam DALMAS	Office of the Chief Medical Officer, Ministry for Health, Valletta
NL	Annemarieke RENDERING	Annemarieke RENDERING	Ministry of Health, Welfare and Sport
NO	Stein KAASA	Stein KAASA	Norwegian Directorate of Health, Hospital Services Department
PL	Anna KAMINSKA	Anna KAMINSKA	Ministry of Health
PT	Nuno MIRANDA	Nuno MIRANDA	Health Directorate General
RO	Florian Alexandru NICULA	Florian Alexandru NICULA	'Prof. Dr. Ion Chiricuta' Institute of Oncology, Cluj-Napoca
SE	Mattias FREDRICSON	Arvid WIDENLOU NORDMARK	MF: Ministry of Health and Social Affairs AWN: National Board of Health and Welfare
SI	Mojca GOBEC	Mojca GOBEC	Ministry of Health
SK	Margita POBIJAKOVA	Jozef MARDIAK Mario MIKLOSI Stanislav SPANIK	MP and MM: Ministry of Health JM: National Institute of Oncology SS: National Expert on Oncology
UK	Jane ALLBERRY	Jane ALLBERRY	Department of Health

Rows corresponding to those countries not returning the filled-in questionnaire are grey-shaded.

8.4. Annex IV: *Tables of individual responses*

List of abbreviations in *Annex IV* Tables

BCS	Breast Cancer Service	EUSOMA	European Society of Breast Cancer Specialists	LTL	Lithuanian Litas
BCSP	Breast Cancer Screening Programme	FCCCC	French Comprehensive Cancer Care Centres	LVL	Latvian Lat
BI-RADS	Breast Imaging-Reporting and Data System	FIMEA	Finnish Medicines Agency	NCCP	National Cancer Control Programme
CORU	Health and Social Care Professionals Council	HiT	Health Systems in Transition	NGO	Non-governmental organisation
CSP	Cancer Screening Programme	GBP	Pound Sterling	NHS	National Health Service
CZK	Czech Koruna	GP	General practitioner	NHSBSP	National Health Service Breast Screening Programme
DKG	German Cancer Society	HIQA	Health Information and Quality Authority	MDH	Mater Dei Hospital
DMP	Disease Management Programme	HRK	Croatian Kuna	OECI	Organisation of European Cancer Institutes
DGS	German Society of Senology	HSE	Health Services Executive	OI	Institute of Oncology
DRG	Diagnosis-related group	HUF	Hungarian Forint	RHA	Regional Health Agency
EMA	European Medicines Agency	HZZO	Croatian Institute for Health Insurance	SEK	Swedish Krona
EPAAC	European Partnership for Action Against Cancer	KPI	Key Performance Indicator	SHI	Statutory health insurance
EUR	Euro	KTQ	Kooperation für Transparenz und Qualität im Gesundheit swesen	SNS	Spanish national health system

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).

Annex IV, Table 1. *Section 2 – The healthcare organisation*

Questions:

- Is the healthcare, and the breast cancer care in particular, in the geographical area under your organisation's responsibility provided by: [multiple choice]?
- Are the private entities supervised by public entities? Are public entities responsible for the initial evaluation and the follow up quality checks?

Country	Provided by	Private entities quality checked	Description
AT	Mainly public	Yes, initially and with follow up quality checks	• AT has several autonomous bodies that are in charge of the provision of healthcare. In-patient care is mainly provided by public hospitals which are owned by the provinces/cities etc. On top of that, there are semi-private hospitals which are owned by religious orders (in AT these are mostly Roman Catholic congregations), and then there are private hospitals which are completely autonomous. • SHI companies are in charge of funding and organising out-patient care. Doctors and out-patient clinics have contracts with the just mentioned health insurance companies according to which they charge provided services. Therefore, most GPs and specialists are in private practices. • For details: http://www.euro.who.int/__data/assets/pdf_file/0009/96435/E89021.pdf. • Brochure about the AT Health Care System: http://www.bmg.gv.at/cms/home/attachments/3/4/CH1066/CMS1291414949078/austrian_health_care_key_facts_2013.pdf.
BE	Other	–	• Health policy is both a responsibility of the federal authorities and federated entities (regions and communities). The federal authorities are responsible for the regulation and financing of the compulsory health insurance; the determination of accreditation criteria; the financing of hospital budgets and heavy medical care units; legislation covering different professional qualifications; and the registration of pharmaceuticals and their price control. Federated entities are responsible for health promotion and prevention; maternity and child healthcare and social services; different aspects of community care; coordination and collaboration in primary healthcare and palliative care; the implementation of accreditation standards and the determination of additional accreditation criteria; and the financing of hospital investment. The compulsory health insurance is managed by the National Institute for Health and Disability Insurance. • Public and private entities (private: non-profit organisation, with accreditation by regional authorities) cooperate, with a preponderance of hospitals under private governance. • Since 2001, national coverage for breast cancer screening was achieved by organisation of a BCSP in each region. • In 2007, a legal framework with accreditation standards for breast cancer units for diagnosis and treatment of breast cancer was established. • See BE *HiT 2010* for further details.

Annex IV, Table 1. *(cont.)*

Country	Provided by	Private entities quality checked	Description
BG	Mainly public	Yes, initially and with follow up quality checks	• Before 1990, the healthcare system was centralised. After the structural reforms of the 1990s, Bulgarian healthcare switched to a system of payroll contributions, establishing a semi-autonomous National Health Insurance Fund. • The *Health Care Establishments Act* outlined procedures for the privatisation of both state and municipality medical establishments. • Healthcare is financed from compulsory and voluntary health insurance contributions, taxes, and formal and informal cost-sharing. One of the key principles of reform was the transition from general taxation budget financing to financing based on the health insurance principle. The compulsory health insurance system is represented by the National Health Insurance Fund and funded primarily from payroll-based contributions, with state and municipal budgets covering low-income and socially disadvantaged sections of the population. • In 1998, the contractual system was introduced between the National Health Insurance Fund and healthcare providers, as well as between municipal healthcare facilities. Hospitals receive funding through case payments (clinical pathways) that are based on a single flat rate per diagnosis. • Specialised out-patient care and laboratories are reimbursed by means of a fixed fee for services provided to patients.
CY	Mainly public	Yes, initially and with follow up quality checks	Not reported
CZ	Mainly public	Yes, initially and with follow up quality checks	• A general healthcare insurance covers all items included in cancer diagnostics and treatment. Screening of breast cancer, colorectal cancer and cervical cancer is covered for these sources as well. The insurance is managed and delivered by eight health insurance companies. • The only specific attribute of breast cancer care management is organisation of national breast cancer screening, which is performed in a certificated national network of diagnostic centres. For details see the internet (http://www.mamo.cz). Organisation of all the other healthcare components is the same for all malignancies. • The core part of cancer healthcare is guaranteed by the network of 13 comprehensive cancer centres which covers all relevant regions. In addition to this, cancer care is located in approximately 200 healthcare facilities. Long term follow-up of cancer patients is organised in cooperation with GPs (approximately 4 400 GPs).

Annex IV, Table 1. *(cont.)*

Country	Provided by	Private entities quality checked	Description
DE	Other	–	• SHI covers about 90% of the population of DE and it is operated by competing not-for-profit non-governmental 'sickness funds'. • SHI covers preventive services, in-patient and out-patient hospital care, physician services, mental healthcare, dental care, prescription drugs, medical aids, rehabilitation, hospice care, and sick leave compensation. • General practice and specialist care in the primary care setting are delivered by medical doctors who are mandatory members of regional associations; they are generally reimbursed on a fee-for-service basis negotiated with sickness funds. • Hospitals are mainly public, non-profit or private for-profit. In-patient care is paid through a system of diagnosis-related groups. • There are different sets of criteria for certification for breast cancer centres. The majority of these centres are certified according to the criteria of the DKG. • There are special DMPs for certain non-communicable diseases, including breast cancer. DMPs currently exist also for diabetes types 1 and 2, coronary heart disease, asthma, and chronic obstructive pulmonary disease. They are modelled on evidence-based treatment recommendations with mandatory documentation and quality assurance, including feedback reports, reminders, quality circles, and patient education. Participation of the healthcare providers and patients is voluntary. DMPs provide a structured and evidence-based approach across sectors (primary, secondary and tertiary care). They aim primarily at improving patient care pathways.
EE	Exclusively public	–	• The Estonian health system is based on a compulsory, solidarity-based insurance and on universal access to health services made available by providers that operate under private law. • The Estonian healthcare system is mainly publicly funded through contributions in the form of earmarked social payroll tax, which amounts to over 60% of total funding. This earmarked payroll tax is then pooled by the independent public body Estonian Health Insurance Fund, which has four regional branches but acts as a single purchaser. Its role includes pooling funds, contracting service providers, reimbursement of health services, pharmaceuticals as well as some responsibilities for sick leave and maternity benefits. • The Ministry of Social Affairs and its agencies are responsible for the financing and management of public health services. Those covered by mandatory health insurance fall into four main categories: those who make their own contributions; those who are covered by contributions from the State; those who are eligible for coverage without contributing; and those who are covered on the basis of international agreements.

Annex IV, Table 1. *(cont.)*

Country	Provided by	Private entities quality checked	Description
ES	Mainly public	No	• SNS is universal coverage-wise, funded from taxes and predominantly operates within the public sector. • Health competences were totally devolved to the regional level as from the end of 2002; resulting in 17 regional health ministries with primary jurisdiction over the organisation and delivery of health services. • The Ministry of Health, Social Services and Equality holds authority over certain strategic areas, such as pharmaceuticals' legislation and as guarantor of the equitable functioning of health services across the country. • The highest body for SNS coordination is the Inter-territorial Council, comprising the 17 regional ministers of health. The decisions must be adopted by consensus and affect matters that have been transferred. • The regional ministry of health is responsible for the territorial organisation of health services within its jurisdiction: the design of the healthcare areas, and the degree of decentralisation to the managerial structures in charge of each. • The activities related to screening are specifically included in the SNS health provisions in the following way: detection of risk groups and early diagnoses of gynaecological and breast cancer in a coordinated and systematic way with specialist care, according the organisation of the health service.
FI	Mainly public	No	• In FI, breast cancer diagnosis and treatment is mainly taken care by the public entities. The treatment is centralised to large hospitals having multidisciplinary teams dedicated to breast cancer management. After treatment the follow-up is mainly taken care by the treating hospitals up to five years, and thereafter at healthcare centres or at private sector. • Minority of patients have their primary treatment at private hospitals, where they also have opportunity to receive chemotherapy and radiotherapy, as well as follow-up care and diagnostic procedures. • At the public sector the diagnostic procedures and treatment costs are covered by the health insurance system. If the patient decides to have treatment at the private sector, she has to pay majority of the costs herself (including diagnostic procedures and treatment, for which they may get some refunds from the Social Insurance Institution of Finland). • Hospital in-patient care is needed usually for few days after surgery. However, most of chemotherapy and radiotherapy in breast cancer is given as out-patient basis. All cancer drugs in licensed indications are free for the patients. • Also breast reconstruction operations for breast cancer patients are provided by the public sector.
FR	Mainly private	Yes, initially and with follow up quality checks. Private entities accredited – certified along defined National European standards	• In FR the healthcare organisation is based on private and state entities: in 2010 49% were public, 42% were private and 9% were private (non-profit) with general public interest. • France has 26 regions and each region has a state RHA responsible for the screening procedure, healthcare and social welfare. The screening programme is established at a national level. • The FCCCCs are private with general public interest. The 20 FCCCCs entirely devoted to the fight against cancer have missions of patient care, research and teaching. • A total of 881 care entities were accredited to treat cancer according to stringent criteria. • The implementation of a new, secure electronic patient file is in development. It is hoped to improve the links between GPs, hospital clinicians and therapists and rapid access to files. • For details on the general situation of cancer in France 2011: http://www.e-cancer.fr.

Annex IV, Table 1. *(cont.)*

Country	Provided by	Private entities quality checked	Description
HR	Mainly public	No	• HR's healthcare system is based on the principles of social health insurance. Provision and funding of services are largely public. • The healthcare system is dominated by the HZZO, that plays a key role in the definition of basic health services covered under statutory insurance, the establishment of performance standards and price setting for services covered. • Health system is centrally controlled by the Ministry of Health and Social Care as well as few NGOs. Public health services are organised through a Network of Public Health Institutes. • Primary healthcare is organised as a network of first-contact doctors. Each insured citizen is required to sign up with a specific GP. • Secondary out-patient healthcare services are mostly delivered through hospitals. The majority of special hospitals are public county-owned. Special hospitals serve the entire population of HR. • Public funds for healthcare originate from contributions for mandatory health insurance (predominantly), and funds collected by general taxation. Medical services are funded separately by the HZZO, according to a combination of a point-based hospital payment system and a DRGs system. • For further details see *HiT report* for Croatia.
HU	Exclusively public	–	• Healthcare in HU is based on a compulsory and comprehensive social insurance system, based on the National Health Insurance Fund Administration. • The Ministry of Human Resources, Secretary of State Responsible for Health covers health policy development, health sector regulation, strategic planning. • The National Public Health and Medical Officers' Service is responsible for the management, coordination and supervision of public health and the supervision of healthcare delivery. The branch called National Centre for Healthcare Audit and Inspection is responsible for monitoring on site in close cooperation with healthcare providers. • The Health Insurance Supervisory Authority acts as health consumer protector and also disseminates quality indicators. • Primary care is based on GPs and the district nursing system. • Out-patient care is mostly provided in polyclinics, mainly owned by local or county authorities. • The vast majority of hospitals are owned by local or county authorities or the state. Hospital care is two-tiered: basic care is carried out by territorial hospitals, while tertiary care is done by specialised centres. • The centralisation of structure of the oncological care system is underway, progressivity levels were defined by minimal requirements.

Annex IV, Table 1. *(cont.)*

Country	Provided by	Private entities quality checked	Description
IE	Mainly public	No	• The Department of Health formulates and evaluates policies for the health services. It also has a role in the strategic planning of health services. This is carried out in conjunction with the HSE, voluntary service providers, government departments and other interested parties. • The HSE is responsible for financial resource allocation and for the management and delivery of health and personal social services. Within the HSE the NCCP is responsible for the delivery of cancer services. There are eight designated cancer centres. The National Cancer Screening Service operates the National Breast, Cervical and Colorectal Cancer Screening Programmes and is part of the National Cancer Control Programme. • The National Cancer Registry collects, classifies and stores and analyses information relating to the incidence and prevalence of cancer.
IT	Mainly public	Yes, initially and with follow up quality checks	• In Italy there is a NHS that provides universal healthcare coverage to its population. • From the 1990s until 2001, the NHS decentralised health service management from the central to the regional level of government. As a result, today, the central government (Ministry of Health) is responsible for ensuring the general objectives and fundamental principles of the NHS; while the regional governments, through their regional health departments, are responsible for ensuring the delivery of a nationally-defined benefit package through a network of public and private service providers (clinics and hospitals). • The benefit package is financed primarily by earmarked central and regional taxes. The regions may choose to provide additional healthcare services with their own resources as well. • In 1996, the Ministry of Health published clinical guidelines for breast, cervical and colorectal cancer, and began providing mass-population screening programmes for them. These CSPs were designed to reduce cause-specific mortality rates in target populations, as defined by age related risk to develop cancer (average-risk population). Since 2001, these CSPs have been included in the nationally-defined benefit package for average-risk populations.
LT	Mainly public	No	• The healthcare institution is divided into three groups based on the services they provide: district hospitals with minimum range of services, regional hospitals with significantly broader range of services and national level hospitals where treatment of most complicated diseases that require sophisticated technologies and highly specialised doctors is concentrated. • Patients suffering from oncological diseases are treated in specialised and multidisciplinary healthcare institutions and scientific centres with modern technical resources and qualified staff. • Oncological patients are provided with out-patient, in-patient and day care services, including palliative care and pain treatment. Services are reimbursed from the Compulsory Health Insurance Fund. • Development of infrastructure of healthcare institutions which provide oncological services is funded from the state budget and the European Union structural funds.

Annex IV, Table 1. *(cont.)*

Country	Provided by	Private entities quality checked	Description
LU	Exclusively public	–	• A nearly universal coverage by compulsory public health- and care insurance free choice and equity of access as well to primary care providers, hospitals, long term settings and medical specialists. • Free establishment of health professionals, but a planned hospital and pharmacy sector, with compulsory authorisation for all the providers who are automatically under contract with the public health-assurance, make that there is no private sector. • Uniform legislation and regulation and thus equity of treatment, for the different providers regardless to their status. • Regulation of end of life dispositions by recent legislation on palliative care and euthanasia. • The universal health insurance called 'Caisse Nationale de Santé', governed by State, trade-unions and employers, as well as the compulsory care insurance, is under the political responsibility of the Minister of Social Security. • The system remains still very hospital-centric; there are five general hospitals and five specialised (two acute and three rehabilitation) hospitals of various status (public institutions, foundations, private for-profit); they assure a quasi-public mission inside the framework given by the national hospital plan and *e.g.* the emergency service. All these establishments are subject to the same legislation and rules of planning, organisation and funding.
LV	Mainly public	No	• The healthcare system is governed by Ministry of Health and it is based on the residence principle. • Negative list of benefits: the state pays for all services except those that are excluded from the scope. • Healthcare benefits are available at the state, municipality and private in-patient and out-patient healthcare institutions. • Screening programme for breast cancer is available in mammography examination rooms in out-patient facilities including mobile mammography unit, two oncology centres and two University hospitals. • A patient should pay a contribution in order to receive healthcare, except for screening examinations: mammography and laboratory examination (cytology) for cervical cancer which is completely covered from state budget. • Further examinations and necessary treatment are covered by the state budget and the patient's own co-payments, and is provided by: - GP. - Specialist's provided healthcare. - Laboratory analysis and medical manipulations with the family doctor's or specialist's referral. - Healthcare in the day stationary. - Home care. - Assistance of emergency medicine brigade. - Emergency medical assistance in the hospitals and trauma centres. - Healthcare in university, regional, municipality, medical hospitals and two oncology centres and out-patient institutions by providing more specialists support and necessary examinations. - Care in the long term healthcare hospitals after treatment phase in the emergency, university, regional hospitals or oncology centres, as well as in cases of exacerbation of chronic diseases. - Rehabilitation after the treatment phase in the emergency, university, regional medical hospitals or dynamic surveillance of the medical rehabilitation. - Reimbursed medicines and medical devices.

Annex IV, Table 1. *(cont.)*

Country	Provided by	Private entities quality checked	Description
MT	Mainly public	No	An update *HiT report* for Malta has been published in 2014: http://www.euro.who.int/en/about-us/partners/observatory/health-systems-in-transition-hit-series/countries-and-subregions/malta-hit-2014.
NL	Mainly public	Yes, initially and with follow up quality checks	• Quality checks are regulated by the general quality regulations for healthcare (laws, inspection, etc). In addition there is a monitor for breast cancer care (in Dutch only) by the Dutch patient organisation, which compares the care in different hospitals (as perceived by patients): http://www.borstkanker.nl/monitor_borstkankerzorg. • For health system details: http://www.euro.who.int/__data/assets/pdf_file/0008/85391/E93667.pdf.
NO	Exclusively public	Yes, initially and with follow up quality checks	• The central government and the local communities have a dominant role both in the delivery and the financing of health services; primary care services are delivered by the municipalities, whereas the delivery system for the specialised healthcare is owned by the government and run by four regional health authorities. • The national insurance scheme covers all inhabitants, regardless of the ability to pay. The healthcare is mainly tax-funded, and the out of pocket-payments only represent approximately 15%. • Breast cancer care is funded by a combination of a block grant and an activity based reimbursement (DRG). Small out of pocket payments are used for out-patient care. • The Norwegian BCSP is nationwide. The Cancer Registry of Norway is responsible for administration and quality assurance of the programme. The interpretation of the screening mammograms and all further assessment is performed at the 16 breast clinics. • Screening is also performed at private clinics (5-10% of the women aged <50 years). • Treatment and follow up of breast cancer patients are mainly performed at the University Hospitals with breast clinics. • Controls are mainly performed at the University Hospitals.
RO	Mainly public	Yes, initially and with follow up quality checks	• Population is mandatory insured at National Health Insurance House. • Family doctors are sending patients to both public and private units of diagnosis, treatment and follow-up, reporting data to population based cancer registries on regional basis. • Cancer registries are financed by Ministry of Health. • All resources for ambulatory, hospital in-patient care, home care, out-patient care are from Health Insurance System, completed for specific drugs for medical oncology with resources from Ministry of Health budget.

Annex IV, Table 1. *(cont.)*

Country	Provided by	Private entities quality checked	Description
SE	Mainly public	Yes, initially and with follow up quality checks	• The health system is divided into approximately 25 counties. They are organised under the Swedish Association of Local Authorities and Regions. • There are also six Regional Cancer Centres that organise all cancer diagnostics and cancer treatment in Sweden with suggestions as to how to work and regulations. • The counties have a certain amount of decision power, they finance the screening and can decide how the breast cancer screening should be carried out in the county (*e.g.* the age group, the interval, the county organisation). • In almost 50% of Sweden private companies are taking care of the screening, but also of the clinical mammography. • The breast cancer screening is almost everywhere in Sweden part of a breast centre. • All breast cancer patients are undergoing surgery in hospitals.
SI	Mainly public	Yes, initially and with follow up quality checks	• SI's health system is funded by compulsory health insurance, state revenues, voluntary health insurance and out-of-pocket spending. The *Health Care and Health Care Insurance Act* of 1992 set out the basis for the system, as well as permitted privatisation of healthcare services and transferring many administrative functions to the Medical and Pharmaceutical Chambers. • The state has administrative and regulatory functions. The Slovene healthcare system remains relatively centralised and the responsibility of local communities is still limited. • Compulsory health insurance contributions constitute the major source of healthcare financing. General national- and municipal-level taxation represent another public source of funding and it primarily covers capital investments in facilities owned by the Ministry of Health or municipalities. • Voluntary health insurance contributors and household out-of-pocket spending represent private source of funds. • For hospital in-patient care, a DRG payment model has been used since 2003. • Out-patient services are paid through a combined system of capitation and fee-for-service payments. • Services provided by pharmacies are paid for by fee-for-service payments. • Healthcare services provided by social institutions are paid for according to days of nursing care and by fee-for-service payments.
SK	Mainly public	Yes, initially and with follow up quality checks	SK is trying to implement BCSP.

Annex IV, Table 1. *(cont.)*

Country	Provided by	Private entities quality checked	Description
UK*	Mainly public	No	• Health services in England are mainly financed from public sources, primarily general taxation and National Insurance contributions. • The NHS publicly funded system consists of organisations that deliver services (service providers) and organisations that contract for (commission) services. • In 2012 the *Health and Social Care Act* reformed the structure of the healthcare system. An overview of the change, which differs from the previous descriptions used in the *HiT UK report* (2011), is: - At local level, local authorities will have responsibility for local population health improvement. - Most NHS care is to be commissioned by clinical commissioning groups, which will give GPs and other clinicians responsibility for using resources. - NHS commissioners will be supported by the NHS Commissioning Board. - The Care Quality Commission will ensure services meet safety and quality requirements. - Health Education England will provide oversight and leadership for professional education and training. - The National Institute for Health and Care Excellence will continue to provide independent advice and guidance to the NHS, and will extend its role to social care. - Action to protect and promote the health of the population will be led nationally by Public Health England.

* Information provided for England only; data submitted are accurate up to 31 March 2013, following which major reform of the health and care system took place, which are not reflected in this report.

Annex IV, Table 2. *Section 2 – The healthcare organisation*

Questions *(not mandatory)*:

- Is alternative medicine offered for cancer patients?
- Is this offered in the field of: [multiple choice]?

Country	Is offered	What
AT	Yes	Palliative care; some alternative therapies are being paid – most of them have to be paid for privately.
BE	Yes	It is offered in the field of prevention, health quality, treatment integration, side effects of treatments and palliative care.
BG	No	–
CY	No	–
CZ	No	–
DE	Yes	Complementary medicine is offered on request in some breast cancer services (hospitals and out-patient units) at different stages for controlling various symptoms and side effects. Alternative medicine is not offered in this context if the term 'alternative medicine' refers to interventions replacing conventional medicine (NCCAM).
EE	No	–
ES	No	–
FI	No	–
FR	Yes	Palliative care and side effects.
HR	No	–
HU	Other	Alternative medicine is offered to relieve side effects, only in the context of clinical trials.
IE	No	–
IT	No	–

Annex IV, Table 2. *(cont.)*

Country	Is offered	What
LT	No	–
LU	Yes	Side effects
LV	Yes	Palliative care.
MT	Yes	Palliative care. Mainly acupuncture in a public context. Other therapies provided by a nonprofit hospice association.
NL	Other	Only covered by some (additional) insurance policies.
NO	No	–
RO	Yes	Palliative care.
SE	Yes	Palliative care.
SI	Other	Only by private providers.
SK	Other	It exists but not as a part of standard treatment.
UK*	Yes	Health quality, treatment integration, side effects, palliative care.

* Information provided for England only; data submitted are accurate up to 31 March 2013, following which major reform of the health and care system took place, which are not reflected in this report.

Annex IV, Table 3. *Section 2 – The healthcare organisation*

Questions *(not mandatory)*:

For Physicians

- Are there mandatory entry-level qualifications?
- Is there any mandatory registration-licensing system?
- Are there any mandatory requirements for training/competence updating (*e.g.* continuous medical education, on-the-job training, etc.)?
- Does any specific training exist in your country in the field of breast cancer care (*e.g.* degree, master, post-degree, private school, etc.)?

Country	Entry level	Registration	Competence updating	Breast cancer training	Details
AT	Yes	Yes	Yes	Yes	*E.g.* The Austrian Medical Association is offering skill enhancement in the field of breast cancer care.
BE	Yes	Yes	Yes	Yes	*R. Decree 26 September 2007* regarding the special criteria for the accreditation of the medical doctor-specialist, holder of the professional title in medical oncology.
BG	Yes	Yes	No	No	–
CY	Yes	Yes	Yes	Yes	In the frames of continuous medical education.
CZ	Yes	Yes	Yes	Yes	Training associated with operation of diagnostic centres involved in the breast cancer treatment plus training improving the skill and capability of diagnostic specialists (mammography, pathologists).
DE	Yes	Yes	Yes	Yes	There is a specialist degree of five years, *Facharzt/Fachärztin für Frauenheilkunde und Geburtshilfe* (specialist for women's medicine and obstetrics). For these specialist doctors, there is a more specific training of three years, *Gynäkologische Onkologie* (gynaecological cancer care), which includes breast cancer care.
EE	Yes	Yes	Yes	No	–
ES	Yes	Yes	No	Yes	Master. Some of them are: Máster Internacional de Especialización en Mastologia (Po2G). XII Master Patología Mamaria (http://www.master-senologia.com/).

Annex IV, Table 3. *(cont.)*

Country	Entry level	Registration	Competence updating	Breast cancer training	Details
FI	Yes	Yes	Yes	Yes	Training is provided for different professionals as part of their education by universities. The Finnish Medical Society Duodecim and Finnish Medical Association provide training in breast cancer management for different medical specialties, but no special medical competence or master degrees exists, *e.g.*, in breast cancer care. Breast cancer patients are treated by clinical oncologists (both medical treatment and radiotherapy). In clinical praxis some clinicians specialise particularly in the management of breast cancer. The Finnish Breast Cancer Group, the Finnish Society of Oncology and The Cancer Society of Finland are also providing multidisciplinary training in breast cancer care.
FR	Yes	Yes	Yes	Yes	–
HR	Yes	Yes	Yes	No	–
HU	Yes	Yes	Yes	Yes	There is a special examination in the field of breast diagnostics (screening and symptomatic).
IE	Yes	Yes	Yes	No	There are no specific courses in breast cancer surgery. All breast surgeons train officially as a Specialist Registrar in general surgery but they will spend up to four years in breast cancer posts, usually one abroad in an international centre.
IT	Yes	Yes	Yes	Yes	Master and post-degree by universities and/or professionals' and patients' associations.
LT	Yes	Yes	Yes	Yes	Only a medical doctor who has acquired medical oncologist chemotherapist's professional qualification or medical oncologist radiotherapists' professional qualification can practice as oncologist. Only a medical doctor who has acquired medical surgeon's professional qualification can practice as surgeon oncologist. For breast surgery there is an additional breast surgeon oncologist specialisation.
LU	Yes	Yes	No	No	–
LV	Yes	Yes	Yes	No	–
MT	Yes	Yes	No	No	–
NL	Yes	Yes	Yes	Yes	Degree in oncology in different levels in healthcare. There is a course for screening radiologists.

Annex IV, Table 3. *(cont.)*

Country	Entry level	Registration	Competence updating	Breast cancer training	Details
NO	Yes	Yes	No	No	–
RO	Yes	Yes	Yes	Yes	Post-degree.
SE	Yes	Yes	Yes	No	–
SI	Yes	Yes	Yes	Yes	Physicians can specialise in several fields that include breast cancer care: oncology and radiotherapy, internal oncology, general surgery, plastic surgery. Professionals can also enrol in post-degree studies where they can focus their research on the field of breast cancer care. The national screening programme for breast cancer also educates medical staff.
SK	Yes	No	Yes	Yes	A training for physicians.
UK*	Yes	Yes	Yes	Yes	Specialist training and ongoing professional development provided through a variety of providers, including research facilities, private training providers, charities, professional bodies.

* Information provided for England only; data submitted are accurate up to 31 March 2013, following which major reform of the health and care system took place, which are not reflected in this report.

Annex IV, Table 4. *Section 2 – The healthcare organisation*

Questions *(not mandatory)*:

For Nurses

- Are there mandatory entry-level qualifications?
- Is there any mandatory registration-licensing system?
- Are there any mandatory requirements for training/competence updating (*e.g.* continuous medical education, on-the-job training, etc.)?
- Does any specific training exist in your country in the field of breast cancer care (*e.g.* degree, master, post-degree, private school, etc.)?

Country	Entry level	Registration	Competence updating	Breast cancer training	Details
AT	Yes	No	Yes	Yes	*E.g.* The Medical University Graz provides a course for breast care nurses.
BE	Yes	No	No	Yes	Organised by hospitals.
BG	Yes	Yes	No	No	–
CY	Yes	Yes	Yes	Yes	Life long education/uni curriculum.
CZ	Yes	Yes	Yes	No	–
DE	Yes	No	No	No	–
EE	Yes	Yes	Yes	No	–
ES	Yes	Yes	No	No	Nurses education in Spain is regulated. There is no oncology specialty for nurses. Nurses acquire their training in specialised units at hospitals.
FI	Yes	Yes	Yes	Yes	Training in breast cancer care is provided, but no special master degree for breast cancer care exists for nurses. After the basic education, the nurses can specialise in cancer care and/or in palliative care. Nursing staff have also training organised in breast cancer care by the hospitals and other institutions, *e.g.* by the Association for Cancer Care Nurses.
FR	Yes	Yes	Yes	No	–

Annex IV, Table 4. *(cont.)*

Country	Entry level	Registration	Competence updating	Breast cancer training	Details
HR	Yes	Yes	No	No	–
HU	Yes	Yes	Yes	No	–
IE	Yes	Yes	Yes	Yes	Nurses working in breast care in specialist roles are required to undertake a Higher Diploma in Oncology if they have not completed it prior to commencing in the role.
IT	Yes	Yes	No	No	–
LT	Yes	Yes	Yes	No	–
LU	Partially	Yes	Yes	No	–
LV	Yes	Yes	Yes	No	–
MT	Yes	Yes	No	No	–
NL	Yes	Yes	Yes	Yes	There is a course for nurses specifically for breast cancer: http://www.mammaopleiding.nl.
NO	Yes	Yes	No	Yes	–
RO	Partially	Yes	Yes	No	–
SE	Yes	Yes	Yes	No	–
SI	Yes	Yes	Yes	Yes	There is no formal education for breast cancer care, but oncology classes are included in the degree programmes for students of nursing schools, as well as master and post-degree students. In these programmes, students can focus on the field of breast cancer care.
SK	No	No	No	No	–
UK*	Yes	Yes	Yes	Yes	Specialist training and ongoing professional development provided through a variety of providers, including research facilities, private training providers, charities, professional bodies.

* Information provided for England only; data submitted are accurate up to 31 March 2013, following which major reform of the health and care system took place, which are not reflected in this report.

Annex IV, Table 5. *Section 2 – The healthcare organisation*

Questions *(not mandatory)*:

For Paramedics

- Are there mandatory entry-level qualifications?
- Is there any mandatory registration-licensing system?
- Are there any mandatory requirements for training/competence updating (*e.g.* continuous medical education, on-the-job training, etc.)?

Country	Entry level	Registration	Competence updating	Details
AT	Partially	Psychotherapists and clinical psychologists	Partially	Concerning breast cancer care only for psychotherapists and clinical psychologists. Depending on the statutory rule.
BE	Yes	Yes	No	–
BG	Yes	Yes	No	–
CY	Yes	Not reported	Yes	–
CZ	Yes	Yes	Yes	–
DE	Yes	No	No	–
EE	Yes	Yes	Yes	–
ES	Physiotherapists	Physiotherapists	No	Physiotherapy education is regulated. There is no oncology specialty for physiotherapists.
FI	Yes	Yes	Yes	For physiotherapists and chiropractors there are mandatory entry-level qualifications. However, for osteopaths these kinds of qualifications do not exist, not at least at the moment. Chiropractors are educated abroad, and therefore very little or no on-the-job or other training exists.
FR	Yes (not for chiropractors)	Yes (not for chiropractors)	Yes (not for chiropractors)	–
HR	Physiotherapists	Physiotherapists	No	–

Annex IV, Table 5. *(cont.)*

Country	Entry level	Registration	Competence updating	Details
HU	Yes	Yes	Yes	–
IE	Partially	Others	No	The Health Service Executive has set qualifications for many health and social care professional posts. CORU is working to put in place professional registration systems for twelve professions. Social workers are the first profession to be regulated by CORU.
IT	Yes	No	No	–
LT	Yes	Yes	Yes	–
LU	Partially	Yes	No	–
LV	Yes	Yes	Yes	Continuous medical education is mandatory.
MT	Yes	Yes	No	The Council for the Professions Complimentary to Medicine regulates the following professions: acupuncturist, audiologist, chiropractor, clinical perfusionist, dental hygienist, dental technologist, dietician, environmental health officer, medical laboratory scientist, nutritionist, occupational therapist, optometrist, orthoptist, osteopath, physiotherapist, podiatrist, psychotherapist, radiographer, speech language pathologist.
NL	Yes	Yes	Yes	For physiotherapists is a registration under the *quality act BIG* (about professions in the individual healthcare): http://www.bigregister.nl/en/registration/inthebigregister/default.aspx. There is no governmental organised system for chiropractors or osteopaths.
NO	Yes	Yes	Physiotherapists for breast cancer	–
RO	Yes	Yes	Yes	–
SE	Yes	Yes	Yes	–

Annex IV, Table 5. *(cont.)*

Country	Entry level	Registration	Competence updating	Details
SI	Physiotherapists	No	No	There are no formal education nor specific training for chiropractors or osteopaths in healthcare system.
SK	Yes	Yes	Yes	–
UK*	Yes	Yes	Yes	–

* Information provided for England only; data submitted are accurate up to 31 March 2013, following which major reform of the health and care system took place, which are not reflected in this report.

Annex IV, Table 6. *Section 3 – Cancer screening*

Questions:

- Is there a screening programme for cancer in your geographical area of concern?
- Is the screening programme organised? (see *Implementation Report* definitions)
- Is it population based?
- Level of coordination: National, Regional with national coordination, Regional, Local regional/national coordinated, No coordination.

	BREAST CANCER		COLORECTAL CANCER		CERVICAL CANCER	
Country	Organised	Coordination	Organised	Coordination	Organised	Coordination
AT	Yes (pilot, some regions are population-based; national screening programme – non organised)	Regional with national coordination (pilot)	Yes	National	Yes	National
BE	Yes	Regional	Yes	Regional	Yes (since Autumn 2013)	Regional
BG	No programme[1]	–	No programme[1]	–	No programme[1]	–
CY	Yes	National	Yes	National, but operating only in certain areas	No programme	–
CZ	Organised but non population-based	National	Yes	National	Yes	National
DE	Yes (population-based)[2]	National	Opportunistic[2]	National	Opportunistic[2]	National

1. At the end of 2013, screening for breast cancer, colon cancer and cervix cancer will start with financial support of the European Project 'Stop and watch himself'.
2. Germany introduced an organised, population-based, quality assured Mammography Screening Programme for the early detection of breast cancer between 2005 and 2009. The law on the *Further Development of the Early Detection of Cancer and Quality Assurance through Clinical Cancer Registries* which had been put forward by the German Federal Ministry of Health came into force on 9 April 2013 (the law takes a two-pronged approach, see *Section 5*). The law creates the necessary legal framework to turn the current opportunistic cervical cancer screening and colorectal cancer screening into population-based, quality assured programmes. Special emphasis is put on the provision of balanced information on the potential benefits and harms of the screening programmes.

Annex IV, Table 6. *(cont.)*

	BREAST CANCER		COLORECTAL CANCER		CERVICAL CANCER	
Country	Organised	Coordination	Organised	Coordination	Organised	Coordination
EE	Yes	National	No programme	–	Yes	National
ES	Yes	Regional	Yes	Regional	No programme	–
FI	Yes	National[3]	Pilot (randomised implementation phase, national coordination in volunteering municipalities)	Other	Yes	National[3]
FR	Yes	National	Yes	National	Yes	Local regionally/ nationally coordinated
HR	Yes	National	Yes	National	No programme	–
HU	Yes	National	Yes	Regional nationally coordinated	Yes	National
IE	Yes	National	Yes (started end 2012)	National	Yes	National
IT	Yes	National	Yes	National	Yes	National
LT	Yes	National	Yes	Regional nationally coordinated	Yes	National
LU	Yes	National	No programme	–	Yes	National
LV	Yes	National	Yes	National	Yes	National
MT	Yes	National	Yes	National (since November 2012)	No programme	–
NL	Yes	National	Roll-out start 2014	National	Yes	National

3. It is the responsibility of the municipalities to organise the screening and they buy the screening service from several service providers.

Annex IV, Table 6. *(cont.)*

	BREAST CANCER		COLORECTAL CANCER		CERVICAL CANCER	
Country	Organised	Coordination	Organised	Coordination	Organised	Coordination
NO	Yes	National	Pilot (randomised trial)	National in the future	Yes	National
RO	No programme[5]	–	No programme[5]	–	Yes	Regionally/ nationally coordinated
SE	Yes	National/Regional/Local depending on the area	No programme	–	Yes	National
SI	Yes	National, but operating only in certain areas	Yes	National	Yes	National
SK	Project	–	No programme	–	No programme	–
UK*	Yes	National	Yes	National	Yes	National

5. Programme in the process of pilot planning, starting probably in 2014.

* Information provided for England only; data submitted are accurate up to 31 March 2013, following which major reform of the health and care system took place, which are not reflected in this report.

Annex IV, Table 7. *Section 3 – Cancer screening*

Questions:

- Year of initial implementation of breast cancer screening.
- Screening method (*e.g.* mammography).
- Target age group range.
- Screening interval (months between rounds).
- Website.

Country	Initial	Method	Target age	Interval	Website	Comments
AT	Pilot ongoing; national screening programme – non-organised	Mammography	50-69 (Vienna, Voralberg, Salzburg) 40-69 (Burgenland) 40-69 (Tirol)	12/24 months (depending on pilot project, age or BI-RADS)	http://www.sozialversicherung.at	Currently AT is preparing the implementation of a national organised breast cancer screening programme.
BE	2001/1002	Mammography	50-69	24	http://www.sante.cfwb.be/index.php?id=1040 http://www.lemammotest.be/spip/ http://www.ccref.org/contexte-sein.php http://www.bevolkingsonderzoek.be http://www.borstkankeropsporing.be	–
BG	–	–	–	–	–	–
CY	2003	Mammography (digital)	50-69	24	not available website; e-mail: breastscreening@mphs.moh.gov.cy	–
CZ	2002	Mammography	44 and over	24	http://www.mamo.cz/–BCSP in the Czech Republic	–
DE	2005/2009 (roll out)	Mammography	50-69	24	http://www.mammo-programm.de/startseite/startseite.php	–
EE	2011	Mammography	50-62	24	http://www.cancer.ee	–

Annex IV, Table 7. *(cont.)*

Country	Initial	Method	Target age	Interval	Website	Comments
ES	1999 (1990/2011 in different regions)	Mammography	50-69 45-69 (7 regions)	24	http://www.programascancerdemama.org/	The National network of screening programmes is contributed by the person responsible of the screening programmes in each Spanish region in order to share experience about the management of programmes.
FI	1987	Mammography	50-69	24 (20-26)	http://www.cancer.fi/syoparekisteri/en/mass-screening-registry/	The Finnish mammography programme is gradually expanding from ages 50-59 years to ages 50-69 years, and will cover all women aged 50-69 years in 2016.
FR	2001	Mammography + clinical breast examination	50-74	24	http://www.invs.sante.fr/Dossiers-thematiques/Maladies-chroniques-et-traumatismes/Cancers/Evaluation-des-programmes-de-depistage-des-cancers	–
HR	2006	Mammography	50-69	24	Under construction	–
HU	2001	Mammography	45-65	24	http://www.antsz.hu	–
IE	2000	Mammography	50-64	21-27	http://www.breastcheck.ie	–
IT	2002	Mammography	50-69 (regions allowed to cover 45-49 and/or 70-74)	24	http://www.osservatorionazionalescreening.it	–
LT	2005	Mammography	50-69	24	http://www.vlk.lt	–
LU	1992	Mammography	50-69	24	http://www.sante.public.lu/fr/rester-bonne-sante/045-cancer-depistage/programme-mammographie/index.html	–
LV	2009	Mammography	50-69	24	http://www.vmnvd.gov.lv/lv/469-veselibas-aprupes-pakalpojumi/veza-savlaicigas-atklasanas-programma/626-veza-savlaicigas-atklasanas-programmas-rezultati	–

Annex IV, Table 7. *(cont.)*

Country	Initial	Method	Target age	Interval	Website	Comments
MT	2009	Mammography	50-60	36	http://www.ehealth.gov.mt	–
NL	1990	Mammography (digital)	50-74	24.7	http://www.bevolkingsonderzoeknaarborstkanker.nl	–
NO	1996	Mammography	50-69	24	http://www.kreftregisteret.no	–
RO	–	–	–	–	–	–
SE	1989	Mammography	40-74	18-21-24 according to age and area	http://www.socialstyrelsen.se/publikationer2012/2012-2-36	In SE, there have been some tenders concerning radiological breast diagnostics both clinical mammography and screening. Unilabs has won almost all tenders and today invite 440 000 women in the age group 40-74 to screening. The rest is managed by the different counties and some private clinical patients in Stockholm.
SI	2008	Mammography	50-69	24	http://dora.onko-i.si/	Non-programme screening had been running for more than ten years, but in 2008 a population-based screening for limited parts of SI started. The organised programme will replace opportunistic screening in the future.
SK	–	–	–	–	–	The National Mammography Screening Programme is being prepared as a part of the National Oncological Programme, which is in the state of being prepared also.
UK*	1988	Mammography	50-70 (extension 47-73 to be completed by 2016)	36	http://www.cancerscreening.nhs.uk/breastscreen/ http://www.hscic.gov.uk/catalogue/PUB10339/bres-scre-prog-eng-2011-12-rep.pdf	–

* Information provided for England only; data submitted are accurate up to 31 March 2013, following which major reform of the health and care system took place, which are not reflected in this report.

Annex IV, Table 8. *Section 3 – Cancer screening*

Questions *(not mandatory)*:

- The year of the last report to which the information refers to.
- Annual number of invitations.
- Annual participation rate.
- Cost per screened woman.

Country	Target year	Invitations (thousands)	Invitation rate in the whole round (%)	Participation rate (%)	Cost per woman screened	
					Local currency	Converted in EUs[1]
AT	–	–	–	–	–	–
BE	2011	Brussels: 52 Flemish: 381 Walloon: 206	Brussels: 100.0 Flemish: 100.0 Walloon: 100.0	Brussels: 10.7 Flemish: 50.2 Walloon: 7.3	Not reported	Not reported
BG	–	–	–	–	–	–
CY	2011	35	100.0	65.0	EUR 20	20
CZ	2010	Not reported	Not reported	51.1 in age group 45-69	CZK 650	25
DE	2008-2009[2]	4801 (2009)	86.9	54.3 (2009)	EUR 73	73
EE	2011	61	86.0	54.0	EUR 27	27
ES	2010	1911	100.0	71.0	Not reported	Not reported
FI	2010	~320	82.6	85.5	EUR ~50	~50
FR	2011	4614	99.0	52.7	EUR 22	22
HR	2009	360	100.0	63.0	HRK 240	32

1. Converted into EUR on 23 April 2013.
2. The *Evaluationsbericht* 2008-2009 of the German screening programme reports yearly data for invitation and participation only and data of the two year period 2008-2009 for the rest of the indicators.

Annex IV, Table 8. *(cont.)*

Country	Target year	Invitations (thousands)	Invitation rate in the whole round (%)	Participation rate (%)	Cost per woman screened	
					Local currency	Converted in EUR[3]
HU	2010	~450-500	100.0	~50.0	HUF ~5000	~17
IE	2011	167	Not reported	74.5	Not reported	–
IT	2011	2500	69.5	56.0	EUR 55	55
LT	2011	79	Not reported[4]	51.4	LTL 65.96	19
LU	2010, 2011	26	98.0	64.0	Not reported	Not reported
LV	2011	180	99.0	34.0	LVL 14	20
MT	2011	13	100.0	60.0	EUR 65	65
NL	2009	1121	91.0	81.5	EUR 57	57
NO	2010	275	97.0	75.0	Not reported	Not reported
RO	–	–	–	–	–	–
SE	2011	1000	100.0	80.0	SEK ~600	~70
SI	2008-2012 (average)	27	28.3	78.6	EUR 106	106
SK	–	–	–	–	–	–
UK*	2010/11	1880	100.0	73.4	GBP 53	62

3. Converted into EUR on 23 April 2013.
4. Women are invited by the order approved by the head of the healthcare institution.

* Information provided for England only; data submitted are accurate up to 31 March 2013, following which major reform of the health and care system took place, which are not reflected in this report.

Annex IV, Table 9. *Section 3 – Cancer screening*

Questions *(not mandatory)*:

- Annual recall rate (% of women recalled for further assessment over all women who had a screening examination).
- Annual cancer detection rate.
- Please describe how the detection rate is calculated.
- Annual positive predictive value (the ratio of lesions that are truly positive to those tested positive).

	Recall rate (%)		Detection rate (‰)		Positive predictive value[1] (%)	
Country	First	Subsequent	First	Subsequent	First	Subsequent
AT	–		–		–	
BE	Flemish: 5.3	Flemish: 2.4	Flemish: 5.5	Flemish: 4.6	Flemish: 12.7	Flemish: 23.5
	Brussels: 7.8		Brussels: 6.3		Brussels: 10.8	
	Walloon: 14.5		Walloon: 8.0		Walloon: 9.7	
BG	–		–		–	
CY	From 5 to 7	From 4 to 5	Not reported		~7.0	
CZ	4.7	2.2	7.6[2]		5.2[3]	
DE	6.1	3.0	8.2	5.6	14.8 (all screened women)	
EE	3.2		4.2		Not reported	
ES	4.9		3.4[2,4]		Not reported	
FI	5.0	2.3	5.3	5.7	10.6	25.2

1. Defined as women with cancer among all women with positive first level mammography.
2. Includes positive confirmed at a later stage.
3. Approximated using the number of women undergoing further assessment in the Czech's one-day-assessment system for screening.
4. Standardised by age.

Annex IV, Table 9. *(cont.)*

	Recall rate (%)		Detection rate (‰)		Positive predictive value[1] (%)	
Country	First	Subsequent	First	Subsequent	First	Subsequent
FR	1.3		7.2-13.3[2,4,5]	6.2[2,4]	16.7	
HR	9.7		5.0[2]		Not clear	
HU	From 4 to 5		500-700 cases/year[2,6]		Not reported	
IE	7.3	2.9	8.7[2]	5.8[2]	Not reported	
IT	8.0	4.5	5.4[2,4]	4.7[2,4]	6.9	10.2
LT	Not reported		Not reported		Not reported	
LU	7.9	4.3	6.7		12.0	
LV	Not reported		1.3[2]		Not reported	
MT	10.5	–	5.4[2,4]	–	8.6	–
NL	4.6	1.6	6.9	5.6	15.0	35.0
NO	4.9	2.6	6.4	5.0	12.5	19.9
RO	–		–		–	
SE	From 3 to 4	From 2 to 3	From 5 to 6	4.0	16.7	
SI	4.5	2.3	8.0	4.0	17.3	17.5
SK	–		–		–	
UK*	4.0		7.8[2,4]		4.2	15.0

5. Depending on attendance to previous opportunistic screening.
6. No further explanations given.

* Information provided for England only; data submitted are accurate up to 31 March 2013, following which major reform of the health and care system took place, which are not reflected in this report.

Annex IV, Table 10. *Section 3 – Cancer screening*

Questions *(not mandatory)*:

- Do the following entities (or any other activities outside of the organised screening programmes) together account for >10% of the total mammograms performed for asymptomatic average risk women?

Country	Opportunistic	Details
AT	Yes	Detailed percentage not known.
BE	Yes	Healthcare structures independent from the organised screening programme; private insurances; private specialists.
BG	–	–
CY	Yes	Healthcare structures independent from the organised screening programme; private specialists.
CZ	Don't know	–
DE	Don't know	–
EE	No	–
ES	No	–
FI	Yes	For women outside the screening age cohorts large amount of mammograms are taken based on referral from private gynaecologists and other practitioners. Also for women in the screening age cohorts, large amount of mammography examinations are taken outside the screening (estimation one third of all mammograms in the screening cohorts), *e.g.* based on symptoms. Also some women choose to have private mammography and pay themselves instead of free of charge organised screening mammography.
FR	Yes	Mammography is based mainly on private practice in the programme. Opportunistic screening for asymptomatic average risk women reimbursed by the health insurance is also available in parallel to the screening programme.
HR	Don't know	–
HU	Yes	About 60% of eligible persons are being screened outside the programme.
IE	Don't know	–

Annex IV, Table 10. *(cont.)*

Country	Opportunistic	Details
IT	Yes	–
LT	No	–
LU	No	–
LV	Don't know	–
MT	Yes	Healthcare structures independent from the organised screening programme; fee paying and insurance.
NL	No	In the NL a permit is needed to screen for cancer according to the *Population Screening Act*, so there is little opportunistic screening.
NO	No	–
RO	–	–
SE	No	–
SI	Yes	Non-programme screening had been running for more than ten years; it is placed in the healthcare structures and some private practices. It is paid from the national insurance company budget if these healthcare structures and private specialists are contracted by the National insurance company for this programme.
SK	–	–
UK*	No	–

* Information provided for England only; data submitted are accurate up to 31 March 2013, following which major reform of the health and care system took place, which are not reflected in this report.

Annex IV, Table 11. *Section 4 – Breast cancer services organisation*

Questions:

- Please choose from the scenarios the one which better represents the situation in your country/region.
- Then you are asked to provide a brief description of your system and report the main differences from the chosen scenario.
- Does the BCS also organise the screening programme?
- Does the BCS carry out mammograms for the screening programme?
- Please specify below whether additional services, which might be relevant for this specific cancer but also for other cancers, are provided (*e.g.* translator, cultural mediator, palliative care, patients' carers support, etc.) (*not mandatory*).

Country	Scenario	Details	Screening organisation	Screening mammograms	Additional services
AT	2c	• AT's statutory insurance providers are currently in charge of activities regarding mammography screening, but a national organised BCSP is in preparation. The procedure can be performed either in radiological practises or in hospitals. • Whenever the outcome of the mammography shows that further treatment is needed the woman is referred to a specialised breast cancer unit or to specialists (usually in hospitals) that perform biopsies. • The initial treatment of breast cancer takes place in hospitals.	No	No	Depend on the particular hospital or practice. Palliative care is available for people who are terminally ill.
BE	1b	• Regional authorities are responsible for organising breast cancer screening, which is performed in authorised centres. • Brussels: http://www.brumammo.be/documents/home.xml?lang=fr. • Flemish: http://www.zorg-en-gezondheid.be/Ziektes/Vlaams-bevolkingsonderzoek-naar-borstkanker/. http://www.bevolkingsonderzoek.be. • Walloon: http://www.ccref.org/contexte-sein.php.	No	Yes	Not reported

Annex IV, Table 11. *(cont.)*

Country	Scenario	Details	Screening organisation	Screening mammograms	Additional services
BG	2a	• Breast cancer screening organisation is planned for the next year. • There are no special BCSs and women with breast cancer are treated in oncology hospitals (12 oncology dispensaries and 6 University hospitals). • Patients with suspicious breast tumours are presented on a weekly basis to the pre-surgical multidisciplinary committee in the oncology hospitals mentioned above. • After operation a post-operative multidisciplinary committee decides the treatment for the patient.	–	–	Some oncology centres have palliative care services. Rehabilitation is provided by private centres.
CY	1a	• Every stage of care and screening are under the responsibility of the same entity (common coordination), but at different locations.	Yes	Yes	Translator, cultural mediator, palliative care, caregivers' support are provided.
CZ	2c	–	Yes	Yes	Additional services are provided, especially palliative care, transport services, etc.
DE	2c modified (see *Annex V*)	• The organised, quality assured and population-based screening programme is organised and run by the *Kooperationsgemeinschaft Mammographie* on behalf of the purchasers and providers (sickness funds and KBV). The service is provided separately from breast cancer centres (see *Scenario 2c modified*). • The invitation system is managed by 13 special units, screening tests and follow up is done in 94 certified screening units. • Five reference centres together with the *Kooperationsgemeinschaft* are in charge of the management of quality assurance. • Most of the breast cancer patients are treated in breast cancer centres certified with DKG/DGS. • http://www.mammo-programm.de/startseite/startseite.php. • http://www.krebsgesellschaft.de/.	No	–	Palliative care is part of the routine cancer care and is a certification criteria for organ cancer centres, as breast cancer centres.

Annex IV, Table 11. *(cont.)*

Country	Scenario	Details	Screening organisation	Screening mammograms	Additional services
EE	2c	• The entity responsible for the screening is the Estonian Health Insurance Fund, which sends the invitations and contracts partners who carry out the screening process. • Treatment of the patients is carried out by two regional hospitals. • Estonia does not have specialised hospitals for breast cancer.	No	Yes	Estonian Cancer Society acts as an umbrella that draws together 16 member associations.
ES	2c	• BCS1: screening centre. Positive women are referred to their physician. • BCS2: primary care team. The person attends the GP when an abnormality in breast is detected or for screening if belonging to a high risk group. • BCS3: specialised care. BCS2 refers the patient to the gynaecologist (BCS3) for high risk screening. • BCS4: hospital breast cancer care unit. The GP (BCS2) or the gynaecologist (BCS3) refers the patient to this unit (BCS4). This unit does not exist in all the hospitals. This unit covers the stages 2, 3 and 4 of the breast cancer care.	Yes	Yes	Palliative care and social support is offered by the BCS2.
FI	2c	• Population-based breast cancer screening is the responsibility of the municipalities, and the service providers are selected locally based on costs and quality. There are a few (large) mammography screening providers, which take care of screening in the whole country. • In case of positive findings, the patient is referred to the hospital responsible for breast cancer treatment. • Breast cancer care follows the *Current Care Guidelines* provided by the Finnish Medical Association Duodecim: http://www.duodecim.fi. • Based on these *Current Care Guidelines*' recommendations, the breast cancer care is taken care by different clinics and service providers. The whole management of breast cancer is discussed in multidisciplinary teams. • The breast cancer management is usually centralised in large hospitals, which take care of the whole management of breast cancer treatment. Also the follow-up examinations, including laboratory and mammography examinations are taken care by the same clinics.	No	No	The rehabilitation of cancer patients is taken care by the Social Insurance Institution of Finland and The Cancer Society of Finland. The palliative care is taken care by several different service providers and there are regional differences. The Cancer Society of Finland and patient organisations provide psycho-social support which is complementary to the services provided by the public sector.

Annex IV, Table 11. *(cont.)*

Country	Scenario	Details	Screening organisation	Screening mammograms	Additional services
FR	6	• The screening programme is established at a national level, each region has a state Regional Health Agency which finances, administers and controls it. • Women are invited by the screening programme by local monitoring centres, if the results after further assessment are positive for cancer, the GP or the radiologist will orient the patient to a hospital or clinic for surgical care. • The screening programme is organised independently from care, the hospitals have to be accredited for breast cancer treatment.	–	–	Additional services are available for all cancers, not especially for breast cancer. This is part of the national 2009-2013 French cancer plan.
HR	6[1]	• The BCSP is organised by the Ministry of Health and the Croatian National Institute of Public Health, and implemented via 21 county institutes of public health. • Referral for further diagnosis/treatment is performed by the GPs according to the screening mammography finding and recommendation. • Diagnostic facilities for breast cancer comprise 51 units performing mammography, 88 ultrasound, 21 magnetic resonance imaging and 10 core biopsies. • For cancer treatment, five centres for radiotherapy and 12 for chemotherapy are available.	No	–	Post-treatment surveillance and management of recurrence are provided at the oncology departments; however, palliative care is not systematically organised and there are no specific departments providing this service. Physical rehabilitation is organised and delivered via physiotherapy departments, while psychosocial support is not organised within the system, but relies largely on voluntary services by patient groups and NGOs.

1. Information not verified with the survey national contact.

Annex IV, Table 11. *(cont.)*

Country	Scenario	Details	Screening organisation	Screening mammograms	Additional services
HU	1b	• National Public Health and Medical Officer Service organise the National Population Breast Screening Programme. Screening centres are controlled by the National Public Health and Medical Officer Service and the National Institute of Oncology. • Mammography is carried out by breast cancer screening stations and clinical breast diagnostic healthcare providers. • Cancer care is provided exclusively in specialised BCSs of progression levels: - GPs: encourage attendance on cancer screening, contribution to early diagnosis of cancer, assigning to special diagnostic centres. - County Oncology Centres: carry out screening, active and chronic treatment. - Regional Oncology Centres: comprehensive oncological treatment of the regional population, diagnostics and radiation therapy, surgery for malignant breast cancer done by surgical departments with more than 50 breast cancer interventions per year. - National Institute of Oncology: every aspect of breast cancer care is offered and performed in the same location.	No	Yes	Not reported.
IE	6	• The NCCP was set up in 2007 to provide a comprehensive programme of cancer control in IE, that would transform how cancer care is delivered, and ensure that cancer services meet the highest standards. Under the programme, there are four managed cancer control networks, each with two cancer centres. • BreastCheck, the national breast screening programme, is part of the National Cancer Control Programme. For details: http://www.breastcheck.ie. • Breast cancer diagnosis and surgery for symptomatic women take place in one of the eight cancer centres. • Follow-on services such as chemotherapy are administered in local hospitals, where appropriate, under the care plan devised by the cancer centre.	No	–	Palliative care for terminal patients is provided in acute-care hospitals, hospices and by palliative care homecare teams. Services are provided both by the Health Service Executive directly and by voluntary providers.

Annex IV, Table 11. *(cont.)*

Country	Scenario	Details	Screening organisation	Screening mammograms	Additional services
IT	2c	• This system is based on different regional approaches which have some elements described in the other scenarios; Italian Ministry of Health is going to update the organisation approach throughout a working group made of State, representatives of Regions and Scientific Societies. • Screening programmes are organised on the 'disease management'-basis by local health authorities (run by regional governments). • Screening programmes encompass the invitation phase and the delivery of first-level and second-level tests as well, according to the *European QA guidelines*. • In some regions (for instance Emilia-Romagna) the screening programme also involves and overviews the hospital-BCS activities.	No	–	Not reported.
LT	2b	• Ministry of Health of the Republic of Lithuania supervise national screening procedures; mammographic services are provided by the institution with mammography machines and mobile mammography equipment, according to the *Minister of Health Order No V-729 2005*. • Mammographic evaluation service is provided by the institutions which have experienced radiologists or the institutions which have agreements with them. • Mammographic assessment services which are paid in accordance with funding programme are given no more frequently than once every two years. • If mammography results are pathologic the patient is referred to a specialist for clarification of diagnosis and treatment.	Yes	Yes	Palliative care services are regulated by the *Order of the Minister of Health No. V-14 2007*, include support system to improve the quality of life and support for patients and their families, and are provided by a multidisciplinary team. *Order of the Minister of Health No. V-50 2008* regulates the procedures of rehabilitation services; after breast surgery patients are provided with in-patient and out-patient rehabilitation.

Annex IV, Table 11. *(cont.)*

Country	Scenario	Details	Screening organisation	Screening mammograms	Additional services
LU	6	• The Mammography Programme is a nationwide population-based BCSP; the Social Security Office reimburses screening mammograms done within the context of the programme. • A coordination centre established within the Health Ministry Directorate monitors the programme. • Mammograms are performed in the radiology departments of five hospitals that all comply with the quality criteria of the Programme. • The assessment of abnormal breast lesions is performed by the gynaecologist either in their private consultation or by the radiologists in the hospitals. • In 2011, multidisciplinary meeting to discuss diagnosis, pathological findings following surgery and to evaluate treatment options were set up. • For 2015, specialised breast units are foreseen, which should be able to organise special services as practical advice, support and counselling from breast care nurses.	No	–	The collaboration with palliative care service has to be addressed.
LV	2c	• Responsibility for sending invitation letters and organising breast cancer screening is National Health Payment Centre. • BCSs are 29: four hospitals with special departments and breast cancer units and 25 out-patient mammography laboratories (radiographer and radiologist).	No	Yes	Not provided.

Annex IV, Table 11. *(cont.)*

Country	Scenario	Details	Screening organisation	Screening mammograms	Additional services
MT	2b	• The Department of Health (headed by the Chief Medical Officer) within the Ministry for Health, the Elderly and Community Care is a supervisor entity that is responsible for the whole breast cancer care process. • The National Breast Screening Programme is led by the National Health Screening Service; mammograms for the screening programme are done at the National Health Screening Service. • Diagnosis and Surgical treatments are mainly done at Breast Care Clinic at MDH. • The multidisciplinary team meetings on breast cancer cases are done at MDH with the participation of all the involved clinical departments (surgery, imaging and pathology currently within MDH), oncology and palliative care departments and the National Screening Service. • Oncology and Palliative Care treatments are mainly performed at the Department of Oncology at Sir Paul Boffa Hospital.	Yes	Yes	All health professionals working in the palliative care team are urged and encouraged to undergo the training for a Certificate in Essential Palliative Care.
NL	6	• National Institute for Public Health and the Environment is responsible for screening organisation. See also: http://www.lrcb.nl/userdata/site_124/documents/Breast%20Cancer%20Screening%20LRCB.pdf, http://www.rivm.nl/en/Topics/Topics/B/Breast_cancer_screening_programme. • There are five regional screening organisations (including assessment units) and one reference centre. • The assessment part after screening is organised in a hospital setting and is as such not a part of the BCSP. Diagnosis happens in hospitals, preferably in specialised clinics. • Treatment (surgery, chemotherapy/hormone-therapy, radiotherapy): see guideline at http://oncoline.nl/mammacarcinoom. • Post-treatment surveillance and management of recurrence (including palliative care and associated support to patients and their carers) happens in hospitals. • Rehabilitation and other activities for improving the quality of life (*e.g.* psycho-oncology, involvement in social groups, etc.) are available.	No	–	See *Cancer Rehabilitation* guideline available at: http://oncoline.nl/index.php?language=en.

Annex IV, Table 11. *(cont.)*

Country	Scenario	Details	Screening organisation	Screening mammograms	Additional services
NO	1b	• Norwegian Breast Cancer Screening Programme is nationwide. The Cancer Registry of Norway is responsible for administration and quality assurance of the programme. The interpretation of the screening mammograms and all further assessment is performed at the 16 breast clinics. • Screening is also performed at private clinics. • Treatment and follow up of breast cancer patients are mainly performed at the University Hospitals with breast clinics. • Controls are mainly performed at the university hospitals.	No	Yes	Not reported.
RO	2c	• Screening programmes are coordinated by Ministry of Health, and breast cancer screening is in the process of pilot planning, starting probably in 2014 within a global new strategy in cancer control in Romania with respect to EPAAC conclusions-guidelines-examples of good practice toward Europe.	–	–	Not reported.
SE	3a	–	Yes	Yes	Not reported.
SI	2c	• An organised, population-based screening named Programme DORA run by a national coordination centre is in place for central part of Slovenia; in other areas a non-organised, opportunistic screening is still in place but it will be hopefully replaced by the organised one. • There are several institutions that deal partly or completely with breast cancer care. • OI Ljubljana is the only comprehensive cancer centre in the country and also the main oncological institution. It covers completely all breast cancer care stages (although not for the entire population), it runs the national breast cancer screening programme, it provides the guidelines and it has the leading role in the national cancer plan. • OI has no direct control of other breast cancer care facilities.	No	Yes	The rehabilitation process is partly done by the OI.

Annex IV, Table 11. *(cont.)*

Country	Scenario	Details	Screening organisation	Screening mammograms	Additional services
SK	6	• BCSs are partially coordinated by the state, partially by other organisations and partially not coordinated.	–	–	Not reported.
UK*	4a	• The 80 breast screening units in England form the NHSBSP, which is nationally coordinated. • A local hospital is responsible for each local screening unit and usually host assessment clinics as well. • The unit is responsible for screened women up to the point a breast cancer is diagnosed, after which her care transfers to a hospital's multi-disciplinary team for breast cancer. • The subsequent treatment is usually carried out at the same hospital if that hospital is responsible for the local screening service, or another local hospital. Some treatments, such as radiotherapy, may take place at a different hospital. • The different independent structures, providing different stages of care, are coordinated by the main hospital responsible for the patient's care. • Women who have breast tissue remaining after surgery for benign or malignant conditions continue to be invited for screening at routine intervals.	No	Yes	The hospital providing surgery intervention also manages palliative care and in most of the cases also provides rehabilitation, although this can be undertaken by primary care in the local community.

* Information provided for England only; data submitted are accurate up to 31 March 2013, following which major reform of the health and care system took place, which are not reflected in this report.

Annex IV, Table 12. *Section 5 – Safety and quality*

Questions:

- In your geographical area of concern are evidence based procedures and reporting systems for clinical risk mandatory/recommended?
- Are those procedures periodically verified?

Country	Clinical Risk	Verified	Details
AT	Procedures mandatory, reporting not	No	Applying evidence-based procedures is required by law. In case of an incident the lack of applying evidence-based procedures can lead to a lawsuit.
BE	Recommended	No	–
BG	Recommended	Yes	Not reported.
CY	Mandatory	Yes	There is a yearly verification by the Ministry of Health.
CZ	Mandatory	Yes	Verified every six months.
DE	Other[1]	Other[1]	Voluntary critical incident reporting system (CIRS). The national safety agency is the *Aktionsbündnis Patientensicherheit* with its *Institut für Patientensicherheit* at the Bonn University.
EE	Mandatory	Yes	Not reported.
ES	Recommended	Yes	Verified quarterly at national level and monthly at local level. There is a notification and learning system for incidents related with healthcare. There are *Cancer care area: quality and security recommendations* at national level (Ministry of Health).
FI	Mandatory	Yes	Compliance with treatment guidelines is continuously monitored by the hospitals and their senior staff members. Also the safety of the patients is continuously monitored, and actual or potential safety hazards are being reported and documented. In case of medicines, severe unexpected adverse events are reported to FIMEA, which is reporting to EMA, when applicable.

1. The law on the *Further Development of the Early Detection of Cancer and Quality Assurance through Clinical Cancer Registries* came into force on 9 April 2013 (the law takes a two-pronged approach, see *Section 3*). The law creates the legal framework to establish comprehensive clinical cancer registries and to improve the quality of cancer care in Germany. The Laender are now obliged to establish the registries which will collect all relevant in- and out-patient data on cancer care (*i.e.* diagnosis, treatment and follow-up, including palliative care and death). After the data have been analysed by the clinical cancer registries there will be feedback from the registries to the healthcare providers to allow quality assurance measures (*e.g.* benchmarking, adherence to guidelines etc.).

Annex IV, Table 12. *(cont.)*

Country	Clinical Risk	Verified	Details
FR	Recommended	Yes	Since 2009 hospitals and clinics that manage and treat cancer patients have to compel to certain technical, safety and quality standards, including radiotherapy and chemotherapy.
HR	Recommended	No	–
HU	Mandatory	Yes	Monthly verification by National Health Fund and by the National Public Health and Medical Officer Service. In cases of non-compliance the healthcare intervention is not funded. At the National Institute of Oncology annual verification by EN ISO 9001:2008 – internal and external audits.
IE	Recommended	Yes	In 2012, HIQA commenced the monitoring programme *National Standards for the Prevention and Control of Healthcare Associated Infections*. Publicly published reports provide assurances that these standards have been implemented. HIQA's *National Standards for Safer Better Health* provides a structure to systematically and continuously improve the safety and quality of services.
IT	Recommended	Yes	Monitoring of sentinel events is mandatory; evidence-based procedures are recommended and used for monitoring of Essential Level of Care. Procedures are verified every three years by Ministry of Health and Regions, the actions taken can be the reduction of amount of money.
LT	Mandatory	Yes but not systematically	Verification of procedures depends on different factors such as financial funding, implementation of new diagnostic methods, etc.
LU	Recommended	No	–
LV	Recommended	No	–
MT	Recommended	Yes (for screening)	For screening only: monthly review of critical incidents and feedback to team at regular meetings. Actions taken to reduce risk according to nature of incident/near-miss (*e.g.* root-cause analysis).
NL	Recommended	Yes	It is part of the national set of quality indicators (*Kwaliteitsindicatoren Basisset Ziekenhuizen* 2012) for hospitals. The Health Care Inspectorate uses this set as a part of their supervision of the quality of (breast cancer) care.
NO	Mandatory	Yes	It is mandatory to report all errors, adverse events and near. There are regional systems that keep track of these reports.
RO	Mandatory	No	–
SE	Mandatory	Yes	Some places four times/year, other places twice/year.

Annex IV, Table 12. *(cont.)*

Country	Clinical Risk	Verified	Details
SI	Procedures mandatory, reporting no	No	A reporting system for sentinel events is in place at the Ministry of Health and reporting is strongly recommended. A prevention and control programme for healthcare associated infections is led by a standing committee at the Ministry of Health.
SK	No	No	–
UK*	Procedures recommended, reporting mandatory	Yes	Guidance is issued by National Institute of Clinical Excellence. Mandatory reporting is in place for infections, adverse incidents and surgical complications. Compliance with guidance is verified through the *National Cancer Peer Review Programme* which requires a self-assessment externally verified every 3rd year. Care Quality Commission produces annual Quality and risk profiles.

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Annex IV, Table 13. *Section 5 – Safety and quality, plus Section 6 – Accreditation and certification schemes*

Questions *(not mandatory)*:

- In your geographical area do BCSs have quality management systems?
- Are BCSs certified under the Regulation EC 765/2008?
- Are BCSs accredited under the Regulation EC 765/2008?
- Do BCSs have different quality assurance schemes not falling under the Regulation EC 765/2008?
- Further details.

Country	Quality management	Accreditation EC 765/2008	Certification EC 765/2008	Quality assurance schemes (others)	Comments
AT	Yes	No	ISO 9001	• Doc-Cert. • EUSOMA. • KTQ. • ProCumCert.	Not compulsory.
BE	Yes	No	No	• Royal Decree for Accreditation of Breast Cancer Care Programmes.	Accreditation by regional authorities based on legal accreditation standards in *Royal Decree for Accreditation of Breast Cancer Care Programmes*: http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=nl&la=N&cn=2007042690&table_name=wet. Flemish Community: project for quality indicators for breast cancer treatment (participation non obligatory) – http://www.zorg-en-gezondheid.be/kwaliteitsindicatorenziekenhuizen/.
BG	Yes	No	No	–	Every year the Bulgarian Oncology Association updates Bulgarian recommendations for the surgical treatment, radiotherapy and drug therapy of breast cancer, according to the European guidelines for these treatments.
CY	Yes	No	No	–	The European guidelines of quality control are followed, but no certification schemes are implemented yet.

Annex IV, Table 13. *(cont.)*

Country	Quality management	Accreditation EC 765/2008	Certification EC 765/2008	Quality assurance schemes (others)	Comments
CZ	Yes	No	ISO 9001:2008	• Personnel, technical and organisational criteria defining the status of Comprehensive Cancer Centre and Children's Cancer Centre.	Specific standards for diagnostic centres involved in breast cancer screening; reference standards for good clinical practice; reference standards for comprehensive cancer centres, including accreditation of radiotherapy departments and central chemotherapy preparation. Standards are mandatory, national, performed by public entity and valid for all malignancies. Breast cancer screening centres have quality assessment system and are certified by third party evaluation (according to ISO/IEC 17000), ISO 9001.
DE	Yes	ISO 15189:2012	ISO 9001:2008	• ÄKZert. • European Foundation for Quality Management (EFQM). • Kooperationsgemeinschaft Mammographie. • DKG (OnkoZert). • Joint Commission International. • KTQ.	For screening, the *Kooperationsgemeinschaft Mammographie* initially checks the structural requirements, and then regularly (every 30 months) checks the process and performance and quality indicators of each individual screening unit. The Certification institute of the DKG (OnkoZert) is accredited by the DAKKS (= German national accreditation body) for ISO-certifications.
EE	Yes	ISO 15189:2012	No	–	All hospitals in Estonia operate under private law as joint-stock companies or non-profit-making foundations and must be licensed by the health department. Estonia does not have specialised hospital(s) for breast cancer. All cancers are treated in the two regional hospitals. Quality management system covers the hospital as a whole. All medical services providers needed the license according to the *Health Services Organisation Act*.
ES	No	No	No	• Certification process for the Andalusian Health Quality. • Sociedad Española de Senología (private).	There is an Evaluation and Accreditation process for specialised education units with evaluation audits (Ministry of Health). There are institutional accreditation schemes in some regions (Catalunya, Andalucía, Galicia) for hospitals and other healthcare centres (not specific for cancer area). Andalucía has a standards guide for Clinic Management Units.

Annex IV, Table 13. *(cont.)*

Country	Quality management	Accreditation EC 765/2008	Certification EC 765/2008	Quality assurance schemes (others)	Comments
FI	Yes	No	ISO 9001:2008	–	The central hospitals taking care of breast cancer management have their own quality systems and standards. Screening, diagnosis, surgery and treatment are standardised and closely following national and international guidelines. For diagnostic procedures (*e.g.* mammography screening) usually ISO certification is required. Some hospitals also report to have the whole management of patient care certified.
FR	Yes	–	–	• Cancer treatment authorisation.	Since 2009, hospitals and clinics managing and treating cancer patients have to compel to certain technical, safety and quality standards, including surgery radiotherapy and chemotherapy. There are mandatory requirements for mammography. A standardised electronic patient file is in the process of being implemented to facilitate access to medical information related to a patient. For details: http://www.e-cancer.fr.
HR	No	No[1]	No[1]	In development[1]	Mandatory requirements for mammography screening units exist.
HU	Yes	No	ISO 9001:2008	• EUSOMA (in process). • National Breast Cancer Care Protocol. • OECI.	The National Institute of Oncology, certified ISO 9001:2008, is a member of OECI, fulfils the EUSOMA requirements (certification in progress) and prepares and maintains guidelines for breast cancer care and other oncology-related issues. It prepares the National Breast Cancer Care Protocol, which is developed and regularly updated mainly under the professional guidance of the Institute, in collaboration with the different national committees.
IE	Yes	No	No	• National Quality Review of Symptomatic Breast Disease Services.	HIQA has mandatory responsibility for ensuring that healthcare facilities comply with standards of quality and safety. BCSs are monitored against these standards. NCCP has agreed a number of KPIs with HIQA which are monitored regularly. National standards (NSSBHC) have been developed which include the Symptomatic Breast Disease Standards and will cover all services under the remit of the Health Service Executive. Monitoring of the KPIs will now be conducted by the NCCP and the KPI results will form part of the evidence sought by HIQA when inspecting hospitals where breast services are offered.

1. Information not verified with the survey national contact.

Annex IV, Table 13. *(cont.)*

Country	Quality management	Accreditation EC 765/2008	Certification EC 765/2008	Quality assurance schemes (others)	Comments
IT	Yes	No	ISO 9001:2008	• Emilia Romagna Region system. • EUSOMA. • Lombardy Region system. • Screening National Observatory. • Veneto Region System.	The Screening National Observatory performs an annual monitoring of quality indicators for screening programmes and it has recently started a site visit pilot project. Some Italian regions (*e.g.* Emilia Romagna, Lombardy, Veneto) have local regulations and quality assurance programmes for breast units, also inspired by EUSOMA criteria.
LT	No	(ISO 15189 see comments)	(ISO 9001:2008 see comments)	–	Healthcare services can be provided by the healthcare institutions which have a license to provide appropriate health services. Licensing procedures are regulated by the Government resolutions and orders of the Minister of Health of the Republic of Lithuania. Healthcare institutions provide laboratory services according to the Order of the Minister of Health which is prepared on basis of ISO 15189. Healthcare institutions provide healthcare services (requirements for quality) according to the Order of the Minister of Health which is prepared on the basis of ISO 9001.
LU	No	No	No	–	As Luxembourg does not yet have BCSs, no specific quality assurance schemes have been developed. For screening, a coordination centre established within the Health Ministry Directorate has the following tasks: (i) technical quality assurance of mammography according to criteria recommended by the European Union; (ii) systematic double reading of mammograms; (iii) centralisation of data collected during the screening process, up to the eventual diagnosis of a cancer, in order to ensure continuous monitoring of the Mammography Programme.
LV	Partial (some quality indicators)	No	No	–	Quality assurance and quality control depends on each BCS, but is not estimated by the authorities.

Annex IV, Table 13. *(cont.)*

Country	Quality management	Accreditation EC 765/2008	Certification EC 765/2008	Quality assurance schemes (others)	Comments
MT	Yes for oncology and screening	No	No	• External review for screening. • In development for Breast Care Clinic.	Most of the oncological treatments (chemotherapy, hormone-therapy and radiotherapy) given to breast cancer patients are covered and conducted according to internationally accepted clinical guidelines. For screening there is an external review based on *European QA guidelines* and recommendations therein and an evaluation from International Agency for Research on Cancer in 2012/13. The Breast Care Clinic has developed an information system that captures a lot of information on each breast cancer case and that is used for clinical reporting and auditing. This information system is already in operation. The development of this information system has been performed with a view of being prepared for future opportunities that may arise for certification or accreditation of this service.
NL	Yes	ISO/IEC 17040:2005	ISO 9001 Health care (NEN 15224)	–	The management of the screening organisations complies with ISO 9001 Health care (NEN 15224). The medical part of the quality control (based on visitations) is based on ISO/IEC 17040 norm (General requirements for peer assessment of conformity assessment bodies and accreditation bodies, 2005). The visitation protocol is focused on auditing and peer review. For radiologists in the screening there is a 'requirement' classification register (registration is valid for five years), but this is not a full certification register.
NO	Yes	No	No	–	The screening programme has recommended desirable levels for early performance measures. The results are available for each region, and also communicated by representatives from the Cancer Registry of Norway. If there is lack of agreement between recommended and achieved measures, possible efforts are discussed.
RO	No	No	ISO 9001:2008	In development	–

Annex IV, Table 13. *(cont.)*

Country	Quality management	Accreditation EC 765/2008	Certification EC 765/2008	Quality assurance schemes (others)	Comments
SE	Yes	By SWEDAC with different standards	By SWEDAC with different standards	• *Regionalt Undersökningsregister Mammografi Hälsokontroll.* • *Nationella Arbetsgruppen för Mammografi.* • Quality assurance system in Stockholm/Gotland.	The Swedish Board for Accreditation and Conformity Assessment (SWEDAC) accredited Unilabs and the Radiology Department at Lund´s University Hospital. See the Internet (http://www.swedac.se/en) for details. *Regionalt Undersökningsregister Mammografi Hälsokontroll* and *Nationella Arbetsgruppen för Mammografi* are still in progress. The *Quality Assurance System for Mammography* in Stockholm/Gotland has been in operation since 1989.
SI	No	No	No	–	–
SK	No	No	No	–	Certification/accreditation schemes have been created, but are not being applied.
UK*	Yes	No	Yes	• National Cancer Peer Reviewed Programme. • NHSBSP quality assurance for breast cancer screening.	NHSBSP sets national standards which are monitored through a national quality assurance network. *National Cancer Peer Review Programme* is a quality assurance programme for all cancer services; it is not mandatory and does not provide certification. It includes all BCS in England (155) and it is run by the NHS. Details: http://www.cquins.nhs.uk.

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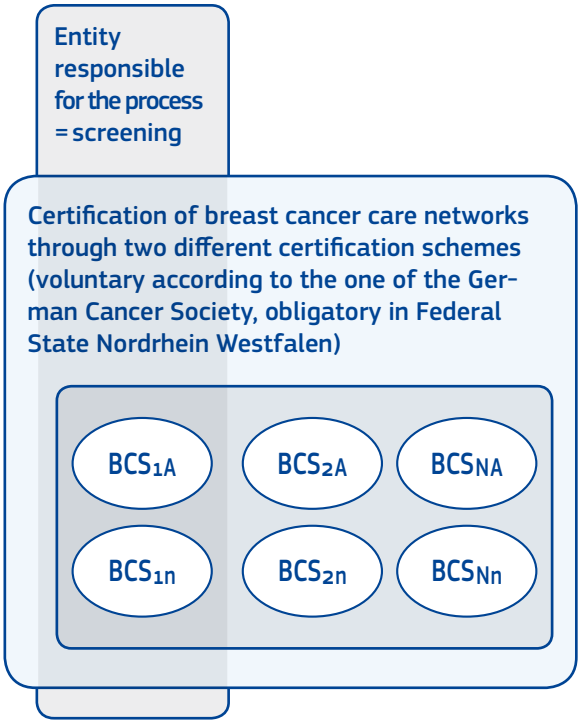
8.5. Annex V: *Scenario 2c modified by Germany*

Two or more breast cancer services (BCSs) are co-operating but neither of them is responsible for the whole process of breast cancer care; however, together they cover all stages of breast cancer care. Supervision for the organisation and quality by an external entity (*e.g.* the Regional Health Authority) is present only for a part of the breast cancer care process (*e.g.* screening is supervised and coordinated; treatment and follow up are supervised through two different German certification schemes. Certification according to the scheme of the German Cancer Society is voluntary, certification in Nordrhein Westfalen is obligatory).



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Abstract

Background: The objective of this survey was to collect information from the countries involved in the European Commission initiative on breast cancer (the 28 Member States, plus Iceland and Norway) regarding the organisation of breast cancer services and other aspects of interest for the initiative (*e.g.* screening programmes, training requirements for professionals, quality and safety aspects, quality assurance schemes, etc.).

Methods: The survey included a questionnaire and a data protection form distributed by e-mail, the participants were nominated upon request of Directorate-General for Health and Consumers via respective health attaches.

Results: Twenty-five out of 30 contacted countries responded, corresponding to a response rate of 83%.

Conclusions: Healthcare systems are diverse across Europe; different quality assurance schemes for breast cancer care are in place for less than 50% of the countries. A European-wide, harmonised, evidence-based and flexible scheme is needed to grant equal and quality benchmarked treatment to patients.

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