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Monitoring breast cancer care quality at national and local level using the French National Cancer Cohort

Sophie Houzard¹, Emilie Courtois¹, Christine Le Bihan Benjamin¹, Marie Erbault², Laurent Arnould³, Emmanuel Barranger⁴, Florence Coussy⁵, Benoît Couturaud⁶, Bruno Cutuli⁷, Patricia de Cremoux⁸, Pia de Reilhac⁹, Chantal de Seze¹⁰, Aude-Marie Foucaut¹¹, Anne Gompel¹², Stéphane Honoré¹³, Anne Lesur¹⁴, Carole Mathelin¹⁵, Laurent Verzaux¹⁶, Philippe-Jean Bousquet¹⁻¹⁷

1 Survey Data Science and Assessment Division, National cancer institute, 52 avenue andré Morizet, 92 100 Boulogne Billancourt, France

2 Quality and Safety Care Improvement Department, French National Authority for Health, 5 Avenue du Stade de France, 93218 Saint-Denis La Plaine CEDEX, m.erbault@has-sante.fr

3 Department of Pathology, GF Leclerc cancer centre, 1 Rue du Professeur Marion, 21000 Dijon, France, larnould@cgfl.fr

4 Department of Surgery, Antoine Lacassagne cancer centre, 33 Av. de Valombrose, 06100 Nice, France, emmanuel.barranger@nice.unicancer.fr

5 Department of Medical Oncology, Institute Curie, 26 Rue d'Ulm, 75005 Paris, France, florence.coussy@curie.fr

6 Department of Surgery, Institute Curie, 26 Rue d'Ulm, 75005 Paris, France, benoit.couturaud@curie.fr

7 Department of Radiation Oncology, Courlancy cancer clinic, 38 Rue de Courlancy, 51100 Reims France, Reims, France, BCUTULI@iccreims.fr

8 Saint Louis university hospital, 1 Av. Claude Vellefaux, 75010 Paris France, Patricia.de-cremoux@aphp.fr

9 Medical gynecology, 3 Place Paul Emile Ladmirault, 44000 Nantes, France, dereilhac@orange.fr

10 Oise Cancer Screening Association, 4 rue Niepce Les Tertiales Batiment C CS 80041, 60321 Compiègne, France, chantal.de.seze@wanadoo.fr

11 Education and Health Promotion Laboratory UR 3412, Université Sorbonne Paris Nord, 74 rue Marcel Cachin, 93000 Bobigny, France, audemarie.foucaut@univ-paris13.fr

12 Gynecological Surgery and Oncology, Reproductive Medicine, Cochin university hospital, 123 boulevard de Port-Royal, 75014 Paris, France, anne.gompel@aphp.fr

13 Pharmaceutical expertise and biomedical research, La Timone university hospital, 264 Rue Saint-Pierre 13385 Marseille Cedex 5, France, stephane.honore@ap-hm.fr

14 Department of senology, Lorraine Cancer Institute - Alexis Vautrin, 6 Av. de Bourgogne, 54519 Vandœuvre-lès-Nancy Lorraine Cancer Institute - Alexis Vautrin, Vandoeuvre Les Nancy , France, lesuranna@gmail.com

15 Department of Senology, Strasbourg university hospital, 1 Av. Molière, 67200 Strasbourg, Strasbourg, France, c.mathelin@icans.eu

16 Radiology practice, 63 Rue Denfert Rochereau, 76600 Le Havre, France, verzaux.laurent@gmail.com

17 Aix Marseille University, INSERM, IRD, Economics and Social Sciences Applied to Health & Analysis of Medical Information (SESSTIM), Marseille, France, pjbousquet@institutcancer.fr

* Corresponding author:

Dr Sophie Houzard, National cancer Institute, 52 avenue andré Morizet, 92 100 Boulogne Billancourt, France, E-mail: shouzard@institutcancer.fr

Abstract

Purpose

The French National Cancer Institute has developed, in partnership with the French National Authority for Health, breast cancer-specific Care Quality and Safety Indicators (BC QIs). With regard to the most common form of cancer, our aim is to support local and national quality initiatives, to improve BC pathways and outcomes, reduce heterogeneity of practice and regional

inequities. In this study, we measure the BC QIs available in the French National medico-administrative cancer database, the French Cancer Cohort, for 2018.

Materials and Methods

BC QIs are developed according to the RAND method. QIs are based on good clinical practice and care pathway recommendations. QI computation should be automatable without any additional workload for data collection. They will be published annually for all stakeholders, and especially hospitals.

Results

Finally, ten feasible and pertinent QIs were selected. In France, BC care was found to be close to compliance with most QIs: proportion of patients undergoing biopsy prior to first treatment (94.5%), proportion of patients undergoing adjuvant radiotherapy after breast-conserving surgery for BC (94.5%), proportion of women undergoing radiotherapy within 12 weeks after surgery and without chemotherapy (86.2%), proportion of DCIS patients undergoing immediate breast reconstruction (54.3%) and proportion of women with NMIBC undergoing breast reintervention (14.4%). However, some are still far from their recommended rate. In particular, some QIs vary considerably from one region, or one patient, to another.

Conclusion

Each result needs to be analyzed locally to find care quality leverage. This will strengthen transparency actions aimed at the public.

Keywords: breast cancer, care pathways, quality indicators, medico-administrative data.

1. Introduction

The French National Cancer Institute (INCa), commissioned with coordinating the national cancer strategy and efforts, wished to develop, in partnership with the French National Authority for Health (HAS), breast cancer-specific Care Quality and Safety Indicators as part of the 2014-2019 Cancer Plan [1].

Breast cancer (BC) is one of the most common cancer worldwide. For France, almost 59,000 new cases were estimated in 2018, representing 99.9 cases for 100,000 person-years (world-standardized incidence rate) [2].

Quality Indicators (QIs) can improve BC pathways and outcomes, reduce heterogeneity of practice and regional inequities [3-5], and track, for each individual hospital, health care provider, and regional health institution, progress in BC care quality compared to themselves over time. Regular QI assessment can be cost-effective and time-saving, streamlined, and prevent redundant cancer care [6]. QIs must be based on good clinical practice and care pathway recommendations.

They supplement a quality support system with cancer care authorizations, health professional certifications, and health facility accreditations.

2. Objective

Our objective is to propose breast cancer-specific QIs, based on best practice guidelines and which can be automated using the French real-life medico-administrative cancer database, to promote the implementation of quality management and to enhance the relevance of care.

In this study, we measure the BC QIs available in the French National medico-administrative cancer database, the French Cancer Cohort (FCC), nationally and regionally, for 2018.

Here, our objective is similar to the European quality approach of EUSOMA [7-9], to enable an annual production of indicators, systematic coverage of all French hospitals, and feasible and easy assessment without referring to the medical file.

3. Methods

3.1. QI Development

As this task requires multidisciplinary and cross-cutting skills, a working group was formed of 15 clinical experts (from learned societies, multidisciplinary, and of varied geographical origin) and interested parties (hospital federations, regional cancer networks, regional health agencies, patient associations, INCa health democracy committee). Experts are therefore required to submit a public declaration of interest (available <https://dpi.sante.gouv.fr/dpi-public-webapp/app/home>).

The RAND method was chosen for rigorous QI development [10]. It consists of four phases: preparatory phase, expert review, national consultation, and trial phase (Figure 1).

First of all, a pool of indicators was selected based on national and international clinical recommendations (ASCO, CCO, ESMO, INCa, SFSPM, NCCN, NICE, SIGN), international benchmarks, and specific requests from interested parties, HAS, and INCa. Experts proposed additional indicators. The selection process was performed without any restrictions.

Secondly, the selected QIs were restricted to those that appeared to be suitable for automatic calculation (feasibility selection). The experts validated their relevance using a 4-phase approach: 1- Individual rating of QIs, 2- Discussion meeting of QIs scores, 3-Second round of individual rating, 4- Validation of the final QI list, and design of a descriptive sheet for each indicator. These included the definition, numerator, denominator, inclusion and exclusion criteria, levels of restitution, method of calculation and codes used, interest, the target and the alert thresholds.

Thirdly, a national consultation including scientific societies and interested parties gathered opinions on consistency, readability, and acceptability. The experts reviewed and incorporated these comments in the final report [11].

Fourthly, a trial phase will assess the reliability of the indicators selected compared with cancer registry data and random patient file data.

3.2. QIs measured in FCC

3.2.1. Data

Data were selected from the French Cancer Cohort (FCC), gathering all cancer patient care pathways extracted from the French National Health Data System (SNDS), and covering the entire French population [12-13].

Information included socio-demographic data, private and public hospitalization data, diagnostic codes based on the 10th version of the International Classification of Diseases (ICD-10), procedure codes based on the French medical classification for clinical procedures (Classification Commune des Actes Médicaux), outpatient healthcare consumption and costs (consultations, paramedical interventions, medications, procedures), and vital status. The hospitals are also known and used to calculate QIs according to hospital and all regional areas.

FCC data have been collected prospectively since 2010, and made available with a 1-year delay. These data are recorded nationally and exhaustively.

3.2.2. Population

QIs focused on women aged 18 years and older, with Ductal Carcinoma in Situ (DCIS) or non-metastatic invasive BC (NMIBC) treated incident breast cancer. Women with other non-mammary cancer during the year before and after the first treatment were excluded in order to ensure that the treatment was for BC. Children and men were not considered.

The stage of the cancer (DCIS, invasive cancer, lymph node involvement, metastasis) was determined according to the hospitalization codes (ICD-10), within one year before, and six months after the first treatment.

Incident cases were women who had no long-term disease exemption (LTD) for BC, and who had no hospital stays with an ICD-10 BC diagnosis from 2010 (first year of available FCC data) to the first diagnosis.

They were all treated.

For each QI, a sub-selection and a time period were proposed according to the definition of the QI.

3.2.3. Analysis

Classic descriptive statistical methods were applied. Quantitative variables were represented by median, first and third quartile, and qualitative variables by numbers and percentages. Care pathways were expressed as percentage, or QIs, with numerator and denominator. Analyses were performed using World Programming System[®] Analytics 4.0.

3.3. Ethics

The study falls within the scope of French Data Protection Authority (CNIL – Comité national informatique et liberté) authorization under French Decree no. 2016-1871 of December 26th, 2016, and Decision 2019-083 of June 20th, 2019.

4. Results

4.1. QI Development (Figure 1)

4.1.1. Preliminary Phase

In all, more than 500 existing BC practice recommendations were extracted from ASCO, CCO, ESO, ESMO, NCCN, NICE, SIGN, and INCa recommendations (published between 2011-2017, in Supplemental file), and broken down into 35 potential QIs that could be calculated with the FCC. International benchmarking identified 45 articles referring to a total of 173 indicators. Stakeholders, including patients, mostly expressed timeless indicators.

The working group identified another 17 indicators. Ultimately, after merging and feasibility assessment, 43 indicators were retained.

4.1.2. Expert Review Phase (Figure 2)

The first round of expert scoring retained 29 QIs out of 43. At the face-to-face meeting, ten indicators were dropped. Out of these 19 indicators, after a second round of scoring and merging, the experts finally selected ten BC QIs.

4.1.3. National Review

Ninety-four people participated in the review process. Most belonged to learned societies or professional groups (61), twenty to hospital federations, and four to patient groups. The national consultation process provided details on the indicators and their descriptive sheets.

Finally, among the ten QIs selected, nine related to the care process (care outcomes in accordance with good practice) measured for each patient, and one to outcomes (breast reintervention QI I). (INCa 2019).

In order to support quality management, QIs are numerically limited, patient- and care pathway-centered.

4.2. QI results at national level

4.2.1. Women's Characteristics

In 2017, 88,042 subjects had at least 1 hospital stay with a coded diagnosis of BC, or an LTD record. Of these, 60,747 women were newly diagnosed with BC. Among the 56,990 incident BC patients without concomitant non-mammary cancer, 2,744 (4.8%) patients had in situ BC, 40,379 (70.9%) local invasive BC, 10,174 (17.9%) regional BC, and 3,120 (5.5%) metastatic BC.

The analyses were therefore restricted to DCIS (N=1,819 [3.5%]) and non metastatic invasive BC (N=50,970[96.5%]). The mean age of the women was 62.0 and 59.1 years, respectively (Table 1).

4.2.2. Care Pathways

Among the DCIS patients, 98.8% underwent diagnostic mammograms, 94.9% a biopsy, 100% surgery, and 61% radiotherapy (Table 1). The most frequent care pathways were partial mastectomy (PM) followed by radiotherapy (60%), and total mastectomy alone (39%).

Among the NMIBC patients, 95.7% underwent diagnostic mammograms, 91.7% a biopsy, 94% surgery, 82% radiotherapy, 31% adjuvant chemotherapy, and 10% neoadjuvant chemotherapy (Table 2). The most frequent care pathways were surgery followed by radiotherapy (47.1%), or surgery followed by chemotherapy and radiotherapy (25%).

4.2.3. QI Results

For five Qis, the target threshold has been reached (or almost reached) (Table 2): proportion of patients undergoing biopsy prior to first treatment (QI B: 94.5%), proportion of patients undergoing adjuvant radiotherapy after breast-conserving surgery for BC (QI E: 94.5%), proportion of DCIS patients undergoing immediate breast reconstruction (QI F: 54.3%), proportion of women undergoing radiotherapy within 12 weeks after surgery and without chemotherapy (QI GA: 86.2%), proportion of women with DCIS undergoing breast reintervention (QI I strata A: 32%), and proportion of women with NMIBC undergoing breast reintervention (QI I strata B: 14.4%).

For the other QIs, the proportion was significantly below the alert threshold: in particular, the proportion of women undergoing their first treatment within six weeks post-mammogram (QI A: 42.3%), proportion of women undergoing their first treatment within four weeks post-biopsy (QI A strata B:37.8%), proportion of pN0 invasive BC patients with sentinel lymph node dissection and no axillary

clearance (IQ D: 30.7%), the proportion of women undergoing chemotherapy within six weeks post-surgery (QI G strata B: 48%).

The focus on delays between major care pathway events, proposed in response to patient representatives, highlighted that the majority of patients are diagnosed and treated within comparable timeframes, according to the recommendations (Figure 3). However, some extreme outliers are observed.

With the aim of supporting stakeholders' improvement initiatives, based on the analysis of local practices, the QI variability ratio between French regions (Figure 4), and between hospitals, must be analyzed.

Some QIs have little interregional variability, while others have a lot (for instance, time between biopsy and treatment, DCIS cases undergoing immediate breast reconstruction).

5. Discussion

This study helped define a set of ten QIs available at national and local levels, which could be computed using the existing national database, without the need for potentially time-consuming additional data collection. As expected, some of the QIs reached the target threshold in 2018 : biopsy prior to first treatment, radiotherapy after breast-conserving surgery, radiotherapy within 12 weeks after surgery, breast reintervention. However, some improvements are required for others.

This study has major strengths: QIs assess BC care pathways, ranging from diagnosis, through treatment, to follow-up; QIs will be calculated and published each year at local, regional and national decision-making levels; analysis relates to real-life data, including data from all types of BC care institutions; data are collected automatically on a national scale. Thus, the feasibility of our Quality project is guaranteed, along with outstanding completeness and quality of the data collected.

5.1. Results

In France, it would seem that many BC care QI results are close to the recommended range. Many studies also analyzed compliance with a selected

panel of QIs, often on large populations [14-22]. Definitions tend to converge, especially as many of them are based on the work of EUSOMA [7-8]. However, caution is needed when comparing with other studies using BC care QIs, because each QI is based on specific, and not fully superimposable, calculation methods, and results concern previous years.

Some observations can be proposed with regard to other international or European QI studies. Regarding QI A, which explores diagnostic delays, the rates are heterogeneous from one study to another [19, 23-25]. Here, a preoperative MRI does not modify the time to access care, as in a French study [23].

Preoperative histologically confirmed malignancy is common in all studies [14-15, 17-18,20,22-23], as in our study with 94.2% undergoing a biopsy prior to their first treatment (QI B).

Our rates on axillary procedures differ widely with lower rates than in other studies [9,14,17-18,20,22]. These rates are explained by incorrect coding practices: sentinel procedures are mostly coded under axillary dissection in France [26].

Radiotherapy after breast-conserving surgery applies to more than 90% of patients, in the majority of studies [9,14-15,17-20], as in ours.

Reconstruction rates are variable, and often lower [16,20,27]. Only Vos [19] find rates similar to ours.

Adjuvant radiotherapy start-up times are shorter than those in other studies [21,28], unlike those in respect of chemotherapy, which are longer [6,16,21,29-30].

Reintervention surgery rates are similar to two studies [9,17], but higher than those found in three other studies [16,18,22].

Finally, Italian patients have follow-up in 55.1 to 72.6% of cases depending on the region [21], corresponding to the French QI J.

5.2. Limitations

The organizational and local context must be taken into account when interpreting QI results [4], especially in terms of small areas. *Some incorrect interpretations can adversely affect the quality and safety of care.* The results of the indicators should be interpreted collectively with all those involved in the care provision (health professionals, institutions, patients). Results can have multiple interpretations, in some cases related to insufficient structure access, non-optimal organization, failure to apply best practice, incompressible organizational delays behind each organizational step, patient choice, database

coding error, overly complex indicators, etc. For instance, the proportions of DCIS and invasive carcinomas with regional lymph node involvement are underestimated [24].

No indicators could be selected for metastatic patients, or for end-of-life care. Likewise, these QIs highlight elements of quality, but do not represent all the quality indicators needed. Our scope is limited to database-accessible indicators and automatic calculation. Other studies focus in particular on multidisciplinary team meetings, which are deemed essential, the completeness of prognostic/predictive BC characterization (i.e. grading, hormonal receptor status, HER2), or appropriate therapy (endocrine, chemotherapy, or HER2-targeted therapy) associated with staging and prognostic factors. This information is not currently available on a national scale, but will be.

5.3. Outlook

The actual use of these ten indicators will depend on the positive predictive value or the negative predictive value of each indicator, which will be calculated during a trial phase. These tests consist of comparing the data contained in the FCC with the source data from the patient file and with registry data.

QIs with positive predictive value (PPV) of 75% or more will be published publicly, after three years of being reserved for health professional publications. Finally, public access to QI results will provide users, patients and professionals, with information sharing, and key transparency.

In addition, when the FCC is enriched with multidisciplinary discussion reports and histopathological information on cancer, the list and definitions of the indicators selected will be updated, because many indicators were rejected due to this lack of available data.

Additional studies need to be carried out to analyze the possibility of benchmarking, the impact of case mixes on results [20], and to analyze the differences observed on a regional level or within hospital. Are these differences caused by bias in the administrative data registry, the volume of hospital activity [27], additional procedures or treatments, or patient characteristics [31], etc.?

Finally, it is important to compare these results with the challenges, especially because some QIs do not reach their target: delays in access to treatment, and delays between the adjuvant treatments have an impact on recurrences and survival (Supplemental file). A quality follow-up makes it possible to detect

recurrences earlier. Earlier diagnosis optimizes the effectiveness of treatment with a proven positive impact on the disease prognosis (supplemental file). In addition, delays generate avoidable anxiety. Similarly, the benefit of radiotherapy on the risk of local in situ or invasive recurrence has been confirmed by the most recent publications (level of evidence A) (supplemental file). Other indicators measure the relevance of care. Histological diagnosis is essential to decide on the best treatment to offer to the patient. Conversely, it is essential not to subject the patient to useless invasive, painful procedures with subsequent consequences (such as lymphoedema).

6. Conclusion

INCa and HAS have developed BC QIs, suitable for automation without any additional data collection workload, and published annually for all stakeholders and especially hospitals, to support local and national quality initiatives. In France, BC care was found to be close to compliance with most QIs. However, some are still far from their recommended rate. QIs need to be analyzed locally to find care quality leverage. This will strengthen transparency actions aimed at the public. Similar approaches can be adopted in many countries at national or regional level.

Clinical Practice Points

The French National Cancer Institute has developed breast cancer Care Quality and Safety Indicators (QIs).

The objective is to support quality initiatives, improve pathways and outcomes, and reduce regional inequities.

QIs are based on good clinical practice and care pathway recommendations.

QIs computation are automatable without any additional workload for data collection and published annually to all French hospitals and institutions.

In France, BC care was found to be close to compliance with most QIs.

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Table 1. BC Care

| | DCIS (N=1,819) | | NMIBC (N=50,553) | | Total (N=52,372) | |
|--------------------------|--------------------|-----|---------------------|-----|---------------------|-----|
| | N | % | N | % | N | % |
| Age | 59.0 [50.0 - 68.0] | | 62.0 [51.0 - 72.0] | | 62.0 [51.0 - 72.0] | |
| Diagnosis | | | | | | |
| Mammogram* | 1,798 | 99% | 48,382 | 96% | 50,180 | 96% |
| Echography** | 1,669 | 92% | 47,250 | 94% | 48,919 | 93% |
| MRI** | 369 | 20% | 17,306 | 34% | 17,675 | 34% |
| Breast Biopsy** | 1,726 | 95% | 46,340 | 92% | 48,066 | 92% |
| Treatment | | | | | | |
| Tumorectomy | 1,485 | 82% | 37,317 | 74% | 38,803 | 74% |
| Mastectomy | 599 | 33% | 12,676 | 25% | 13,275 | 25% |
| Hormonal therapy | 86 | 5% | 37,827 | 75% | 37,913 | 72% |
| Targeted therapy | 2 | 0% | 5,720 | 11% | 5,722 | 11% |
| Adjuvant chemotherapy | 4 | 0% | 15,489 | 31% | 15,493 | 30% |
| Neoadjuvant Chemotherapy | | | 4,914 | 10% | 4,914 | 9% |
| Adjuvant radiotherapy | 1,106 | 61% | 41,590 | 82% | 42,696 | 82% |

*= the date of the last (hospital and out-of-hospital) mammogram, if there has not been another mammogram 1 month before; otherwise, the date of the previous mammogram.

**= hospital and out-of-hospital diagnostic examinations

Table 2. 2018 QI Results

| QI | subgroup | QI title | Target threshold | Alert threshold | N/D* | % |
|--------|-----------|---|------------------|-----------------|--------|-----------|
| | DCIS | | | | 19,563 | 42 |
| QI A | or NMIBC | Proportion of women undergoing their first treatment within 6 weeks post-mammogram | >=90% | <80% | /46,29 | .3 |
| QI A | DCIS | Proportion of women undergoing biopsy within 2 weeks post- | | | 30,626 | 66 |
| strata | or | mammogram | | | /46,29 | .2 |
| QI A | NMIBC | | >=90% | <80% | 6 | % |
| QI A | DCIS | Proportion of women undergoing their first treatment within 4 | | | 17,490 | 37 |
| strata | or | weeks post-biopsy | | | /46,29 | .8 |
| QI B | NMIBC | | >=90% | <80% | 6 | % |
| | DCIS | | | | 46,730 | 94 |
| QI B | or NMIBC | Proportion of women undergoing biopsy prior to first treatment | >98% | =<95% | /49,46 | .5 |
| | | Proportion of women treated for DCIS with breast-conserving surgery not undergoing sentinel lymph node excision or axillary | | | | 67 |
| QI C | DCIS | dissection | >95% | <90% | 938/13 | .5 |
| | | | | | 90 | % |
| QI D | pN0 NMIBC | Proportion of women with pN0 NMIBC undergoing sentinel lymph node excision without axillary dissection | >95% | <90% | 11,390 | 30 |
| | | | | | /37,14 | .7 |
| QI D | DCIS | | | | 3 | % |
| QI E | or | Proportion of women undergoing radiotherapy after breast- | >95% | <90% | 34,341 | 94 |
| | | | | | /36,31 | .5 |

| | | | | | | |
|-----------|-------|---|------|------|--------|-----------|
| | NMIBC | conserving surgery | | | 6 | % |
| | | Proportion of women with DCIS undergoing immediate breast reconstruction | | | 318/58 | 54 |
| QI F | DCIS | | <30% | | 2 | % |
| QI G | DCIS | Proportion of women undergoing adjuvant radiotherapy within 12 weeks post-surgery | | | 23,350 | 86 |
| strata or | NMIBC | | >95% | <90% | /27,09 | 2 |
| QI G | DCIS | Proportion of women undergoing adjuvant chemotherapy within 6 weeks post-surgery | | | 7,659/ | 48 |
| strata or | NMIBC | | >90% | <85% | 15,970 | % |
| B | | Proportion of women undergoing adjuvant chemotherapy within 6 weeks post-radiotherapy | | | 11,698 | 81 |
| QI H | NMIBC | | >95% | <90% | /14,28 | 9 |
| QI I | | | | | 454/14 | 32 |
| strata | DCIS | Proportion of women with DCIS undergoing breast reintervention | <20% | >30% | 19 | % |
| A | | | | | | 14 |
| QI I | | Proportion of women with NMIBC not treated with neoadjuvant chemotherapy undergoing breast reintervention | | | 4,986/ | 4 |
| strata | NMIBC | | <10% | >20% | 34,561 | % |
| B | | | | | | 9 |
| QI I | | Proportion of women with NMIBC treated with neoadjuvant chemotherapy undergoing breast reintervention | | | 259/2, | 9 |
| strata | NMIBC | | | | 606 | % |
| C | DCIS | Proportion of women who have had their first follow-up mammogram | | | 28,503 | 61 |
| QI J | NMIC | | >98% | <95% | /46,33 | 5 |
| | | | | | | 8 |
| | | | | | | % |

*Numerator/Denominator

Ethics approval: The study was performed on national database (authorisation from CNIL (French data protection authority) - decree of 26 December 2016 No. 2016-1871.).

Declaration of Interest statement: The authors declare that they have no conflict of interest.

Authors' contributions

Emilie Courtois : conceptualization, methodology, writing, supervision

Christine Le Bihan-Benjamin, Sophie Houzard, Delphine Lefeuvre, Marie Erbault : methodology, writing, supervision, software, data curation

Laurent Arnould, Emmanuel Barranger, Florence Coussy, Benoît Couturaud, Bruno Cutuli, Patricia de Cremoux, Pia de Reilhac, Chantal de Seze, Aude-Marie Foucault, Anne Gompel , Stéphane Honoré, Anne Lesur, Carole Mathelin, Laurent Verzaux : conceptualization, expertise, validation, review

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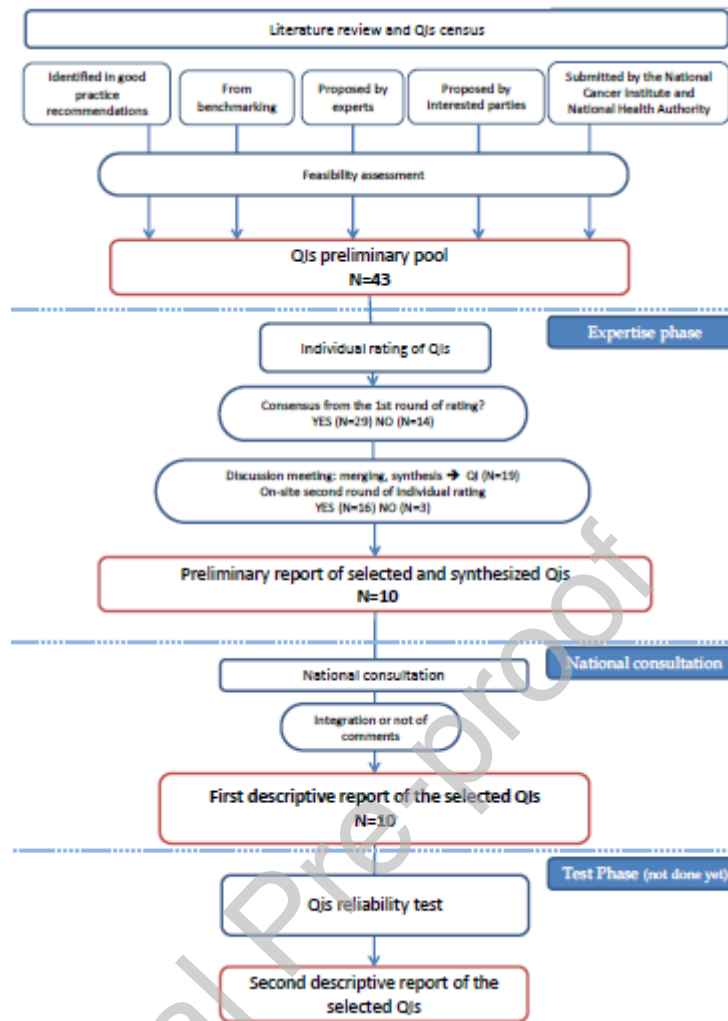


Figure 1. RAND method phases

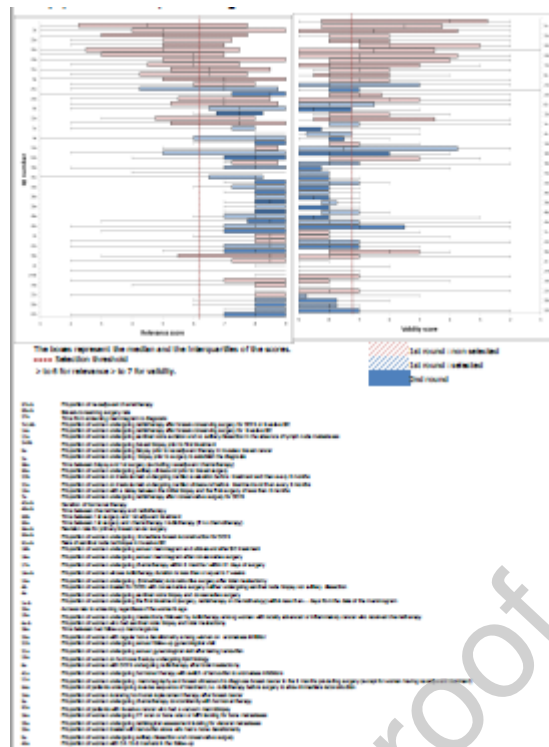


Figure 2. QI Relevance and validity scores at the 1st (a) and 2nd (b) round of expert rating

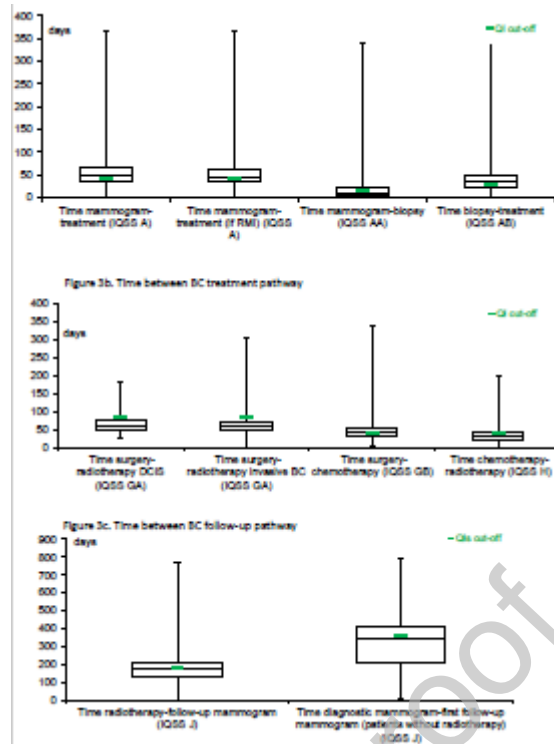


Figure 3. Time between BC care pathway events
3a. Time between BC diagnosis pathway

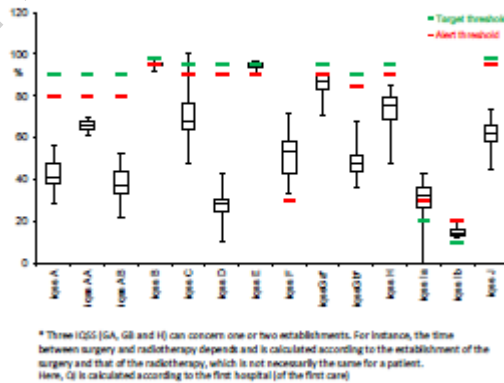


Figure 4. Variability of QIs ratio by region (median-range)