Indicators based on registers and administrative data for breast cancer: routine evaluation of oncologic care pathway can be implemented

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Abstract

Rationale, aims and objectives Assuring the best standards of care – in a sustainable way – in chronic diseases as breast cancer is nowadays an important challenge for any health system. The aim of this study was to present the methodology used to define a set of quality indicators, computable from administrative data for the pathway of care of breast cancer, and its application at a population level.

Method The cohort of 2007–2009 incident cases of breast cancer was identified through a network of six cancer registers in Northern Italy. Cases of sarcoma and lymphoma, patients with multiple primary cancers and those metastatic at diagnosis were excluded; 9614 women were retained for the analysis. For each indicator, the sub-cohort of women eligible for the diagnostic/therapeutic procedures was identified and calculations were performed through record linkage between the cohort and sources of health information. Data on potential available confounders or prognostic factors were also collected.

Results For a few indicators, such as cyto-histological assessment before surgery (62%) and intensive follow-up (79%), deviation from recommendations was evident. Younger patients (≤50 years) more frequently needed a short term re-intervention, while older patients less frequently underwent reconstructive surgery and received palliative care. Several indicators had a great variability across hospitals. In some cases, this heterogeneity appeared to be related to the hospital size, with high-volume hospitals being more compliant to guidelines.

Conclusion It is possible to evaluate the quality of cancer care delivered in clinical practice in recent years, in order to implement interventions aimed to improve adherence to international standards of care.

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Introduction

Cancer is the second cause of death worldwide, accounting for 8.2 million deaths in 2012 [1] and causing an increase in health care costs [2]. Consequently, interest in evaluating and optimizing the standard of care for oncologic patients has grown in recent years [3,4]. Particularly, breast cancer is the first oncologic disease of women in developed countries [1] and has already been the object of measurement of adherence to standard care by several quality initiatives [5,6]. Developing measures of the quality of care delivered to breast cancer patients shares the challenges of the entire oncologic field [7]: firstly, there is a long interval between delivery of the initial care and outcome [8]; secondly, breast cancer treatment is best delivered from providers with a multidisciplinary network organization [9]; lastly, standards of care change rapidly over time. These considerations suggest to use process indicators, in addition to outcome indicators such as long-term survival, to evaluate the compliance of the delivered care to current standards.

Quality of cancer care can be looked at from many perspectives [10], including identification and monitoring of procedures influencing hard outcomes [11], patients' satisfaction [12] and cost effectiveness, both at the single provider or at a population level [13]. Each level can result in a different methodological approach. For example, indicators derived from administrative routine data will have a lower detail compared with those calculated on *ad hoc* databases. Yet, the former do not have problems of selection bias and cover larger populations. Previous experiences at a population level using administrative data have been conducted by The Scottish Cancer Taskforce [14] and the Cancer Care System of Ontario [15].

In the last decade in Lombardy, a region in Northern Italy, reliable data from routine collection of information on outpatient delivered care and drug prescriptions, in addition to national hospital records, have become available [16,17]. These information, linked to cancer registers, allow to calculate a set of quality indicators encompassing the entire process of care of the primary tumour. In this work, we describe the methodology to define a set of indicators and show their application in the cohort of the 2007–2009 incident cases of breast cancer included in the cancer registers of six local health authorities (LHA) in Lombardy.

Methods

Selection and description of participants

The cohort was identified through the network of certified cancer registers of the six LHAs, covering the largest metropolitan population within Northern Italy (2 774 097 female inhabitants at 1 January 2010 [18]). The registers are based on the same automated methodology, use clinical sources of information (archive of death causes, hospital discharge forms and histo-cytopathology) and have developed an efficient system of record linkage and algorithm recognition to match all data at the individual level. Incidence date was defined, according to international cancer registration rules, as the first available date among those of pathological examination, clinical diagnosis or death. Cases of sarcoma and lymphoma were excluded, as well as all cases with multiple primaries cancers and patients with metastasis at diagnosis.

Identification of the set of indicators

We systematically revised the medical literature searching for process indicators, with the aim of obtaining a set of measures with a proved potential to affect either 5-year survival or quality of life [19], and to evaluate the appropriateness of the entire primary breast cancer diagnostic and treatment pathway.

We referred to the KCE Reports 150 [3] for breast cancer quality indicators published up to 31 November 2009. We additionally performed a Medline search of the literature from November 2009 to January 2013 (Supporting Information Appendix S1), and screened additional databases of indicators [14,20]. From the final list of indicators, we then removed those not computable from the administrative data. The remaining indicators were evaluated by epidemiologists and clinicians of the cancer networks of the six LHAs for clinical validity and reliability. For a few indicators, we adapted the calculation to the available administrative data by defining – or modifying – a time window for database search of the events. We grouped the indicators in three domains – diagnosis (D), treatment (T) and follow-up (F) –and numbered them within domain, for example, the second indicator in the diagnosis domain is referred as D2.

In order to calculate the indicators, each LHA used all available computerized sources of health information from January 2006 to December 2011. These included hospital discharge form, medical fee waivers for specific diseases, outpatients' records of diagnostic and therapeutic procedures, and prescriptions of drugs reimbursed by the National Health Service. An algorithm, based on the health sources listed above and on co-payment waivers for specific diseases, was applied to identify the main chronic conditions [17]. The aim was to trace the entire pathway of care and to use multiple independent sources of information, to improve the reliability of the indicators. After anonymization, the sub-cohorts of each LHA were merged and consistency checks made before subsequent analyses. At all steps, we followed standardized procedures.

At the provider level, we applied the achievable benchmark (ABC™) and computed the 'pared mean' [21], that is, roughly the value of the indicator calculated on the top ranked providers including the 10% of the study cohort. For each indicator, we constructed a funnel plot [22] to visualize the distribution of the health care providers around the 'pared mean' against the volume of yearly performed breast surgical interventions.

Calculation of each indicator at the patient level

The date of incidence was obtained from the cancer registers. The date and type of the primary surgery was derived from hospital discharge records, searching for the first breast surgical intervention (ICD9-CM codes 85.22–23, 85.33–36, 85.41–48; 85.20–21 only if none of the others was present) performed in the interval –6 to +12 months from the date of incidence. We also collected data on potential available confounders and effect modifiers. At the patient level: age at diagnosis, known to influence both the diagnostic and therapeutic processes [23]; presence of diabetes and cardiovascular diseases; histopathological tumour grading according to Elston–Ellis; TNM (T size of the tumor, N lymph nodes, M metastasis) pathological stage, important both as a potential confounder and to determine the denominator of several indicators; performed treat-

ment, classified as 'surgical' (conservative vs. radical), 'medical only' and 'not treated'. At the hospital level, we calculated the mean yearly volume of breast surgery on the 3 years of the study. This is relevant as case-mix may vary among providers with different surgical volumes, and because there are proofs that patients operated in high-volume hospitals have a better survival [24].

Statistics

We first calculated each indicator as the proportion of patients who received the procedure, in the defined time window, among those eligible. We described the variability of the indicators among LHAs, providers and from year to year. Crude indicators were stratified by volume (<150 interventions per year vs. ≥ 150); age (<50, 50–69 and ≥70 years); co-morbidities and, for those aged 50–69 years, cancer diagnosis (screening vs. otherwise detected). Then, in order to explore the determinants of adherence to guidelines, we fitted a hierarchical generalized linear model (HGLM) with a binomial random error for each indicator. The hierarchical structure of the HGLM model had patients as the primary level, health care providers as the second random level and LHA as the third fixed level. All models included age as a natural cubic spline among predictors. Type of treatment/surgery, pathological stage, grading and co-morbidities were the additional first-level covariates, included on the basis of epidemiological considerations. The only second-level covariate was the surgical volume of the provider (<150 interventions per year vs. ≥ 150).

Missing data on covariates were handled with multiple imputations, using the cohort that included also stage IV patients, where missingness was 8% for stage, 14% for grading and 8% for hospital volume. We assumed missing at random for stage, grade and hospital volume given health provider, while hospital volume missingness was assumed to be at random given extra-regional migration for surgery and absence of hospitalization. Imputation was performed by fitting a multivariate normal model including the three variables, the 16 indicators that are meaningful for the entire cohort, age, presence of co-morbidity, performed treatment, LHA of residence and year of incidence (20 imputed dataset, MCMC algorithm, quadrature point 50, MI SAS procedure). In the Results section, we report the crude indicators calculated on the complete case series, as we verified that results were superimposable to those obtained on the imputed datasets. On the contrary, the presented results from the HGLM models are those obtained on the imputed dataset, in order to increase power. All analyses were performed with SAS software (v.9.3, SAS Institute, Cary, NC, USA).

Results

Participants

From 1 January 2007 to 31 December 2009, there were 10 733 incident cases of female invasive breast cancers in the registers. After exclusions ($n = 22$ sarcomas and lymphomas, $n = 668$ multiple primary cancers, $n = 429$ metastases at diagnosis), the analysed cohort included 9614 cases, whose characteristics are reported in Table 1.

The study cohort was mainly composed of women aged 50–69 (45%), diagnosed in stage I (43%) and surgically treated (93%).

Table 1 Patients and tumour characteristics from the cohort of female breast-invasive cancers 2007–2009 incident cases, not metastatic at diagnosis, from the nationally accredited cancer registers of six health care districts in the Lombardy region, Northern Italy

	No. (%)
Year of incidence*	
2007	3856 (40)
2008	2874 (30)
2009	2884 (30)
Age class	
<35	157 (2)
35–49	2002 (21)
50–69	4368 (45)
70–84	2504 (26)
≥ 85	583 (6)
Treatment	
Surgical	8878 (93)
Radical	6409/8878 (72)
Breast conserving	2469/8878 (28)
Chemo/radio/hormonotherapy only	607 (6)
No treatment	129 (1)
Hospital's surgical volume†	
<150 breast surgical intervention/year	4300 (46)
≥ 150 breast surgical intervention/year	4915 (53)
Unknown‡	50 (1)
TNM stage at diagnosis	
I	4165 (43)
II	3342 (35)
III	1322 (14)
Unknown	785 (8)
Grading	
1	961 (10)
2	4585 (48)
3	2844 (29)
Unknown	1224 (13)
Diabetes and/or CV co-morbidities	
No	6009 (62)
Yes	3605 (38)
Total number of patients	9614

*For 2008–2009, data from the Milan register were not available.
†Excluding 349 patients that were never hospitalized.
‡1% of patients had surgery outside the Lombardy region. The surgical volume of those hospitals is unknown.

About half of the patients received primary treatment in a hospital with a mean yearly volume ≥ 150 breast surgical interventions. About 40% of the patients had diabetes, a chronic cardiovascular disease or both.

Identified set of indicators

Supporting Information Fig. S1 shows the selection process of the indicators. The literature search resulted in 367 potential indicators. For neoadjuvant treatment, we added one indicator [25]. After excluding quality measures that could not be calculated from administrative data ($n = 327$) and those regarded as not relevant after discussion between epidemiologists and clinicians ($n = 19$),

Table 2 Definition of the indicators of diagnosis and their raw calculation

Label	Indicator of diagnosis in the final formulation. Proportion of women:	First study presenting the indicator	Numerator	Denominator	%†
D1	Aged 50–69 years who had a screening mammography performed in the 3 months preceding diagnosis	Caldarella (2012)	1449	4368	33.2
D2	Aged over 50 who received bilateral mammography 3 months before surgery*	Chung (2007)	4397	6237	70.5
D3	Newly diagnosed in stage I–III who underwent mammography or breast sonography within 3 months prior to surgery*	Cheng (2009)	6268	7789	80.5
D4	With cytological and/or histological assessment in the 3 months prior surgery*	Chung (2007)	4978	8050	61.8
D5	Undergoing SLNB in the setting of breast-conserving surgery for T1 tumours*	Quan (2010)	3128	4167	75.1
D6	Who underwent SLNB and breast-conserving surgery concurrently*	Quan (2010)	3749	5955	63.0
D7	In stage I, and not undergoing mastectomy , undergoing bone scanning or thoracic CT or liver US or abdominal CT /MR or tumour markers measurement in the 3 months prior to surgery*	KCE (2009)	500	3347	14.9
D8	With stage III breast cancer who undergo baseline staging tests (bone scanning and chest X-ray/thoracic CT and liver US or abdominal CT/MR)	Rosselli del Turco (2012)	289	1322	21.9

*Excluding patients undergoing neoadjuvant treatment.
†The higher the better, with the exception of D7.

we obtained the final list of 22 indicators (Tables 2 and 3). Diagnostic indicators described in Table 2 divide into those assessing: the imaging diagnostic process, that is, mammography as a screening technique in the 50–69 age group (D1) and mammography or sonography as a mandatory diagnostic evaluation before surgery (D2–D3); the histological confirmation of the cancer before surgery and the use of sentinel lymp-node biopsy (SLNB) technique for patients undergoing breast-conserving surgery (D4–D6); needless (D7) or mandatory pre-surgical investigations (D8) according to clinical stage.

Therapeutic indicators (Table 3) divide into those assessing: the use of neoadjuvant therapy in stage III, where it is indicated (T1); the use of the appropriate surgery technique in low-stage tumours (T2–T4) that should receive a single conservative intervention with no axillary clearance; the use of reconstructive surgery in patients undergoing mastectomy (T5–T6); the promptness (T7) and the frequency of adjuvant therapy: according to a proxy of menopausal state for chemotherapy (50 years, T8–T9), and to type of surgery for radiotherapy (T10–T11); the use of palliative services for terminal patients (T12).

Concerning follow-up indicators (Table 3), the first one measures the recourse to intensive follow-up (F1, at least one of the following procedures: chest CT, bone scan, liver imaging, tumour markers measurement) and the other (F2) assesses the mandatory use of mammography for follow-up.

Lack of adherence to guidelines

In the diagnostic domain, we observed low percentages of screen detected cancers (D1, 33%) in the population eligible for organized breast cancer screening programmes. A deviation from recommendations was apparent for cyto-histological assessment before surgery (D6), having a value of 62% while it should be mandatory. Among stage I patients undergoing conservative breast surgery and not receiving neoadjuvant therapy (D7), 15% performed at least one diagnostic procedure not recommended in the guidelines among bone scanning, thoracic CT, liver US/CT/MR or tumour markers dosage. In detail, 7% underwent a bone scan, 1% a thoracic CT, 12% a liver diagnostic examination and 7% a dosage of tumour markers. Among stage III patients, only 22% received all the procedures recommended for pre-surgical staging (bone scan and chest X-ray/CT and liver US/CT/MR, D8). The single diagnostic procedures performed more frequently were bone scanning (64%) and liver examination (61%). For the therapeutic domain, we found a low percentage of patients undergoing reconstructive surgery within a year after mastectomy (T5, 27%). The proportion of patients starting adjuvant treatment after surgery either with chemotherapy within 60 days or radiotherapy within 90 days was 75% (T7), but the proportion starting within 30 days for chemotherapy and 60 days for radiotherapy – which should be the target – was only 28% (not in tables).

For follow-up, we found that intensive follow-up (F1) was applied in 79% of patients, although there is no evidence of its impact on survival [26]. Considering the procedures included in the indicator one by one, 77% of patients received a marker dosage, 72% liver imaging, 54% a bone scan and 8% a thoracic CT.

Predictors of lack of adherence

Table 4 contains the raw value of each indicator across strata of important factors (age, hospital surgical volume, major co-morbidities and screening) for the complete cases. Descriptively, younger patients (<50 years) more frequently needed a short-term re-intervention (T3) compared with the women over fifty. On the contrary, women >= 50 years less frequently got reconstructive surgery (T5) and received palliative care (T12). Older patients (≥70 years) underwent less frequently sentinel lymph node biopsy (D4), neoadjuvant therapy in stage III (T1), reconstructive surgery (T5), radiation treatment after breast-

Table 3 Definition of the indicators of treatment and follow-up and their row calculation

Label	Indicator of treatment/follow-up in the final formulation. Proportion of women:	First study presenting the indicator	Numerator	Denominator	%†
T1	With stage III tumours undergoing neoadjuvant systemic therapy (either hormonal or chemo)	ESMO (2011)	202	1245	16.2
T2	In stage I and II who undergo breast-conserving surgery	Chung (2007)	5927	7633	77.6
T3	Undergoing a second surgery within 3 months from the first breast-conserving surgery, excluding reconstructions	Mc Cahill (2009)	242	6409	3.8
T4	With pathological stage I breast cancer undergoing axillary clearance at first surgery or within 3 months	Scottish taskforce (2012)	594	4037	14.7
T5	With reconstructive surgery in the following year among patients who underwent mastectomy*	Caldarella (2012)	636	2311	27.5
T6	With immediate reconstructive surgery among patients who underwent mastectomy	KCE (2009)	338	2469	13.7
T7	Whose first post-operative treatment was initiated within 60 days of surgery in the event of chemotherapy and within 90 days in the event of radiotherapy	Ferrua M (2012)	4896	6490	75.4
T8	>50 years with pathological stage II–III receiving adjuvant hormone therapy or chemotherapy in the following year*	Chung (2007)	2945	3185	92.5
T9	<50 years with pathological stage II–III receiving adjuvant chemotherapy in the following year*	Chung (2007)	774	1048	73.9
T10	Who receive radiation treatment within a year after breast-conserving surgery*	Chung (2007)	4787	6249	76.6
T11	Who receive radiotherapy within a year after mastectomy*	Brucker (2010)	596	2311	25.8
F1	Receiving chest CT or bone scans or liver US/CT/MR or tumour markers measurement in the year following surgery, excluding patients developing metastasis*	KCE (2009)	6720	8471	79.3
F2	>50 years undergoing mammography within 18 months after surgery*		5311	6519	81.5
T12	Enrolled in palliative care within 6 months of death	Grunfeld (2008)	371	1193	31.1

*Excluding patients deceased in the year after surgery.
†The higher the better with the exception of T3, T4 and F1.

conserving surgery (T10), follow-up mammography (T11) and palliative care (T12) compared with women <50 years. Concerning secondary prevention, cases not screening-detected in the 50–69 years old showed a lower adherence for some indicators of diagnosis (D2, D4, D5), surgery (T2-T4, T6), medical treatment (T8, T10), and for follow-up mammography (F2).

Table 5 shows odds ratios (OR) for the categorical variables included in the hierarchical model on each indicator. Many of the significant associations found were expected, as the lower odd of having a screen detected cancer (D1) for patients with a stage III vs. I–II tumour (OR = 0.5, 95% IC = 0.4–0.7) or a higher odd of undergoing adjuvant chemotherapy for young patients (T9) with grade 3 tumour compared with grade 1–2 (OR = 3.9, 95%IC = 2.6–5.8). The models provided new insights on variables related to the care delivering structure and significantly influencing clinical practice: in high-volume vs. small-volume hospitals the odd to undergo sentinel lymph node biopsy tripled (D4, OR = 3.0, 95%CI = 1.3–6.6), to get neoadjuvant treatment in stage III doubled (T1, OR = 1.9, 95%CI = 1.0–4.0), and to have a re-intervention almost halved (T3, OR 0.6, 95%CI = 0.4–0.9). In the models, adjusting for other covariates and for age, there was no significant evidence of a detrimental relationship between the presence of cardiovascular chronic disease or diabetes and the value of the treatment indicators. Concerning intensive follow-up (F1), even if the crude indicator showed similar values by stage (77% in stage I, 81% in II and 82% in III), in the model the risk for stage III vs. I–II was significantly higher (OR = 1.3, 95% CI = 1.1–1.6). Finally, there was a higher odd of receiving intensive follow-up (F1) and mammography in the 18 months after surgery (F2) for patients with co-morbidities. For many indicators, we found a significant non-linear effect of age in the HGLM model (data not shown).

Supporting Information Table S1 shows the variability across providers and LHA. Some of the indicators had a great variability across hospitals. In some cases, this heterogeneity did not appear to be related to the size of the hospital, as the OR for high- vs. low-volume hospital was close to 1, such as for reconstructive surgery (T5). For others indicators, the high variability across hospitals was concomitant to a higher odd of having the procedure performed for patients undergoing surgery in high-volume hospitals compared with low volume ones, as for sentinel lymph node biopsy regardless of timing (D4) or concurrent to breast-conserving surgery (D5), or immediate reconstructive surgery (T6; Table 5). Figure 1 shows the funnel plot for intensive follow-up (F1), allowing to easy visualize the relationship between the hospital volume and the indicator, with very small volume providers having an unduly high value.

Concerning variability among LHA, there were nine indicators having a range greater than 20% (Supporting Information Table S2), and even after accounting for differences in the

Table 4 Stratified values of the indicators calculated on complete case series

Indicator (abbreviation)	Value of the indicator (%)								
	Age class			Hospital surgical volume		Major co-morbidities		Screening*	
	< 50	50–69	≥ 70	<150/yr	≥ 150/yr	No	Yes	No	Yes
D1	–	33.2	–	35.6	31.0	30.2	39.3	–	100.0
D2	–	71.4	69.1	72.8	68.3	69.2	72.0	60.2	91.9
D3	79.3	82.4	78.3	80.6	80.5	79.9	81.4	75.3	95.4
D4	67.2	61.9	57.7	56.6	66.8	63.3	59.3	65.7	55.0
D5	80.1	79.3	60.1	64.4	83.5	78.2	69.1	77.6	81.8
D6	69.6	67.5	47.9	52.3	72.6	66.8	56.0	65.8	70.2
D7	12.8	13.4	20.2	17.4	13.1	15.0	14.8	13.1	13.8
D8	19.4	25.3	20.0	18.3	25.7	21.2	22.8	28.6	14.5
T1	18.3	17.8	13.3	12.0	20.7	17.5	14.5	20.4	9.5
T2	75.1	83.4	70.0	77.2	78.1	78.0	77.1	80.3	89.0
T3	7.0	3.2	2.0	4.7	3.0	4.4	2.6	3.6	2.6
T4	15.6	13.5	16.5	17.1	13.0	14.3	15.5	15.1	10.9
T5	53.7	34.2	3.3	20.2	34.5	37.5	11.0	33.4	36.9
T6	27.8	16.8	2.1	6.4	20.7	18.9	5.5	15.8	20.4
T7	79.0	75.7	69.7	75.2	75.7	76.8	72.5	77.5	72.3
T8	–	97.2	86.2	91.9	93.0	93.3	91.5	97.0	97.8
T9	73.9	–	–	83.9	67.4	73.9	73.0	–	–
T10	85.8	80.7	59.5	82.1	72.1	79.7	71.0	79.2	83.2
T11	29.1	31.1	18.5	24.0	27.3	27.3	23.3	32.5	26.2
F1	83.1	81.6	72.3	81.3	77.8	79.9	78.3	81.5	82.0
F2	–	85.5	74.6	79.7	83.2	81.8	81.0	83.1	90.3
T12	58.3	41.3	24.1	29.2	34.3	35.6	27.9	43.4	32.0

*The stratification on whether the tumour was screened detected or not is made for the subpopulation 50–69 years only.

population through age and tumour stage in the model, there was a significant effect of the LHA (global F test in the HGLM model) for 10 indicators (marked with an asterisk in Supporting Information Table S2).

Discussion

This work presents a set of indicators derived from administrative databases, and capable to monitor the entire diagnostic and therapeutic pathway of an oncologic cohort at the population level. This type of indicators can be repeatedly measured over time and can be implemented to have a relatively short delay. In fact, as soon as a year is available in the registry (i.e. 1–2 years delay for modern registries), it can be retrospectively linked to the administrative databases and give information on very recent clinical practice at a population level, allowing stakeholders to have a feedback on the adherence to up-to-date guidelines. They also allow to monitor the impact of quality improvement initiatives. For instance, an indicator that is very heterogeneous among providers reveals that the underlying process of care is not appropriately carried out in all the study areas. Based on this, *ad hoc* policies to remove causes that prevent the application of guidelines into practice can be implemented. In our application, an example is intensive follow-up after initial treatment in early stages, where the clinical practice guideline is systematically overlooked [27]. Whether this is caused by a refusal of the guideline itself or by defensive medicine, measuring the indicator is the starting point to understand how to improve practice. Another important finding is that age and hospital volume are among determinants of the compliance to specific guidelines, such as sentinel lymph node biopsy and immediate reconstructive surgery.

Indicators for routine evaluation of the quality of care have been implemented in many health systems for acute but not for chronic conditions, such as breast cancer. In fact, breast cancer, as other chronic conditions, requires a complex evaluation of procedures performed by different health professionals, providers and times. Some countries, for example, England, perform a routine evaluation of adherence to organizational standards for the most frequent cancers [28]. A previous similar work performed in Belgium and including 13 indicators [3] also found heterogeneity across hospital, which was often related to volume. In the United States, an analysis of regional variations of health care costs suggested that nearly one-third could be reduced without depriving any patient of beneficial care [29]. Also, the American Society of Clinical Oncology identified a list of practices widely used in cancer patients but that have not been proven to increase either quality of life or outcomes (e.g. the use of positron emission tomography, CT and bone scans to stage early breast cancer patients at low risk for metastasis) [27].

We did not use benchmark target values for the indicators, derived from guidelines or previous experiences in this field, not only because there is lack of general consensus on benchmark for many indicators, but also because administrative data do not allow to identify the small subpopulation that should not be included in the denominators, either because of medical contraindication or patient refusal, and guidelines are often applicable only to sub-

Table 5 Results of the hierarchical mixed effect model on each indicator, accounting for intra-hospital correlation

Indicator	Factors					
	Stage III vs. I–II	Treatment, surgery vs. medical/no	Surgery, radical vs. conservative	Co-morbidities, yes vs. no	Hospital volume, ≥150 vs. < 150	Grading, 3 vs. 1–2
	Odds ratio (95% confidence interval)§					
D1	0.5 (0.4–0.7)	3.6 (1.9–6.7)	n.i.	1.3 (1.1–1.5)	1.1 (0.7–1.8)	n.i.
D2	0.9 (0.8–1.1)	n.i.	0.8 (0.7–0.9)	1.1 (1.0–1.3)	0.8 (0.6–1.0)	n.i.
D3	0.8 (0.7–0.9)	n.i.	0.9 (0.8–1.0)	1.2 (1.0–1.4)	0.9 (0.5–1.4)	n.i.
D4	0.9 (0.8–1.1)	n.i.	1.2 (1.0–1.3)	1.0 (0.9–1.2)	1.5 (0.8–2.7)	n.i.
D5	n.i.	n.i.	n.i.	0.9 (0.8–1.1)	3.0 (1.3–6.6)	0.7 (0.6–0.9)
D6	0.2 (0.2–0.3)	n.i.	n.i.	0.9 (0.8–1.1)	2.5 (1.1–5.5)	n.i.
D7	n.i.	n.i.	n.i.	0.8 (0.6–1.0)	0.8 (0.4–1.9)	1.0 (0.8–1.3)
D8	n.i.	1.0 (0.6–1.7)	n.i.	1.0 (0.7–1.4)	1.1 (0.6–2.0)	n.i.
T1	n.i.	n.i.	2.6 (1.7–3.9)	0.9 (0.6–1.3)	1.9 (1.0–4.0)	1.0 (0.7–1.6)
T2	0.29 (0.25–0.33)*	n.i.	n.i.	1.2 (1.0–1.4)	1.1 (0.7–1.6)	0.7 (0.6–0.8)
T3	2.3 (1.5–3.3)	n.i	n.i	1.0 (0.7–1.4)	0.6 (0.4–0.9)	1.1 (0.8–1.5)
T4	n.i.	n.i.	2.8 (2.2–3.6)	1.0 (0.8–1.3)	0.7 (0.3–1.5)	1.6 (1.3–2.0)
T5	0.5 (0.4–0.6)	n.i.	n.i.	0.9 (0.6–1.2)	1.1 (0.5–2.5)	0.7 (0.6–1.0)
T6	0.5 (0.3–0.7)	n.i.	n.i.	0.9 (0.6–1.4)	2.2 (0.8–6.2)	0.9 (0.6–1.3)
T7	1.1 (0.9–1.4)	n.i.	1.6 (1.3–2.0)	1.0 (0.8–1.1)	0.9 (0.6–1.6)	1.2 (1.0–1.4)
T8	1.1 (0.8–1.6)†	n.i.	0.9 (0.7–1.2)	1.6 (1.1–2.1)	0.8 (0.6–1.1)	0.5 (0.4–0.7)
T9	2.7 (1.8–4.2)†	n.i.	0.9 (0.6–1.2)	0.9 (0.5–1.7)	0.5 (0.3–0.9)	3.9 (2.6–5.8)
T10	1.4 (1.1–1.9)	n.i.	n.i.	1.1 (0.9–1.4)	0.5 (0.3–0.9)	1.0 (0.9–1.3)
T11	16.4(12.5–21.6)	n.i.	n.i.	1.1 (0.8–1.4)	1.1 (0.6–2.0)	1.1 (0.9–1.4)
F1	1.3 (1.1–1.6)	n.i.	1.0 (0.9–1.2)	1.4 (1.2–1.7)	0.7 (0.3–1.3)	1.2 (1.0–1.4)
F2	0.7 (0.6–0.8)	n.i.	0.6 (0.5–0.7)	1.4 (1.2–1.6)	1.1 (0.8–1.5)	0.8 (0.7–0.9)
T12	1.1 (0.8–1.4)	1.1 (0.8–1.7)	n.i.	1.2(0.9–1.6)	1.0 (0.8–1.4)	n.i.

§The odds ratios represent the relative increase in the odd of performing the procedure of one category of the covariate against the other, holding the other variables in the model fixed and adjusting for age and local health authority (n.i. indicates that the covariate was not included in the model).
*Stage II vs. I.
†Stage III vs II.

groups of patients. This is the reason why many indicators employed in previous experiences, as well as those used in this work, restrict the denominator (i.e. the subpopulation for which the recommendation is applicable), an alternative being to account for an estimated proportion of not eligible patients in the benchmark [7]. Nevertheless, the lack of information on hormonal and ERB receptor status, and other possible prognostic factors that determine the individual risk profile (and thus the appropriateness of certain recommendations), together with the presence of not analysed co-morbidities that would prevent certain treatments, have to be kept in mind. This is the reason why benchmarking should be used with caution when medical reasons for correct exception to a guideline cannot be directly assessed [30].

A limitation, which derives from the use of administrative data, is that not all the indicators judged to be important to monitor the care process can be calculated. Nevertheless, this type of project should also be the trigger to implement administrative data collection – both to code and include in the administrative flows those information that would be necessary to monitor processes and diseases, which are relevant from a public health perspective – and automatic computer acquisition of data from clinical documentation.

The analysed cohort represents the entire population of breast cancer female patients of a geographic and administrative area, with a homogeneous public health care system, and this allows to analyse phenomena such as migration from one hospital to the other, to understand determinants of adherence, and to plan interventions at a population level. For instance, the fact that only 33% of breast cancers in the population eligible to screening has been detected by the screening programme (range by LHA, 22–40%) raises the question of the impact of such programmes (across HLAs, coverage was nearly 100% and response rate was about 75%) and should entail a revision of the way the screening is offered in the areas with a lower value of this indicator. The main strength of the present work is that it uses all the available administrative data sources to detect the measured process. This is important both as a great part of the cancer care is delivered to outpatients, and because the reliability of administrative data increases when multiple databases are linked on an individual level.

The developed set of indicators demonstrates how it is possible to monitor, through a method that is endorsed both from epidemiologist and clinicians, the procedures actually delivered to patients with a severe chronic disease, with the ultimate goal to increase appropriateness, compliance to guidelines and promoting harmonization of the care delivered from a health system.

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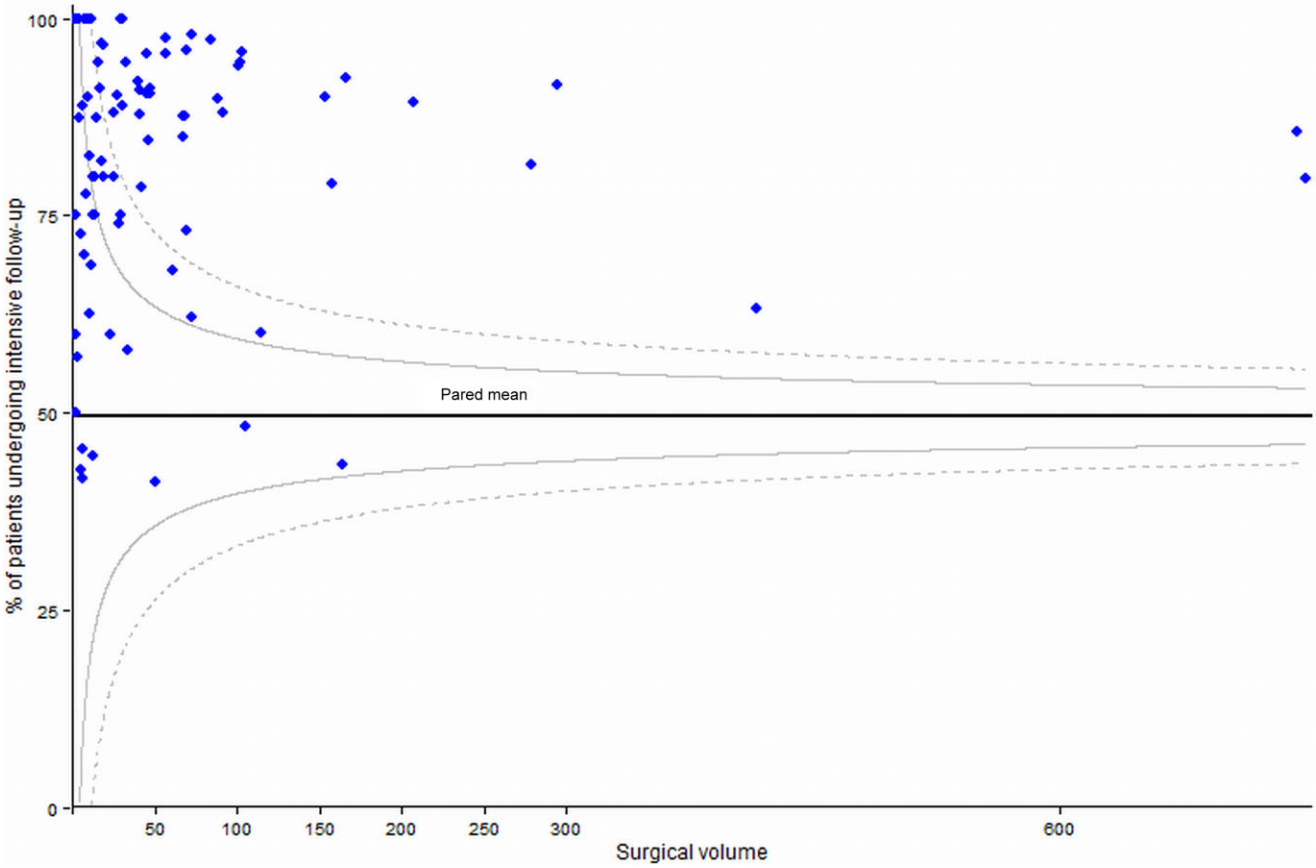

Figure 1 Funnel plot for the indicator of intensive follow-up (F1). The graph shows the dispersion around the 'pared' mean of the providers as a function of hospital volume. The 'pared' mean is roughly the value of the indicator calculated on the top ranked – in this case, having the lower value – hospitals including the 10% of the study population. Grey lines represent the 95% (solid) and 99.9% (dashed) confidence interval around the 'pared' mean.

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