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Audit system on Quality of breast cancer diagnosis and Treatment (QT): results of quality indicators on screen-detected lesions in Italy, 2011-2012

Il "progetto SQTM" sulla qualità della diagnosi e della terapia entro i programmi di screening in Italia: risultati 2011-2012

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Abstract

This annual survey, conducted by the Italian group for mammography screening (GISMa), collects individual data on diagnosis and treatment of about 50% of screen-detected, operated lesions in Italy. The 2011-2012 results show good overall quality and an improving trend over time. A number of critical issues have been identified, including waiting times (which have had a worsening trend over the years) and compliance with the recommendation of not performing frozen section examination on small lesions. Pre-operative diagnosis improved constantly over time, but there is still a large variation between Regions and programmes. For almost 90% of screen-detected invasive cancers a sentinel lymph node (SLN) biopsy was performed on the axilla, avoiding a large number of potentially harmful dissections. On the other hand, potential overuse of SLN dissection for ductal carcinoma in situ, although apparently starting to decline, deserves further investigation.

The detailed results have been distributed, among other ways by means of a web-based data-warehouse, to regional and local screening programmes, in order to allow multidisciplinary discussion and identification of the appropriate solutions to any issues documented by the data. The problem of waiting times should be assigned priority. Specialist Breast Units with adequate case volume and enough resources would provide the best setting for making monitoring effective in producing quality improvements with shorter waiting times.

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Riassunto

Questa survey annuale, condotta dal Gruppo italiano per lo screening mammografico (GISMa), raccoglie dati individuali su diagnosi e terapia di circa il 50% dei casi screen-detected operati in Italia.

I risultati 2011-2012 mostrano nel complesso una buona qualità e un trend in miglioramento nel tempo. Sono stati identificati alcuni aspetti critici, tra cui i tempi di attesa (che continuano a peggiorare anno dopo anno) e il rispetto della raccomandazione di non eseguire l'esame estemporaneo al

congelatore nelle lesioni piccole. L'indicatore sulla diagnosi preoperatoria è migliorato progressivamente negli anni ma esiste ancora un'elevata variazione tra Regioni e tra programmi. In quasi il 90% dei casi di cancro invasivo identificati allo screening è stato eseguito linfonodo sentinella (LNS) per la stadiazione, evitando un gran numero di dissezioni ascellari potenzialmente dannose. D'altra parte, il possibile eccessivo utilizzo del LNS nei carcinomi duttali in situ, che peraltro negli ultimi anni accenna a ridursi, merita indagini ulteriori.
I risultati dettagliati di questa survey sono stati distribuiti, anche attraverso una data-warehouse accessibile sul web, ai responsabili dei programmi di screening regionali e locali, allo scopo di permettere la discussione multidisciplinare, la verifica dei dati e l'identificazione delle soluzioni appropriate ai problemi che venissero così documentati. Al problema dei tempi di attesa dovrebbe essere assegnato carattere di priorità e urgenza. Unità diagnostico-terapeutiche di senologia con adeguati volumi di attività e sufficienti risorse fornirebbero il contesto adeguato per far sì che il monitoraggio sia efficace nel produrre miglioramenti nella qualità e tempi di attesa accettabili.

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Parole chiave: screening per il cancro della mammella, qualità, diagnosi, terapia, Italia

INTRODUCTION

Mammography screening rests upon a delicate balance of human benefits and costs which is highly sensitive to the quality, not only of the screening itself, but of the entire process of care for screen-detected lesions. Therefore, screening programmes should perform audits of further assessments, histopathology, diagnosis, and treatment, as well as the screening test itself.[1,2]
The mammography screening movement in Europe has been on the front line in introducing quality assurance and monitoring in all stages of breast cancer management and care. The European breast cancer screening network created an individual records database and audit system called QT (audit system on Quality of breast cancer Treatment) which can be downloaded at www.qtweb.it. At the same site, extensive documentation is available. QT can be used in six languages (English, French, German, Italian, Spanish, and Hungarian) and has been adopted by Breast units in several European countries. Within the Italian group for mammography screening (GISMa), a voluntary quality assurance programme for screen-detected breast cancer care has been ongoing since 1997,[3] and results of this activity have been published yearly in the reports of the National centre for screening monitoring since their first edition in 2003. The aim of this report is to publish results of the monitoring of diagnosis and treatment indicators in screen-detected lesions operated with open surgery in Italy during 2011-2012.

METHODS

Individual data on diagnosis and treatment of screen-detected operated lesions (benign or malignant) are recorded on QT either by clinical staff in charge of the patients or by local screening organization and evaluation units. Regional programmes report anonymous data yearly to the national co-ordination office, which performs data quality control and analysis.
Sources of outcome measures are Italian[4,5] and European[2,6-8] guidelines. This report includes indicators defined recently by a Senonetwork-GISMa consensus group.[9] Regions were excluded from the analysis of a given indicator if missing values for that indicator exceeded 30%.
Even though most programmes in Italy have designated surgical units where the majority of the cases are referred, the study protocol required that participating programmes record all screen-detected cases, regardless of where treatment had taken place. Piemonte, Valle d'Aosta, and Toscana use as index date the date of the screening test that originated surgical referral, while the remaining regions use date of surgery. To avoid selection bias, the study protocol requires that participating programmes record all screen-detected operated lesions. Known interval cases, operated in the index year, could also be included, but this was not required.
The results reported here were presented, in their preliminary version, at the National centre for screening monitoring's annual meeting in January 2014 in Bologna. Preliminary results were checked locally and updated. In several of the regions, data were discussed at specific multidisciplinary meetings prior to publication. Data have been made available to regional and screening coordinators on a web-based data-warehouse which allows for analysis and benchmarking.
In 2011-2012, data were reported for a portion only of the following regions: Lombardia (Milano), Friuli-Venezia Giulia (Trieste), Puglia (Lecce) and Toscana (Firenze). For the remaining four regions, data were reported region-wide. For the first time, results in this report are shown for ages 45-74, as some regions have extended the screening target population beyond the traditional 50-69 age group.
All indicators are proportions; 95% confidence intervals are given. Data analysis was performed with the tools included in SQTM and statistical programme R.

RESULTS

During 2000-2012, about 40,000 lesions in thirteen Italian regions were documented in QT. In 2011-2012, thirty-seven screening programmes belonging to GISMa participated in the QT project and individual data on 8,809 cases (including 7,284 malignant lesions) in eight regions were recorded in women between 45 and 74 years of age (**table 1**, p. 42).
Ductal carcinoma in situ (DCIS) accounted for 16.0% of all malignant lesions. Of invasive tumours, 35.1% had pathological size ≤10 mm. Operated benign or intraepithelial lesions (atypical hyperplasia, lobular "carcinoma" in situ grade 1 or 2,

Number of programmes	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Piemonte and Valle d'Aosta	8	9	10	10	10	10	10	10	10	10	10	10	10
Lombardia	1	-	-	-	1	1	1	-	-	1	1	1	1
Veneto	2	1	12	12	12	12	10	9	1	-	-	-	-
Friuli-Venezia Giulia	-	-	-	-	-	-	-	-	-	-	-	-	1
Emilia-Romagna	6	8	9	9	8	10	11	11	11	11	11	11	11
Toscana	1	1	1	1	1	9	9	11	11	1	1	1	1
Umbria	-	-	1	-	-	-	-	-	-	-	-	-	-
Lazio	2	5	3	7	7	6	6	8	8	10	11	11	12
Campania	1	-	-	-	-	-	-	-	-	-	-	-	-
Puglia	-	-	-	-	-	-	-	-	-	-	-	1	1
Sardegna	-	-	-	-	-	-	-	1	1	1	1	-	-
Sicilia	2	1	2	-	1	-	-	-	-	-	-	-	-
Total	**23**	**25**	**38**	**39**	**40**	**48**	**47**	**50**	**42**	**34**	**35**	**35**	**37**
Number of cases													
Piemonte and Valle d'Aosta	589	709	812	852	1,170	1,175	1,212	1,098	1,216	1,229	1,196	1,563	1,538
Lombardia	69	-	-	-	51	138	139	-	-	439	374	418	434
Veneto	158	76	270	426	369	432	392	191	176	-	-	-	-
Friuli-Venezia Giulia	-	-	-	-	-	-	-	-	-	-	-	-	57
Emilia-Romagna	394	796	663	742	856	920	992	984	1,107	1,129	1,103	1,536	2,016
Toscana	144	138	151	195	213	522	526	710	551	192	88	75	71
Umbria	-	-	33	-	-	-	-	-	-	-	-	-	-
Lazio	137	142	128	245	339	239	286	375	325	567	467	502	443
Campania	9	-	-	-	-	-	-	-	-	-	-	-	-
Puglia	-	-	-	-	-	-	-	-	-	-	-	61	95
Sardegna	-	-	-	-	-	-	-	74	72	17	62	-	-
Sicilia	135	23	36	-	10	-	-	-	-	-	-	-	-
Total	**1,635**	**1,890**	**2,093**	**2,460**	**3,008**	**3,426**	**3,547**	**3,432**	**3,447**	**3,573**	**3,290**	**4,155**	**4,654**

Table 1. Italian survey on diagnosis and treatment of screen-detected breast lesions, 2000-2012, age 49-70 (up to 2010) age 45-74 (from 2011). Number of screening programmes and cases, by region.

Tabella 1. Survey sulla diagnosi e la terapia delle lesioni mammarie screen-detected, 2000-2012, età 49-70 (fino al 2010), età 45-74 (dal 2011). Numero di programmi e di casi, per Regione.

atypia with columnar cells, atypical papillary lesions) represented 13% of cases with known diagnosis. However, benign and intraepithelial lesions were systematically recorded only by 5 out of 8 regions: Piemonte, Valle d'Aosta, Emilia-Romagna, Lazio, and Puglia. Within these regions, benign or intraepithelial lesions accounted for 15% of cases (benign/malignant ratio= 0.18, a value very similar to the one found in the GISMa aggregated data survey). The proportion of benign and intraepithelial lesions, as well as of DCIS, was greater in younger women (**table 2**).

The proportion of N+ invasive cases was 27.4% (missing: 9.1%). Grade of invasive carcinoma was distributed as follows: 20.5% I, 54.6% II, and 24.9% III (missing: 9.5%). Nuclear grade of DCIS was 25.4% I, 40.2% II, and 34.4% III (missing: 10.5%).

Results of outcome measures are shown in tables 3 and 5.

Eighty-two per cent of cancers had pre-operative cytological or micro-histological diagnosis (**table 3**). This figure is higher compared to previous years and is over the new[9] acceptable target of 80%. However, considerable variation exists between regions (range 45%-91%) and especially between programmes. Cases for which pre-operative diagnosis was not available are distributed by reason in **table 4**. Failure in performing any non-operative diagnosis was responsible for 14% of these cases (16% in 2010). A non-operative diagnosis involving "suspicion" of malignancy – C4 or B4, according to the classification proposed by the EC Working group on breast screening pathology[7] – rather than a higher degree of certainty was responsible for 50% of the cases (48% in 2010). The proportion of inadequate cytology and absolute sensitivity[7] of C5 were above the target (**table 3**).

Waiting times were still far from the target and had even worsened compared to previous years (**tables 5**, p. 44 and **7**, p. 46). Forty-three per cent of cancers received surgery within one month of referral (range between regions: 34%-79%), and 30% within two months of the screening date (22%-62%) (**table 5**). Just slightly more than 65% of cases received surgery within three months after screening (59%-92%).

Histopathological diagnosis	Age 45-49		Age 50-59		Age 60-69		Age 70-75		Missing		Total	
	N	%	N	%	N	%	N	%	N	%	N	%
benign	231	18.0	293	11.6	199	6.2	34	3.6	21	2.4	778	8.8
intraepithelial	118	9.2	115	4.6	80	2.5	14	1.5	3	0.3	330	3.7
lobular carcinoma in situ (LIN 3)	2	0.2	1	0.0	4	0.1	0	0.0	1	0.1	8	0.1
ductal carcinoma in situ	208	16.3	351	14.0	375	11.7	123	13.0	91	10.5	1,148	13.0
micro-invasive	15	1.2	40	1.6	43	1.3	14	1.5	2	0.2	114	1.3
invasive (1A/1B)	40	3.1	136	5.4	178	5.6	31	3.3	49	5.6	434	4.9
invasive (other)	172	13.4	461	18.3	760	23.8	264	27.8	145	16.7	1,802	20.5
invasive (unknown size)	443	34.6	949	37.7	1,414	44.3	439	46.3	292	33.6	3,537	40.2
malignant not specified	10	0.8	48	1.9	67	2.1	13	1.4	103	11.8	241	2.7
unknown	41	3.2	122	4.8	75	2.3	16	1.7	163	18.7	417	4.7
Total	**1,280**	**100**	**2,516**	**100**	**3,195**	**100**	**948**	**100**	**870**	**100**	**8,809**	**100**

Table 2. It. Italian survey on diagnosis and treatment of screen-detected breast lesions, 2011-2012. Distribution by final histopathology diagnosis and age.
Tabella 2. Survey sulla diagnosi e la terapia delle lesioni mammarie screen-detected, 2011-2012. Distribuzione per diagnosi istopatologica definitiva ed età.

Outcome measure	Eligible cases	Missing %	Result %	95%CI	Minimum % required	Target %
pre-operative diagnosis in cancers (C5,B5)	6,878	2.6	82.2	81.3 - 83.1	≥80	≥90
non-inadequate cytology if final diagnosis is cancer	4,381	0.6	91.9	91.1 - 92.7		≥90
absolute sensitivity C5	4,381	0.6	67.6	66.2 - 69.0		≥60

Table 3. Summary on diagnostic indicators, 2011-2012, age 45-74. Results are calculated on eligible cases minus cases with missing information.
Tabella 3. Indicatori diagnostici, 2011-2012, età 45-74. I casi con informazione mancante sono esclusi dal denominatore.

Guidelines recommend avoiding intra-operative frozen section examination (even on margins) in lesions under or equal to 10 mm because of limited accuracy and the risk of deteriorating the specimen and impairing subsequent examination.[1,4-7] The result of this indicator (**table 5**) was still below the target, but had improved compared to the previous period, as in 2007 frozen section examination was performed in about one fourth, in 2008-2009 in about one fifth, and in 2010 and 2011-2012 in one eighth of cases only (the range between regions is wide: 9%-80%). Recent Italian guidelines[9] recommend the performance of two-view specimen X-rays on all lesions showing micro-calcifications only and set the numerical target at 90%. The indicator (**table 5**) gives a result of 66.0%. The number of missing data however is high (21%).
Breast conservation, both for invasive cancer (up to 3 cm)[9] and DCIS (up to 2 cm), was at high levels, 85% the former and 90% the latter. The proportion of axillary dissections with an adequate number of lymph nodes excised (92%) exceeded the target (**table 5**). The indicator on performing no more than one operation on the breast for clearing margins met the 90% target both for invasive cancer and DCIS. Margins were left wider than 1 mm in 93% of cases (**table 5**).
This survey investigated the gradual introduction over the years of the sentinel lymph node (SLN) biopsy, which makes staging possible with considerably fewer complications than axillary clearance.[4,8] An increasing proportion of invasive cancers and DCIS were studied with SLN biopsy over time until 2007-2008, then the use of SLN biopsy in invasive cancers reached a plateau around 87% while in DCIS it seemed to start decreasing from a maximum of 62% in 2010 to 53% in 2012 (**figure 1**, p. 44). The proportion of node-negative invasive cases staged by SLN biopsy only (**table 5** and **table 7**) was 91% in 2011-2012, with an increasing trend over the years and moderate variability by region (range 73%-100%). In 92% of cases no more than 3 sentinel lymph nodes were excised, as prescribed by the target (**table 5**).
In 2011-2012, 3.3% of DCIS (range between regions: 0%-7%) received clearance of the axilla (**table 5**), a procedure not recommended in these cases. The result of this indicator has improved over the years (**table 7**).
Overtreatment may also result from unnecessary open surgery in the breast on benign lesions. This issue is illustrated in **table 6** (p. 45) where operated benign or intraepithelial lesions are distributed by histopathology type. Benign lesions at no increased risk (all except intraepithelial lesions, papilloma, sclerosing adenosis, radial scar, and phylloid tumours) were 524 in 2011-2012 (49% of all operated benign or intraepithelial

	N	%
pre-operative diagnosis not performed	171	14.3
unsatisfactory	136	11.4
false negative (C2 or B2)	43	3.6
dubious (C3 o B3)	252	21.1
suspicious (C4 o B4)	592	49.6
Total	**1,194**	**100.0**

Table 4. Distribution of malignant cases without pre-operative diagnosis C5 or B5 by reason, 2011-2012, age 45-74.
Tabella 4. Distribuzione delle lesioni maligne senza diagnosi preoperatoria C5 o B5, per motivo della mancata diagnosi preoperatoria, 2011-2012, età 45-74.

Outcome measure	Eligible cases	Missing %	Result %	CI95%	Minimum % required	Target %	Excluded
waiting time for surgery from referral ≤30 days	7,263	16.7	43.5	42.3-44.8	≥75	≥90	Lombardia, Puglia
waiting time for surgery from first diagnostic test ≤42 days	7,263	8.3	28.8	27.8-30.0	≥75	≥90	Lombardia, Puglia
waiting time for surgery from screening test ≤60 days	7,123	10.2	29.9	28.8-31.0	≥75	≥90	Lombardia, Puglia, Toscana
waiting time for surgery from screening test ≤90 days	7,123	10.2	65.4	64.2-66.5			Lombardia, Puglia, Toscana
frozen section not performed in cancers ≤10 mm	1,423	12.0	87.5	85.6-89.3		≥95	Lazio, Lombardia, Toscana
specimen X-ray in cases with microcalcifications only	768	21.2	66.3	62.3-70.0	≥90	≥98	Puglia
only one operation after pre-operative diagnosis (invasive)	5,728	0.7	92.9	92.2-93.6	≥80	≥90	
only one operation after pre-operative diagnosis (in situ)	1,112	0.4	89.9	87.9-91.6	≥80	≥90	
conservative surgery in invasive cancers ≤30 mm	5,367	10.5	84.7	83.6-85.7	≥70	≥90	
conservative surgery in DCIS (ductal carcinoma in situ) ≤20 mm	511	1.2	90.1	87.1-92.5	≥80	≥90	
margins >1 mm after last surgery	4,547	18.5	92.8	91.9-93.6			Lazio, Lombardia
number of lymph nodes >9 in axillary dissection (sampling excluded)	1,057	2.3	92.3	90.4-93.8	≥80	≥90	
axillary staging by SLN only in pN0	3,407	0	91.1	90.1-92.0	≥80	≥90	
no axillary dissection (sampling included) in DCIS	1,106	6.1	96.7	95.4-97.7	≥90	≥95	
no more than 3 LNs at SLN biopsy	5,726	29.5	92.4	91.5-93.2	≥80	≥90	Lombardia, Puglia

Table 5. Summary on surgical indicators, 2011-2012, age 45-74. Results are calculated on eligible cases minus cases with missing information. Due to missing values exceeding 30%, some regions were excluded from the calculation of specific indicators.
Tabella 5. Indicatori chirurgici, 2011-2012, età 45-74. I casi con informazione mancante sono esclusi dal denominatore. Sono state escluse dal calcolo di specifici indicatori le Regioni con una proporzione di valori mancanti >30%.

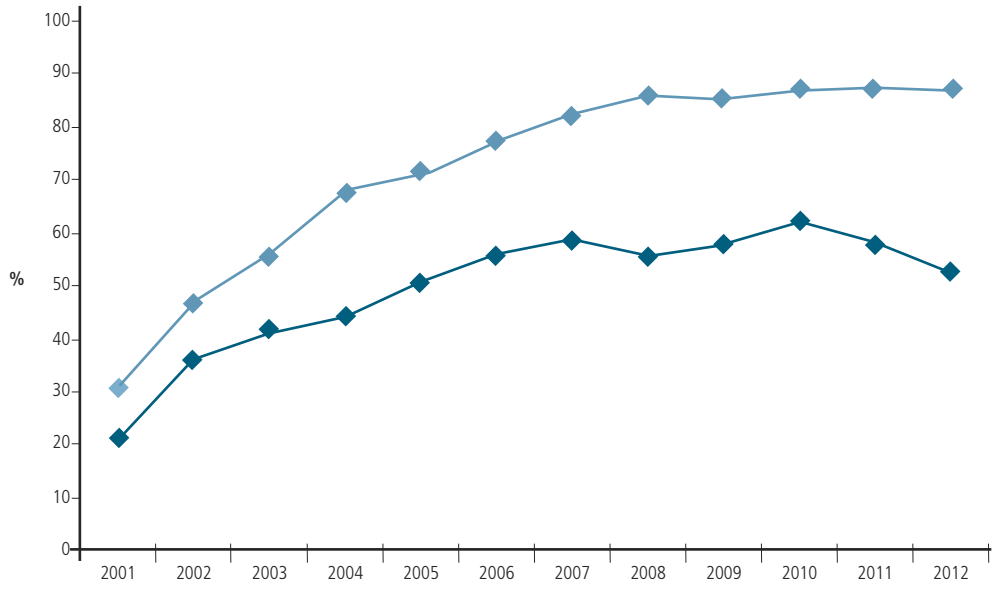

Figure 1. Italian survey on diagnosis and treatment of screen-detected breast cancers. Trend (%) in the use of SLN technique (age 49-74). Years 2001-2012.
Figura 1. Survey sulla diagnosi e la terapia dei carcinoma della mammella screen-detected. Trend (%) nell'uso della tecnica del linfonodo sentinella (età 49-70). Anni 2001-2012.

		N	%
benign	normal tissue	15	1.4
	fibroadenoma	161	15.1
	cysts	17	1.6
	columnar cell change without atypia	8	0.7
	fibrocystic breast diseae	102	9.5
	benign phylloid tumour	20	1.9
	sclerosing adenosis	80	7.5
	radial scar	21	2.0
	papilloma/papillomatosis	110	10.3
	other	149	13.9
	unknown	72	6.7
	total benign	**755**	**70.6**
intraepithelial	atypical lobular hyperplasia (LIN1)	16	1.5
	lobular carcinoma in situ (LIN2)	65	6.1
	atypical columnar cell change (DIN1a)	66	6.2
	atypical ductal hyperplasia (DIN1b)	165	15.4
	atypical papillary lesion	2	0.2
	total intraepithelial	**314**	**29.4**
Total		**1,069**	**100.0**

Table 6. Distribution by histological type of benign and intraepithelial lesions operated by open surgery (excluding synchronous lesions), age 45-74. Years 2011-2012
Tabella 6. Distribuzione per tipo istologico delle lesioni benigne e intraepiteliali operate (lesioni sincrone escluse), età 45-74. Anni 2011-2012.

lesions, excluding double lesions and lesions with missing histological type: a result similar to previous years).
Table 7 shows time trends from 2000 to 2012 for selected performance parameters. The frequency of pre-operative diagnosis and avoidance of frozen section examination in small lesions showed improvement over time. Waiting times had a consistent and important negative trend over the years.

DISCUSSION

In 2011-2012, most outcome measures were near or met the target set by GISMa.[5,9] Major exceptions, similarly to 2010, were waiting times for surgery, compliance with the recommendation on avoiding frozen section examination on small lesions and performing specimen X-rays.
The proportion of cancers with pre-operative diagnosis has clearly increased over the years, due to increasing use of microhistology techniques, and reached the acceptable target for the first time in 2005. However, the result only slightly increased compared to 2007, despite the fact that a wide margin for improvement still exists in order to reach the European desirable target of 90%.[7] This is also supported by the finding of a considerable variation between programmes: about 25% did not reach the acceptable target, while more than 20% did. Pathologists and radiologists should be involved with surgeons in analyzing the reasons for underperformance in programmes scoring in the lower part of the range. It may be worthy of notice that fine needle aspiration cytology (FNA) was still used for pre-operative diagnosis in the majority of cases: out of 7,449 lesions receiving needle biopsies, 3,560 (48%) received FNA only, 2,620 (35%) core or vacuum assisted biopsy only, and 1,269 (17%) both.
Waiting time from screening to surgery embraces much of the entire process of care (time from screening to first assessment, time from first assessment to result, time from result of assessment to first surgery). Results have been worsening over the years, and in 2011-2012 the decreasing trend continued, with as few as 30% of patients being operated within 60 days of the screening examination. Regional authorities should inspect the reasons for this considerable delay, especially in regions in the lower part of the range. Even though two or three months of treatment delay are not expected to affect clinical outcomes,[10] they can cause anxiety and impair quality of life, in addition to contradicting the idea itself of early detection. Furthermore, many cases experience a delay greater than three months.
Avoiding the use of frozen section examination entails a difficult change in attitude by the surgeon, when it is not due to lack of pre-operative diagnosis. This procedure, even when aimed at the evaluation of margins in impalpable lesions, should be substituted by two-view specimen X-ray.[4,9]
Use of axillary dissection in DCIS was in compliance with the target (less than 5%) but could further decrease, since this procedure is useless in DCIS and is a potential cause of complications. Pre-operative multidisciplinary discussion is the way to minimize this problem, as only through discussion with the pathologist and radiologist can the surgeon learn about the non-invasiveness of the lesion.[8] This should also help in decreasing the use in benign lesions, LIN, and low- and intermediate-grade DCIS, of SLN dissection, which is not free of complications. Importantly, for the first time, this survey shows a decline in the use of SLN biopsy in DCIS.
The proportion of missing values is still relatively large for waiting time, frozen section examination, and performance of specimen X-ray.
Although this survey includes a large share of screen-detected

Indicator	Eligible	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	Min. % req.	Target
pre-operative diagnosis in cancers (C5,B5)	33,397	52.4	58.1	61.4	66.5	69.9	73.2	73.7	75.8	78.2	76.9	80.3	81.5	84.3	≥80	≥90
waiting time for surgery from referral ≤30 days	24,362	63.1	54.8	59.0	59.0	56.4	60.6	58.2	53.8	52.2	45.3	43.6	44.7	42.5	≥75	≥90
waiting time for surgery from first diagnostic test ≤42 days	29,560	69.2	49.6	47.4	46.6	41.3	42.7	42.3	36.8	32.9	35.3	31.3	30.2	27.9	≥75	≥90
waiting time for surgery from screening test ≤60 days	27,918	60.4	54.2	58.5	55.4	55.2	52.3	48.7	44.2	39.6	41.2	38.0	32.9	26.9	≥75	≥90
waiting time for surgery from screening test ≤90 days	27,918	87.0	79.6	82.7	80.1	80.4	79.2	78.9	75.7	70.0	73.6	71.1	68.9	61.9		
frozen section not performed in cancers ≤10 mm	6,200	44.4	51.8	59.6	68.3	79.5	73.0	69.3	75.8	81.0	86.1	87.2	90.8	89.4	≥95	≥95
specimen X-ray in cases with microcalcifications only	1,960	77.7	58.2	61.2	34.2	45.1	45.3	57.1	32.9	44.2	64.8	68.8	64.2	68.4	≥90	≥98
only one operation after pre-operative diagnosis (invasive)	23,523	84.9	85.4	87.1	87.8	87.9	88.7	90.0	90.4	91.3	91.8	92.8	92.4	92.4	≥80	≥90
only one operation after pre-operative diagnosis (non-invasive)	4,443	74.8	81.6	82.9	86.0	86.0	86.6	86.1	87.3	86.4	88.5	90.5	90.3	89.0	≥80	≥90
conservative surgery in invasive cancers ≤30 mm	20,680	85.2	84.3	83.1	86.6	86.9	88.4	87.9	88.0	88.9	88.6	86.6	87.1	84.7	≥70	≥90
conservative surgery in DCIS (ductal carcinoma in situ) ≤20 mm	2,956	89.8	89.4	89.0	88.5	93.5	93.0	89.1	92.3	91.0	95.5	93.9	92.8	88.2	≥80	≥90
margins >1 mm after last surgery	20,579	85.5	85.1	83.2	87.3	89.0	90.1	89.4	89.2	89.4	93.6	90.9	93.5	93.4		
number of lymph nodes >9 in axillary dissection (sampling excluded)	7,048	92.9	95.0	95.1	92.1	90.4	93.3	92.4	92.6	91.0	90.2	91.5	93.8	90.8	≥80	≥90
axillary staging by SLN only in pN0	14,741	0	14.7	47.9	60.2	69.1	75.6	82.9	86.3	89.4	91.7	90.1	90.3	92.2	≥80	≥90
no axillary dissection in DCIS	4,103	79.7	85.9	93.2	89.2	96.0	94.5	93.6	93.8	97.4	97.3	97.8	95.0	98.3	≥90	≥95
no more than 3 LNs at SLN biopsy	20,276	-	94.0	95.5	93.2	94	94.5	92.8	92.9	92.3	93.6	94.0	92.7	94.2	≥80	≥90

Table 7. Time trends for selected indicators (%), 2000-2012, age 49-70. Only regions having contributed data for the whole period (Piemonte, Valle d'Aosta, Emilia-Romagna, Toscana, Lazio) were included. Due to missing values exceeding 30%, Lazio was excluded from the indicators for waiting time for surgery from referral, specimen X-ray, and no more than 3 LNs at SLN biopsy.

Tabella 7. Andamento temporale (%) per alcuni indicatori, 2000-2012, età 49-70. Sono incluse solo le Regioni che hanno contribuito per l'intero periodo (Piemonte, Valle d'Aosta, Emilia-Romagna, Toscana e Lazio). Avendo una proporzione di valori mancanti >30%, il Lazio è escluso dal calcolo degli indicatori sui tempi di attesa dalla prescrizione, l'esecuzione della Rx sul pezzo e il numero di linfonodi sentinella escissi.

malignant cases in Italy (about 50% of cases documented in the GISMa aggregated data survey), a selection towards inclusion of cases from better-organized Regions cannot be excluded. Benign operations, furthermore, are under-recorded in some of the Regions. A larger participation in the survey by Italian regions and programmes would be appropriate, perhaps coupled with simplified data collection methods. On the other hand, it is important to maintain the connection between screening and clinical Breast units[11,12] that has been established by this project over the years: a strong point of this project is the production of timely and detailed information of interest to both clinicians and public health professionals.

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References/Bibliografia

1. National Co-ordination group for surgeons working in breast cancer screening. *Quality assurance guidelines for surgeons in breast cancer screening*. NHSBSP, Publication n. 20, 1996.
2. Perry N, Blichert-Toft M, Cataliotti L et al. Quality assurance in the diagnosis of breast disease. *Eur J Cancer* 2001;37:159-72.
3. Distante V, Mano MP, Ponti A. Monitoring surgical treatment of screen-detected breast lesions in Italy. *Eur J Cancer* 2004;40:1006-12.
4. Forza operativa nazionale sul carcinoma mammario. *I tumori della mammella. Linee guida sulla diagnosi, il trattamento e la riabilitazione*. Firenze, 2003. Updated in: *Attualità in Senologia* 2005;46:33-106.
5. Mano MP, Distante V, Ponti A et al. Monitoraggio e promozione della qualità del trattamento del carcinoma mammario nelle Unità di senologia e nei programmi di screening in Italia. *Attualità in Senologia* 2001;10 (Suppl 1).
6. Rutgers EJT, Bartelink H, Blamey R et al. Quality control in loco-regional treatment for breast cancer. *Eur J Cancer* 2001;37:447-53.
7. Perry N, Broeders M, de Wolf C et al. *European guidelines for quality assurance in breast cancer screening and diagnosis.* 4th edition. European commission, Europe against cancer programme, Luxembourg 2006.
8. Rosselli del Turco MR, Ponti A, Bick U et al. Quality indicators in breast cancer care. *Eur J Cancer* 2010;46:2344-56.
8. Mano MP, Ponti A, Angiolini C et al. *Indicatori di qualità per la cura del carcinoma mammario nelle Breast Unit in Italia: una proposta congiunta GISMa-Senonetwork*. [www.senonetwork.org].
10. Richards MA, Westcombe AM, Love SB et al. Influence of delay on survival in patients with breast cancer: a systematic review. *Lancet* 1999;353:1119-26.
11. Blamey R, Blichert-Toft M, Cataliotti L et al. Breast units: future standards and minimum requirements. *Eur J Cancer* 2000, 36: 2288-93.
12. Wilson RA, Marotti L, Bianchi S et al. The requirements of a specialist Breast Centre. *Eur J Cancer* 2013;49:3579-87.