

European Commission

Initiative on Breast Cancer

(ECIBC): Plenary 2016

When Science and Policy collaborate for Health

Bramesfeld, A; Ambrosio, M; Bocchi, G; Deandrea S; Dimitrova, N; Saz-Parkinson, Z; Ulutürk Tekin, A; Lerda, D.



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

Contact information

Name: Health in Society Unit

Address: Joint Research Centre, Directorate F-Health, Consumers and Reference Materials

Via Enrico Fermi 2749, TP 127, 21027 Ispra (VA), Italy

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

Tel.: +39 0332 78 6201 Web: ecibc.jrc.ec.europa.eu

JRC Science Hub

https://ec.europa.eu/jrc JRC 106915 EUR 28683 EN

PDF ISBN 978-92-79-70521-2 ISSN 1831-9424 doi:10.2760/87978

Luxembourg: Publications Office of the European Union, 2017

© European Union, 2017

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

Front cover image © Isaac Lane Koval/Corbis/VCG and © European Union

Table of contents

Acknowledgements	5
1. Introduction	8
2. Day 1 – Science for policy development	11
2.1 Welcome & Opening	11
2.1.1 Welcome note (Charlina Vitcheva, JRC)	11
2.1.2 The patient's perspective on the ECIBC (Marja Aarnipuro, Apu magazine, Finland)	12
2.1.3 Launch of the first set of <i>European Breast Guidelines</i> Recommendations (Elke Anklam, JRC)	13
2.2 Keynote	14
2.2.1 What kind of science is successful in supporting policy development – the scientist's perspective (Josep Figueras, European Observatory on Health Systems & Policies)	14
2.3 News and updates from the ECIBC projects (moderated by Elke Anklam, JRC, and Zofija Mazej Kukovič, Slovenian policymaker)	15
2.3.1 Session introduction (Zofija Mazij Kukovič)	16
2.3.2 Status of the development of the European Quality Assurance scheme for Breast Cancer Services (Robert Mansel, QASDG chair)	17
2.3.3 Status of the development of the European guidelines for breast cancer screening and diagnosis (Chris de Wolf and Holger Schünemann, GDG co-chairs)	18
2.3.4 Status of the development of the <i>Guidelines Platform</i> (Donata Lerda, JRC)	20
2.3.5 Training on digital mammography: a European approach (Aslı Ulutürk, JRC)	20
2.3.6 Monitoring the impact of the ECIBC (Nadya Dimitrova, JRC)	22
2.3.7 ECIBC video presentation (Ciarán Nicholl, JRC)	22
2.4 Making comparable performance assessment possible in Europe using the accreditation legal framework (moderated by Jane Beaumont, Accreditation Advisor, and Marc van den Buckle, Scientific Institute of Public Health, Brussels)	23
2.4.1 What is the accreditation legal framework? What are	

	its benefits and shortcomings? (Ed Wieles, Dutch Accreditation Council, the Netherlands)	23
	2.4.2 The role of the accreditation legal framework in the European QA scheme (Silvia Deandrea, JRC & Aliki Stathopoulou, QASDG member)	24
	2.4.3 Experience with using ISO 15189 as an option for accrediting pathology laboratories (Marco Pradella, Local Health Authority, Asolo, Italy)	25
	2.4.4 Experiences with implementing ISO 15189 (Katrien Gruenberg, Radboud University Medical Center (UMC), Nijmegen, the Netherlands)	26
3. D	ay 2 – Policy for science implementation	27
	3.1 Country presentations: Breast cancer services in European countries and the <i>European QA scheme</i> : country profiles (moderated by Tit Albrecht, National Institute of Public Health, Slovenia & Stefan Schreck, DG SANTE)	28
	3.1.1 Scotland (Hillary Dobson, NHS Scotland)	28
	3.1.2 The Netherlands (Ruud Pijnappel, UMC Utrecht, on behalf of Sabine Siesling, University of Twente)	29
	3.1.3 Romania (Luciana Neamțiu, on behalf of Florian Nicula, Romanian programme for cancer prevention and control)	29
	3.2 Country tables (Donata Lerda, JRC)	32
	3.2.1 European Breast Guidelines	33
	3.2.2 European QA scheme	34
	3.3 Round table discussion	35
	3.4 Conclusions (Alojz Peterle, President of MEPs Against Cancer (MACs), European Parliament)	37
4. E\	valuation	38
5. C	onclusion	39
6. Aı	nnexes	41
	Participants	44
	References	48



Acknowledgements

We would like to thank the country delegates, experts, patient representatives and all other participants who attended the 2016 ECIBC Plenary for their engagement. Thanks to their input, the 2016 ECIBC Plenary succeeded in not only informing stakeholders but, most importantly, providing the JRC with valuable information, feedback and suggestions for further developing the initiative. Beyond this, we wish to thank all presenters, as well as the round table participants, for their well-prepared, thoughtful and inspiring contributions that shaped and provided anchor points for the discussions.

As the ECIBC is coordinated by the JRC and supervised by DG SANTE, continued support from the JRC hierarchy and DG SANTE colleagues is essential to its success and should be acknowledged.

Finally, we wish to thank Brigitte Westritschnig and Chiara Margagliano for their invaluable support in the organisation of ECIBC Plenaries, and Nicola Davenport from RETELL for drafting this report and assisting in its finalisation.

Authors

Bramesfeld, Anke; Ambrosio, Massimo; Bocchi, Giulia; Deandrea, Silvia; Dimitrova, Nadya; Saz-Parkinson, Zuleika; Ulutürk Tekin, Asli; Lerda, Donata.

| 5

Abstract

The European Commission Initiative on Breast Cancer (ECIBC) Plenaries are an opportunity to inform representatives from the 28 EU Member States and 7 other countries participating in the ECIBC, as well as patients and other stakeholders, policymakers, and the scientific and health policy communities, about the aims, activities and achievements of the ECIBC. They also provide a platform for the exchange of ideas, feedback and input into the ECIBC.

The 2016 ECIBC Plenary, entitled "When science and policy collaborate for health", took place on 24-25 November in Varese, Italy. Its main focus was the implementation of both the voluntary European Quality Assurance scheme for Breast Cancer Services (*European QA scheme*) and the European guidelines for breast cancer screening and diagnosis (*European Breast Guidelines*). In this context, the first concrete results were presented, with the launch of the first four *European Breast Guidelines* recommendations on screening.

The first day of the Plenary was dedicated to the JRC informing the audience about the various tools that ECIBC is developing. The second day instead, gave the floor to the audience, who informed the JRC of their views in terms of the challenges and opportunities related to implementing the ECIBC in the respective European countries.

The event opened with welcome speeches from the European Commission's Joint Research Centre (JRC), a moving presentation from a breast cancer survivor and reflections on how to ensure science makes its way into policy. The JRC and ECIBC working group members then brought the audience up to date with progress on the *European QA scheme*, the *European Breast Guidelines*, as well as the *Guidelines Platform*, the template for training on digital mammography, as well as about how ECIBC plans to monitor its impact.

Participants also received in-depth explanations of the accreditation framework selected for the *European QA scheme*, as well as two countries' experiences of using the ISO 15189 standard for accreditation, which is foreseen for the *European QA scheme*.

The second day saw a focus on the individual countries represented at the Plenary. Presentations assessed how the *European QA scheme* could potentially fit into three different health systems (Scotland, the Netherlands, Romania), while a special breakout session gave national representatives from the 27 countries present (out of the 35 countries participating in the ECIBC) the chance to discuss implementation of the *European Breast Guidelines* and the *European QA scheme* themselves. The results, collected through questionnaires, fed into a roundtable debate on what needs to be done at European and national level to ensure ECIBC implementation.

The meeting was closed by Member of the European Parliament and President of MEPs Against Cancer (MACs), Alojz Peterle.

An evaluation of the event revealed that the third ECIBC Plenary met its aims to inform stakeholders: all responding participants felt that the event succeeded in providing a comprehensive overview of how the ECIBC is progressing, and what the challenges are. Discussions also provided the JRC with valuable information and feedback.

The fourth ECIBC Plenary will take place once the results from piloting the *European QA* scheme are available.



Introduction

In response to the Council of the European Union's conclusions on reducing the burden of cancer, the European Commission (EC) founded the European Commission Initiative on Breast Cancer (ECIBC) (ecibc.jrc.ec.europa.eu). **The ECIBC aims at ensuring and improving the quality of breast cancer services, and through this, at improving health and reducing health inequalities in Europe**. To attain these aims, the ECIBC is developing the following tools:

- the European guidelines for breast cancer screening and diagnosis (European Breast Guidelines) which are based on the latest knowledge and evidence;
- a platform for breast cancer guidelines (Guidelines Platform) that hosts current high quality and evidence-based recommendations on breast cancer treatment, rehabilitation follow-up and end-of-life care;
- **the voluntary European Quality Assurance scheme for Breast Cancer Services** (*European QA scheme*), which is based on the EU legislative framework on accreditation, and evidence derived from the *European Breast Guidelines* and the *Guidelines Platform*;
- a European template for training on digital mammography (DM training), directed at health professionals involved in screening programmes, including the essential requirements for those wishing to adhere to the European QA scheme;
- a long-term web hub hosting all the deliverables (information, output and tools) developed within the ECIBC, making it the communication interface with stakeholders and including, whenever feasible, stakeholders' input on desirable features.

The ECIBC is coordinated by the Joint Research Centre (JRC), which is responsible for its scientific and technical content and deliverables, while the EC's Directorate General for Health and Food Safety (DG SANTE) is the overall responsible for EU cancer policies.

The ECIBC organises Plenaries to inform EU Member States and other participating countries, patients and other stakeholders, such as national accreditation bodies, associations of professionals, policy makers and the scientific and health-policy communities, about the aims, activities, and achievements of the ECIBC; in particular the state of development of the various tools. At the same time, the ECIBC uses the plenaries to collect feedback and input on its activities. Finally, the plenaries are intended to induce ECIBC implementation by informing, engaging and linking policy makers and stakeholders active in breast cancer care with the ECIBC initiatives.

The first ECIBC Plenary in 2013 launched the initiative and collected input from concerned countries and professionals on how to design it. The second, in 2015, marked the uptake of the actual development work. This is supported by two working groups comprising experts and representatives of patients and citizens: the Guidelines Development Group (GDG) and the Quality Assurance Scheme Development Group (QASDG). The third ECIBC Plenary in 2016, which is the subject of this report, addressed the future implementation of both the *European Breast Guidelines* and the *European QA scheme*.

The first y ear of d evelopment w ork succeeded in finalising the scope for both the European Breast Guidelines and the European QA scheme, defining and publishing the methodology to be used by both working groups, and finally launching the first four guidelines recommendations. The Plenary drew attention to the feasibility of implementing the European Breast Guidelines, and in particular the European QA scheme, in each of the 35 countries involved in the ECIBC. Its title, "When science and policy collaborate for health", conveys the exact challenge faced by the ECIBC: not only the development of scientifically sound tools, but also how to develop and disseminate them in such a way that they will be of added value to health services and systems in European countries and be implemented there.

The first day of the Plenary was dedicated to the JRC informing country representatives and stakeholders about the various tools that ECIBC is developing. The second day instead, gave the floor to country representatives and stakeholders, who were invited to inform the JRC of their views on the challenges and opportunities related to implementing ECIBC in the respective European countries.

The first day of the Plenary focused on "Science for policy development". It looked at the conditions required to transfer science into policy **and informed participants of the current state of development of the ECIBC tools**. As the *European QA scheme* will be operating within the EU legislative framework on accreditation, the Plenary dedicated the afternoon of the first day to exploring in-depth the implications that this has for implementation in individual countries, and for breast cancer services and related pathology laboratories in particular.

The second day focused on "Policy for science implementation", and looked at each country separately in terms of facilitators for — and obstacles to — implementing the guidelines and the QA scheme. The JRC was particularly keen to learn about organisations, bodies and persons which could be approached in each country to facilitate discussions and overcome obstacles.

2. Day 1 — Science for policy development

2.1 Welcome & Opening

The Welcome & Opening session reminded participants of the aims and implications of the ECIBC from an EU perspective, as well as the perspective of the ultimate beneficiaries of the ECIBC: patients and citizens. In this context, the first concrete outcome of the ECIBC, the first recommendations from the *European Breast Guidelines*, were launched.

2.1.1 Welcome note (Charlina Vitcheva, JRC)

The subject of the Plenary — science and policy collaborating for health — is close to the JRC's heart and mission, Vitcheva explained. The JRC's mission is to provide the evidence and the scientific facts and figures that can support policymaking, so as to ensure future policies are credible and robust.

The ageing population has meant a shift in the causes of mortality, with cancer now responsible for an increasing share of deaths. In 12 out of 28 EU countries, cancer is the leading cause of death. The European Commission is therefore stepping up its efforts to tackle the disease. "We need to examine what we can do better, to improve healthcare, to collect the right information to underpin policies, and to improve management of system around cancer services," said Vitcheva.



Within the ECIBC, the JRC and DG SANTE are joining forces to improve cancer detection and care. Vitcheva thanked all involved, including experts, stakeholders, patient organisations, businesses, and colleagues from both the JRC and DG SANTE. She closed by calling on all present to continue being as ambitious as they have been to date.

2.1.2 The patient's perspective on the ECIBC (Marja Aarnipuro, Apu magazine, Finland)

Aarnipuro's presentation was a reminder to all those present of the importance of tackling the quality of breast cancer care, in particular in respect to informing patients. She spoke of three periods of fear she experienced when being diagnosed with cancer in 2009. The first period while waiting one week for her biopsy results; she even planned her funeral, thought about how her children would cope without their mother, and convinced herself she would die within weeks or months. "This is because I didn't know enough."





Although the diagnosis was given over the phone, it was a relief, because Aarnipuro finally had facts. It was time for action. "Ignorance increases pain, not knowledge."

Aarnipuro experienced the second period of fear during the two weeks after her operation until she found out that her cancer was not metastatic; she described these weeks as the longest of her life. Appealing to those present, Aarnipuro asked for practitioners to provide facts as soon as possible and to shorten the wait for initial biopsy results, and those of follow-up pathology tests.

The third period came when the treatment was over, and "the cancer clinic door closed behind me". Aarnipuro felt she was now expected to be normal again, instead she began noticing symptoms, although nothing could be found, and felt very alone. Each time she waited a week or so before going to her doctor, scared of what tests might find. After living in fear for two years, Aarnipuro gradually started to trust life again. She pointed out that there has been great progress in many fields in Finland since her diagnosis and every patient now fills in a questionnaire and is provided with psychosocial help if necessary. A breast cancer treatment pathway is also available online, while an e-health application, currently undergoing testing, allows a patient to report any symptom whenever she wants, even in the middle of the night. If the symptom seems severe, a nurse will contact her the next working day.

2.1.3 Launch of the first set of *European Breast Guidelines*Recommendations (Elke Anklam, JRC)

These first four recommendations were published around a year after the GDG took up its work. The <u>recommendations</u> are published on the ECIBC web hub; different entry points for women, professionals and policymakers ensure that each target group finds the information it needs. The recommendations are presented with additional information on the group's confidence in the evidence on which the recommendations are based. In summary they suggest:

- No implementation of mammography screening for asymptomatic women aged 40 to 44, with an average risk of breast cancer (Conditional recommendation).
- Organised mammography screening programmes for asymptomatic women aged 45 to 49 with an average risk of breast cancer (Conditional recommendation).
- Organised mammography screening programmes for asymptomatic women aged 50 to 69 with an average risk of breast cancer (strong recommendation).
- Organised mammography screening programmes for asymptomatic women aged 70 to 74 with an average risk of breast cancer (Conditional recommendation).

"This is an example for European added value" Anklam said, "common recommendations for all women based on evidence. Let's go on, let's proceed!"

2.2 Keynote

2.2.1 What kind of science is successful in supporting policy development – the scientist's perspective (Josep Figueras, European Observatory on Health Systems & Policies)

Neither the *European Breast Guidelines* recommendations nor the *European QA scheme* will be of value if not taken up and used by European countries and breast centres. However, the transfer of scientific results into policy and clinical implementation is one of the major challenges faced by many scientific initiatives. How to tackle this challenge and what to consider when drafting an implementation strategy were outlined in a keynote presentation that tied together Day 1 on science development and Day 2 on policy implementation.

Figueras started by asking why some countries and/or sectors implement guidelines, and others not. Increasing uptake relies heavily on understanding the policy decision-



making process, but the process is rarely clear-cut, and never a simple, linear process. Relevant factors include politics, equity, ethics, consumer and industry lobbying, and the media. It is also important to remember who the key actors are — in this instance, they include insurance companies and regulators.

Psychology is also important. People tend to use heuristics or mental shortcuts when faced with complex choices. They are also inclined to look at results that confirm what they want to do. Sunk costs bias also plays a role — it can be difficult to change course after investing in a particular approach. So there is a tendency to look for the least complex solution, not one based on evidence.

Figueras recommended targeting networks and working with opinion leaders, while ensuring that knowledge-brokering organisations are invited to meetings, and not only the "usual suspects".

Context is also key. This can include political structures (devolved or not) and administrative arrangements, health system characteristics, timelines (there are moments when it is easier to introduce a new initiative), perceived severity of the problem addressed, resource availability and cultural proximity.

Finally, the tools used to encourage implementation are also important. From benchmarking to naming and shaming, auditing, legislation and regulation, incentives and penalties — each can have a role to play.

2.3 News and updates from the ECIBC projects (moderated by Elke Anklam, JRC, and Zofija Mazej Kukovič, Slovenian policymaker)

To update the audience on the current status of ECIBC projects as a baseline for discussing implementation, the chairs of the GDG and QASDG presented their groups' work and achievements during the 11 months since the previous Plenary in 2015. Achievements included finalising the scope for the *European Breast Guidelines* and the *European QA scheme*, collecting feedback via a public consultation with stakeholders and countries, and having them approved by the respective working group. In addition, both working groups defined their methodological approach and began development work: the QASDG started to identify requirements and indicators to be included in the *European QA scheme* and the GDG developed the first guidelines recommendations.



JRC colleagues also informed Plenary participants about further tools under development or completed, including an ECIBC video clip.

But before the session started, Zofija Mazij Kukovič from Slovenia, who was health minister at the time of the Slovenian EU council presidency when the Council of the European Union's conclusions on reducing the burden of cancer were adopted, spoke of events at that time. It was thanks to her intervention that the <u>council conclusions</u> invited the Commission to "explore the potential for the development of voluntary European accreditation schemes for cancer screening and appropriate follow-up of lesions detected by screening, such as a European pilot accreditation scheme for breast cancer screening and follow-up based on the European guidelines for quality assurance in breast cancer screening and diagnosis."

2.3.1 Session introduction (Zofija Mazij Kukovič)

When Slovenia selected cancer as a health priority for its EU Council Presidency in the first half of 2008, one in three EU citizens was suffering from the disease. The decision led to a 2008 European Parliament Resolution on combatting cancer that called for improved EU collaboration and an end to fragmentation. This has led to a more integrated strategy, and probably saved lives of cancer sufferers, said Kukovič.

The ministerial meeting had agreed on a recipe for a common approach, but it was unclear how to balance different health budgets, insurance systems, education systems, levels of expertise for screening, diagnosis and treatment, and psychological and social support. The Member States were



invited to find ways of working together, and they are now doing so within the ECIBC. "It's very rare in politics that you see such progress in eight years" said Kukovič.

2.3.2 Status of the development of the European quality assurance scheme for breast cancer services (Robert Mansel, QASDG chair)

Mansel began with a reference to Marja Aarnipuro's speech that he saw as evidence of the need for the ECIBC: change is needed, he said. Patients should not receive their diagnosis over the telephone, for example, as she had experienced.

Updating listeners on the progress that the Quality Assurance Scheme Development Group (QASDG) is making in developing the European Quality Assurance scheme for Breast Cancer Services (*European QA scheme*), Mansel explained that it **will address the entire breast cancer pathway and will have a modular structure** to accommodate the fact that not every cancer centre provides care at every step of the pathway.

The QASDG's work began back with a public call for feedback on the scope of the *European QA scheme* that addressed the ECIBC National Contacts, national accreditation bodies, healthcare organisations, professional organisations and individuals. **This call for feedback confirmed that the modular approach of the** *European QA scheme* **was applicable to the healthcare system of each country, as was the breast cancer treatment pathway published on the ECIBC web hub. The ISO standards proposed were also considered acceptable.**

Respondents to the call for feedback raised two concerns: one on the applicability of ISO 15189 as an accreditation standard for pathology laboratories in Germany, and the other on a lack of detailed information on the methodology used for the selection of requirements and indicators. These concerns are respectively taken up in the report on the call for feedback on the scope, and in a methodology document that can be found on the ECIBC web hub.

To date, the QASDG has consented on a methodology for identifying requirements and indicators using Delphi rounds and all QASDG members have been trained for participating. The QASDG has begun identifying requirements/indicators for surgery and the organisational structure of breast centres. However to complete this process, the group awaits evidence from the *European Breast Guidelines* and the *Guidelines Platform* that is currently under construction; the set of requirements/indicators for the *European QA scheme* is expected to be finalised by 2018.

For the accreditation of conformity assessment bodies, a first draft of the scheme owner requirements is under development. For accreditation of imaging services, medical and pathology laboratories, work is ongoing to identify testing and examination activities that fall under the scope of accreditation (to be ready by mid-2017), as well as the reference documents needed to set performance levels (to be ready by mid-2018).

Finally, to assess breast centres, data will be needed. **IT solutions are under development to support breast centres in aggregating data** for requirements and indicators in a way that is reliable and sound while respecting data protection requirements. The *European QA scheme* will be piloted from 2018 in breast centres around Europe.

2.3.3 Status of the development of the European guidelines for breast cancer screening and diagnosis (Chris de Wolf and Holger Schünemann, GDG co-chairs)

As with the QASDG, discussions to determine the scope and purpose of the *European Breast Guidelines*, as well as the target audience, preceded work by the GDG. A public call for feedback in 2016 resulted in 81 responses from organisations and individuals. The final scope, which included modifications in line with feedback received, will be available on the ECIBC web hub in 2017, along with the feedback report.



The working group is developing recommendations for screening and diagnosis using GRADE methodology. This means that they formulate questions to the evidence using a structured format, generally called "PICO", which stands for Population under study (for example women of certain age); Intervention (for example a medical examination); Comparator (for example an alternative medical examination); and Outcomes (results). The evidence is searched for using existing systematic reviews or by conducting new ones. In this phase, the GDG rates the overall quality of the collected evidence (resulting from a combined rating of the quality of evidence for each outcome and the quality of evidence for each recommendation across all outcomes). It is then discussed and the quality level of evidence is agreed within the GDG.

In order to go then from the evidence to the recommendation, the GDG uses evidence-to-decision frameworks (Etds). These take into account the magnitude of the problem, the balance of benefits and harms of the intervention, resources needed, cost-effectiveness, peoples'values and preferences in regard to the main outcomes, impact on health equity, acceptability of the intervention and feasibility of implementing the intervention. According to this assessment, the GDG reaches a consensus, or votes if they cannot agree, on the criteria that influence a recommendation or decision. Agreement is reached on the direction of each recommendation (in favour or against the intervention) and its strength (strong or conditional), leading to recommendations such as the four launched at the Plenary. Potential conflicts of interest are managed strictly on a question by question basis.



The development of recommendations, published online, in versions tailored to patients/citizens, healthcare professionals and policy makers, and translated into all EU languages, will continue until 2018.

2.3.4 Status of the development of the *Guidelines Platform* (Donata Lerda, JRC)

While the *European Breast Guidelines* provide the evidence for screening and diagnosis used by the *European QA Scheme* as a reference, **evidence for all treatment-related processes comes from the** *Guidelines Platform* **— a collection of current evidence-based guidelines on breast cancer care.**

An initial search sought guidelines documents published after 2006 and relevant for all treatment-related processes covered by the pathway. A total of 2 551 publicly available records were found, of which 230 were considered eligible. A survey was launched to identify non-public guidelines, leading to an additional 50 eligible ones.

A contractor is now evaluating the evidence base of all the guidelines collected and scoring them according to AGREE II domains. Only guidelines that score above a set threshold will be included in the platform. The contractor is blind in respect to this threshold, which the JRC will set based on the evidence and expert opinions of two other independent contractors. **Maximum independence is thus guaranteed**.

Recommendations included in the *Guidelines Platform* will be presented, wherever possible, in the same format as those of the *European Breast Guidelines*.

2.3.5 Training on digital mammography: a European approach (Aslı Ulutürk, JRC)

Well trained professionals are needed to ensure high quality breast cancer care and crucial in a population-based intervention like screening. The JRC is therefore developing a template for training on digital breast cancer screening. The template is intended for radiologists and radiographers/radiation technologists, and will cover minimum training requirements.

The initiative has now moved into the development phase from the preparatory research phase. The four key research activities performed include:

- 1. A Europe-wide survey on training requirements, training practice, licensing practices, continued professional development, audit processes. Of the replies received to this survey by mid-November, two thirds said that screening-specific training was mandatory in their organisation, and one third said that continued professional development was mandatory.
- **2.** A systematic search for existing templates for radiologist and radiographer/radiation technologist training. This involved searching databases and websites of professional organisations, health authorities and entities providing screening.
- **3.** A call for training templates.
- **4.** A search for existing e-modules for training, diploma programmes, minimum requirements etc.

The template for the European training for radiologists and radiographers/radiation technologists will be based on results gathered by the survey and will respect countries' existing frameworks.



2.3.6 Monitoring the impact of the ECIBC (Nadya Dimitrova, JRC)

Examining the impact of the ECIBC, and in particular its two main outcomes, the *European QA scheme* and the *European Breast Guidelines*, will be of utmost importance. To do this, it is necessary to first **define indicators that will show the ECIBC's impact** at different levels e.g. populations, services, patients/citizens, and then to collect relevant data for these indicators.

The JRC is currently considering various scenarios for evaluating the ECIBC's impact:

- comparing indicators before and after implementation in the same population/ service;
- comparing services and populations implementing the guidelines and QA scheme with those not doing so;
- a modelling approach.

All three approaches could be used in a complementary fashion or separately, depending on the data available. The next step will be to consult experts and stakeholders before developing a roadmap to a monitoring and evaluation plan.

2.3.7 ECIBC video presentation (Ciarán Nicholl, JRC)

A <u>video</u> introducing the ECIBC was developed in-house within the JRC and presents the inclusive, patient-centric and multi-disciplinary nature of the ECIBC. Under the motto "**ECIBC is Europe that cares**", the video outlines the benefits expected to come out of the ECIBC for women: guaranteed quality without inequality and empowered women.



2.4 Making comparable performance assessment possible in Europe using the accreditation legal framework (moderated by Jane Beaumont, Accreditation Advisor, and Marc van den Buckle, Scientific Institute of Public Health, Brussels)

The European QA Scheme will be run within the EU's legal framework for accreditation.

This session was intended to explore more in depth, in particular for those participants who have not worked within the accreditation legal framework previously, what accreditation means. The session therefore began with an explanation of the legal basis and of the infrastructure provided, before moving on to how it would impact the *European QA Scheme*, and ending with experiences in two countries about its usability for accrediting pathology laboratories. This showed the advantages that accreditation under the legal framework offers, such as providing a trans-European harmonised benchmarking and auditing system, but also its limitations, due to a prevalent focus of the legal framework on processes rather than on outcomes.

2.4.1 What is the accreditation legal framework? What are its benefits and shortcomings? (Ed Wieles, Dutch Accreditation Council, the Netherlands)

Prior to 2010, individual countries had different structures for accreditation, and both private and public accreditation bodies — and sometimes multiple bodies — were active. Some had no legal status. Bodies were usually allowed to accredit outside their own country, and there was no formal requirement for peer evaluations. There was also no formal recognition of the European co-operation for Accreditation (EA).

In 2010, **EC Regulation No 765/2008 on accreditation** and market surveillance was implemented. It **requires each accreditation body to have a mandate as a public authority and limits national accreditation bodies to one per EU Member State**. It prohibits profit distribution to shareholders and competition (no cross-border application unless there are exceptional circumstances), and places emphasis on accountability to stakeholders.

The Regulation was intended **to give Europe more confidence in the work of assessment, inspection and certification bodies**. It made it possible to compare the results of different bodies and created a level playing field. The Regulation also facilitated trade through the "tested once, accepted everywhere" principle.

The EA is the association of national accreditation bodies (NABs) within Europe. Members must be officially recognised by their national government. There are 36 full members and 12 associate members. EA members are required to participate in technical work and peer evaluations, and to use documents endorsed by the EA.

The NABs signatories of the EA's multilateral agreement (MLA) already recognise and accept the equivalence of accreditation systems operated by other signatories (even if they are different), and agree that they are equally reliable. EA members also share experience and expertise.

Using the accreditation legal framework in Europe has improved the harmonised application of standards, but challenges remain: accreditation services must still be developed for new markets and regulators. If no standard is available, accreditation cannot however be developed. Challenges concerning content and maintaining sufficient resources for peer evaluations also remain.

2.4.2 The role of the accreditation legal framework in the European QA scheme (Silvia Deandrea, JRC & Aliki Stathopoulou, QASDG member)

The *European QA scheme* will incorporate accreditation processes related to the accreditation legal framework in two areas:

- 1. The certification bodies, certifying a breast centre under the European QA scheme, will need to be accredited for this task by the national accreditation body according to ISO standard 17065. The overall aim is to provide confidence to all interested parties that all breast centres providing a certified service fulfil all specified requirements, meaning that the certification service is standardised across the different certification bodies providing it.
- 2. Medical laboratory, pathology and imaging services related to a breast centre wishing to obtain certification under the European QA scheme will need to be accredited according to ISO 15189 or equivalent standards. This standard is intended for medical laboratories and sets requirements for quality and competence. It was developed with involvement from the medical, scientific and clinical community. "The standard has been recognised by the International Laboratory Accreditation Cooperation (ILAC) as the international standard for the accreditation of medical laboratories worldwide," said Stathopoulou.

The use of ISO 17065 and ISO 15189 was approved following a call for feedback from country representatives. In the feedback, the vast majority of respondents consented to the use of ISO 17065, and 70% consented to ISO 15189 (see the <u>feedback report</u>). Concerns expressed relate to the current use of alternative standards (the JRC is looking into using equivalence derogations within the scheme owner's requirements), and applying a standard developed for medical laboratories to imaging services. Official responses to these issues will be published on the ECIBC web hub.

2.4.3 Experience with using ISO 15189 as an option for accrediting pathology laboratories (Marco Pradella, Local Health Authority Asolo, Italy)

In Italy, ISO 15189 has peculiarities, according to Pradella. To date, 113 testing labs, 11 proficiency testing organisers, 6 medical labs and 1 reference medical lab have been accredited with this standard. No anatomic or pathology lab is yet accredited with it. Why are there so few accredited bodies in Italy? "It's not because ISO doesn't work," said Pradella. There are three obstacles to taking up the internationally accepted ISO standard 15189:

- **1. Interference with "institutional accreditation"** (licensing) that is required by law. The mandatory requirement for institutional accreditation, which may differ according to the Italian region, results in organisations not considering additional accreditation within the ISO system as feasible and useful.
- **2. The use of ISO 9001** by many laboratories, which is considered to be an alternative to ISO 15189, although it is not.
- **3. A lack of investment in quality**, due to cuts to the national health service budget in the recent years.

The number of ISO 15189 accredited labs is however growing. For further growth, the country needs:

- 1. government commitment;
- **2.** accreditation body regulations, procedures and modules that overcome regional barriers;
- **3.** empowerment of laboratory personnel. To increase the uptake of ISO 15189, partnership with manufacturers (they can produce conformity evidence) and laboratory empowerment are required.

2.4.4 Experiences with implementing ISO 15189 (Katrien Gruenberg, Radboud University Medical Center (UMC), Nijmegen, the Netherlands)

In 2015, the pathology department at Radboud University Medical Center transitioned from a Dutch standard to ISO 15189. This decision was taken in March 2015, the request for accreditation was submitted in July 2015 and the audit carried out in December 2015. Accreditation was awarded in 2016. **The result was a rise in productivity and a decrease in costs**.

The first thing the UMC did when preparing for accreditation was to install a quality management steering committee involving a chair, process coordinator, technician and pathologist. An advisor plus resident and incidents administrator were also involved.

The team then designed work processes (analysed workflow, described it, defined the critical steps, set indicators — and made it leaner along the way). This led to an organisation chart defining tasks and responsibilities; on the basis of this organisation chart, standard operating procedures were defined.

In addition, quality management was put on the agenda of every relevant meeting, including the morning transfer meeting.

The benefits of going through this process in preparation for the accreditation **included the clarification of organisational factors** (team leaders, no more work-arounds), processes (inefficiency reduced, problem solving easier), and learning more from things that do not go to plan. **The disadvantage is the amount of work involved** and the expense (fees, personnel). "**But we think it pays off**", said Gruenberg.

The department now has very high operational efficiency. But accreditation applying ISO 15189 does not per-se guarantee clinical effectiveness or a correct diagnosis. It was therefore decided to create a pathology review committee as a peer review instrument, and to set limited indicators, such as on speed (turnaround time), numbers, verifiability (number of revisions, percentage of (in)significant discordances). "This is a way to look into the mirror and see whether peers see you the same way you see yourself," explained Gruenberg.

3. Day 2 – Policy for science implementation

The ECIBC will only have an impact if its central tools — the European Breast Guidelines and European QA scheme — are taken up by countries and implemented within breast cancer services. The ECIBC's European added value comes from its being based on evidence and respecting women's rights to receive high-quality, evidence-based breast cancer care in Europe, across borders and regardless of the health system from which they are seeking treatment. Implementation of the European Breast Guidelines and the European QA scheme was discussed in three different formats:

- individual country presentations, both as plenary presentations and during a guided poster tour that took place during the first day;
- in a breakout session (country tables), where participants from the same country grouped together and discussed facilitators and challenges to implementation;
- in a final round table discussion.



3.1 Country presentations on Breast cancer services in European countries and the *European QA scheme*: country profiles (moderated by Tit Albrecht, National Institute of Public Health, Slovenia & Stefan Schreck, DG SANTE)

Schreck began by emphasising that **responsibility for health remains with national ministries, but that the EU seeks to complement what the EU Member States are doing,** where there is European added value. "If there is no European added value by doing something at European level, then we shouldn't be doing it," he said. Schreck also underlined DG SANTE's commitment to the ECIBC.

Tit Albrecht paid tribute to oncologist Umberto Veronesi, who recently passed away. He was one of the founders of the "Europe against cancer" programme; "we have to continue the legacy he started," said Albrecht.

3.1.1 Scotland (Hillary Dobson, NHS Scotland)

Scotland receives financial allocations based on population and demographics for health care, but develops its health policy independently.

Scotland has a cancer action plan that is updated regularly and sets the direction for its strategy. How cancer will be managed is decided by health boards. The cancer quality framework works through three cancer networks, which have developed Quality Performance Indicators (QPIs), including for breast cancer.

The cancer networks meet once a year to discuss what the data on QPIs shows about the services. **To achieve this focus on quality, the NHS ensures accountability at the highest level**. The CEOs of each health board were made responsible for developing action plans on quality improvement. An independent body assesses every three years whether the action plan is still appropriate. These assessments also lead to a list of recommendations for areas in which quality targets are deemed not to have been met, or quality has not improved. A data dashboard has been developed to present data at regional, unit or surgeon level.

Quality measurement and improvement for each QPIs are reviewed regularly. The target standards were raised as a result of such a review as all centres were meeting them easily. QPIs were added for three additional areas, whereas two QPIs were archived as every unit was reaching the standard required and it was felt this had now become part of clinical practice.

3.1.2 The Netherlands (Ruud Pijnappel, UMC Utrecht, on behalf of Sabine Siesling, University of Twente)

Incidences of breast cancer are rising in the Netherlands. Cases of invasive breast cancer, for example, rose from 8 000 in 1990 to 14 551 in 2015. The survival rate is however increasing. Some 77% of patients diagnosed between 2004 and 2007 are still alive 10 years later.

A national breast cancer screening programme was launched in 1990, initially for women aged 50-70, and since 1999 up to the age of 75. Women are invited for screening every two years. Mobile units ensure high attendance (around 80%).

The Netherlands also has a national breast cancer network (NABON, founded in 2011). The multidisciplinary group brings together clinicians, patients and health insurers. It has formulated three indicators for radiology, four for pathology, two for surgery and seven on waiting time. Once a year the indicators are sent to a transparency portal, which is open to health insurers. They are therefore able to see whether or not their contracted hospital is performing well.

Coupling the national pathology archive with the national cancer and national discharge registries provides a complete overview of diagnosis and time of death.

Pijnappel reported challenges for implementing a *European QA scheme*, but spoke positively of the options it will open up, such as benchmarking against other countries and attaining international accreditation. **To ease the burden of adapting, Pijnappel advised limiting the registration burden, attempting to fit the scheme within existing structures, making not all indicators compulsory, and maintaining a patient-oriented approach.**

3.1.3 Romania (Luciana Neamtiu, on behalf of Florian Nicula, Romanian programme for cancer prevention and control)

While breast cancer incidence in Romania is relatively low compared to the rest of the EU, mortality is comparatively high.

Population based screening does not exist, but was piloted with 5 000 women aged 50-69 in 2014.

Oncology units exist in most major cities, and there is at least one in each of the 42 Romanian counties. However, radiotherapy centres are scarce.

The national accreditation body — RENAR — awards accreditation, but it is currently only used for medical laboratories, medical imaging and radiology. It is however in each hospital's interests to be accredited as **only those with accreditation receive funding from the national insurance house**.

Will it be possible to implement the *European QA scheme* in Romania? "I would say yes," said Neamtiu. Certain hospitals are already using guidelines and protocols internally. Plus there is a quality management system, and an oncology cluster has been built up. Romania has all the services needed for the *European QA scheme* and now needs to work with the accreditation bodies to implement it. It will also be important to involve the national insurance house. "If it's not involved, it won't work," said Neamtiu. Already willing to take the initiative forward, Neamtiu stated that the Oncology Institute "Prof Dr Ion Chiricuță" will be able to pilot the *European QA scheme*, supported by the Ministry of Health.

Guided poster tour

During the lunch break of day one, a guided tour of posters took place. Posters from nine European countries and from Bahrain were submitted. They all referred to the present system of care for breast cancer in the country depicted and addressed the implementation of the ECIBC in European countries:

- **Czech Republic**, O. Ngo, O. Majek, J. Danes, P. Tesarova, Department of screening programmes: Breast cancer care in the Czech Republic; ECIBC National Contact.
- **Greece**, N. Dimitropoulos, Athens University: Breast cancer care in Greece; on behalf of the ECIBC National Contact.
- Germany, S. Curelea, T. Beutler, DakkS: Accreditation activities in the field of breast cancer; National Accreditation Body.
- **Hungary**, D. Magdolna, D. Lajos, National Public Health and Medical Officer Service (ÁNTSZ): Breast cancer care in Hungary; ECIBC National Contact.
- Italy, A. Federici, Ministry for Health: Implementing the *European QA scheme*; ECIBC National Contact.
- **Latvia**, I. Engele, K. Arcimovica, M. Epermane, Riga East Clinical University Hospital: The nationwide mammography screening programme in Latvia Implementing the *European QA scheme*; ECIBC National Contact.
- **Norway**, P. Andersen, Norwegian Directorate of Health: Breast cancer care in Norway; on behalf of the ECIBC National Contact.
- Slovakia, K. Pohlodek, A. Kállayová, M Ondrušová, J. Slobodníková, University Hospital of Bratislava: Breast cancer screening in Slovakia; ECIBC National Contact.
- **Switzerland**, A. Kässner, Federal Office of Public Health: The characteristics of breast cancer care in Switzerland; on behalf of the ECIBC National Contact.
- **Turkey**, M. M. Kurt Soykan, D. Kiziltan, Turkak: Breast cancer care characteristics in Turkey; on behalf of the ECIBC National Contact.
- **Bahrain**, Z. Fedorowicz, J. Sprakel, T. Al Alawa, Cochrane Bahrain: A breast cancer clinical guideline for the Kingdom of Bahrain.

3.2 Country tables (Donata Lerda, JRC)

Discussing the feasibility of ECIBC implementation in European countries

"It's your turn to tell us what you need. There is no impact without implementation," said Lerda as she introduced the country tables session and expected outcomes. Representatives from national health authorities and stakeholders joined European Breast Guidelines and European QA scheme group members around country tables.

A total of 15 tables were set up, of which 8 brought together representatives from more than one country. Out of the 35 countries participating in the ECIBC, 27 were represented. Each table received factsheets presenting their country's responses to the past open calls for feedback on the scope of the *European Breast Guidelines* and the *European QA scheme*, and each country was asked to fill in a short questionnaire on ECIBC implementation opportunities.

Country table outcomes where expected to provide the basis for the roundtable discussion that followed. The outcomes were therefore summarised and presented at the end of the breakout by Lerda.

After lively discussions at each table, a questionnaire was received from **all** participating countries. All contained responses on both the *European Breast Guidelines* and the





European QA scheme. The majority of countries also provided information on additional national contacts to be approached by the JRC in preparation for implementation.

3.2.1 European Breast Guidelines

Some 25 countries out of the 27 present reported either having a screening programme or being in the process of rolling one out. All 25 complied with the *European Breast Guidelines* recommendations, having a screening programme at least for the age group 50 to 69.

For those countries reporting issues with the ECIBC recommendations, most related to the age range 45-49.

Comments collected from the questionnaires called for more awareness-raising of the recommendations and **more discussion on screening for women aged 70-74 years.** Comments also noted current alignment with the recommendations. In general, the questionnaires showed the recommendations were viewed as a useful basis for a dialogue with policy makers on the necessity of population-based screening programmes and the ages to be prioritised.

3.2.2 European QA scheme

All but one of the 27 countries reported a national/regional policy for the organisation of breast cancer care. The modules proposed by the *European QA scheme* were deemed appropriate for 24 out of 27 countries. Two reported concerns about the end-of-life care module. The option to compare quality of breast cancer care between EU countries with the help of the *European QA scheme* was appreciated by most respondents.

The responses showed that the accreditation infrastructure foreseen is not yet fully understood by all, while seven questionnaires expressed doubts about the readiness of their country's accreditation structure to adopt this part of the scheme. **The JRC offered to sit with representatives from each individual country and clarify** the specific issues in relation to implementation and how they could be solved. Lerda offered reassurance that the *European QA scheme* aims to be as flexible as possible to **find solutions tailored to each country's needs**. A dialogue with one national accreditation body has already led to an agreement on a more flexible structure for accreditation requirements. One country table welcomed a QA scheme that would reassure breast cancer services that "the efforts that they are taking are indeed going in the right direction".

Lerda described the country table exercise as very successful in providing extremely useful information about the (potential) impact of the ECIBC on national health policies. The material that the JRC received through the call for feedback on the scope of the European QA scheme and through the country tables will help to deepen understanding of implementation opportunities for the ECIBC in different countries. This knowledge will be further expanded over the next two years, during which time the JRC will also seek a direct exchange with individual countries.



3.3 Round table discussion

What needs to be done at European and national levels to implement the European QA scheme? (moderated by Ciarán Nicholl, JRC)

Participants: Roswitha Britz, Europa Donna President ¹; Zofija Mazej Kukovič, Slovenian policy maker; Alojz Peterle, President of "MEPs Against Cancer" (MACs), European Parliament; Iveta Nagyova, EUPHA; Birgit Beger, ECCO; Stefan Schreck, DG SANTE; Elke Anklam, JRC

Nicholl reassured participants that the JRC will be approaching each country to ensure that the ECIBC initiatives will not have a negative impact on existing health schemes. "That would be counter-productive," he said. "We are committed to the Member States, that's the function of the EU."

In response to appeals for flexibility, MEP Alojz Peterle (president of "MEPs Against Cancer" (MACs)) said, "There are areas where we can be very flexible, and areas where we can't be" if we are to ensure the highest quality of care for patients. He also called for political promotion of the *European QA scheme*.

¹ Roswitha Britz's speech can be found here

Other comments from the floor addressed a need for additional information on the benefits of the accreditation proposed by the ECIBC, and the prior existence of well-implemented screening programmes and QA schemes in certain countries that are tailored to each country's individual circumstances.

Stefan Schreck of DG SANTE also reminded participants that the recommendations are not law. "Follow or don't follow if something doesn't apply to your circumstances. But **if** you do something other than what is recommended in the guidelines, please explain why."

To support from elsewhere in the audience, one participant requested that the JRC contacts ministries directly as they do not always listen to experts: "They have to understand why changes are necessary, and you have the evidence."

Zofija Mazej Kukovič called for a **change in "mind set" towards common standards for quality in breast cancer care**. Implementing common standards among EU Member States has been done before in other policy fields. In the beginning such a process is always associated with much effort: 'There will be lot of administration, and people will say this is typical of EU'. But once standards are implemented the administrative effort will become less and the benefits will be appreciated. "Everything will be more transparent, and **patients will for sure have greater trust in the system**."

The discussion turned to the question of continuity of care, with one participant highlighting that as the *European QA scheme* will be modular, and certification can be attained step-by-step, it remains a **challenge to guarantee that quality of care is assured across the interfaces of care modules and care responsibilities**. "It will be a long-term aspiration to join up these different modules, however in the end this is what counts for the patient."

Discussions also covered who has the authority to ensure implementation of the screening recommendations, and how efficient it would be to target ministers; they may change frequently, and with each new minster lobbying must start again from scratch. Instead of ministers it might be more useful to approach screening programme managers, some suggested. It is likely that the **level of policy maker to approach when lobbying for implementation will vary from country to country**. The JRC concluded that it needs to develop a communication and dissemination strategy for ECICB output.

Peterle provided words of reassurance and proposed to include health issues in the European semester, "which at the moment is limited to economic issues. This would lead to more continuity."

Schreck reassured the Plenary that the JRC and DG SANTE would talk to everyone relevant, including ministers, high-, mid- and low-level officials and chief medical officers.

Round table participant Nagyova advocated activating public health and patient organisations who can take a bottom-up approach to lobbying for change. Other targets for lobbying include the directors of national cancer plans.

The roundtable discussion finished with a reminder that the tools that the ECIBC is developing will be watched and absorbed by countries outside Europe as well as within. Francesco Sardanelli, vice chair of QASDG marked from the audience that there needs to be an awareness that, "from the point of view of other countries for example in Latin America, Africa and others, Europe is a role model".

3.4 Conclusions (Alojz Peterle, President of MEPs Against Cancer (MACs), European Parliament)

Peterle, who is a cancer survivor himself and knows the JRC and its work well, declared the Plenary's two rainy days as sunny days. "Science and policy met – this has to happen." He welcomed the inclusive nature of the gathering, marking it out as a European initiative.

Looking ahead, to ensure continuation of the important work begun, **Peterle** called for **proactive sharing of the**

relevance of the *European Breast Guidelines* and *European QA scheme*, as well as efforts to ensure an even more favourable political context. "We can do more at all levels. Let's continue the good work," he said, closing the 2016 Plenary.

4. Evaluation

About one fifth of the 150 participants responded to a survey evaluating the event. Evaluation was carried out online and reminders were sent. Those who responded confirmed that the Plenary's aim — to inform stakeholders — was met: **all respondents felt that the event succeeded in providing a comprehensive overview of how the ECIBC is progressing**, and what the challenges are (see figure 1).

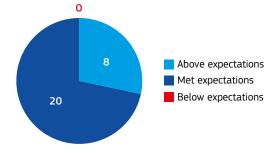
On the organisation of the event, respondents' expectations were overwhelmingly met or exceeded in terms of the speakers and the balance of the sessions, while feedback on the logistics was equally positive, with expectations frequently surpassed for location, communication and the time allocated to networking.

The section of the Plenary devoted to ECIBC news and updates received overwhelmingly positive reviews, which was also the case for all other Plenary sessions on the first day. Some however thought that more time for discussion would have been helpful: "I miss the discussion between the participants and the project team. It is good to have some overview of the projects. The value should be the input of the experts during discussion."

The country tables were viewed positively. While some participants would have preferred to see more time allocated to this session, in particular for interaction with other participants, many survey respondents highlighted the relevance of the country tables for them: "I am an accreditation person, so for me it was very useful to see the other side."

Other survey comments highlighted increased motivation following the event to further advance evidence-based breast cancer care in their country, and the wish for further exchange and collaboration: "For a country like ... and for me as the coordinator for the breast cancer screening program, this was a very important meeting. Perfectly organized and perfect speakers, also many nice people. Now, staying in contact and following the ECIBC is the next important step."

Figure 1: The ECIBC Plenary rated for "clearly outlining the current state of the development and challenges of the ECIBC".





5. Conclusions

The 2016 ECIBC Plenary was an overall success in meeting the mandate and expectations of participants and organisers alike. As the evaluation of the event revealed, participants felt well informed in terms of the development of ECIBC tools, and in particular the *European Breast Guidelines* and the *European QA scheme*.

The launch of the first four guidelines recommendations, which are based entirely on the latest evidence, not only marked an important milestone in the progression of the ECIBC, but moreover in the progression of Europe's approach to clinical guidelines in general. For both, the guidelines and the QA scheme, the clinical experience of experts, together with the evidence, is being translated into relevant recommendations and requirements that should ultimately result in improved quality of breast cancer care. And during the entire process, the ECIBC keeps the patient at the centre of all deliberations.

Placing the focus on individual countries on the second day, and in particular on encouraging stakeholders from the same country to talk to one another about the options for implementing the *European Breast Guidelines* and the *European QA scheme* proved valuable. The lively discussion not only provided valuable information to the JRC,

helping to clarify issues, but also created a momentum which will hopefully spill over as countries begin preparing for implementation. It was reassuring for the Commission to see the extent to which the guidelines recommendations were welcomed as a basis for policy discussion on breast cancer at national level, and to see that some of the recommendations are already de facto in place or are at the policy uptake stage.

What happens next? While the 2016 ECIBC Plenary sought to prepare the ground for the implementation of both the guidelines and the QA scheme, the next Plenary will see the presentation of the *European Breast Guidelines* and the *European QA scheme* as they approach finalisation. The ensuing fourth ECIBC Plenary will present results from the first implementation phase of the *European QA scheme*; the pilot implementation will take place in breast cancer services across Europe, which represent the different contexts in EU Member States and within health systems. Discussing experiences of the pilot phase within the Plenary will help to adjust the tools so that they are ready for implementation.

The pilot is scheduled for 2018, but country representatives and other stakeholders will be asked to contribute before then. Before the *European QA scheme* is piloted, they will receive a final set of requirements with a request for feedback and their approval of the feasibility of technical implementation. They will also be invited to get into direct exchange with the JRC on implementation.

6. Annexes

Agenda

Day 1: Science for Policy Development		
09:30-10:10	Welcome & Opening	
	Welcome note	
	Charlina Vitcheva, JRC	
	The patient's perspective on ECIBC	
	Marja Aarnipuro , Apu magazine, Finland	
	Launch of the first set of European Breast Guidelines	
	recommendations	
	Elke Anklam, JRC	
10:10-10:15	Presentation of the agenda	
	Donata Lerda, JRC	
10:15-11:00	What kind of science is successful in supporting policy development—	
	the scientists perspective	
	Josep Figueras, European Observatory on Health Systems & Policies	
11:00-11:30	0-11:30 Coffee	
11:30-13:00	News and update from the ECIBC projects	
	Moderated by Elke Anklam, JRC and Zofija Mazej Kukovič, ,	
	Slovenian policy maker	
	Session introduction	
	Zofija Mazej Kukovič , , Slovenian policy maker	
	Status of the development of the European quality assurance	
	scheme for breast cancer services	
	Robert Mansel, QASDG chair	
	Status of the development of the European guidelines for breast	
	cancer screening and diagnosis	
	Chris de Wolf, GDG co-chair and Holger Schünemann, GDG co-chair	
	Status of the development of the Guidelines Platform	
	Donata Lerda, JRC	
13:00-14:30	Walking lunch and Guided poster tour	
	Moderated by Anke Bramesfeld, Silvia Deandrea , JRC	

14:30-15:00	Continued: News and update from the ECIBC projects Moderated by Elke Anklam, JRC and Zofija Mazej Kukovič, Slovenian policy maker • Training on digital mammography: a European approach Aslı Ulutürk, JRC • Monitoring the impact of ECIBC
	Slovenian policy maker • Training on digital mammography: a European approach Aslı Ulutürk, JRC
	• Training on digital mammography: a European approach Aslı Ulutürk , JRC
	Aslı Ulutürk, JRC
	,
	Monitorina the impact of ECIBC
	· · · · · · · · · · · · · · · · · · ·
	Nadya Dimitrova, JRC
	Presentation of ECIBC video
	Elke Anklam, JRC
15:00-16:00	Making comparable performance assessment possible in Europe
	by using the accreditation legal framework
	Moderated by Jane Beaumont , Accreditation Adviser, and M
	arc van den Bulcke, Scientific Institute of Public Health, Brussels
	 What is the accreditation legal framework, what are its benefits
	and shortcomings
	Ed Wieles, Dutch Accreditation Council, The Netherlands
	• The role of the accreditation legal framework in the European QA
	scheme
	Silvia Deandrea, JRC and Aliki Stathopoulou, QASDG member
16:00-16:30	Coffee
16:30-17:30	Experience with using ISO 15189 as an option for accrediting
	pathology laboratories
	Marco Pradella, Local Health Authority Asolo, Italy
	• Experiences with implementing ISO 15189
	Katrien Grünberg, Radboud University Medical Center,
	Nijmegen, The Netherlands
19:00	Gala dinner at Villa Panza, Varese
	Bus transport to/from hotels.

Day 2: Poli	cy for science Implementation		
09:30-10:45	Break out session		
	Discussing feasibility of implementation of the European QA scheme		
	in different European Countries		
	• Introduction		
	Donata Lerda, JRC		
	Coffee + Country tables		
	National accreditation bodies, ECIBC National Contacts and stake-		
	holders meet at their own national coffee table to discuss the		
	possible implementation of the European QA scheme in their country		
10:45-11:30	Breast cancer services in European countries and the <i>European</i>		
	QA scheme: country profile		
	Moderated by Tit Albreht , National Institute of Public Health,		
	Slovenia and Stefan Schreck , DG SANTE		
	• Scotland		
	Hillary Dobson, NHS Scotland		
	The Netherlands		
	Sabine Siesling, University of Twente		
	• Romania		
	Florian Nicula, Romanian programme for cancer prevention and control		
11:30-11:35			
	Ciarán Nicholl, JRC		
11:35-11:45	,		
	Donata Lerda, JRC		
11:45-12:45			
	What needs to be done at European and national levels		
	to implement the European QA scheme		
	Moderated by Ciarán Nicholl, JRC		
	Elke Anklam, JRC		
	Simona Bonafè,* Member of the European Parliament Roswitha Britz, President of Europa Donna		
	Nessa Childers ,* Member of the European Parliament		
	Miriam Dalli,* Member of the European Parliament		
	Alojz Peterle, President of the MEPs Against Cancer (MACs),		
	European Parliament		
	Charlina Vitcheva, JRC		
12:45-13:00			
12.43 13.00	Alojz Peterle, President of the MEPs Against Cancer (MACs),		
	European Parliament		
13:00	Lunch		

Participants

List of speakers, including CVs can be found in the plenary booklet

Marja	AARNIPURO	Apu magazine / A-lehdet Oy	Finland
Tit	ALBREHT	National Institute of Public Health	Slovenia
Pablo	ALONSO	Iberoamerican Cochrane Centre	Spain
Per Kr.	ANDERSEN	Norwegian Directorate of Health	Norway
Elisabeth	ANDRITSCH	International Society of Psycho-Oncology	Canada
Kathi	APOSTOLIDIS	ECPC European Cancer Patient Coalition	Belgium
Krista	ARCIMOVICA	Riga East University Hospital	Latvia
Myrto	AZINA-CHRONIDES	Ministry of Health	Cyprus
Mónica	BALLESTEROS	Iberoamerican Cochrane Centre	Spain
Partha	BASU	International Agency for Research on Cancer	France
Jane	BEAUMONT	Accreditation Advice	United Kingdom
Birgit	BEGER	European CanCer Organisation (ECCO)	Belgium
Karen	BENN	Europa Donna The European Breast Cancer Coalition	Italy
Elizabeth	BENNS	Independent Cancer Patients' Voice	United Kingdom
Elizabeth	BERGSTEN NORDSTRÖM	Swedish Breast Cancer Association	Sweden
Gunita	BERKE	Europa Donna Latvia/Latvian Cancer Patients Association " Dzivibas koks"	Latvia
Jacques	BERNIER	Genolier Swiss Medical Network	Switzerland
Thomas	BEUTLER	Deutsche Akkreditierungsstelle GmbH (German Accreditation Body)	Germany
Magdalena	BIELSKA-LASOTA	National Institute of Public Health - National Institute of Hygiene	Poland
Christian	BOEHLER	Independent consultant	Austria
Hanno	BOHL	Estonian Cancer Society	Estonia
Bettina	BORISCH	Université de Genève	Switzerland
Andrew	BOTTOMLEY	EORTC	Belgium
Julia	BOYSEN	Stadtspital Triemli	Switzerland
Marco	BRAMBILLA	European Federation of Organisations for Medical Physics	Italy
Roswitha	BRITZ	Europa Donna	Spain
Mireille	BROEDERS	Dutch Reference Centre for Screening	Netherlands
Inga	BROKERE	National Health Service	Latvia
Sara	BRUCKER	Research Centre for Women's Health at Tübingen University	Germany
Jean-Luc	BULLIARD	Lausanne University Hospital- Faculty of Biology and Medicine	Switzerland
Marie	CANTWELL	Queen's University Belfast	United Kingdom
Flavia	CARDINALI	Agenzia Nazionale per i Servizi Sanitari Regionali	Italy
Francesca	CAROZZI	Institut of Cancer Prevention ISPO	Italy
Antonino	CARTABELLOTTA	Fondazione GIMBE	Italy
Paloma	CASADO	Ministry of health social services and equality. Spain.	Spain
Isabella	CASTELLANO	University of Turin	Italy

Xavier	CASTELLS	Hospital del Mar de Barcelona	Spain
Luigi	CATALIOTTI	Breast Centres Certification	Italy
Saskia	CLAASSEN	Catharina Hospital	Netherlands
Sue	COHEN	Public Health England	United Kingdom
Edoardo	COLZANI	European Centre for Disease Prevention and Control (ECDC)	Sweden
Mike	CORNBLEET	Healthcare Improvement Scotland	United Kingdom
Massimo	CORSARO	Pfizer	Italy
Simona	CURELEA	DAkkS (German Accreditation Body)	Germany
Jan	DANEŠ	Charles University in Prague- First Faculty of Medicine	Czech Republic
Magdolna	DANK MD	Semmelweis Egyetem Onkologiai Kozpont	Hungary
Nynke	DE JONG	National Institute for Public Health and the Environment	Netherlands
Isabel	DE LA VILLA	ENAC	Spain
Christophorus	DE WOLF	ADSAN	Switzerland
Maria Victoria	DE ZABALA	Europa Donna Belgium	Belgium
Nikolaos	DIMITROPOULOS	DELTA DIGITAL SA	Greece
Hilary	DOBSON	NHS SCOTLAND	United Kingdom
Stephen	DUFFY	Queen Mary University of London	United Kingdom
Adrie	DUMAIJ	National Institute for Public Health and the Environment	Netherlands
Maie	EGIPT	Estonian Cancer Society	Estonia
Miriam	ELFSTRÖM	Regional Cancer Center of Stockholm-Gotland- Stockholm County Council	Sweden
Ilze	ENGELE	Riga Eastern University hospital	Latvia
Josep A	ESPINAS	Catalan Cancer Plan	Spain
Antonio	FEDERICI	Ministero della salute, Dipartimento di prevenzione	Italy
Zbys	FEDOROWICZ	Cochrane BAHRAIN	Bahrain
Maria Conceicao	FERREIRA	Pfizer GmbH	Germany
Rosanna	FIDANZIA	Europa Donna Italia	Italy
Josep	FIGUERAS	European Observatory on Health Systems and Policies	Belgium
Markus	FOLLMANN	German Cancer Society	Germany
Claudio	GALLI	Abbott Diagnostics	Italy
Cristina	GARCIA VIVAR	European Federation of Nurses Associations (EFN)	Belgium
Franco	GATTAFONI	ACCREDIA	Italy
Sija	GEERS- VAN GEMEREN	European Federation of Radiographer Societies	Netherlands
Daniele	GENERALI	Azienda Socio Sanitaria Territoriale (ASST) di Cremona	Italy
Alessandra	GENNARI	E.O.Galliera	Italy
Livia	GIORDANO	Azienda Ospedaliera Citta della Salute e della Scienza di Torino	Italy
Paolo	GIORGI ROSSI	AUSL Reggio Emilia	Italy
Jola	GORE-BOOTH	EuropaColon Ltd	United Kingdom
Urska	GRAHEK	Joint Research Centre	Belgium
Axel	GRÄWINGHOLT	Self employed	Germany
Andre	GRIVEGNEE	INSTITUT JULES BORDET	Belgium
Katrien	GRUNBERG	Radboud University Medical Center	Netherlands
Freja	HAGSUND	European Regional and Local Health Authorities (EUREGHA)	Belgium

Stephen	HALLORAN	NHS Bowel Cancer Screening Programme	United Kingdom
Sirpa	HEINAVAARA	Cancer Society of Finland / Finnish Cancer Registry	Finland
Belinda	HENSHAW	Healthcare Improvement Scotland	United Kingdom
Solveig	HOFVIND	Norwegian Breast Cancer Screening Program	Norway
Christopher	HOLCOMBE	NHS in England	United Kingdom
Svetlana	JIDKOVA	Center for cancer detection	Belgium
Henrik Lykkegaard	JØRGENSEN	DANAK	Denmark
Anja	KAESSNER	Federal Office of Public Health	Switzerland
Damla	KIZILTAN	Turkish Accreditation Agengy	Turkey
Thanos	KOSMIDIS	Care Across	United Kingdom
Tibor	KOVACS	European Society of Surgical Oncology	Belgium
Merve Meltem	KURT SOYKAN	TURKISH ACCREDITATION AGENCY	Turkey
Viola	KUTAS	National Accreditation Authority	Hungary
Miranda	LANGENDAM	Academic Medical Center / University of Amsterdam	Netherlands
Zbigniew	LES	Evidence Prime	Poland
Jesus	LÓPEZ ALCALDE	Cochrane Madrid	Spain
Anne	MACKIE	Public Health England	United Kingdom
Robert	MANSEL	EUSOMA	United Kingdom
Lorenza	MAROTTI	EUSOMA	Italy
Zofija	MAZEJ KUKOVIC	Former Member of European Parliament	Slovenia
Helen	MCGARRIGLE	Cardiff and Vale Breast Unit	United Kingdom
Ana	MOLINA	Fundación para el Fomento de la Investigación Sanitaria y Biomédica (FISABIO)	Spain
Lydia	MOUZAKA	Hellenic Senologic Society	Greece
lveta	NAGYOVA	European Public Health Association - EUPHA	Netherlands
Peter	NAREDI	ECCO	Belgium
Luciana	NEAMTIU	Institutul Oncologic "Prof. Dr. Ion Chiricuta" Cluj-Napoca	Romania
Eva	NEGRI	Istituto di Ricerche Farmacologiche Mario Negri	Italy
Ondrej	NGO	Institute of Biostatistics and Analyses- Masaryk University	Czech Republic
Lennarth	NYSTRÖM	Umeå University	Sweden
Ruben	ORDA	SIS/ISS (SENOLOGIC INTERNATIONAL SOCIETY/ INTERNATIONAL SCHOOL OF SENOLOGY	Israel
Eugenio	PACI	formerly ISPO Cancer Research and Prevention Institute - Florence (retired)	Italy
Elsa	PEREZ	University Hospital Dr. Josep Trueta	Spain
Elena	PÉREZ SANZ	Dirección General de Salut Pública de Comunitat Valenciana	Spain
Alojz	PETERLE	European Parliament	Belgium
Niall	PHELAN	BreastCheck	Ireland
Ruud	PIJNAPPEL	Dutch Reference Center for Screening	Netherlands
Kamil	POHLODEK	Comenius University of Bratislava- Faculty of Medicine- Bratislava- Slovakia	Slovakia
Marco	PRADELLA	ULSS 8 Asolo	Italy
Liisa	PYLKKANEN	Cancer Society of Finland	Finland
Daniela	QUAGGIA	Cittadinanzattiva - Active Citizenship Network	Italy

Ulla	RAID	Health System Development Department – Ministry of Social Affairs	Estonia
Alexandra	RAMSSL-SAUER	Gesundheit Österreich GmbH	Austria
Vitor	RODRIGUES	Faculdade de Medicina - Universidade de Coimbra	Portugal
Dolores	SALAS	Direccion General Salud Pública Valencia Community- FISABIO	Spain
Anna	SAPINO	Institute of Cancer Research	Italy
Francesco	SARDANELLI	University of Milan- Research Hospital Polilcinico San Donato	Italy
Holger	SCHUNEMANN	McMaster University	Canada
Elisabetta	SESTINI	Europa Donna Italia	Italy
Sabine	SIESLING	Comphrehensive Cancer Centre the Netherlands (IKNL	Netherlands
Christian	SINGER	Medical University Vienna	Austria
Julie	SPRAKEL	Bahrain Breast cancer Society- Think Pink Bahrain	Bahrain
Aliki	STATHOPOULOU	HELLENIC ACCREDITATION SYSTEM - ESYD	Greece
Svetlana	TEMELKOVSKA	University Clinic of radiology Skopje	the former Yugoslav Republic of Macedonia
Luzia	TRAVADO	Champalimaud Clinical Centre- Champalimaud Foundation	Portugal
Francisco	TRESSERRA	HOSPITAL UNIVERSITARIO DEXEUS	Spain
Martin	UNDERWOOD	Warwick Clinical Trials Unit	United Kingdom
Marc	VAN DEN BULCKE	Scientific Institute of Public Health	Belgium
Cary	VAN LANDSVELD- VERHOEVEN	LRCB Dutch Reference Centre for Screening	Netherlands
Chantal	VAN ONGEVAL	University Hospitals Leuven	Belgium
Elke	VAN ROSSEN	BELAC	Belgium
Elizabeth	VERSCHUUR-VAN DER VOORT	Dutch Breast Cancer Society	Netherlands
Charlina	VITCHEVA	Joint Research Centre	Belgium
Sue	WARMAN	Independent	United Kingdom
Elisabete	WEIDERPASS VAINIO	Cancer Registry of NorwayInstitute of Population Based Cancer Research	Norway
Ed	WIELES	Dutch Accreditation Council RvA	Netherlands
Margaret	WILCOX	Independent Cancer Patients Voice	United Kingdom
Mary	WOODS	The Royal Marsden NHS Foundation Trust	United Kingdom
Stephanie	XUEREB	National Screening Programmes- Ministry of Health	Malta
Wendy	YARED	European Cancer Leagues (ECL)	Belgium
Kenneth	YOUNG	Royal Surrey County Hospital	United Kingdom
Marco	ZAPPA	ISPO	Italy
Janez	ŽGAJNAR	Institute of Oncology Ljubljana	Slovenia

References

Additional ECIBC documents and publications are available online.

Council of the European Union's conclusions on reducing the burden of cancer	http://eur-lex.europa.eu/legal-content/EN/TXT/ PDF/?uri=CELEX:52014DC0584&from=en
recommendations	http://ecibc.jrc.ec.europa.eu/recommendations/
methodology document	http://ecibc.jrc.ec.europa.eu/qa-methodology
video	http://ecibc.jrc.ec.europa.eu/ecibc-for-you
Feedback report	https://bookshop.europa.eu/en/report-on-the-call-for-feedback-about-the-scope-of-the-european-quality-assurance-scheme-for-breast-cancer-services-pbLANA28188/
Booklet	http://ecibc.jrc.ec.europa.eu/-/ecibc-plenary-2016
ECIBC reports	http://ecibc.jrc.ec.europa.eu/reports
ECIBC documents	http://ecibc.jrc.ec.europa.eu/other-documents
Roswitha Britz	http://europa.eu/!Xw34Kb

GETTING IN TOUCH WITH THE EU

In person

All over the European Union there are hundreds of Europe Direct information centres. You can find the address of the centre nearest you at: http://europea.eu/contact

On the phone or by email

Europe Direct is a service that answers your questions about the European Union. You can contact this service:

- by freephone: 00 800 6 7 8 9 10 11 (certain operators may charge for these calls),
- at the following standard number: +32 22999696, or
- by electronic mail via: http://europa.eu/contact

FINDING INFORMATION ABOUT THE EU

Online

Information about the European Union in all the official languages of the EU is available on the Europa website at: http://europa.eu

EU publications

You can download or order free and priced EU publications from EU Bookshop at: http://bookshop.europa.eu. Multiple copies of free publications may be obtained by contacting Europe Direct or your local information centre (see http://europa.eu/contact).

JRC Mission

As the science and knowledge service of the European Commission, the Joint Research Centre's mission is to support EU policies with independent evidence throughout the whole policy cycle.



EU Science Hub

ec.europa.eu/jrc



● EU_ScienceHub



f EU Science Hub - Joint Research Centre



in Joint Research Centre



You EU Science Hub



doi: 10.2760/87978 ISBN 978-92-79-70521-2