

ECIBC

the **EUROPEAN COMMISSION INITIATIVE**

on BREAST CANCER

The
Quality Assurance
Scheme

ONS GISMa

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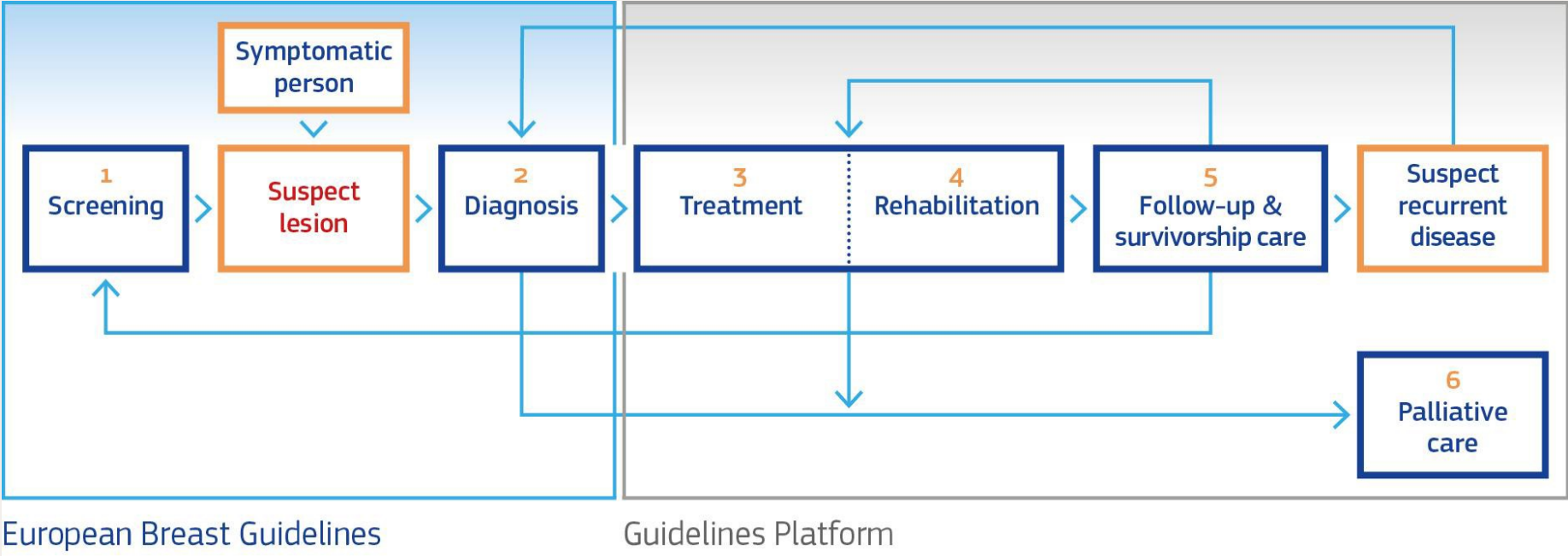


The *European QA scheme* is a collection of requirements, indicators and protocols

The application of the *European QA scheme* is not mandatory by law.

It covers the full extent of breast cancer management: from screening to treatment to palliative care.

Services, interventions, diseases, and care processes covered



Quality Assurance Scheme Development Group

Italian experts (included P Poletti)



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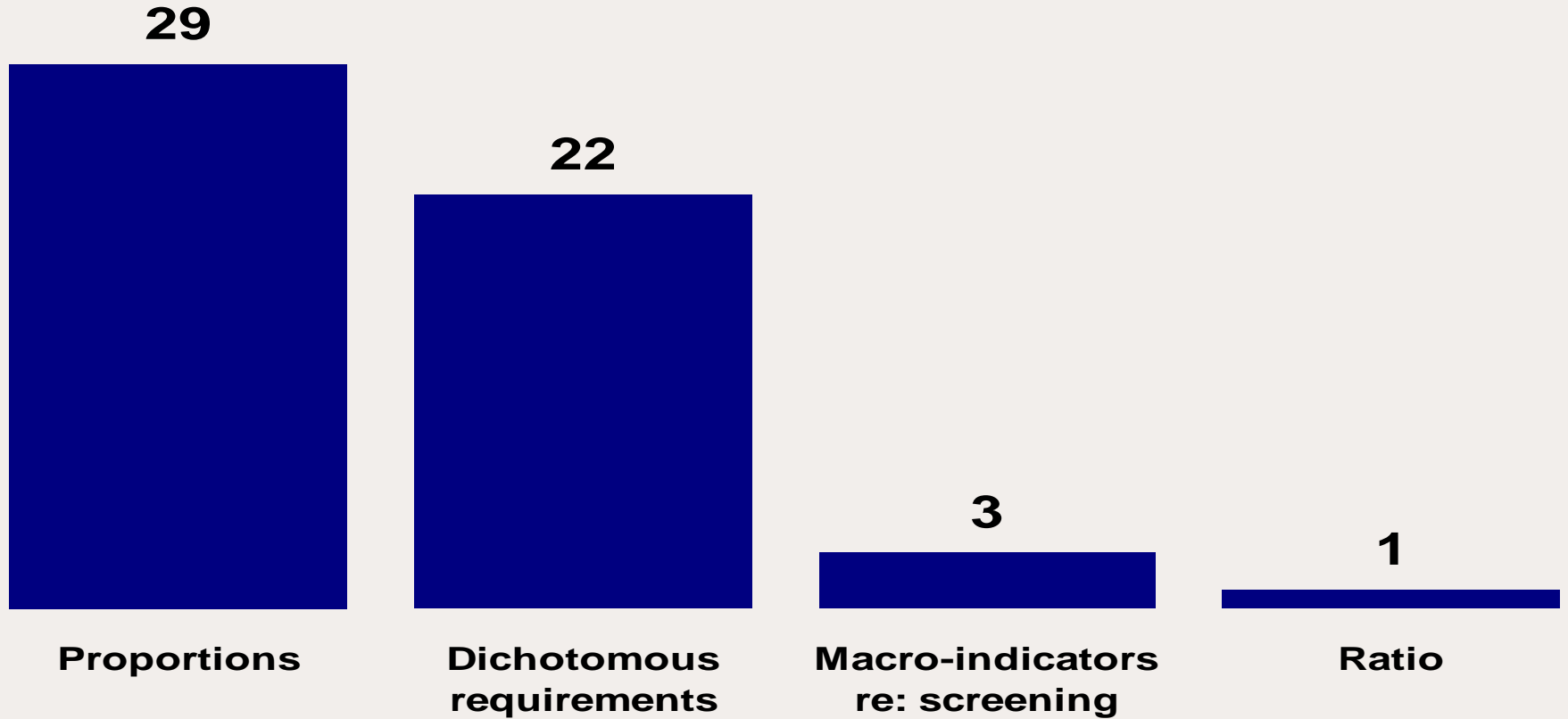
Important terms

1. QA scheme
2. Scheme owner
3. Breast cancer services
4. Audit
5. Certification
6. Accredited certification (or conformity assessment) bodies
7. National accreditation bodies

Indicators and protocols

The European Breast QA scheme assesses whether requirements are being met by using qualitative and quantitative indicators and site visits

55 QASDG indicators



Lists of indicators

WORK IN PROGRESS – NOT FOR CITING

Example of one quantitative indicator

9a Definition: Proportion of patients (invasive cancer only) who received a single (breast) operation for the primary tumour (excluding reconstruction).

Minimum standard: 80%

Target: 90%

Example of dichotomous qualitative indicators

- ✓ **The Breast Cancer screening centre must have a written policy for counseling about nutrition and physical activity for women attending screening**

- ✓ **The Breast Centre must have a written policy for counseling about nutrition and physical activity for breast cancer survivors**

Examples of QA screening indicators

- ✓ The Breast screening programme must comply with European Guidelines ...
- ✓ Early recalls
- ✓ Time intervals

Quality indicators calculator (QIC)

JRC IT team will develop the QIC, based on the technical documentation (list of variables, algorithms, quality checks)

29 indicators (proportions) will be included

Demo QIC ready

Quality indicators calculator - demo

1) loads the test data set (.csv)



European Breast QA Scheme

..... Small description

Load CSV...

Build Indicators

Export indicators

| | Patient ID | Sex | Date incidence | Age | Basis diagnosis | Topography | Morphology behavior | Behaviour | Grade | Laterality | Multiple sequence | Total tumors | T |
|---|------------|-----|----------------|-----|-----------------|------------|---------------------|-----------|-------|------------|-------------------|--------------|---|
| ▶ | 9120110279 | 2 | 19.01.2011 r. | 59 | 7 | C500 | 85003 | 3 | 3 | 2 | 1 | 1 | 9 |
| | 9120092009 | 2 | 27.04.2009 r. | 72 | 7 | C500 | 82603 | 3 | 2 | 2 | 1 | 1 | 9 |
| | 9120095461 | 2 | 01.11.2009 r. | 58 | 7 | C504 | 85003 | 3 | 2 | 1 | 1 | 1 | 9 |
| | 9120114194 | 2 | 06.10.2011 r. | 69 | 7 | C504 | 85003 | 3 | 9 | 2 | 1 | 1 | 9 |
| | 9120093151 | 2 | 13.07.2009 r. | 60 | 7 | C505 | 85203 | 3 | 9 | 2 | 1 | 1 | 9 |
| | 9120104781 | 2 | 28.10.2010 r. | 53 | 7 | C508 | 85203 | 3 | 9 | 2 | 1 | 1 | 9 |
| | 9120090554 | 2 | 16.01.2009 r. | 47 | 7 | C504 | 85013 | 3 | 2 | 1 | 1 | 1 | 9 |
| | 9120100157 | 2 | 11.01.2010 r. | 41 | 7 | C504 | 85003 | 3 | 3 | 1 | 1 | 1 | 9 |
| | 9120100676 | 2 | 25.02.2010 r. | 74 | 7 | C504 | 85003 | 3 | 2 | 1 | 1 | 1 | 9 |
| | 9120101824 | 2 | 24.06.2010 r. | 64 | 7 | C508 | 85203 | 3 | 3 | 2 | 1 | 1 | 9 |
| | 9120094103 | 2 | 02.11.2009 r. | 45 | 7 | C508 | 85003 | 3 | 2 | 1 | 1 | 1 | 9 |
| | 9120104946 | 2 | 03.12.2010 r. | 69 | 7 | C508 | 85223 | 3 | 2 | 1 | 1 | 1 | 9 |
| | 9120102844 | 2 | 21.09.2010 r. | 56 | 7 | C508 | 85223 | 3 | 2 | 2 | 1 | 1 | 9 |
| | 9120094778 | 2 | 03.12.2009 r. | 60 | 7 | C504 | 85203 | 3 | 9 | 2 | 1 | 1 | 9 |

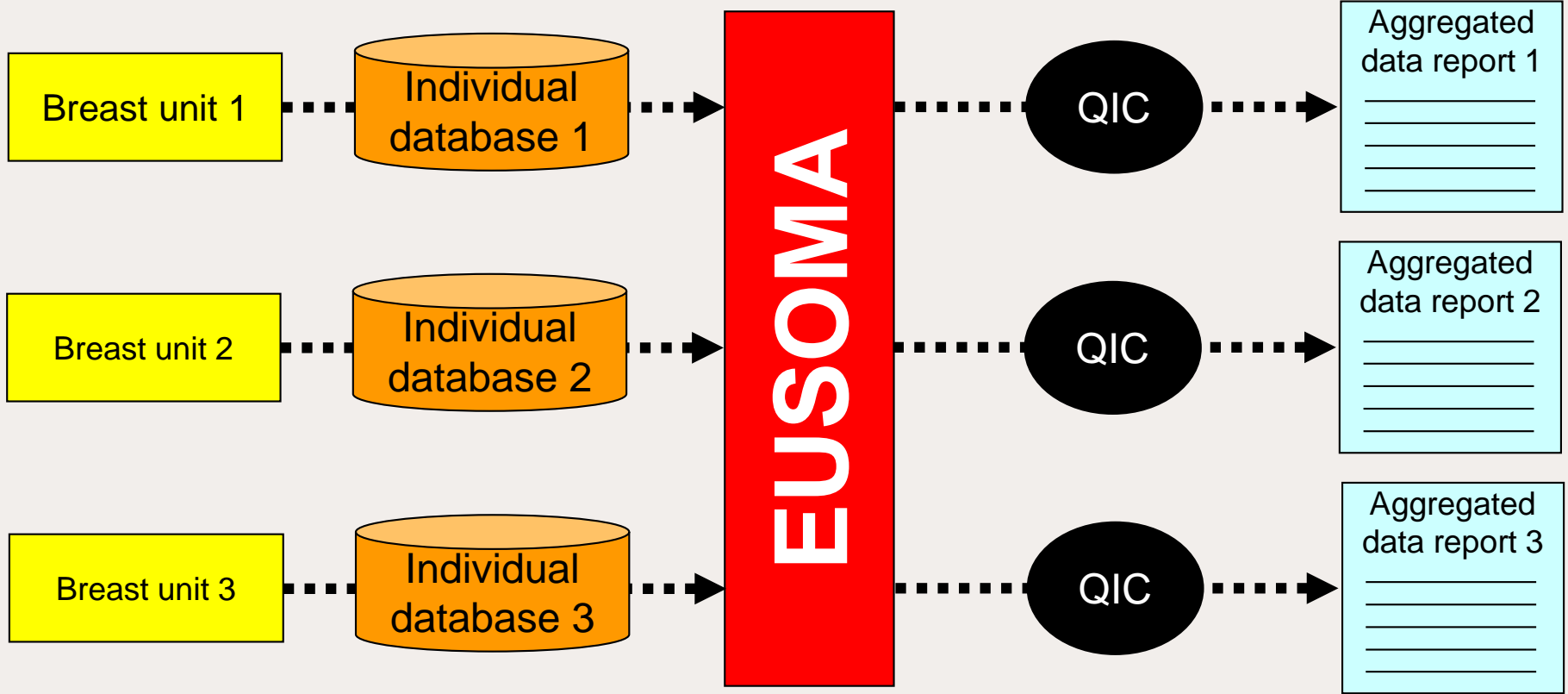
2) computes the indicators following the predefined algorithms



| | Code | Title | Type | Process | Numerator | Denominator | Value | Eligible | Missing |
|---|----------------------|---|---------|-----------|-----------|-------------|-------|----------|---------|
| ▶ | RAD10_Invasive_Mast | Proportion of women with invasive M0 breast cancer with ≥ 4 lymph nodes involved who underwent local regional radiother... | Process | Treatment | 134 | 187 | 71,7 | 187 | 0 |
| | RAD9_Invasive_BCS | Proportion of women with M0 invasive breast cancer treated with breast conserving therapy who underwent whole breast ra... | Process | Treatment | 412 | 488 | 84,4 | 488 | 0 |
| | SYST1_Chemo_Leadtime | Lead time between last surgery and first adjuvant chemotherapy cycle in women with invasive M0 breast cancer must be no... | Process | Treatment | 274 | 396 | 69,2 | 396 | 0 |
| | SYST3_Chemo_ER- | The proportion of surgically treated women with ER- (T > 1 cm or Node+) invasive M0 breast cancer who underwent adjuva... | Process | Treatment | 69 | 121 | 57 | 121 | 0 |
| | SYST4a_Imm_HER2+ | The proportion of women with HER2+ (N+ or T>1cm) invasive M0 breast cancer treated with surgery and chemotherapy wh... | Process | Treatment | 61 | 147 | 41,5 | 147 | 0 |
| | SYST6_Hormone | The proportion of surgically treated women with hormone sensitive (ER+ and/or PR+) invasive M0 breast cancer who were ... | Process | Treatment | 780 | 1004 | 77,7 | 1004 | 0 |

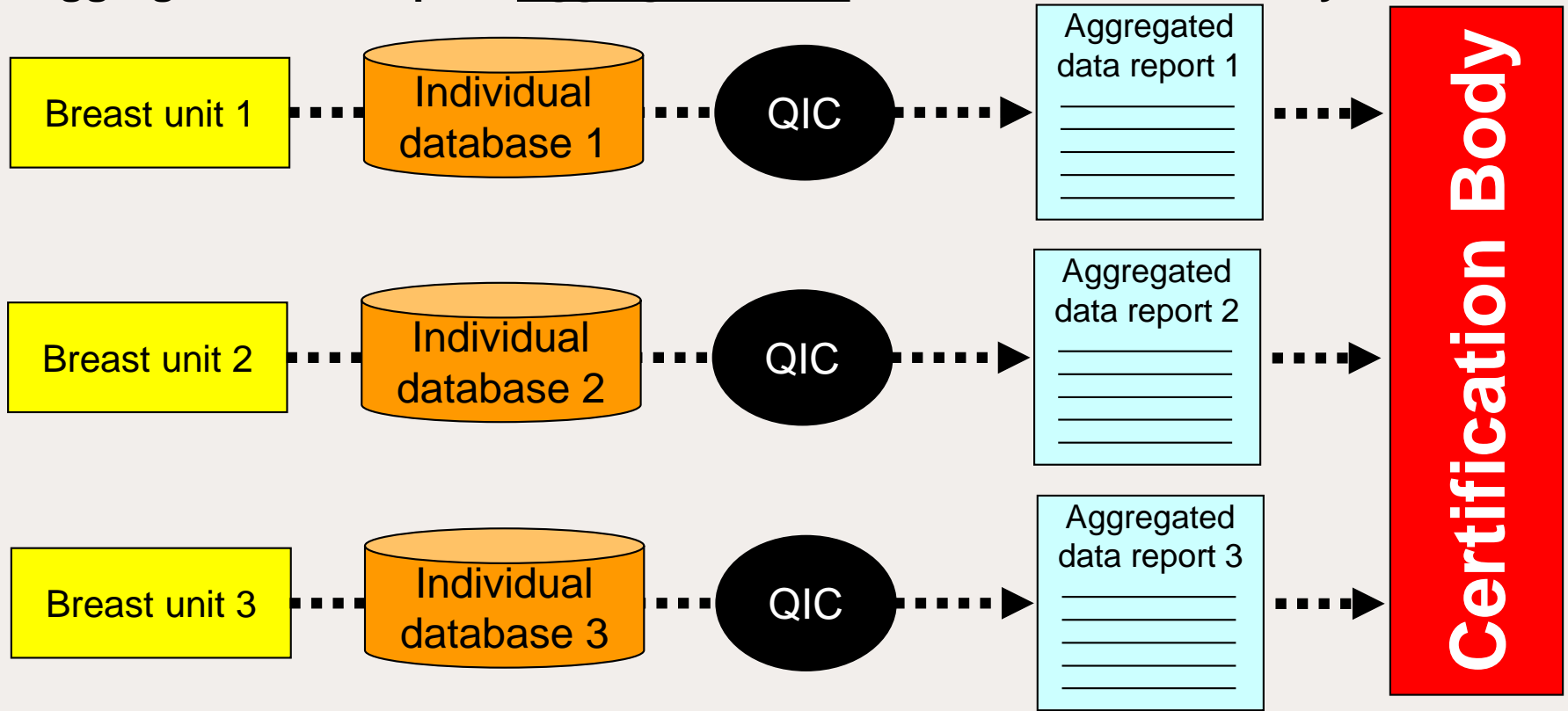
3) exports the computed indicators in an excel file

**Currently, anonymized individual data is sent to EUSOMA
EUSOMA uses a QIC to produce aggregated data report**



QIC = Quality Indicators Calculator

In the future, breast units will use the European QIC to produce aggregated data report. Aggregated data is sent to the Cert. body



QIC = Quality Indicators Calculator

QIC: Algorithms for computation

An algorithm for computation of each indicator is provided, including also how the missing values are managed when calculating indicators

Example of one indicator

9a Definition: Proportion of patients (invasive cancer only) who received a single (breast) operation for the primary tumour (excluding reconstruction).

Minimum standard: 80%

Target: 90%

Eligibility *DIAGNOSIS IN (3,4,8) AND N00=1*

Denominator *H01 IN (1,2,3)*

Numerator *H01=1*

Example of one indicator: eligibility

9a Definition: Proportion of patients (invasive cancer only) who received a single (breast) operation for the primary tumour (excluding reconstruction).

Minimum standard: 80%

Target: 90%

Eligibility

DIAGNOSIS IN (3,4,8) AND N00=1

Denominator

H01 IN (1,2,3)

Numerator

H01=1

| | | |
|-----------|---|-------------------------------|
| DIAGNOSIS | 1 | Benign |
| | 2 | In situ |
| | 3 | Microinvasive |
| | 4 | Invasive |
| | 7 | In situ (Core biopsy) |
| | 8 | In situ (Sentinel lymph node) |

| | | |
|-----|---|---------------------|
| N00 | 0 | No surgery |
| | 1 | Surgery |
| H01 | 1 | 1 intervention |
| | 2 | 2 interventions |
| | 3 | 3 interventions |
| | 9 | Unknown no. Interv. |

Example of one indicator: 2 relevant proportions

9a Definition: Proportion of patients (invasive cancer only) who received a single (breast) operation for the primary tumour (excluding reconstruction).

Minimum standard: 80%

Target: 90%

| | | | |
|-----------------|-----------------------|-----------------------|----------------|
| <i>Lesion 1</i> | <i>No eligibility</i> | | |
| <i>Lesion 2</i> | <i>Eligible</i> | <i>No denominator</i> | <i>Missing</i> |
| <i>Lesion 3</i> | | <i>Denominator</i> | <i>Failure</i> |
| <i>Lesion 4</i> | | | <i>Success</i> |

$$\frac{\text{Success}}{\text{Success} + \text{Failure}} \%$$

$$\frac{\text{Missing}}{\text{Missing} + \text{Success} + \text{Failure}} \%$$

QIC: Data quality checks

Internal consistency of the data variables in each record;

checks for duplications of records in the data file;

checks for completeness of information for all data record variables.

Next steps

- QA Manual for breast services
- QA Manual for scheme owner
- Quality indicators calculator
- Self-assessment tool
- Pilot (2020)

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