Breast Health Global Initiative

Global Summit on International Breast Health and Cancer Control:

Improving Breast Health Care through Resource-Stratified Phased Implementation

Quality Assurance in Treatment Essential Monitoring and Evaluation

Robert Mansel, MD
Cardiff University (United Kingdom)

BHGIatFredHutch BreastHealthGlobalInitiative

FRED HUTCH CURES START HERE® susan g. komen® BREAST CANCER INITIATIVE 2.5 NCCN National Comprehensive Cancer Network®

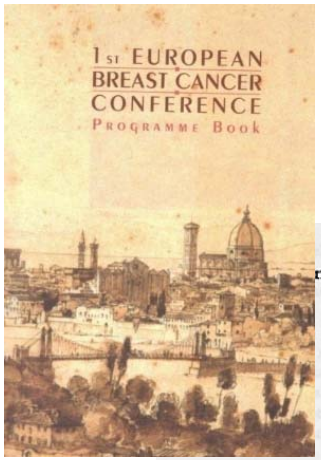
ECIBC

the EUROPEAN COMMISSION INITIATIVE on BREAST CANCER

Prof ROBERT MANSEL
Chair QASDG

3 sections to this talk

- Benefits of multidisciplinary working
- The Eusoma system – an example of an accreditation scheme
- The ECIBC scheme – the pan European project



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Position Paper

Florence Statement on Breast Cancer, 1998 Forging the Way Ahead for More Research on and Better Care in Breast Cancer

L. Cataliotti,[1] A. Costa,[2] P.A. Daly,[3] L. Fallowfield,[4] G. Freilich,[5] L. Holmberg,[6] M. Piccart,[7] C.J.H. van de Velde[8] and U. Veronesi[2]

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STUDY ON SPECIALIST CARE (MDT)- Scotland

- 13,722 women with breast cancer
- 1 health Board with specialist care compared with general surgery care

- After introduction of MDT/specialist care in 1995 specific breast cancer mortality fell by 18%

Kesson et al BMJ May 2012

HOSPITAL VOLUME IN BELGIUM

- Cancer registry study using 11 process quality indicators
- 25,000 BC pts between 2004-6
- Hospitals graded v.low (<50), low (50-99), med (100-149) and high (≥150)
- 5 year survivals were 75%,79%,80%,83%
- Hazard Ratio for death was 1.42 in very low.
- Vrijens et al Breast 2012,21:261

The EUSOMA scheme

QUALITY CONTROL

EUSOMA
European Society of Breast Cancer Specialists

European Journal of Cancer (2013) 49, 3579–3587

Available at www.sciencedirect.com

ScienceDirect

journal homepage: www.ejcancer.com

ELSEVIER

EJC

The requirements of a specialist Breast Centre

A.R.M. Wilson [a,*], L. Marotti [b], S. Bianchi [c], L. Biganzoli [d], S. Claassen [e], T. Decker [f], A. Frigerio [g], A. Goldhirsch [h], E.G. Gustafsson [i], R.E. Mansel [j], R. Orecchia [k], A. Ponti [g], P. Poortmans [l], P. Regitnig [m], M. Rosselli Del Turco [n], E.J.Th. Rutgers [o], C. van Asperen [p], C.A. Wells [q], Y. Wengström [i], L. Cataliotti [r]

EUROPEAN JOURNAL OF CANCER 46 (2010) 2344–2356

available at www.sciencedirect.com

ScienceDirect

ELSEVIER

EJC

Updated paper in 2017

Position Paper

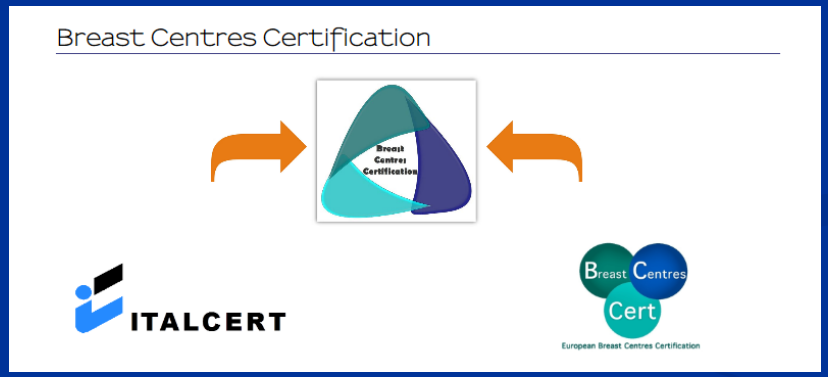
Quality indicators in breast cancer care

M. Rosselli Del Turco [a,], A. Ponti [b], U. Bick [c], L. Biganzoli [d], G. Cserni [e], B. Cutuli [f], T. Decker [g], M. Dietel [c], O. Gentilini [h], T. Kuehn [k], M.P. Mano [j], P. Mantellini [i], L. Marotti [a], P. Poortmans [l], F. Rank [m], H. Roe [n], E. Scaffidi [h], J.A. van der Hage [o], G. Viale [p], C. Wells [q], M. Welnicka-Jaskiewicz [r], Y. Wengstöm [s], L. Cataliotti [t]*

Summary Table of Quality Indicators in Breast Cancer Care

	Indicator	Level of evidence	Mandatory/ Recomm.	Minimum standard	Target
1.	Completeness of clinical and imaging diagnostic work-up (Proportion of women with breast cancer who pre-operatively underwent mammography, ultrasound and physical examination)	III	M	90%	95%
3.	Proportion of women with breast cancer (invasive or in situ) who had a pre-operative definitive diagnosis (B5 or C5)	III	M	80%	90%
4b	Proportion of invasive cancer cases with primary surgery, for which the following prognostic/predictive parameters have been recorded: histological type, grading, ER & PR, HER 2, pathological stage (T and N), size in mm for the invasive component, peritumoral vascular invasion, distance to nearest radial margin	II	M	95%	98%
Surgery and loco-regional treatment 8.	Multidisciplinary discussion (proportion of cancer patients to be dicussed)	IV	M	90%	99%
9. c	Proportion of patients (invasive cancers) and a clinically negative axilla (+US ±FNA/CNB) who had sentinel lymph-node biopsy	II	M	90%	95%
9d	Proportion of patients with invasive cancer and axillary clearance performed with at least 10 lymph nodes examined	III	M	95%	98%

Italcert in partnership with BCCCert has developed a certification scheme in compliance with EUSOMA requirements



www.breastcentrescertification.com

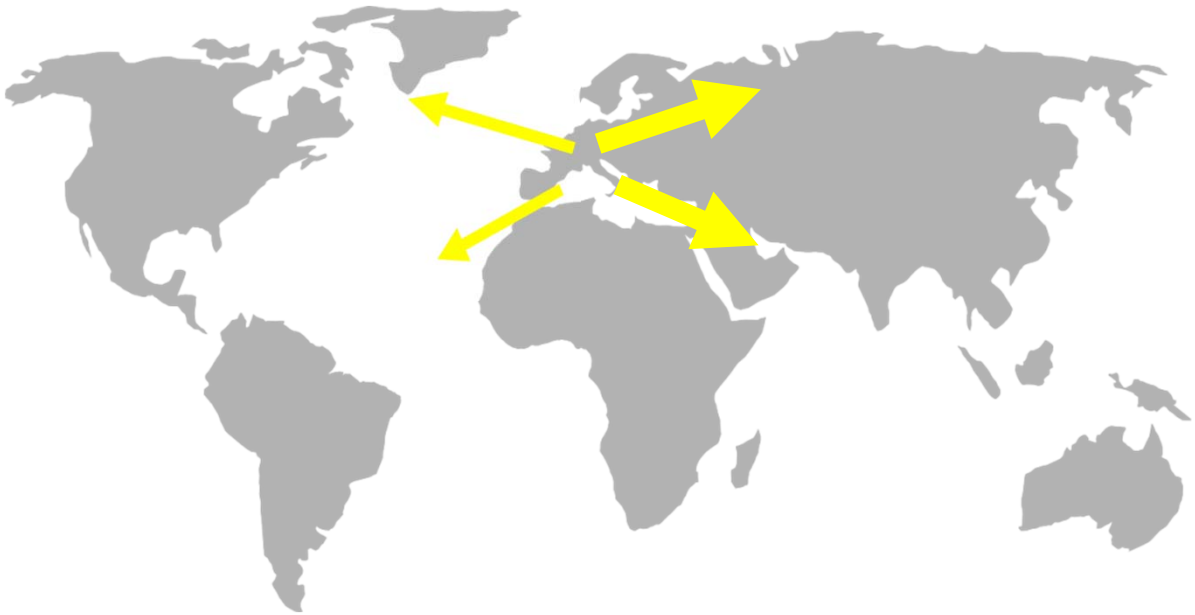
EUSOMA Network web data system

Quality indicators 2003-2012 in certified Units

EUSOMA database – 48 units – 43256 invasive cancers

1	Cancers with a pre-operative diagnosis (B5 or C5)	32438 / 38989	=	83.2%	✗	1523 miss. (3.8%)	32438	1523	6551
2	Invasive ca with hist.type, grading, ER/PR, stage & size recorded	33085 / 35794	=	92.4%	✗	0 miss.	33085		2709
3	Non-invasive ca with size, hist.pattern & grading recorded	3778 / 4794	=	78.8%	✗	0 miss.	3778		1016
4	Invasive ca with axillary clearance with >= 10 LNs examined	13119 / 14922	=	87.9%	✗	613 miss. (3.9%)	13119	613	1803
5	M0 invasive ca receiving postoperative RT after BCT	19609 / 20721	=	94.6%	✗	2612 miss. (11.2%)	19609	2612	1112
6	Invasive ca <= 3 cm (incl. DCIS component) treated with BCT	19612 / 24502	=	80%	✓	743 miss. (2.9%)	19612	743	4890
7	Non-invasive ca <= 2 cm treated with BCT	2245 / 2668	=	84.1%	✓	151 miss. (5.4%)	2245	151	423
8	DCIS with no axillary clearance	4030 / 4308	=	93.5%	✗	27 miss. (0.6%)	4030	27	278
9	Endocrine sensitive invasive ca receiving HT	22994 / 24324	=	94.5%	✓	6481 miss. (21%)	22994	6481	1330
10	ER- (T > 1 cm or N+) invasive ca receiving adjuvant CT	3670 / 4035	=	91%	✓	500 miss. (11%)	3670	500	365
11	Invasive ca receiving just 1 operation (excl. reconstruction)	28518 / 35521	=	80.3%	✗	55 miss. (0.2%)	28518	55	7003
12	DCIS receiving just 1 operation (excl. reconstruction)	2775 / 4455	=	62.3%	✗	3 miss. (0.1%)	2775	3	1680
13	Invasive ca pN0 not receiving axillary clearance (SLN only)	16439 / 21549	=	76.3%	✗	7 miss. (0%)	16439	7	5110

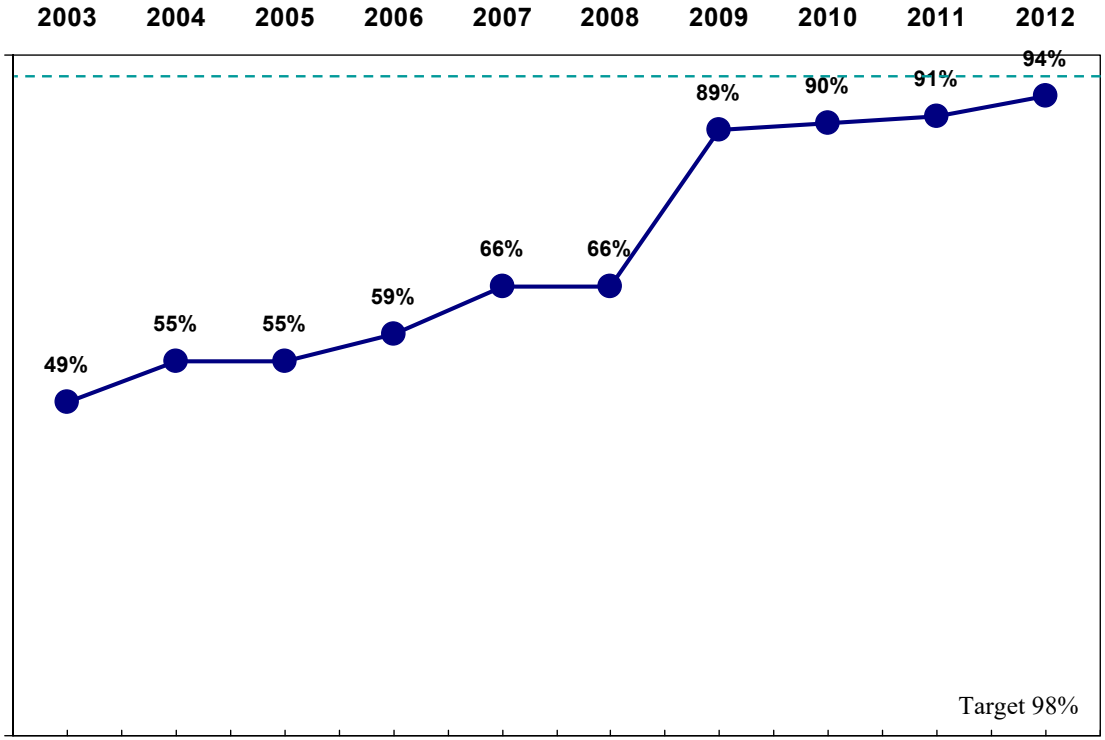
BREAST CERTIFICATION COVERS EUROPE AND NOW EXTENDING TO CHINA AND INDIA



GUILIN AUDIT TEAM 2018

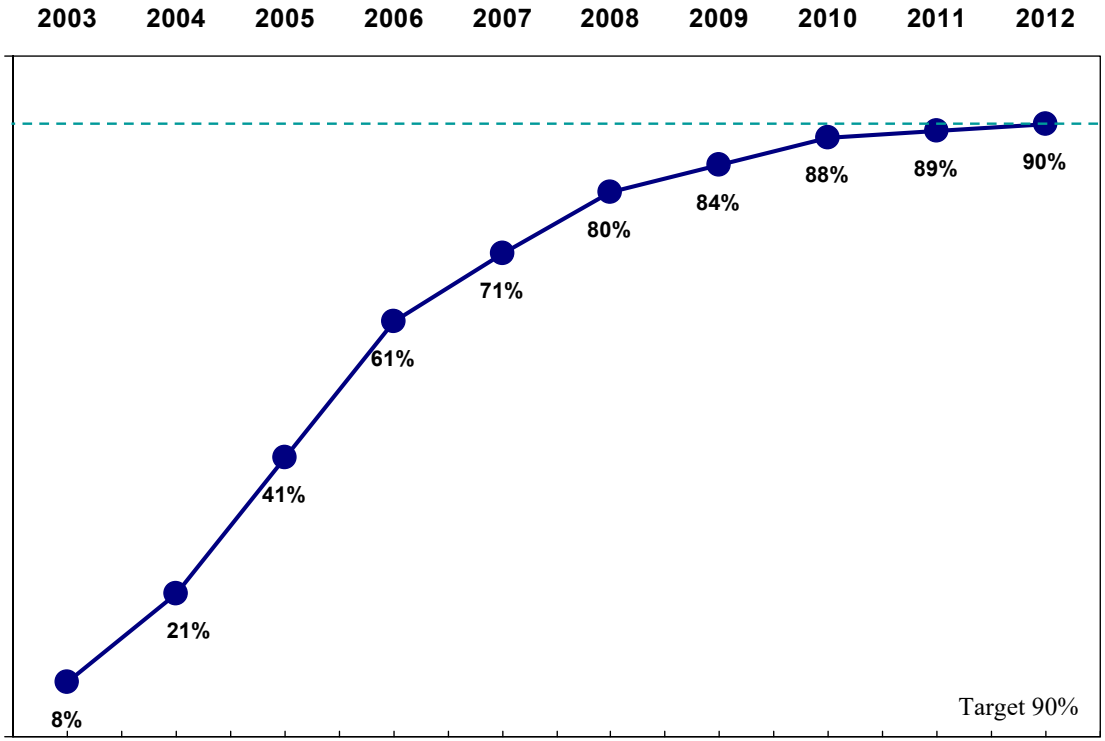
EUSOMA Network web data system

3 – DCIS with main histopathology parameters recorded

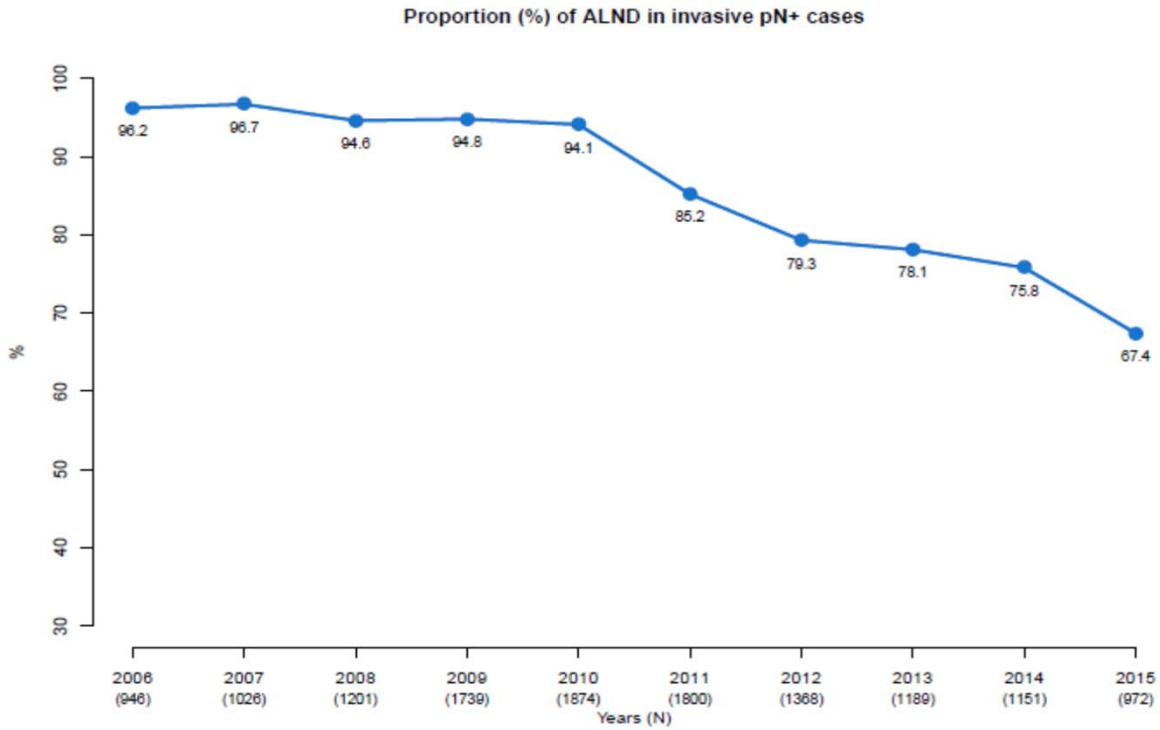


EUSOMA Network web data system

13 - SLN only in pN0



THE Z - 11 EFFECT



Comparison of Eusoma indicators before vs after Certification 2006-2012

Indicator	N	Before %	N	After%	Or	P-value
Cancers with a pre-operative diagnosis (B5 or C5)	7571	85.5	22873	86.4	1.08	0.041
Invasive or MI ca with hist. type, grading, ER/PR, stage & size recorded	6677	91.4	20207	94.8	1.69	<0.001
M0 invasive ca receiving post operative RT after BCT	4376	93.9	13249	94.8	1.17	0.045
DCIS with no axillary clearance	811	93.1	2391	95.8	1.68	0.003
Invasive or MI ca pN0 staged by SLN only	3968	78.6	12222	83.5	1.38	<0.001

Van Dam P et al, EJSO 2015

ECIBC

the EUROPEAN COMMISSION INITIATIVE on BREAST CANCER

EUROPEAN ACTION BASED ON PARLIAMENTARY RESOLUTIONS

- European Commission via JRC (joint research centre based in Ispra, Italy - part of the public health division of the EC –DG Sante) has commissioned a 4yr programme to update European Breast Guidelines and produce an accreditation plan to be used across all European Breast Centres according to European Parliament resolutions

- Large investment of around 8 million Euros for the project

Info at JRC Science hub https://ec.europa.eu/jrc/en/research-topic/healthcare-quality

Nomination of GDG (guidelines) and QASDG (Accreditation) groups

The EC was in 2014 requested to create the working groups based on a public call for experts (open from 24 October to 11 December 2014) – nominations completed in July 2015 (validity, eligibility, competence, independence)

Quality Assurance Scheme Development Group (QASDG)

63 applications:
- Professionals
- Individuals

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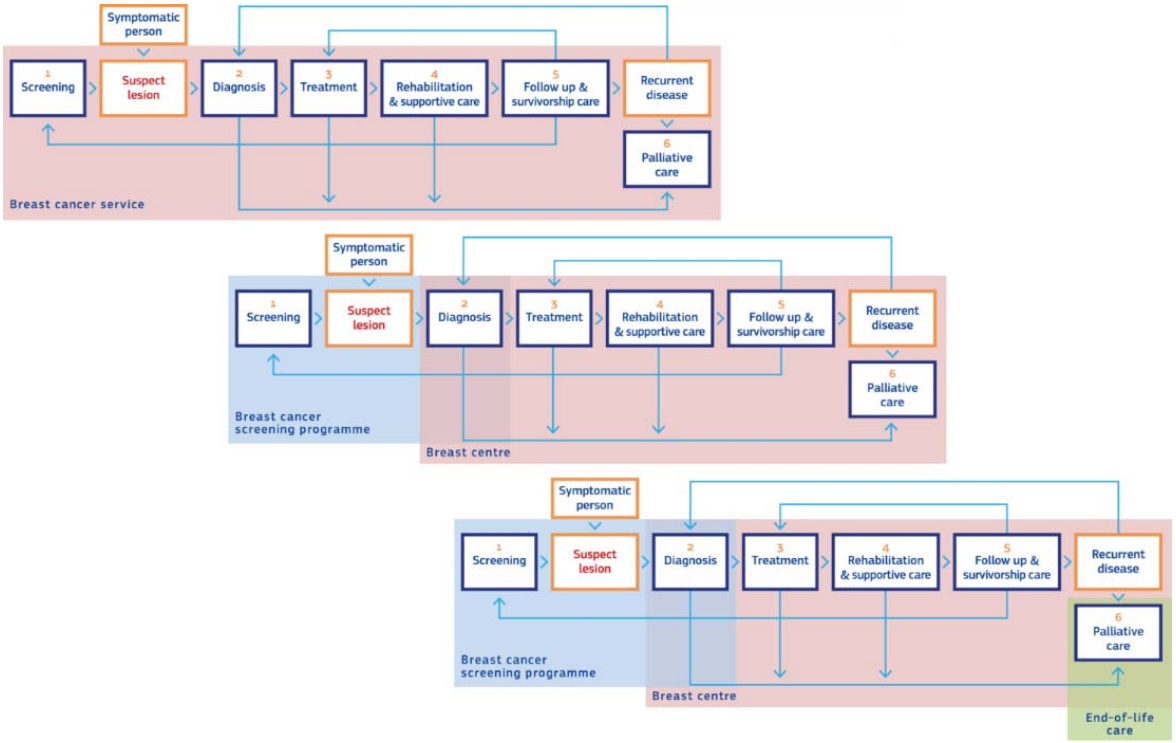
European Commission

European Commission Initiative on Breast Cancer (ECIBC)

A modular approach for European breast cancer services



European Commission

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Working modality

- Agreed rules of procedure
- Physical meetings at JRC premises and online collaboration

- Explicit and transparent approach to define requirements for breast cancer services (Delphi rounds)
- GRADE approach and trustworthy guidelines for clinical recommendations
- Call for feedback on key documents (scope & PICOs)

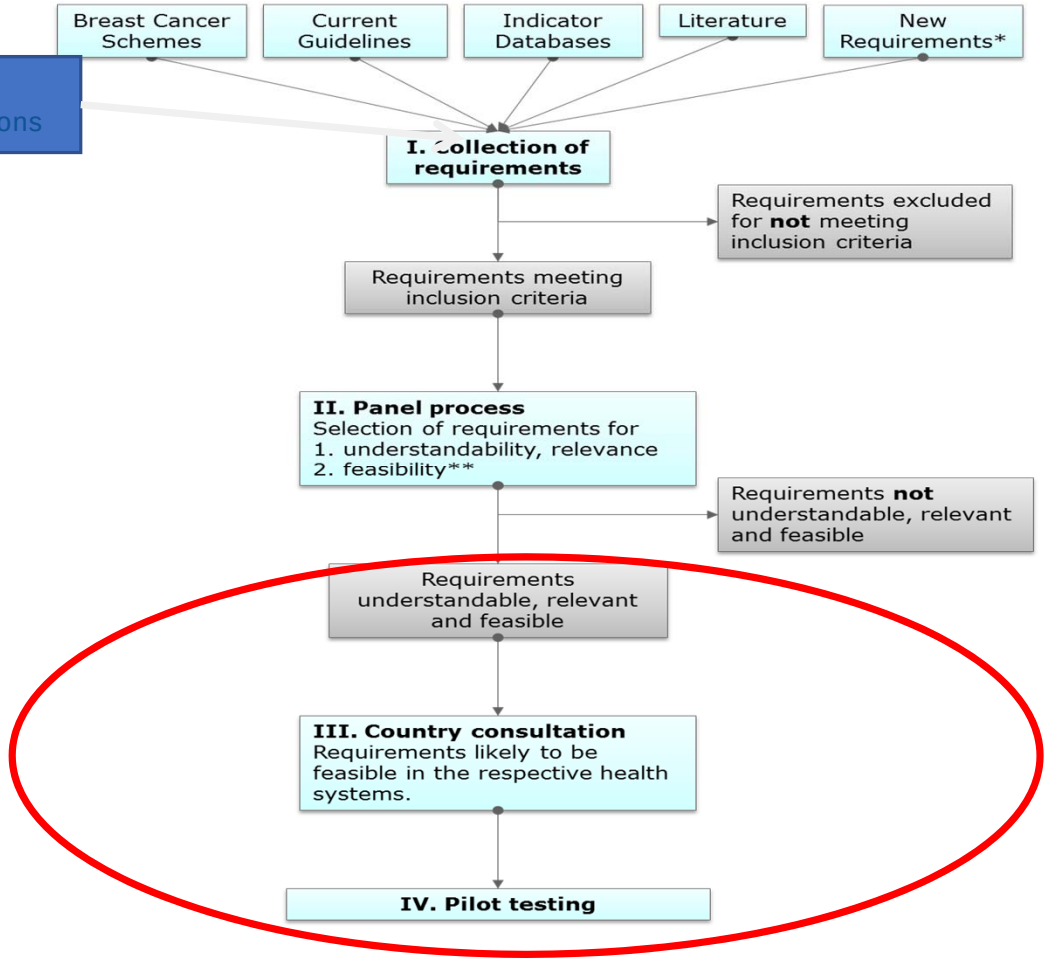
European Commission | CIRCABC

GRADE

EUSurvey

European Commission

Method: identifying requirements and Indicators



PATIENT EMPOWERMENT IN THE QASDG PROCESS

4 patients /advocates full members of the committee (all very experienced in the field of advocacy)

Full voting rights on all issues including clinical matters

Open debate with full participation of the patients/advocates

Transparency in all issues with all conflicts openly declared on each topic being debated

Delphi process to allow balancing of differing views

All subgroup work open to patients/advocates who choose which groups they wish to join.

European Commission

ECIBC QUALITY INDICATORS (1)

GEN13_MDT	The breast center must hold at least weekly a multidisciplinary case management meeting to discuss all patients prior to treatment (including patients with metastatic disease) and also post-operatively and at change of treatment
Rationale	Multidisciplinary teams are assumed to optimize decision making in diagnosis, treatment and support of patients. All women with breast cancer visiting the breast center should be discussed in the multidisciplinary team.
Numerator	Number of women with breast cancer discussed by the multidisciplinary team prior to treatment (including patients with metastatic disease), post-operatively and at change of treatment
Denominator	Total number of women with breast cancer treated in the breast center
Inclusion	All women with breast cancer visiting the breast center
Exclusion	Not applicable
Norm	≥90% (to be decided by QASDG)
Reference to norm	• ≥90% of all breast cancer cases should be discussed pre- and/or post treatment in multidisciplinary team (NABON 2016) • ≥95% of patients discussed at the multidisciplinary team before definitive treatment (NHS Scotland 2016)
Evidence for recommendation	Recommendation : Conditional/provisional Evidence : Low to very low quality (Risk of bias and imprecision)
Data source	Protocols, agendas and minutes of multidisciplinary meeting are available. Breast center provides document explaining what strategies have been implemented to assure that each patient is discussed at the appropriate time. To be checked in audit.
Guideline recommendations	IberoAmerican Cochrane Centre (Martinez 2016) We suggest that women with breast cancer are discussed in multidisciplinary meetings *(provisional and conditional recommendation)* Five observational studies. Significant effects reported in favor of MDT for 5 year breast cancer mortality (RR 0.82, 95%CI 0.73 to 0.91), 5 year mortality (HR 0.83, 95%CI 0.78 to 0.89) and breast cancer specific 5 year survival (RR 1.04, 95%CI 1.02 to 1.07). Significantly more women satisfied with MDT than in the non-MDT group (RR 1.28,

Indicator examples

Patients operated on in a defined time between Diagnosis and Surgery

All patients undergoing surgery

Addresses patient concerns about timeliness

Clinicial node negative patients undergoing surgery having sentinel node biopsy

All clinical node negative patients undergoing surgery

Addresses overtreatment

Implementation of the accreditation programme

EC has no mandate for implementation of health policies-these are sole remit of each member country, but DG Sante (the European Commission Health Department) is able to recommend health improvement and equality of healthcare but cannot enforce any changes.

The ECIBC plan is due to be launched in 2019 and the implementation is the responsibility of each country and is a voluntary process.

Using a common set of quality indicators and process monitoring should allow identification of problems in breast units and allow for the introduction of improvement plans.

Current problematic areas are the added costs of implementing accreditation and the issue of “ownership” and the legal basis of accreditation.

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European Commission

PROBLEMS OF ACCREDITATION

"Healthcare systems based on reimbursement find the effective implementation of MDM more challenging

MDM structure has enormous potential to harmonise and improve cancer care through better documentation,staging,audit of outcomes and clinical research."

(Gina Brown BMJ Editorial 2012;344:e2780)

Currently the 2 biggest problems will be correct MDT working and accuracy of databases.

Timeline for QASDG requirement development

CONCLUSIONS

Large input from patients/advocates in the ECIBC process

This balances the effects of the “expert” opinion

These inputs should increase the acceptability of the accreditation programme for users and stakeholders.

Quality indicators relevant and feasible

The key is multidisciplinary working (but it is not cheap!)

European Commission

Thank you and keep in touch!

ecibc.jrc.ec.europa.eu

European Commission Initiative on Breast Cancer

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