The EU vision

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Joint Research Centre

The European Commission's in-house science service

The Joint Research Centre within the European Commission

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The Joint Research Centre within the European Commission

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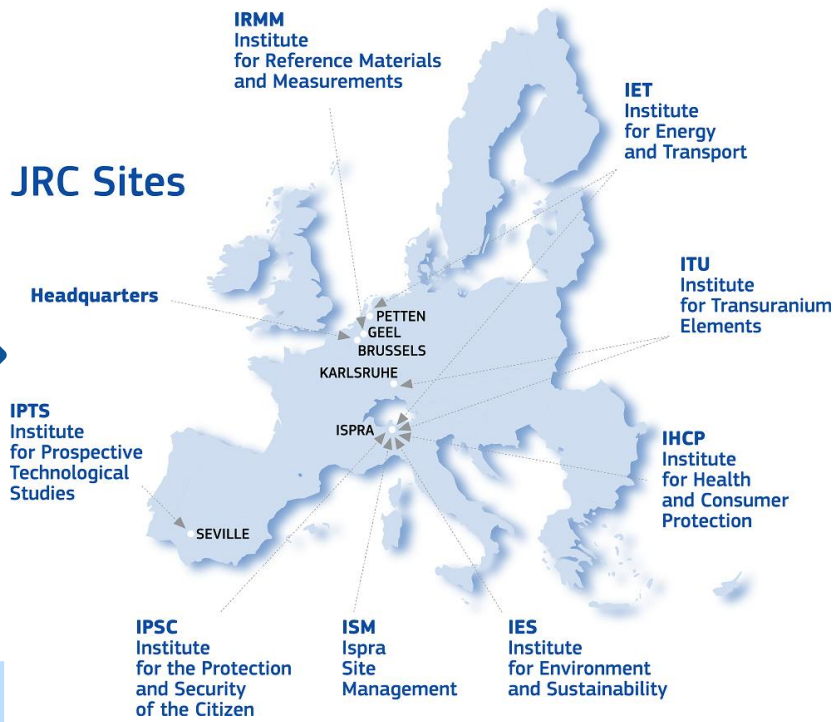


European Commission

The Mission of the Joint Research Centre

- To provide **customer-driven scientific and technical support** for the conception, development, implementation and monitoring of EU policies.
- As a service of the European Commission, the **JRC** functions as a **reference centre of science and technology** for the Union.
- Close to the policy-making process, it **serves the common interest** of the Member States, while being **independent** of private or national special interests.

European Commission

Institute for Health and Consumer Protection

Director

K. Maruszewski

Chemical Assessment and Testing	Public Health Policy Support	Molecular Biology and Genomics	Nano-Biosciences	Systems Toxicology
				
P. Aguar	**C. Nicholl**	**J. Kreysa**	**H. Stamm**	**M. Whelan**

European Commission

IHCP Policy Support Areas

Genetically Modified Organisms

Nanotechnology

Public Health

Food and Consumer Products

Chemical Assessment & Alternatives to Animal Testing

- **Healthcare Quality**
- Nutrition
- Disease registries
- Behavioural Sciences
- Medical Devices

EC Initiative on Breast Cancer: *Aim – Method – Timeframe*

AIM: To provide women with a **high degree of confidence** and assurance in all processes directly concerning them in relation to **all stages of breast cancer care**, via:

1 - the establishment of a platform of evidence (guidelines – A PRIORITY)

2 - based on such platform, the implementation and monitoring (auditing) of a European **set of quality standards**

METHOD: *draft* proposals – open consultation – consensus (TRANSPARENCY – INCLUSIVENESS – PEER EVALUATION)

TIME FRAME: project completion due by 2016 (guidelines, QA scheme pilot, web-hub).

Breast cancer initiative: *objectives*

- Development and publication of **web-based and evidence based New European Guidelines** for Breast Cancer Screening and Diagnosis.

- Development of a **European Quality Assurance (QA) Scheme for Breast Cancer Services**, underpinned by the EU's legal framework of accreditation and by a set of evidence-based guidelines.

Background for the EC initiative on BC (1)

Breast cancer in 2012 (year of latest observations) is still by far the most deadly cancer affecting women every year, with an average of 22,4/100 000 (15,1 -> 29,5) women dying of breast cancer in the EU

Treaty of Lisbon (Title XIV, Article 168) *"The Commission may, in close contact with the Member States, take any useful initiative […] aiming at the* ***establishment of guidelines and indicators****, the organisation of* ***exchange of best practice****, and the preparation of the necessary elements for* ***periodic monitoring and evaluation****'"*

European Parliament resolution of 2003 on breast cancer *"Calls on the Member States and on the Commission to make the fight against breast cancer a health policy priority and to develop and implement effective strategies for improved preventive health care"* and *"calls on the* ***Member States****, therefore, to establish a network of* ***certified multidisciplinary breast centres"***

Background for the EC initiative on BC (2)

Council Recommendation in 2003 for cancer screening in accordance with the *European Guidelines*

European Parliament Resolution of April 2008 acknowledges "…*unacceptable differences* (between Member States) in the *quality of cancer treatment facilities*…"

the **Council Conclusions** of June 2008 invite 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 […]" and to "*facilitate the development and updating of […] web-based quality assurance and evidence-based guidelines on cancer […]*"

Guidelines

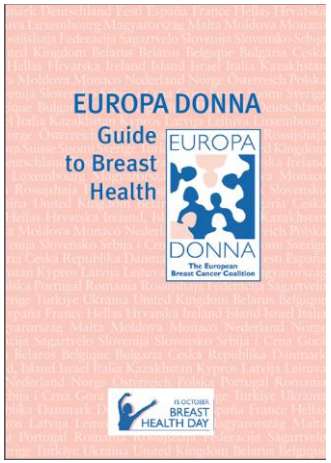
European Institutions are active in this area since 1987:

Since 1993 European guidelines for quality assurance (QA) in breast cancer screening and diagnosis were supported by the European Commission (four editions so far).

They were essential for the development of screening programmes in Europe.

- 4th edition issued in 2006.
- Supplements just published; coordinated by the same Editorial Board.

It is the main basis for the EUROPA DONNA Guide to Breast Health



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QA schemes

Many schemes active in Europe (private and public)

- EUSOMA - ECCC (Breast Units concept – multidisciplinarity)
- DKG – DGS (dual certification process coupled to S3 guidelines)
- EUREF (diagnostic breast imaging and breast screening services)
- OECI (accreditation & designation programme for cancer centres)
- SIS – ISS (accreditation program for breast centres / units)

- National Institute for Cancer and French Ministry of Health (Cancer treatment authorisation) - FR
- Health Information and Quality Authority (National Quality Assurance Standards for Symptomatic Breast Disease Services) – IE
- Royal Decree for accreditation of Breast Cancer Care Programs - BE

Essential requirements selected considering those already in use (databases not to be reinvented)

The EC initiative on BC

JRC will build on past and on-going experiences

Via Commission Implementing Decision of 1 December 2011 **JRC is asked to coordinate the European Commission Initiative on Breast Cancer**, constituted by the two main pillars, Guidelines and QA scheme.

JRC concept: Guidelines underpin the QA scheme and their application is enhanced by the QA scheme

JRC provides:

- Sustainable / long-term organisational framework
- Transparent platform for stakeholders involvement
- A platform for consultation and feed-back collection on Initiative's documents

Guidelines go hand in hand with QA scheme

Guidelines

Systematically developed statements to assist practitioner and patient decisions about appropriate healthcare.[1] [and support policy makers]

Evidence-based guidelines are essential for the QA Scheme.

Quality Assurance Scheme

Quality requirements for clinical aspects should correspond to **key recommendations from guidelines**, supported by the best available evidence.

[1] Field MJ, Lohr KN, editors; Committee to Advise the Public Health Service on Clinical Practice Guidelines, Institute of Medicine. Clinical practice guidelines: directions of a new program. Washington, DC: National Academy Press; 1990

The what / the how

1. The EC aims proposing **requirements applicable by all countries and impacting on quality of care in a reasonable timeframe**

2. **The JRC,** in its role of providing scientific evidence to policies**, will coordinate the development of the platform of evidence and its use for underpinning the QA scheme requirements**

3. **Based on evidence and new available technologies,** countries' might decide on which model to apply in order to attain those requirements

To conclude:

EC suggests and support with evidence the set of essential QA scheme requirements

Countries implement them in total autonomy (according to treaties)

Breast Cancer Initiative: Expected outcomes (1)

1a. The New **European Guidelines** for Breast Cancer Screening and Diagnosis.

1b. A platform of **high quality guidelines** for the QA scheme for stages not covered in the revised version of European Guidelines.

2. A **sustainable maintenance process** for the guidelines and the QA scheme.

3. A set of Key Performance Indicators (**KPIs**)

4. A **pilot European quality assurance (QA) scheme**, **accreditation** underpinned by the European legislative framework for breast cancer services.

Breast Cancer Initiative: Expected outcomes (2)

5. **Tools for identifying reference documents for Guideline and Scheme users**
   QA Guidelines, Technical Annexes, Best Practices, Implementation Examples, Guiding Documents, Training Documents (for auditors and auditees), Decision Aids (for professionals and for patients).

6. A **web-hub hosting all the outcomes** (targeted users/targeted objects).

If this concept proves to be successful, JRC would provide support for its application for **other healthcare areas**.

For more information

Website

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

Email

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

European Commission

Thank You for Your Attention

Joint Research Centre

Breast Cancer Initiative: *DESIRABLE (1)*

1. **Woman/patient is at the centre of the process**
2. **ONE set of guidelines** for screening and diagnosis for Europe
3. **Controlled criteria** for the selection of guidelines for other stages
4. **ONE scheme publicly available** for all Europe ensuring that guidelines are applied and essential requirements are fulfilled

Breast Cancer Initiative: *DESIRABLE (2)*

5. **KPI monitoring – KPI stability** (quality requirements vs. target case volumes?)

6. **Up to date**: New remote technologies, genetic testing, delocalised care for certain stages

7. **Modular** with strong interface requirements (applicable to all organisational frames in Member States)

8. **NOT endangering** existing (national & private) schemes

9. **Sustainable** (ex-ante evaluation, health economy tools for countries)

Breast Cancer Initiative: NOT DESIRABLE

1. **Inequality across countries**.
2. **No evidence** supporting choice of essential requirements from guidelines.
3. **Opportunistic screening**.
4. **Opportunistic treatment**.
5. **Multiplication of schemes** (not under Health Authorities control – not understandable by women).
6. **Increased costs**.

BC Initiative preparation (1)

a. **A database** of existing networks, projects, entities.

b. **Knowledge platform** (>1000 papers collected and organised).

c. **A survey** on screening & organisation of breast cancer services.

d. **A study** on existing QA schemes (***23 detected in Europe***).

e. **A short questionnaire** on the application of European QA Guidelines in European countries.

f. **A review of validated questionnaires** used to collect feed-back on satisfaction of women receiving BC screening.

BC Initiative preparation (2)

g. **Bilateral meetings** with key stakeholders.

h. **Two workshops (WSs) at the beginning of 2013** to present the project concept and to obtain consensus.

i. **A concept document** describing the objectives and a proposed working modality.

j. **Web-hub conceptualisation**.

Guidelines

Guidelines: Systematically developed statements to assist practitioner and patient decisions about appropriate healthcare.

Concept after WSs conclusions

1. SCREENING
2. DIAGNOSIS

→ **THE 5th edition of EUROPEAN GUIDELINES**

3. TREATMENT
4. REHABILITATION
5. FOLLOW-UP

→ **PLATFORM of HIGH QUALITY GUIDELINES**

European Commission

QA scheme

Concept after WSs conclusions

Covered by Regulation (EC) No 765/2008 and including:

1 - Quality Management (ISO 9001 / CEN 15224)

2 – Testing activities (ISO 15189 / 17025 /12052 – digital imaging)

3 – Data collection (KPI, quality checks from ENCR, relevant ISO standards)

4 - Patient Safety (Directive 2011/24/EU & Council Recommendation of 2009)

5 - Specific requirements from Guidelines and Experts (all stages of care)