



THE ECIBC – OVERVIEW OF ISO STANDARDS AND QA SCHEMES IN EUROPE FOR BREAST CANCER CARE

Joint Research Centre

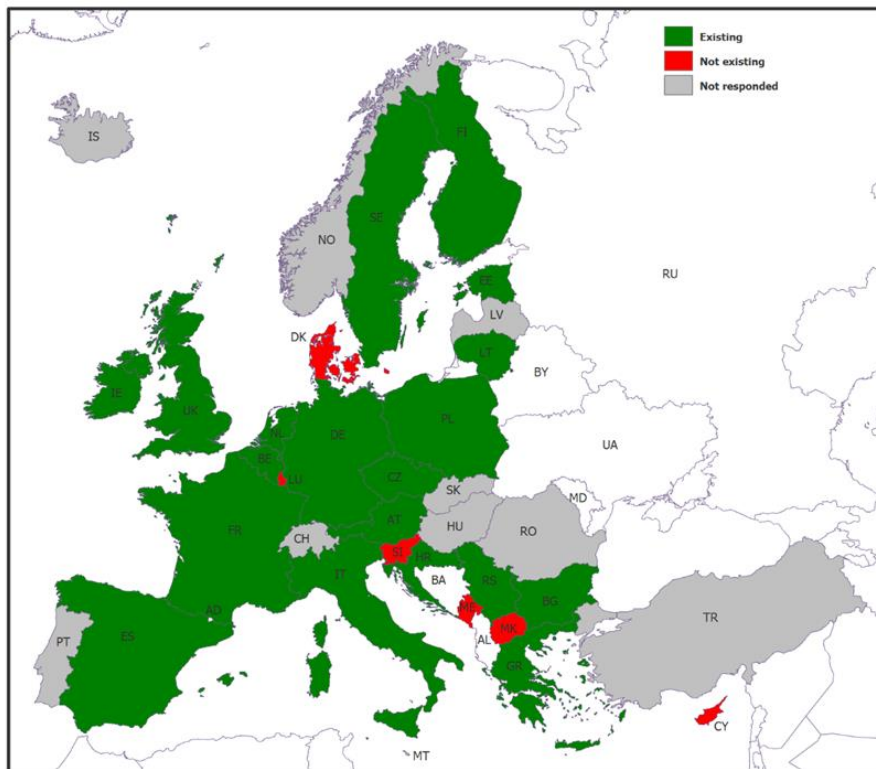
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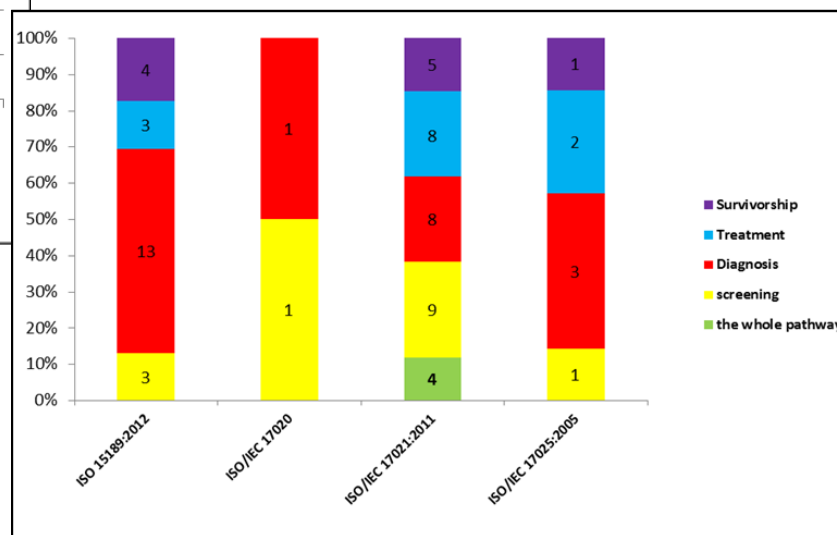
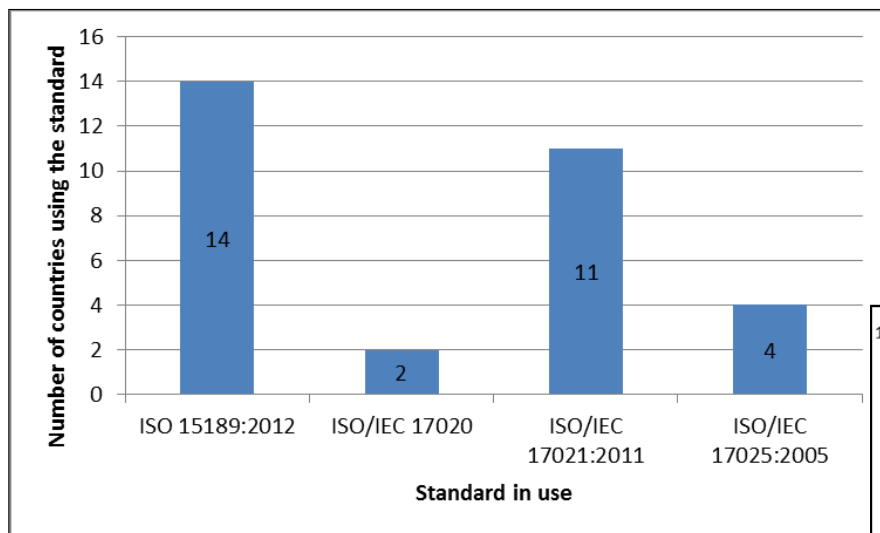
Report of a survey on accreditation and conformity assessment in the field of breast cancer in Europe - 1

- To understand the wide picture of accreditation and conformity assessment in the field of breast cancer care across Europe
- To include the experiences already built in the use of standards in setting-up of

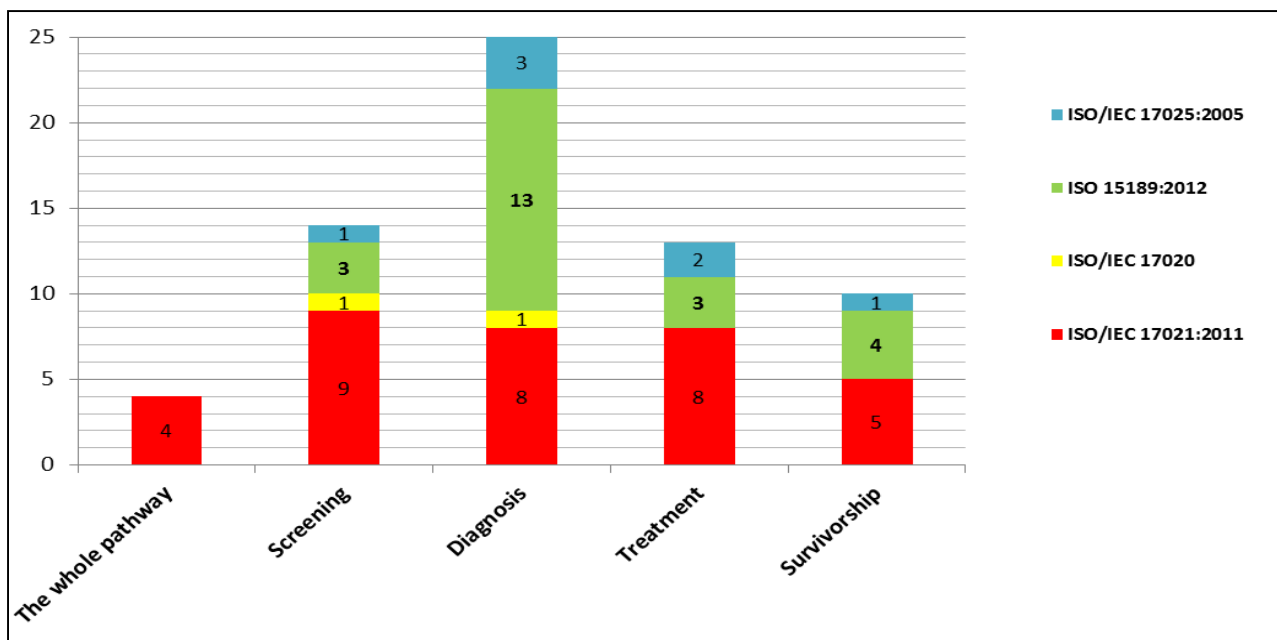


- ISO 15189:2012
- ISO/IEC 17020:2012
- ISO/IEC 17021:2011
- ISO/IEC 17025:2005

Report of a survey on accreditation and conformity assessment in the field of breast cancer in Europe - 2



Report of a survey on accreditation and conformity assessment in the field of breast cancer in Europe - 2



Report of a survey on accreditation and conformity assessment in the field of breast cancer in Europe – 3

Conclusions:

- ISO standards are in place in healthcare
- Need for enhancement and unification of quality assurance in breast cancer care services throughout Europe
- ISO 15189:2012 and ISO/IEC 17021:2011 were the most used standards
- Diagnosis was most widely addressed

ISO STANDARDS PROPOSED FOR THE EUROPEAN QA SCHEME:

ISO 15189:2012 for testing

ISO 17065:2012 for service certification

Review and analysis of external quality assessment of breast cancer services in Europe - METHODOLOGY

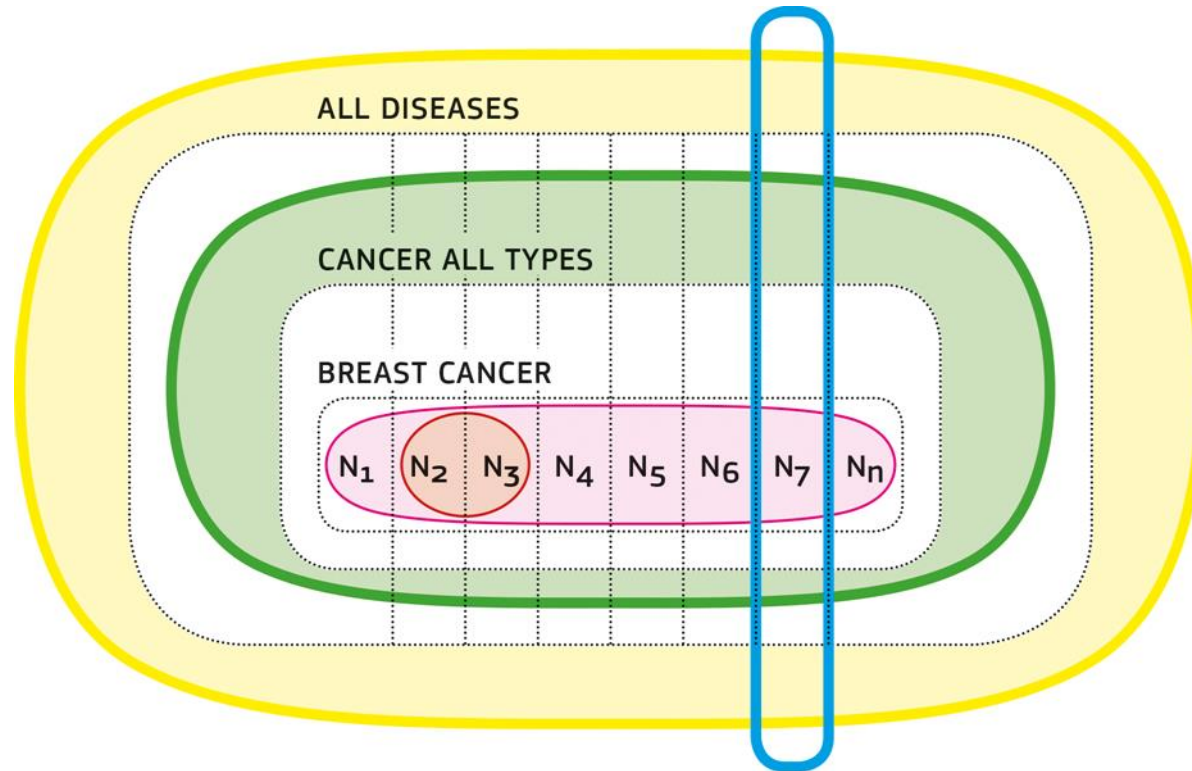
Sources

Pubmed, Google, JRC 2012 Survey, JRC 2013 Workshops, bilaterals, conferences, ISQua website, previous reviews on the topic

Inclusion criteria for breast cancer schemes

- fully implemented
- with evidence of current activity
- with at least one centre in Europe currently holding the certificate awarded by that organisation
- foreseeing a third-party audit / on-site survey
- [with at least basic information, such as name of the programme, name of the organisation and scope, available in one of languages mastered by the reviewers at B2 level or more (i.e. English, Italian, Spanish, French, Greek, Romanian, Turkish)]

CONCEPTUAL MODEL OF BREAST CANCER QUALITY ASSESSMENT



List of entities providing quality schemes in Europe

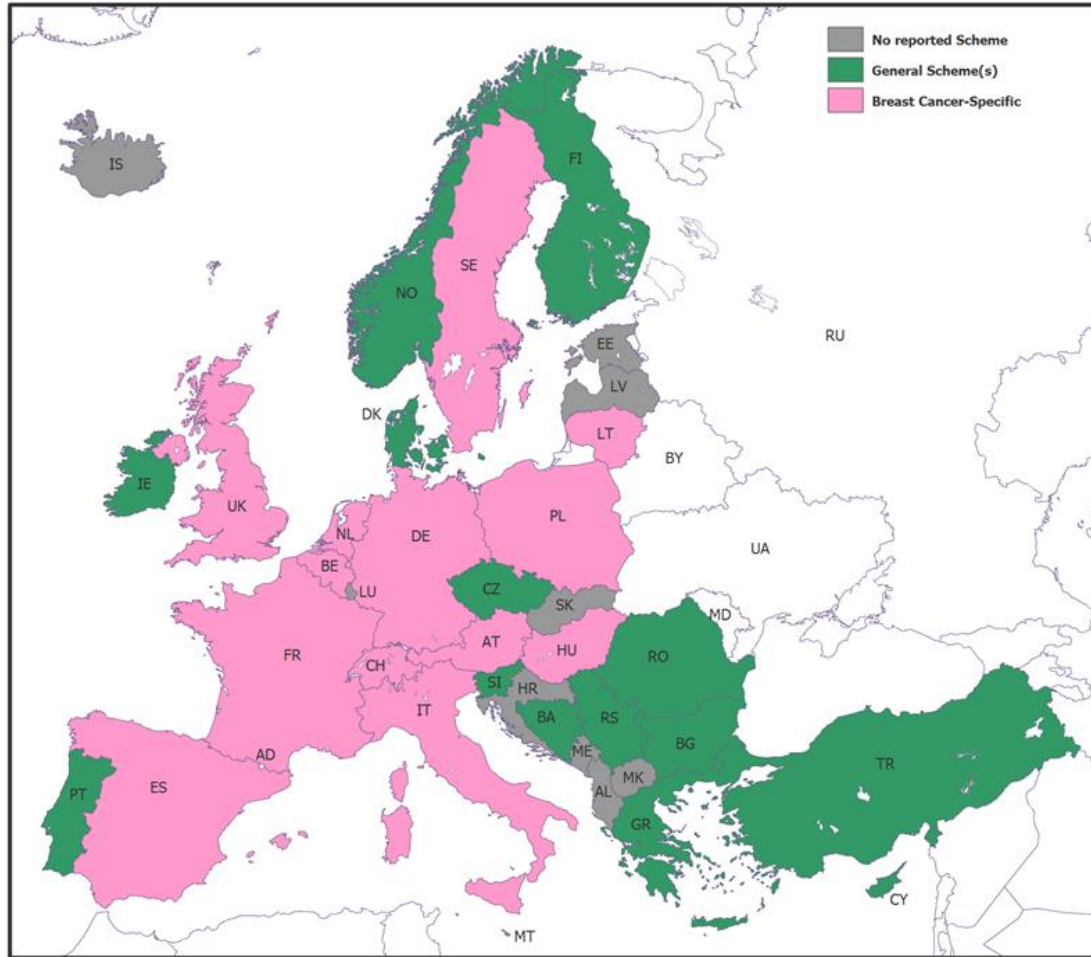
Unregulated, voluntary schemes

- Generic; N= **22**
- Cancer-specific; N= **6**
- **Breast cancer-specific**; N= **17** – meeting the Report's eligibility criteria N= **9**

Supervisory organisations and regulatory bodies

E.g. Institute for Quality and Accreditation in Healthcare (DK), French National Authority for Health (FR), Netherlands Institute for Accreditation in Health Care (NL), etc.

Europe's map of quality schemes



BREAST cancer quality schemes in Europe – info available – updated March 2015

PROGRAMME NAME	ENTITY	COUNTRIES	NR OF CENTRES AWARDED	TYPE
International Accreditation Program for Breast Centres/Units	Senologic International Society / International School of Senology	FR, PL, LT	4	Private
Breast Centres Certification Label de qualité	Anticancer Swiss League / Senology Swiss Society	CH	15	Private
Mammography screening certification Zertifizierung nach § 22 Krebsfrüherkennungs-Richtlinie	Kooperationsgemeinschaft Mammographie GbR	DE	94	Public
Certification system for breast cancer centers from the German Cancer Society and German Society for Breast Diseases	German Cancer Society / German Society for Breast Diseases	DE, CH, IT, AT	277	Private
Breast Centres Certification	European Cancer Care Certification / European Society of Breast Cancer Specialists	BE, IT, CH, NL	15	Private
National protocol of accreditation of breast cancer units	Senology and Breast Pathology Spanish Society	ES	24	Private
Quality Assurance in National Health Service Breast Screening Programme	National Health Service National Breast Screening Programme	UK	80	Public
Voluntary certification of high quality diagnostic breast imaging and breast screening services	European Reference Organisation for Quality Assured Breast Screening and Diagnostic Services	CH	3	Private
National Cancer Peer Review Programme	National Cancer Action Team	UK	152 peer reviewed in 2012-2013	Public

Breast cancer quality schemes - topics



Conclusions: implications for ECIBC and the *European QA scheme*

- Several schemes already running in Europe → hundreds of requirements and technical documents used and potentially relevant for the *European QA scheme*
- Lack of harmonisation and likelihood of inconsistent practices in place
- Several ISO standards already in use, especially for diagnostics
- Potential for the *European QA scheme* to get to a uniform level of service provision for breast cancer care through a healthcare-targeted use of ISO 15189 and ISO 17065