**FONCaM-GISMa Workshop multidisciplinare dell'equipe diagnostico-terapeutica**

# "Monitoraggio degli indicatori di qualità: confronto tra attività europee, nazionali e regionali"

**Peschiera del Garda 12-13 Marzo 2009**


## LINEE GUIDA E INDICATORI DI DIAGNOSI E TERAPIA

*

## LINEE GUIDA E INDICATORI FONCAM


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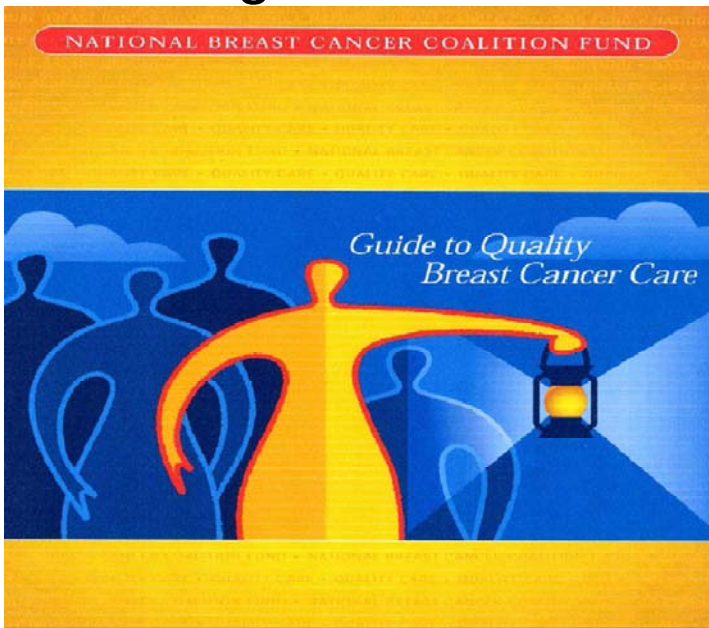
# LE LINEE GUIDA PER LA PRATICA CLINICA

Definizione

*"Raccomandazioni elaborate in modo sistematico per assistere medici e pazienti nelle decisioni che devono essere prese in specifiche circostanze cliniche"* Institute of Medicine, Washington, DC



ESMO European Society for Medical Oncology

# What Are Clinical Practice Guidelines?

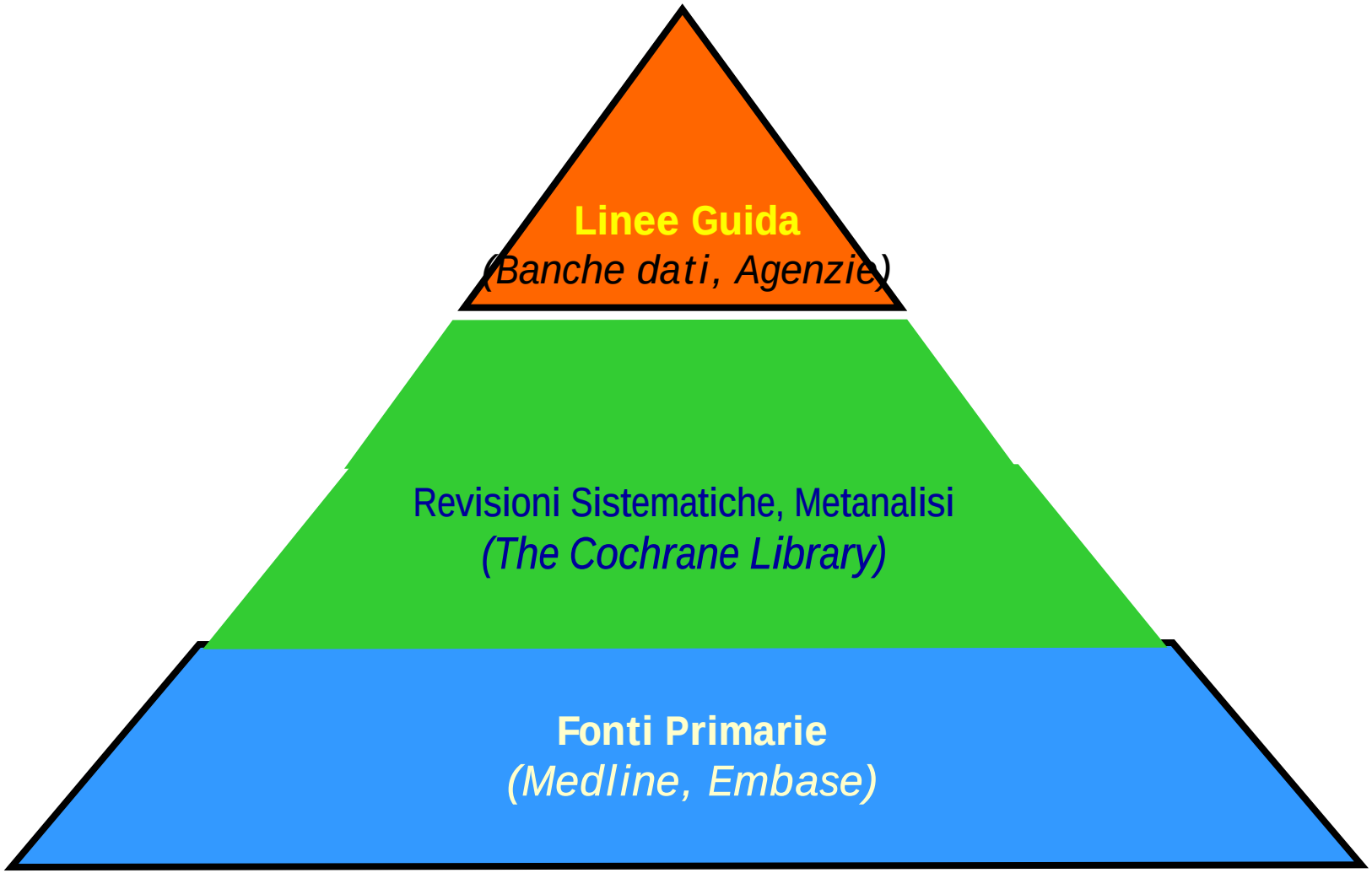
**Systemically developed evidence-based statements aiming:**

1. **To assist practitioners in appropriate clinical decision-making**
2. **To improve quality of healthcare and outcomes for patients**
3. **To influence national policies for efficient allocation of resources and for better delivery systems.**

PROVIDE THE RIGHT CARE,
AT THE RICHT TIME,
FOR THE RIGHT PERSON
IN THE RIGHT WAY

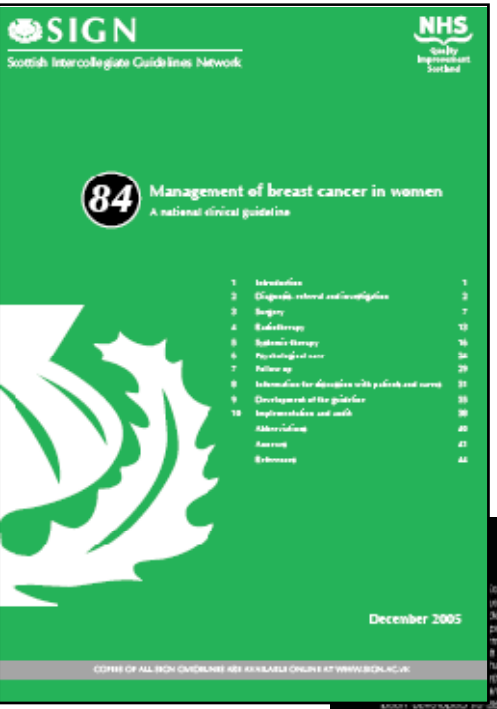
JAMA 2000, 284:2100-07

# DOVE CERCARE CHE COSA

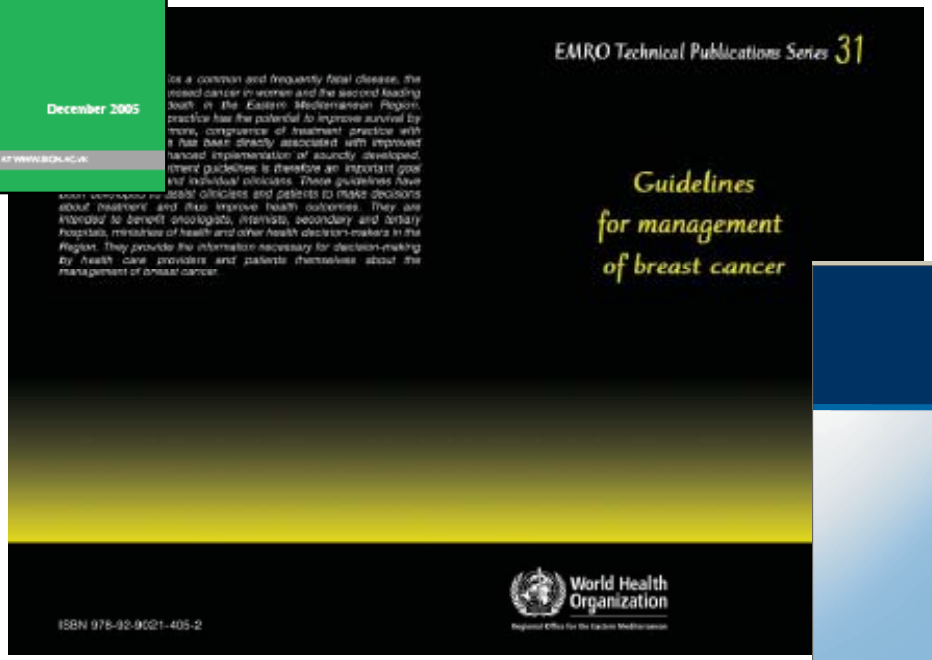


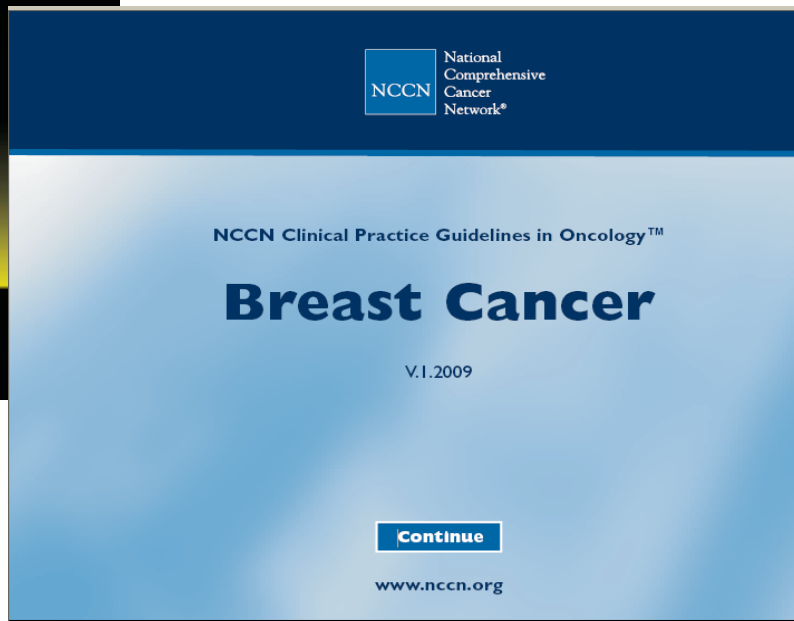

http://www.asmn.re.it/Biblioteca/guide.asp

# DOCUMENTI INTERNAZIONALI




ASCO® American Society of Clinical Oncology
*Making a world of difference in cancer care*

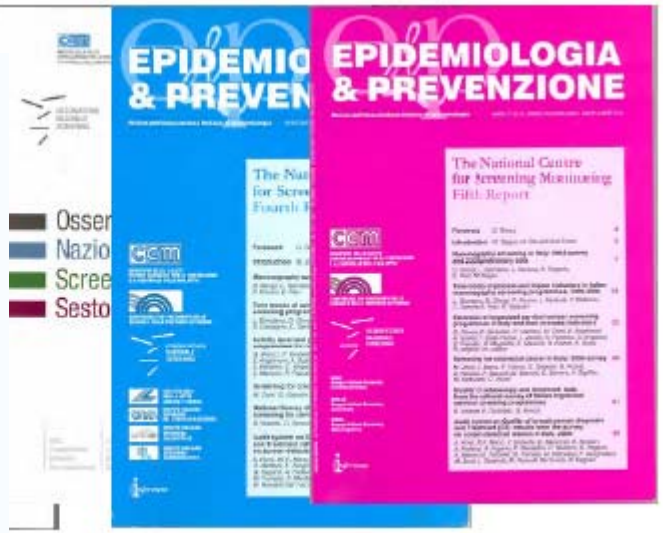


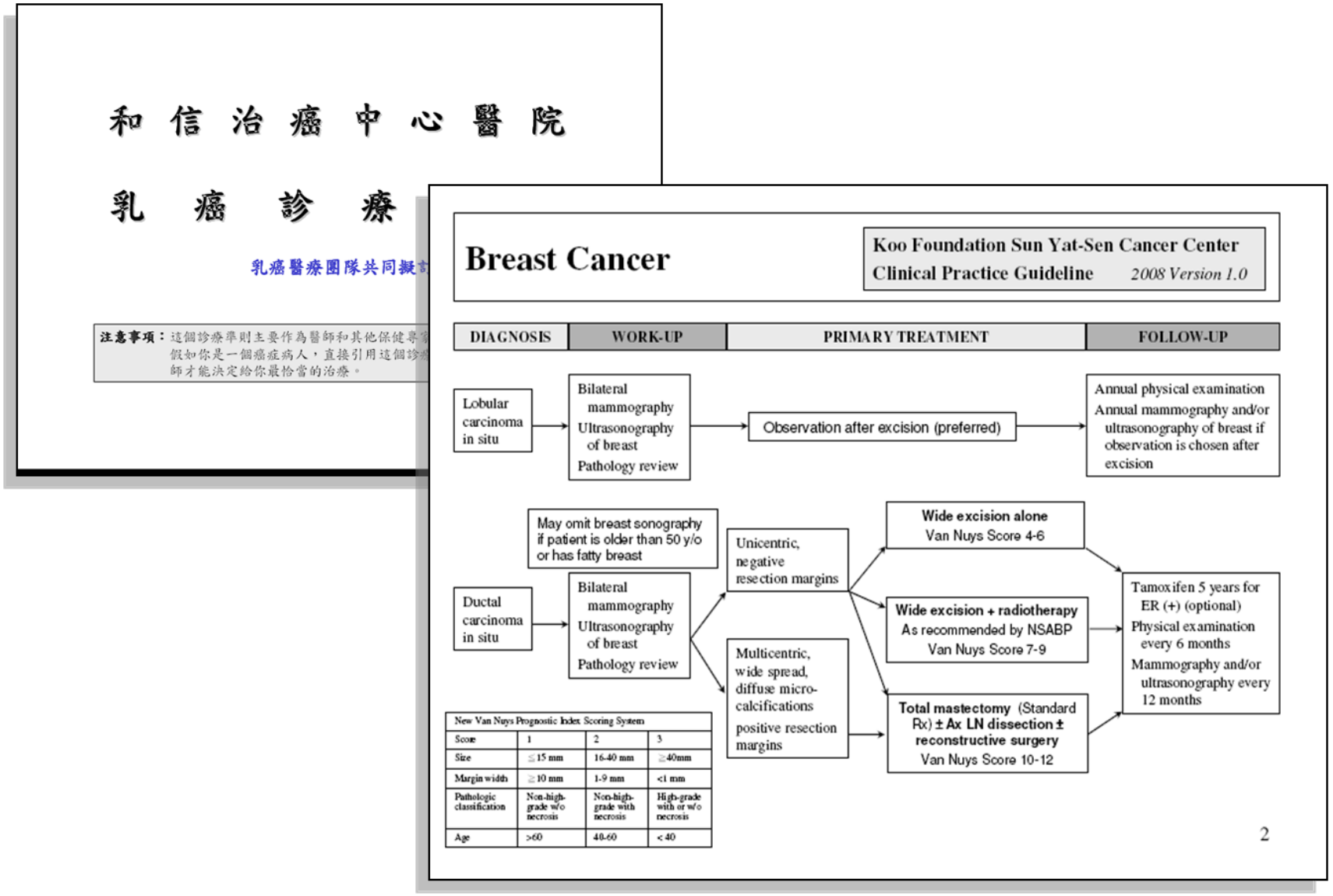
# DOCUMENTI NAZIONALI







# QUALI LINEE GUIDA UTILIZZARE ?



和 信 治 癌 中 心 醫 院

乳 癌 診 療

乳癌醫療團隊共同擬

注意事項：這個診療準則主要作為醫師和其他保健專
假如你是一個癌症病人，直接引用這個診
師才能決定給你最恰當的治療。

**Breast Cancer**

Koo Foundation Sun Yat-Sen Cancer Center
Clinical Practice Guideline *2008 Version 1.0*

| DIAGNOSIS | WORK-UP | PRIMARY TREATMENT | FOLLOW-UP |
|---|---|---|---|

Lobular carcinoma in situ → Bilateral mammography, Ultrasonography of breast, Pathology review → Observation after excision (preferred) → Annual physical examination; Annual mammography and/or ultrasonography of breast if observation is chosen after excision

Ductal carcinoma in situ → Bilateral mammography, Ultrasonography of breast, Pathology review (May omit breast sonography if patient is older than 50 y/o or has fatty breast)

- Unicentric, negative resection margins → **Wide excision alone** Van Nuys Score 4-6
- Unicentric, negative resection margins → **Wide excision + radiotherapy** As recommended by NSABP Van Nuys Score 7-9
- Multicentric, wide spread, diffuse micro-calcifications; positive resection margins → **Total mastectomy** (Standard Rx) ± **Ax LN dissection ± reconstructive surgery** Van Nuys Score 10-12

→ Tamoxifen 5 years for ER (+) (optional); Physical examination every 6 months; Mammography and/or ultrasonography every 12 months

| New Van Nuys Prognostic Index Scoring System | | | |
|---|---|---|---|
| Score | 1 | 2 | 3 |
| Size | ≤15 mm | 16-40 mm | ≥40mm |
| Margin width | ≥10 mm | 1-9 mm | <1 mm |
| Pathologic classification | Non-high-grade w/o necrosis | Non-high-grade with necrosis | High-grade with or w/o necrosis |
| Age | >60 | 40-60 | <40 |

2

# ESMO
# Clinical Recommendations

# ESMO Clinical Recommendations

*What kind of Guidelines ?*

- **Disease or topic oriented**
- **Evidence based**
- **Emphasis on Medical Oncology**
- **Regularly updated (annually)**
- **Three-page format, with up to 10 references**

# LINEE GUIDA

## **SIGN** – Scottish Intercollegiate Guidelines Network

**Liv. di evidenza 1++**: evidenza ottenuta da meta-analisi, revisioni sistematiche di trial clinici, o trial clinici con bassisimo rischio di bias;

**Liv. di evidenza 1+:** evidenza ottenuta da meta-analisi, revisioni sistematiche di trial clinici, o trial clinici con rischio di bias;

**Liv. di evidenza 1-:** evidenza ottenuta da meta-analisi, revisioni sistematiche di trial clinici, o trial clinici con alto rischio di bias;

**Liv. di evidenza 2++:** evidenza ottenuta da revisioni sistematiche di studi caso-controllo o di coorte di alta qualità. Studi di coorte o caso-controllo di buona qualità con basso rischio di bias o fattori di confondimento e con alta probabilità che la relazione sia causale.

**Liv. di evidenza 2+:** Studi di coorte o caso-controllo con basso rischio di bias o fattori di confondimento e con una probabilità moderata che la relazione sia causale.

**Liv. di evidenza 2-:** Studi di coorte o caso controllo con un alto rischio di bias o fattori di confondimento e con un significativo rischio che la relazione non è causale.

**Liv. di evidenza 3:** studi non analitici (es. case-report o serie di casi).

**Liv. di evidenza 4:** Opinione di esperti.

**Grado di raccomandazione.**

**A** = deriva da studi classificati 1++ o 1+;

**B** = deriva da studi classificati 2++ o evidenze estrapolate da studi classificati 1++ o 1+;

**C** = deriva da studi classificati 2+ o evidenze estrapolate da studi classificati 2++;

**D** = deriva da livelli di evidenza 3 o 4 o estrapolazioni di studi classificati 2+

# LINEE GUIDA

## GRADES OF RECOMMENDATION

The grade of recommendation relates to the strength of the evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation.

**A**: At least one meta-analysis, systematic review of randomized controlled trials (RCTs), or RCT rated as 1++ and directly applicable to the target population; *or*

A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results

**B**: A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 1++ or 1+

**C**: A body of evidence including studies rated as 2+, directly applicable to the target

population and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 2++

**D**: Evidence level 3 or 4; *or*

Extrapolated evidence from studies rated as 2+

**Good Practice Points**: Recommended best practice based on the clinical experience of the guideline development group

SIGN, 2005

# SCHEMA DI GRADING

**NICE** – National Institute for Health and Clinical Excellence

**A** Evidenze da studi clinici randomizzati o da revisioni sistematiche di studi randomizzati

**B** Evidenze da studi non randomizzati od osservazionali

**C** Consenso di professionisti.

# ASCO and NCCN Breast Cancer Guidelines

- ASCO recommendations and NCCN treatment guidelines are generated by expert consensus using a more rigorous process than the St. Gallen guidelines

- ASCO guidelines are based on evidence from relevant publications, conference presentations, and additional data requested from pharmaceutical companies; greater weight is given to published randomised trials[1]

- All NCCN guideline recommendations are weighted by level of clinical evidence and degree of panel consensus reached through a continuous review and feedback process[2]

- ASCO and NCCN guidelines are highly detailed and prescriptive

1. Winer et al. *J Clin Oncol.* 2005;23:619.
2. NCCN. http://www.nccn.org/professionals/physician_gls/about.asp.

## When anticipated benefits exceed risks, harms (and costs)…

**Benefits**

Risks, Harms, Costs

We can make a **(strong) recommendation** to…

## When anticipated risks, harms, (costs) exceed benefits…

Benefits

**Risks, Harms, Costs**

We can make a **(strong) recommendation not** to…

## When anticipated benefits are balanced by risks, harms (and costs)…

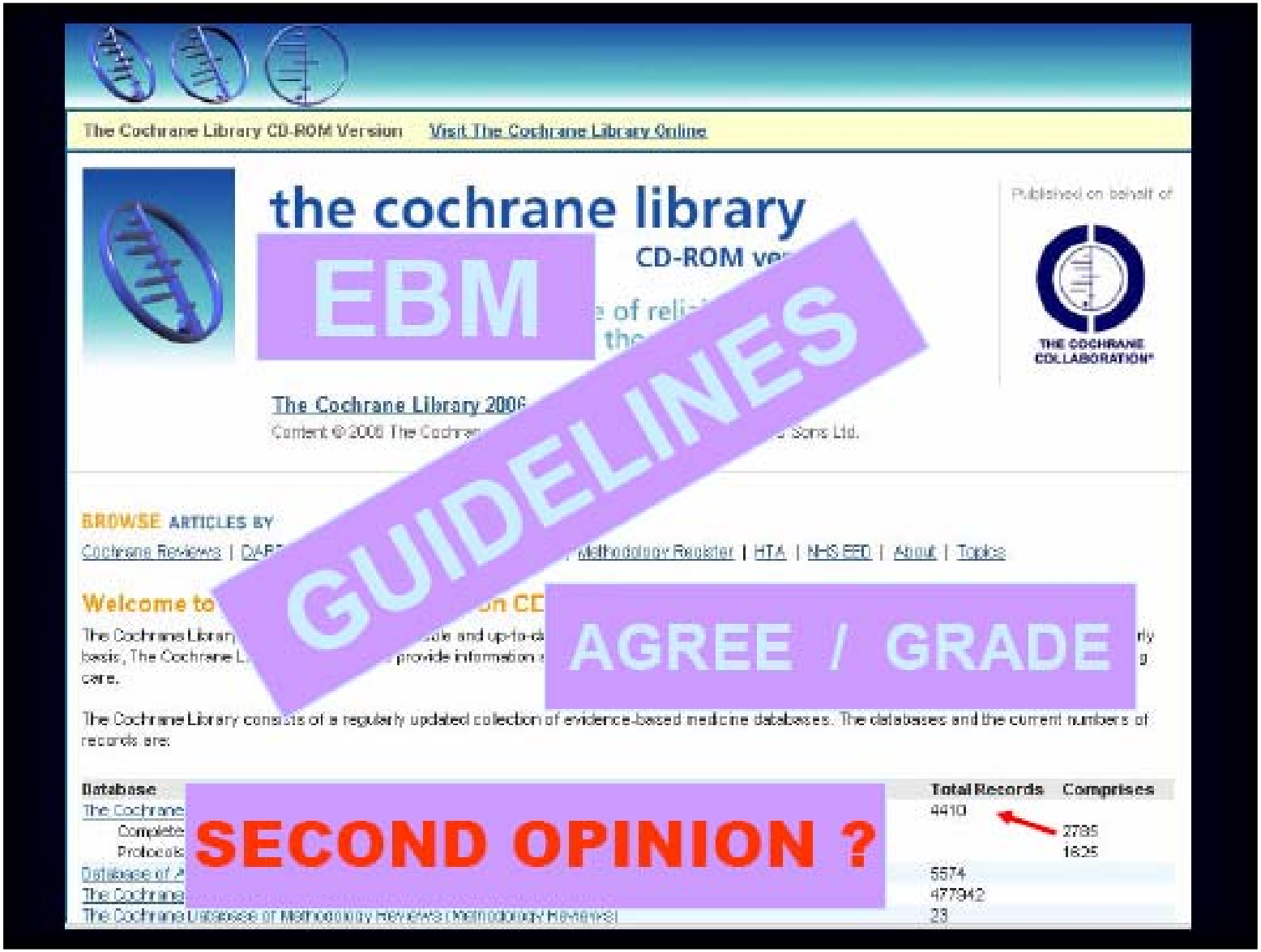
Benefits

Risks, Harms, Costs

We can offer an **option** to…

## VERBS

- Active voice
  - Passive masks the actor
  - "Mistakes were made…"
  - "Drug X should be prescribed…"
- Appropriate choice of deontic operators
  - The clinician must, must not; the Committee strongly recommends
  - The clinician should, should not; the Committee recommends
  - The clinician may; the Committee suggests
- The dreaded "consider"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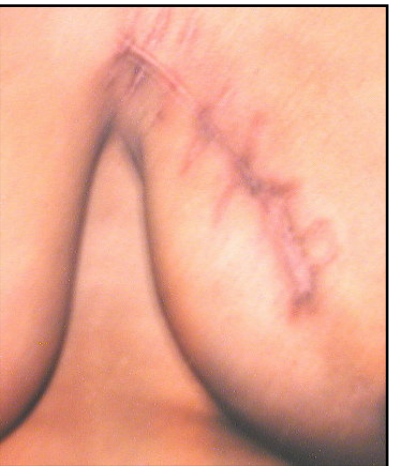
Welcome to
The Cochrane Library consists of a regularly updated collection of evidence-based medicine databases. The databases and the current numbers of records are:
Database
Total Records
Comprises
4410
2785
1625
5574
477942
23

# OSTACOLI ALL'APPLICAZIONE DELLE EBM E DELLE LINEE GUIDA

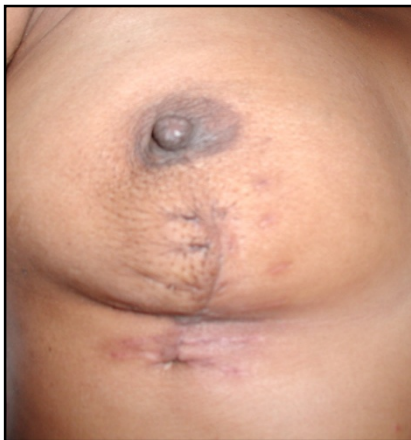
- Autonomia professionale
- Opinion leaders contrari
- Privilegi e conflitti di interesse
- Difficoltà di accesso e di vaglio della letteratura
- Percezione di "razionamento"

# RESULT OF ERRORS IN GUIDELINES

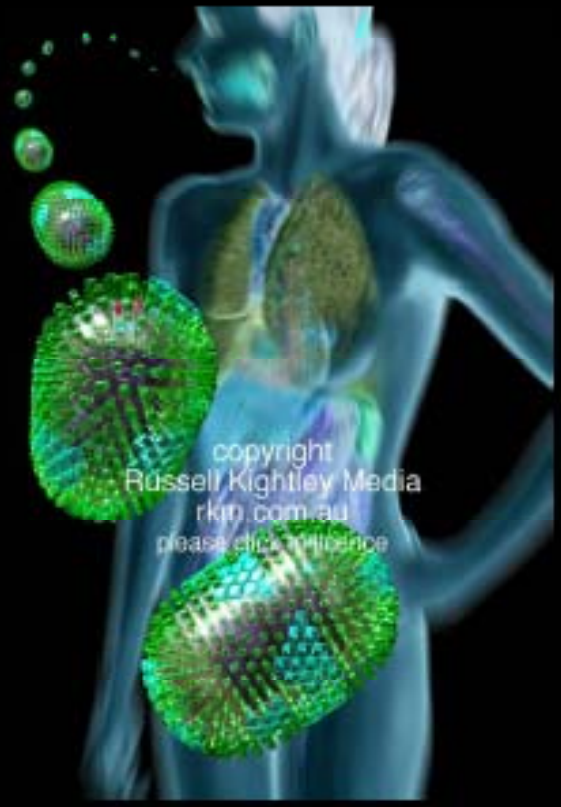
- Public has inflated expectations of the effectiveness of treatment
- Clinician is locked into screening, treatment and follow-up protocols with intrinsic limitations
- Clinician get set-up for wide variety of court actions- breast cancer is most common malpractice litigation



**ERROR IN SKIN INCISION**



# LA MEDICINA È NEL CONTEMPO UN`ARTE, UNA SCIENZA E UNA TECNICA.



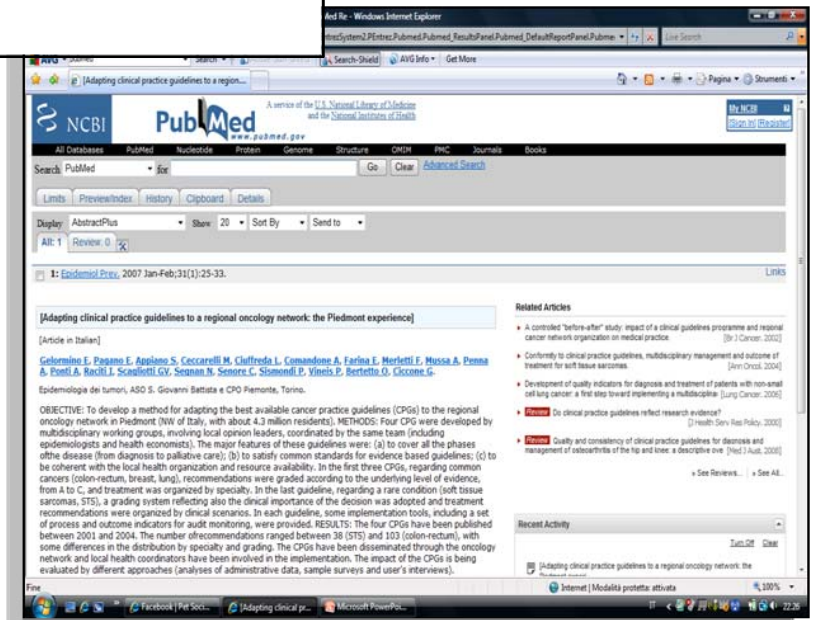
**ARTE** → INTUIZIONE, ESPERIENZA, CREATIVITÀ, RELAZIONE E EMPATIA, COMPASSIONE
(paziente « unico » , individuo)

**SCIENZA TECNICA** → « EVIDENZA » ( REV.SIST./ META ANALISI , GUIDELINES)
STANDARDIZZAZIONE, REGOLAMENTAZIONE
(paziente statistico)

# UTILITA'
# IMPIEGO LINEE GUIDA

## Strategies

- **Authors**: Sculpting recommendations to fit evidence
- **Implementers**: Operationalizing recommendations in systems that influence behavior




CONCLUSIONS

To adapt evidence based guidelines to a specific regional health organization is feasible and may be usefull for diseases requiring a multidisciplinary approach and continuity of care.

# Percorsi Diagnostico -Terapeutici (PDT)


Mira ad ottimizzare la qualità dell'assistenza (*best practices*), operando scelte *evidence-based* e razionalizzando l'utilizzo delle risorse a disposizione

**Sono gli adattamenti di Linee Guida internazionali alle caratteristiche organizzative e gestionali locali**

# CONTESTO “SOCIALE”/ PROTAGONISTI SCENARIO LINEE GUIDA

Researchers

Guideline Authors

Measurement Folks

Computer Geeks

# LINEE GUIDA E INDICATORI

## *Sviluppo degli indicatori di qualità delle attività sanitarie*

«È esplosa l'**industria** degli indicatori di qualità delle attività sanitarie.

Dopo due decenni di ambizioni di **verifica professionale**, di aspirazioni di **accreditamento** e di mania di **linee guida**, l'interesse della "**comunità** del miglioramento della qualità" sembra si sia spostato verso il fenomeno degli indicatori»

Klazinga e coll. Intern. J. Qual. Health Care 2001; 13: 433-38

## *Cambiamento della situazione per quanto riguarda la valutazione della qualità delle attività sanitarie per mezzo di indicatori*

| | Vecchia tendenza | Nuova tendenza |
|---|---|---|
| Iniziativa | Di singoli soggetti (spesso ricercatori) | Di Organizzazioni (governative) |
| Tipo di attività | Studio analitico | Attività istituzionale |
| Modalità | Ricerca, sperimentazione | Procedure, normative |
| Atteggiamento operatori | Indifferenza, inerzia, ostilità | Coinvolgimento attivo |
| Uso indicatori | Per verificare qualità e performance | Per pagare le prestazioni, per informare la gente |

# LINEE GUIDA E INDICATORI

## A cosa servono gli indicatori?

**Gli indicatori servono a diversi scopi:**

- Fare confronti: tra professionisti, tra ospedali, nel tempo …
- Esprimere valutazioni: mediante il confronto con standards
- Individuare priorità: dove intervenire e con quale ordine?
- Valutare attività e servizi: ho ottenuto i risultati attesi?
- Misurare l'efficienza: quali sono i costi dell'intervento?
- Orientare i pazienti nelle scelte: dove e da chi farsi curare?

*"Misura ciò che è misurabile e rendi misurabile ciò che non lo è"*

*Galileo Galilei (1564-1642)*

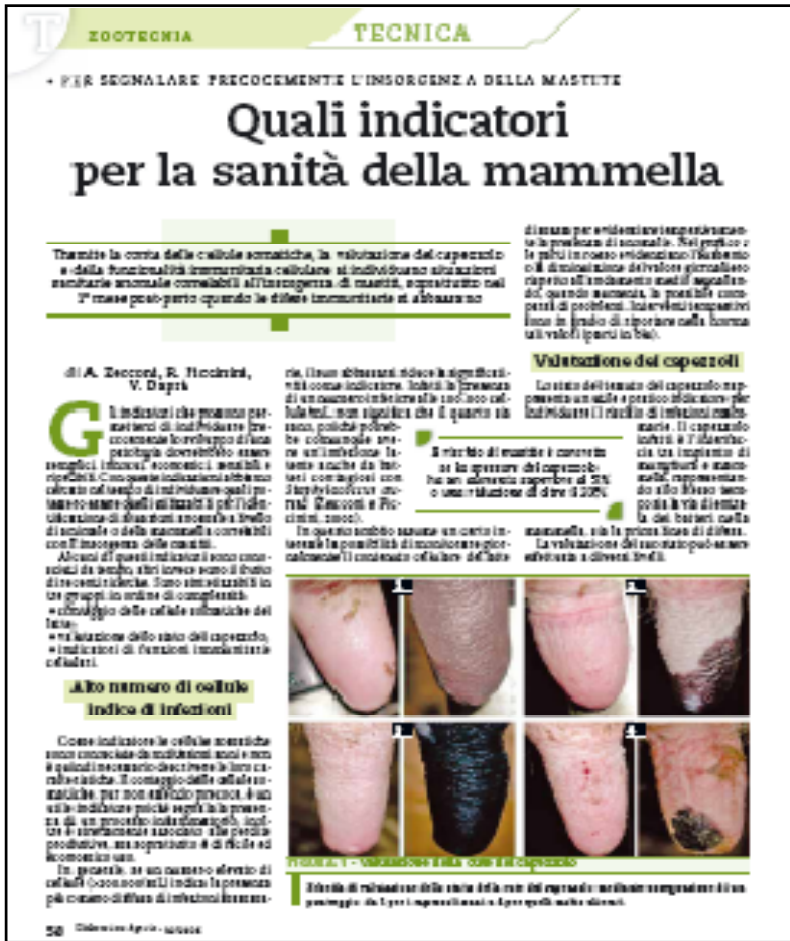
## Caratteristiche degli indicatori

- Pertinenza: affrontare temi che riguardano l'oggetto di rilevazione
- Specificità: esprimere soltanto (*precisione*) ed esclusivamente (*accuratezza*) il fenomeno che si intende registrare
- Sensibilità: capacità di registrare i mutamenti del fenomeno osservato
- Facilità di rilevazione: dati facilmente reperibili, senza eccessivi costi di raccolta
- Utilità decisionale
- Riproducibilità: rilevazioni diverse nel tempo presentano carattere di confrontabilità
- .....

# QUALI INDICATORI ??

## Indicatori tecnici

**SenoRx, Inc.** (NGM)
Intervallo: 1g 5g 3m 6m **1a** 2a Tipo:Barre | **Linea** | CdlScala:Lineare | **Log**Dimensioni:**M** |L
Media mobile: 5 | 10 | 20 | 50 | 100 | 200EMA:5 | 10 | 20 | 50 | 100 | 200
Indicatori: MACD | MFI | ROC | RSI | Slow Stoch | Fast Stoch | Vol | Vol+MA | W%R
Copertura: Bande di Bollinger | Parabolic SAR | Split | Volumi



ZOOTECNIA TECNICA

• PER SEGNALARE PRECOCEMENTE L'INSORGENZA DELLA MASTITE

# Quali indicatori per la sanità della mammella

Tramite la conta delle cellule somatiche, la valutazione del capezzolo e della funzionalità immunitaria cellulare si individuano situazioni sanitarie anomale correlabili all'insorgenza di mastiti, soprattutto nel 1° mese post-parto quando le difese immunitarie si attivano no

di A. Zecconi, R. Piccinini, V. Dapra

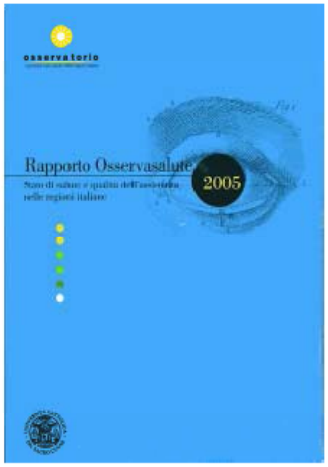
Valutazione del capezzoli

Alto numero di cellule indice di infezioni

# QUALI INDICATORI ??

I

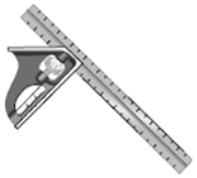
*Due strumenti che aiutano al reperimento di dati per la costruzione degli indicatori*


# INDICATORI DI QUALITA' : CALCOLO E MONITORAGGIO

## Misurare e valutare (1)

**Misurare**: **determinare** mediante appositi strumenti, **la quantità o l'estensione** di un oggetto, di una grandezza, di un fenomeno



**Valutare**: **accertare il valore di un intervento** attraverso la comparazione tra criteri predefiniti e dati raccolti ad hoc, al fine di prendere decisioni più informate o per capire le cause di un certo fenomeno

## Perché valutare ciò che facciamo?

Molto di ciò che costituisce il nostro lavoro inizia e finisce senza lasciare alcuna traccia

I processi di apprendimento e di miglioramento implicano la verifica dei risultati raggiunti e l'individuazione delle azioni correttive. **Senza verifica non è possibile immaginare alcun progresso**

Disporre di molti dati e di molti indicatori non ci rassicura affatto sulla qualità delle cure. Dati ridondanti o poco significativi generano solo sprechi e confusione


# INDICATORI DI QUALITA’

L‘INDICATORE DI QUALITA’ DERIVA DALLE RACCOMANDAZIONI MA
NON E’ UN PARAMETRO BENSI’ UN RAPPORTO CHE IDENTIFICA ,DEFINISCE E MISURA UN PROCESSO O UN INSIEME.

***INDICATORI DI ESITO / PROCESSO STRUTTURA / INDIVIDUALI***

# INDICATORI DI QUALITA’

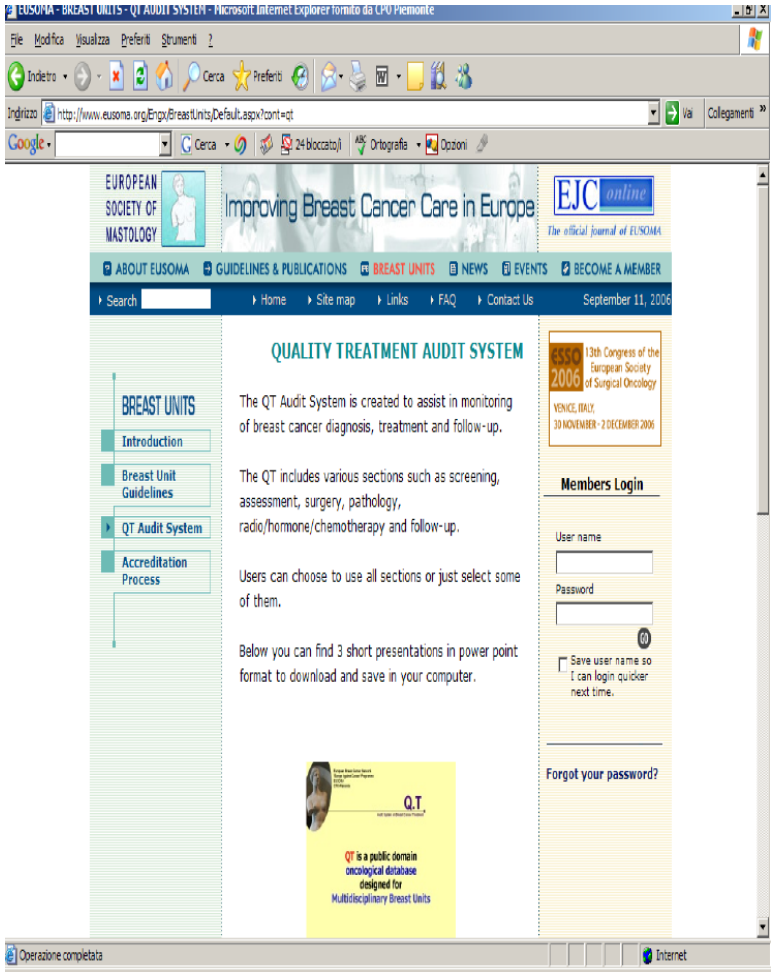
## Indicatori e qualità delle cure

Gli indicatori non misurano direttamente la qualità

Essi rappresentano dei **segnali** che dirigono l’attenzione verso aspetti delle cure destinati ad essere approfonditi

*Gli indicatori sono come il cane che **punta** la preda: è il cacciatore che interpreta i segnali e interviene al momento opportuno*

# INDICATORI DI QUALITA ESPERIENZA SQTM E QT’

# INDICATORI SQTM

**Indicatori sulla chirurgia (tabella 4)**

| Indicatori | Obiettivo |
|---|---|
| **Attesa dell'intervento chirurgico**<br>Indica la proporzione di pazienti operate la prima volta per lesioni mammarie sospette (qualsiasi diagnosi; solo pazienti per le quali la prima terapia è la chirurgia) entro tre ("desiderabile") o quattro ("accettabile") settimane dall'indicazione chirurgica, sul totale delle pazienti operate per lesione mammaria sospetta per le quali si dispone dell'informazione. | ≥80% |
| **Attesa dell'intervento dalla mammografia di screening**<br>Indica la proporzione di pazienti operate la prima volta per lesioni mammarie sospette (qualsiasi diagnosi; solo pazienti per le quali la prima terapia è la chirurgia) entro 60 e 90 giorni dalla mammografia di screening, sul totale delle pazienti operate per lesione mammaria sospetta per le quali si dispone dell'informazione. | - |
| **Escissione alla prima biopsia chirurgica**<br>Indica la proporzione di pazienti con lesioni non palpabili (benigne o maligne) escisse alla prima biopsia chirurgica, sul totale delle pazienti operate per lesioni non palpabili. La valutazione della correttezza dell'escissione non riguarda lo stato dei margini ma il fatto che la biopsia sia fallita (alla mammografia successiva si riscontra la medesima lesione identificata alla mammografia diagnostica). | ≥95 |
| **Esecuzione congelatore lesioni diametro ≤1 cm**<br>Proporzione di pazienti operate per carcinoma mammario invasivo (esclusi i microinvasivi) di diametro patologico massimo ≤1 cm per le quali sia stato eseguito l'esame estemporaneo intraoperatorio (sulla lesione o sui margini) sul totale di pazienti con la medesima diagnosi. | ≤5 |
| **Rx pezzo operatorio**<br>Proporzione di pazienti per le sia stata eseguita la radiografia a due proiezioni del pezzo operatorio, sul totale delle pazienti sottoposte a biopsia escissionale o a intervento conservativo per lesione non palpabile (qualsiasi diagnosi). | ≥95 |
| **Un solo intervento a seguito di diagnosi preoperatoria**<br>Proporzione di pazienti nelle quali il primo intervento non è stato seguito da ulteriori interventi locali per escissione incompleta, sul totale delle pazienti con cancro mammario invasivo o *in situ* operate in presenza di diagnosi preoperatoria citologica o istologica positiva per cancro (C5 o B5). | ≥90 |
| **Interventi conservativi nei casi pT1**<br>Indica la proporzione di pazienti con diagnosi di carcinoma mammario invasivo di diametro patologico e diametro ≤20 mm (pT1, inclusi i microinvasivi), non clinicamente multicentrico o multifocale, operate con intervento di tipo conservativo, sul totale delle donne operate con la medesima diagnosi. | ≥85% |
| **Interventi conservativi nei CDIS ≤2 cm**<br>Indica la proporzione di pazienti con diagnosi di carcinoma mammario *in situ* di diametro patologico ≤20 mm, non clinicamente multicentrico o multifocale, operate con intervento di tipo conservativo, sul totale delle donne operate con la medesima diagnosi. | ≥85% |
| **Margini indenni all'intervento definitivo**<br>Indica la proporzione di interventi conservativi (considerare l'ultimo intervento sulla mammella) per cancro invasivo o *in situ* che abbiano assicurato l'indennità dei margini (in questo caso definita come distanza minima >1 mm), sul totale delle pazienti operate conservativamente. La distanza minima scelta è arbitraria e non deve essere interpretata come una raccomandazione clinica. L'obiettivo indicato è dunque convenzionale ed è stato definito per consentire il monitoraggio e assistere nell'approfondimento di questa problematica. | ≥95% |
| **Numero linfonodi asportati >9**<br>Indica la proporzione di pazienti operate per carcinoma mammario invasivo e sottoposte a dissezione ascellare (qualsiasi livello) in cui siano stati asportati almeno 10 linfonodi, sul totale delle pazienti operate per carcinoma mammario invasivo e linfoadenectomizzate. | ≥95% |
| **Stadiazione ascellare con solo linfonodo sentinella negli N0**<br>Indica la proporzione delle pazienti pN0 in cui è stato eseguito il solo linfonodo sentinella sul totale delle pazienti con carcinoma invasivo della mammella sottoposte a stadiazione ascellare. | ≥95% |
| **Dissezioni ascellari nei CDIS**<br>Indica la proporzione di pazienti con diagnosi di carcinoma duttale *in situ* (esclusi i microinvasivi) sulle quali sia stato eseguito intervento di dissezione ascellare (qualsiasi livello) o sampling, sul totale delle pazienti operate con tale diagnosi. | ≤5% |
| **Esecuzione inappropriata di linfonodo sentinella o dissezione ascellare (benigni, lobulari e *in situ* di grado basso e intermedio)**<br>Indica la proporzione di pazienti con diagnosi di lesione benigna, carcinoma lobulare *in situ* o carcinoma duttale *in situ* (esclusi i microinvasivi) di basso grado e intermedio sulle quali sia stato eseguito un intervento di dissezione ascellare (qualsiasi livello) o linfonodo sentinella sul totale delle pazienti operate (escluse lesioni sincrone) con tale diagnosi. | ≥90% |
| **Ricostruzione immediata**<br>Calcola la proporzione di pazienti (carcinomi invasivi o *in situ*) mastectomizzate per le quali è stata eseguita ricostruzione immediata, sul totale delle pazienti per le quali è disponibile l'informazione. | - |
| **Ricostruzione immediata negli N0 (CDIS e invasivi ≤3 cm)**<br>Calcola la proporzione di pazienti mastectomizzate con lesioni N0 *in situ* e microinvasive di qualsiasi dimensione o invasive con diametro ≤3 cm per le quali è stata eseguita la ricostruzione immediata, sul totale delle lesioni con le medesime caratteristiche per le quali è disponibile l'informazione. | ≥80% |

# ESEMPI INDICATORI SQTM

## 21B2. INTERVENTO ENTRO 60 GIORNI DALLA MAMMOGRAFIA DI SCREENING

Calcola la proporzione di pazienti operate la prima volta per lesioni mammarie sospette (qualsiasi diagnosi, solo pazienti per le quali la prima terapia è la chirurgia) entro 60 giorni dalla mammografia di screening, sul totale delle pazienti operate per lesione mammaria sospetta per le quali si dispone dell'informazione. Calcola separatamente il numero di pazienti per le quali non si dispone della data dell'intervento o della data della mammografia di screening. Il calcolo di questo indicatore richiede la compilazione del dato relativo alla variabile C09 (data mammografia di screening) della sezione screening. Nel caso non tutte le lesioni abbiano tale provenienza, prima del calcolo dell'indicatore selezionare le lesioni identificate allo screening impostando la selezione D01=1.

**Campi considerati**: N00, D24, C09, E05, G07, B03, D01, C02

**Casi eleggibili**: (N00=1 OR ISNULL(N00)) AND (NOT (D24 IN (4,5,6)) OR ISNULL(D24)) AND NOT (B03 IN (2,3)) AND (D01<'2' OR ISNULL(D01)) AND (NOT C02 IN (3,8) OR ISNULL(C02))

di cui al **denominatore**: (DATEDIFF(d,[C09],[E05])>0 AND (NOT ISNULL(C09)) AND (NOT ISNULL(E05))) OR (DATEDIFF(d,[C09],[G07])>0 AND (NOT ISNULL(C09)) AND (ISNULL(E05)) AND (NOT ISNULL(G07)))

di cui al **numeratore**: (DATEDIFF(d,[C09],[E05])<=60 AND NOT ISNULL(E05)) OR (DATEDIFF(d,[C09],[G07])<=60 AND ISNULL(E05) AND NOT ISNULL(G07))

# ESEMPI INDICATORI SQTM

**PO1. DIAGNOSI CITO/ISTOLOGICA PRE-OPERATORIA POSITIVA O SOSPETTA**

Calcola la proporzione di pazienti operate per cancro invasivo o in situ (palpabile o impalpabile) che avevano avuto una diagnosi pre-operatoria citologica o istologica positiva o sospetta per cancro, sul totale di pazienti operate per cancro invasivo o in situ per le quali si dispone dell'informazione sul fatto che abbiano eseguito o non abbiano eseguito agoaspirato mammario oppure agobiopsia (tru-cut, core biopsy) prima dell'intervento.

Calcola separatamente il numero di pazienti per le quali non si sa se hanno avuto una diagnosi preoperatoria o non si conosca la natura di tale diagnosi.

**Campi considerati**: N00, I01,D08,D09

**Casi eleggibili**: (I01 IN (2,3,4)) AND (N00 IN (1,9) OR ISNULL(N00))

di cui al **denominatore**: DIAPRE IN (0,1,2,3,4,5)

di cui al **numeratore**: DIAPRE IN (4,5)

# ESEMPI INDICATORI SQTM
## MISURAZIONE RECETTORI ORMONALI

**18C. MISURAZIONE RECETTORI ORMONALI DISPONIBILE**

Calcola la proporzione di pazienti operate per carcinoma mammario invasivo (esclusi microinvasivi) in cui sia stata fornita la misurazione, sul totale delle pazienti operate per carcinoma mammario invasivo. Calcola separatamente il numero di pazienti operate per carcinoma mammario invasivo per le quali non si sa se sia stato fornito il dato.

**Campi considerati**: I01, N00, B03, I38

**Casi eleggibili**: I01=4 AND (N00=1 OR ISNULL(N00)) AND NOT (B03=3)

di cui al **denominatore**: I38 IN (0,1,2)

di cui al **numeratore**: I38 IN (1,2)

# ESEMPI INDICATORI SQTM
## CHIRURGIA

### 21B3. INTERVENTO ENTRO 90 GIORNI DALLA MAMMOGRAFIA DI SCREENING

Calcola la proporzione di pazienti operate la prima volta per lesioni mammarie sospette (qualsiasi diagnosi, solo pazienti per le quali la prima terapia è la chirurgia) entro 90 giorni dalla mammografia di screening, sul totale delle pazienti operate per lesione mammaria sospetta per le quali si dispone dell'informazione. Calcola separatamente il numero di pazienti per le quali non si dispone della data dell'intervento o della data della mammografia di screening. Il calcolo di questo indicatore richiede la compilazione del dato relativo alla variabile C09 (data mammografia di screening) della sezione screening. Nel caso non tutte le lesioni abbiano tale provenienza, prima del calcolo dell'indicatore selezionare le lesioni identificate allo screening impostando la selezione D01=1.

**Campi considerati**: N00, D24, C09, E05, G07, B03, D01, C02

**Casi eleggibili**: (N00=1 OR ISNULL(N00)) AND (NOT (D24 IN (4,5,6)) OR ISNULL(D24)) AND NOT (B03 IN (2,3)) AND (D01<'2' OR ISNULL(D01)) AND (NOT C02 IN (3,8) OR ISNULL(C02))

di cui al **denominatore**: (DATEDIFF(d,[C09],[E05])>0 AND (NOT ISNULL(C09)) AND (NOT ISNULL(E05))) OR (DATEDIFF(d,[C09],[G07])>0 AND (NOT ISNULL(C09)) AND (ISNULL(E05)) AND (NOT ISNULL(G07)))

di cui al **numeratore**: (DATEDIFF(d,[C09],[E05])<=90 AND NOT ISNULL(E05)) OR (DATEDIFF(d,[C09],[G07])<=90 AND ISNULL(E05) AND NOT ISNULL(G07))

# ESEMPI INDICATORI SQTM
## CHIRURGIA

### 15A. INTERVENTO CONSERVATIVO IN CASI Pt1

Calcola la proporzione di pazienti con diagnosi di carcinoma mammario invasivo di diametro patologico e diametro totale (che include la componente in situ che si estende oltre il carcinoma invasivo) uguale o inferiore a 20 mm (pT1, incluso microinvasivi), non clinicamente multicentrico o multifocale, operate con intervento di tipo conservativo, sul totale delle donne operate con la medesima diagnosi. Calcola separatamente il numero di pazienti con la medesima diagnosi per le quali non si dispone dell'informazione sul tipo di intervento eseguito.

**Campi considerati**: I01, ULTINT, D11, PT, I22, B03

**Casi eleggibili**: (I01 IN (3,4)) AND (D11 IN (0,9) OR ISNULL(D11)) AND (PT IN (1,1A,1B,1C)) AND (NOT (I22<20 AND I22<999) OR ISNULL(I22)) AND (NOT (B03=3))

di cui al **denominatore**: ULTINT IN (1,2,3,4,5,6,7)

di cui al **numeratore**: ULTINT IN (1,2,3,4)

# ESEMPI INDICATORI SQTM
## CHIRURGIA

### 14. CDIS SENZA DISSEZIONE ASCELLARE

Calcola la proporzione di pazienti con diagnosi di carcinoma duttale in situ o C.I.S. non altrimenti specificato (esclusi microinvasivi) sulle quali non sia stato eseguito intervento di dissezione del cavo ascellare (nemmeno I livello), sul totale delle pazienti operate con tale diagnosi. Calcola separatamente il numero di pazienti con la stessa diagnosi per le quali non si sa se sia stata eseguita dissezione ascellare.

**Campi considerati**: I01, I11, G01, B03

**Casi eleggibili**: I01 = 2 AND (i11<10 OR ISNULL(I11<10)) AND NOT B03=3

di cui al **denominatore**: G01 IN (0,1)

di cui al **numeratore**: G01=0

# ESEMPI INDICATORI SQTM
## CHIRURGIA /RICOSTRUZIONE

**12C**. **RICOSTRUZIONE IMMEDIATA**

Calcola la proporzione di pazienti (Ca invasivi o in situ) mastectomizzate per le quali è stata eseguita ricostruzione immediata, sul totale delle pazienti per le quali è disponibile l'informazione.

**Campi considerati**: I01, H04, ULTINT

**Casi eleggibili**: I01 IN (2,3,4,5) AND ULTINT IN (5,6,7)

di cui al **denominatore**: (NOT ISNULL(H04) AND H04<9) OR ULTINT=7

di cui al **numeratore**: H04=1 OR ULTINT=7

# LINEE GUIDA / INDICATORI DIAGNOSI

review

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## European guidelines for qu cancer screening and diagnosis. Fourth edition—summary document

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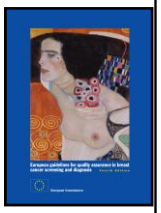
review

Breast cancer is a major cause of suffering and death and is of significant concern to many women. Early detection of breast cancer by systematic mammography screening can find lesions for which treatment is more effective and generally more favourable for quality of life. The potential harm caused by mammography includes the creation of unnecessary anxiety and morbidity, inappropriate economic cost and the use of ionising radiation. It is for this reason that the strongest possible emphasis on quality control and quality assurance is required. Development of the *European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis* has been an initiative within the Europe Against Cancer Programme. The fourth edition of the multidisciplinary guidelines was published in 2006 and comprises ~400 pages divided into 12 chapters prepared by >200 authors and contributors. The multidisciplinary editorial board has prepared a summary document to provide an overview of the fundamental points and principles that should support any quality screening or diagnostic service. This document includes a summary table of key performance indicators and is presented here in order to make these principles and standards known to a wider scientific community.

**Key words:** best practice, breast cancer screening, certification, multidisciplinary diagnosis, quality assurance guidelines, specialist breast units



### summary document

Breast cancer is currently the most frequent cancer and the most frequent cause of cancer-induced deaths in women in Europe [1]. Demographic trends indicate a continuing increase in this substantial public health problem. Systematic early detection through screening, effective diagnostic pathways and optimal treatment have the ability to substantially lower current breast cancer mortality rates and reduce the burden of this disease in the population.

In order that these benefits may be obtained, high-quality services are essential. These may be achieved through the underlying basic principles of training, specialisation, volume levels, multidisciplinary team working, the use of set targets and performance indicators and audit. Ethically these principles should be regarded as applying equally to symptomatic diagnostic services and screening.

The fourth edition of the European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis [2] maintains the focus on screening for breast cancer of the previous editions while at the same time supporting the provision of highly effective diagnostic services and the setting up of specialist breast units for treatment of women, irrespective of whether a breast lesion has been diagnosed within a screening programme or not. This approach also supports the resolutions of the European Parliament in June 2003 and October 2006, calling on the European Union (EU) member states to make the fight against breast cancer a health policy priority and to develop and implement effective strategies for improved health care encompassing screening, diagnosis and treatment throughout Europe [3, 4].

The primary aim of a breast screening programme is to reduce mortality from breast cancer through early detection. Unnecessary workup of lesions which show clearly benign features should be avoided in order to minimise anxiety and maintain a streamlined cost-effective service. Women attending a symptomatic breast service have different needs and anxieties

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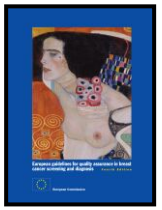
# LINEE GUIDA E INDICATORI DIAGNOSI

## PERFORMANCE INDICATORS

| Performance indicator | Acceptable level | Desirable level |
|---|---|---|
| 1. Target OD (2AT4.1) | 1.4–1.9 OD | 1.4–1.9 OD |
| 2. Spatial resolution (2AT4.1) | >12 lp/mm | >15 lp/mm |
| 3. Glandular dose—PMMA thickness at 4.5 cm (2AT4.1) | <2.5 mGy | <2.0 mGy |
| 4. Threshold contrast visibility (2AT4.1) | <1.5% | <1.5% |
| 5. Proportion of women invited that attend for screening (1T32) | >70% | >75% |
| 6. Proportion of eligible women reinvited within the specified screening interval (1T32) | >95% | 100% |
| 7. Proportion of eligible women reinvited within the specified screening interval + 6 months (1T32) | >98% | 100% |
| 8. Proportion of women with a radiographically acceptable screening examination 3.8, (5.4.3.1) | 97% | <97% |
| 9. Proportion of women informed of procedure and timescale of receiving results (3.8, 5.4.3.1) | 100% | 100% |
| 10. Proportion of women undergoing a technical repeat screening examination (1T32, 3.8, 4T2, 5.4.3.1) | <3% | <1% |
| 11. Proportion of women undergoing additional imaging at the time of the screening examination in order to further clarify the mammographic appearances (1T32) | <5% | <1% |
| 12. Proportion of women recalled for further assessment (1T32, 4T2) | | |
| Initial screening examinations | <7% | <5% |
| Subsequent screening examinations | <5% | <3% |
| 13. Proportion of screened women subjected to early recall following diagnostic assessment (4T2) | <1% | 0% |
| 14. Breast cancer detection rate, expressed as a multiple of the underlying, expected, breast cancer IR in the absence of screening (1T33, 4T1) | | |
| Initial screening examinations | 3 × IR | >3 × IR |
| Subsequent-regular screening examinations | 1.5 × IR | >1.5 × IR |
| 15. Interval cancer rate as a proportion of the underlying, expected, breast cancer IR in the absence of screening (1T33) | | |
| Within the first year (0–11 months) | 30% | <30% |
| Within the second year (12–23 months) | 50% | <50% |
| 16. Proportion of screen-detected cancers that are invasive (1T33, 4T1) | 90% | 80%–90% |
| 17. Proportion of screen-detected cancers that are stage II+ (1T33) | | |
| Initial screening examinations | NA | <30% |
| Subsequent-regular screening examinations | 25% | <25% |
| 18. Proportion of invasive screen-detected cancers that are node negative (1T33) | | |
| Initial screening examinations | NA | >70% |
| Subsequent-regular screening examinations | 75% | >75% |
| 19. Proportion of invasive screen-detected cancers that are ≤10 mm in size (1T33, 4T1) | | |
| Initial screening examinations | NA | ≥25% |
| Subsequent-regular screening examinations | ≥25% | ≥30% |
| 20. Proportion of invasive screen-detected cancers that are <15 mm in size (7A.2) | 50% | >50% |
| 21. Proportion of invasive screen-detected cancers <10 mm in size for which there was no frozen section (5.8.2, 9T1) | 95% | >95% |
| 22. Absolute sensitivity of FNAC 5.5.3, 6A A1.3 | >60% | >70% |
| 23. Complete sensitivity of FNAC (5.5.3, 6A A1.3) | >80% | >90% |
| 24. Specificity of FNAC (5.5.3, 6A A1.3) | >55% | >65% |
| 25. Absolute sensitivity of core biopsy (5.5.3, 6A A1.3) | >70% | >80% |
| 26. Complete sensitivity of core biopsy (5.5.3, 6A A1.3) | >80% | >90% |
| 27. Specificity of core biopsy (5.5.3, 6A A1.3) | >75% | >85% |
| 28. Proportion of localised impalpable lesions successfully excised at the first operation (4T2, 5.8.2, 7A.3) | >90% | >95% |
| 29. Proportion of image-guided FNAC procedures with insufficient result (4T2, 5.5.2) | <25% | <15% |
| 30. Proportion of image-guided FNAC procedures from lesions subsequently proven to be malignant, with an insufficient result (4T2, 5.5.2) | <10% | <5% |
| 31. Proportion of patients subsequently proven to have breast cancer with a preoperative FNAC or core biopsy at the diagnosis of cancer (7B.2) | 90% | >90% |
| 32. Proportion of patients subsequently proven to have clinically occult breast cancer with a preoperative FNAC or core biopsy that is diagnostic for cancer (7B.2) | 70% | >70% |

| Performance indicator | Acceptable level | Desirable level |
|---|---|---|
| 33. Proportion of image-guided core/vacuum procedures with an insufficient result (4T2) | <20% | <10% |
| 34. Benign to malignant open surgical biopsy ratio in women at initial and subsequent examinations (1T32, 4T2, 5.8.2, 7A.3) | ≤1 : 2 | ≤1 : 4 |
| 35. Proportion of wires placed within 1 cm of an impalpable lesion before excision (4T2, 5.8.2, 7A.3) | 90% | >90% |
| 36. Proportion of benign diagnostic biopsies on impalpable lesions weighing less than 30 grams (5.8.2, 7A.3) | 90% | >90% |
| 37. Proportion of patients where a repeat operation is needed after incomplete excision (7A.4) | 10% | <10% |
| 38. Time (in wd) between | | |
| Screening mammography and result (4T2) | 15 wd | 10 wd |
| Symptomatic mammography and result (5.9) | 5 wd | |
| Result of screening mammography and offered assessment (4T2) | 5 wd | 3 wd |
| Result of diagnostic mammography and offered assessment (5.9) | 5 wd | |
| Assessment and issuing of results (5.9) | 5 wd | 3 wd |
| Decision to operate and date offered for surgery (5.9) | 15 wd | 10 wd |
| 39. Time (in wd) between | | |
| Screening mammography and result[a] | | |
| ≤15 wd | 95% | >95% |
| ≤10 wd | 90% | <90% |
| Symptomatic mammography and result[a] | | |
| ≤5 wd | 90% | >90% |
| Result of screening mammography and offered assessment[a] | | |
| ≤5 wd | 90% | >90% |
| ≤3 wd | 70% | >70% |
| Result of symptomatic mammography and offered assessment[a] | | |
| ≤5 wd | 90% | >90% |
| Assessment and issuing of results[a] | | |
| ≤5 wd | 90% | >90% |
| Decision to operate and date offered for surgery[a] | | |
| ≤15 wd | 90% | >90% |
| ≤10 wd | 70% | >70% |



N. Perry et al, Ann of Oncol, 2008

# RACCOMANDAZIONI


2007



- Education and training.

The following sections expand on these points. An oncoplastic service will also consider the evolution of a surgical career. Consideration needs to be given to the needs and requirements of newly appointed and mature surgeons as well as those surgeons in the latter stages of their career.

**The patient's journey**

*Diagnosis*

All women with suspected breast cancer should undergo formal assessment and investigation in accordance with practice defined in the NHS Breast Screening Programme (www.cancerscreeing.nhs.uk/breastscreen) guidelines or guidelines for symptomatic women produced by the ABS at BASO.[3] [IV]

*Decision-making*

- patients are aware of the potential long-term implications of oncoplastic surgery;
- patients are aware that complete breast reconstruction including the nipple–areola reconstruction may require several separate surgical procedures[6] [IV];
- women who decide against immediate reconstruction should be reassured that they can discuss delayed reconstruction subsequently.

Women who find the decision about reconstruction particularly difficult may benefit from referral to a psychologist to help them through the decision-making process. It may be preferable for these women to consider reconstruction as a delayed procedure.

Deciding upon and undergoing breast oncoplastic surgery may be stressful and can have profound psycho-social sequelae. Members of the breast care team can help to alleviate the impact of these decisions by developing an ethos of care in which psycho-social and appearance-related concerns can be freely raised and addressed.[7] [III]

Adjusting to an altered body image after breast reconstruction can be a lengthy process and may never be fully solved. The patient has to adjust to: scarring, altered or ss of sensation, changes at any donor sites, concerns out implants and complications of surgery.[8] [III], 9,10 [III]

The patient's own perceptions about the results of her rgery may not concur with the perception of a third party. y decisions regarding further surgery to enhance the aesetic result of surgery must be made by the patient, after nsultation with the reconstruction team.

It is important to recognise that the experience of oncoastic surgery will also have an impact upon the patient's rtner and family, who may also need access to informaon about reconstructive surgery and support through the ocess.

*onsent*

Informed consent should follow nationally established idelines (ref: www.doh.gov.uk/consent; Good practice consent: achieving the NHS Plan commitment to patient ntred consent practice).

*erioperative preparation and anaesthesia*

*Introduction*

Oncoplastic surgical operations are often long and frequently complex. As so often in surgical practice, careful patient selection (which factors in both co-morbidity and patient expectation) is the key to success.

*Preoperative assessment*

This should pay particular attention to cardiovascular disease, respiratory disease, obesity, smoking and diabetes. These are known to increase the risks of surgery, especially cardiac events, chest complications, deep venous

ages of a variety of reconstructive techniques;
- to discuss perceived risks and benefits;
- to discuss the full range of additional procedures that may be required.

This implies that the patient will frequently require more than one preoperative consultation.

The team must also ensure that:

- patients contemplating oncoplastic surgery have realistic expectations about the outcome of breast reconstruction;

**The patient's journey**

*Diagnosis*

All women with suspected breast cancer should undergo formal assessment and investigation in accordance with practice defined in the NHS Breast Screening Programme (www.cancerscreeing.nhs.uk/breastscreen) guidelines or guidelines for symptomatic women produced by the ABS at BASO.[3] [IV]

# LINEE GUIDA E MONITORAGGIO INDICATORI

## ESPERIENZA NORVEGESE

**2007**

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CANCER

### Using the European guidelines to evaluate the Norwegian Breast Cancer Screening Program

**Solveig Hofvind · Berta Geller · Pamela M. Vacek · Steinar Thoresen · Per Skaane**

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**Abstract** This is an evaluation of selected process indicators achieved during the first 10 years of performance of the Norwegian Breast Cancer Screening Program (NBCSP). The indicators are compared with the recommended levels given in the European Guidelines. The program invites all female residents aged 50–69 years old to two-view mammography biennially. The attendance rate was 76.2%. The recall rates due to positive mammography

**Keywords** Breast cancer screening · Interval cancer · Mammography · Surrogate measures

**Introduction**

The major benefits of breast cancer screening are early

tumors. The NBCSP meets the recommendations given in the European Guidelines for most of the process indicators evaluated in this study. Based on the results, we anticipate a future mortality reduction from breast cancer in women invited to the NBCSP.

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in mortality from the
ages are unnecessary
gnostic work up, false
xaminations, overdi-
to radiation [3, 4].
the Word Health
ing women aged 50–
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uate the effect of
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high quality to be
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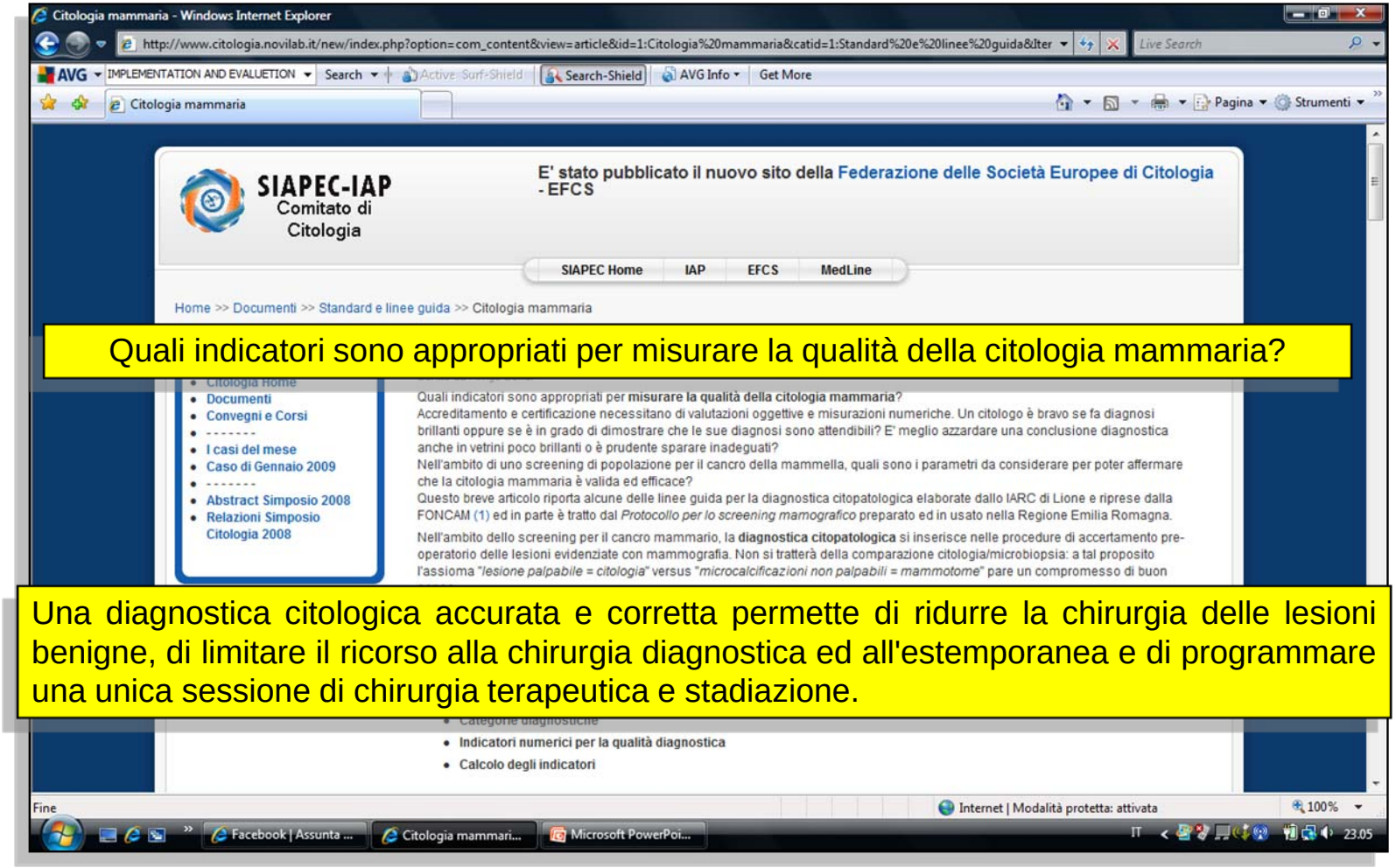
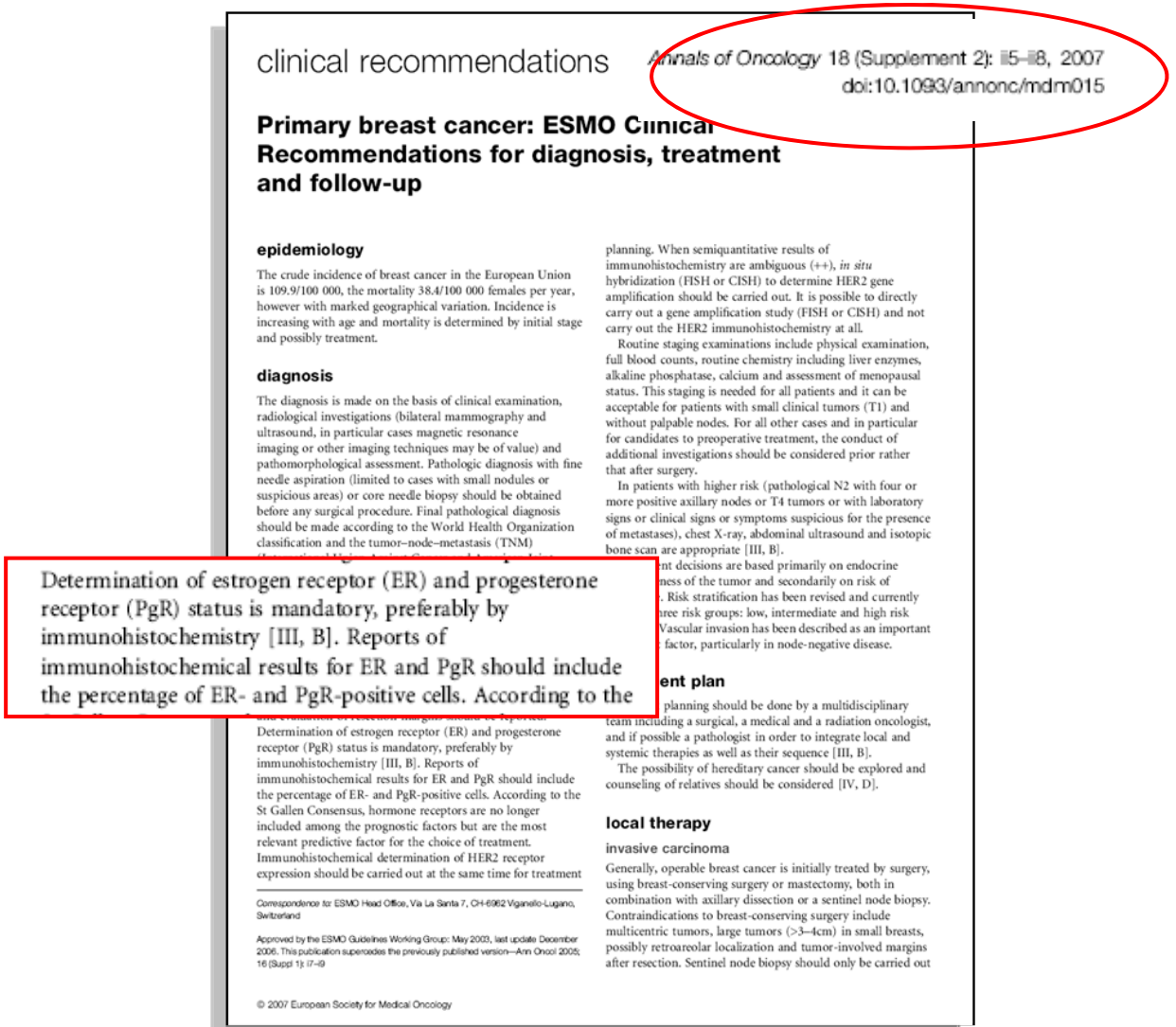
reening detected and
tics that may predict
a future mortality reduction from the disease [7, 8]. Monitoring those parameters, commonly is called process indicators, is particularly important at the inception of a screening program to ensure establishment of well functioning procedures, and should become an integrated part of the protocol in a breast cancer-screening program.

The Norwegian Breast Cancer Screening Program (NBCSP) created its own quality assurance manual contemporaneously with the start up of the pilot project in

# INDICATORI
# DIAGNOSI PRE-OPERATORIA



# LINEE GUIDA/INDICATORI ANATOMIA PATOLOGICA



clinical recommendations

*Annals of Oncology* 18 (Supplement 2): ii5–ii8, 2007
doi:10.1093/annonc/mdm015

## Primary breast cancer: ESMO Clinical Recommendations for diagnosis, treatment and follow-up

### epidemiology

The crude incidence of breast cancer in the European Union is 109.9/100 000, the mortality 38.4/100 000 females per year, however with marked geographical variation. Incidence is increasing with age and mortality is determined by initial stage and possibly treatment.

### diagnosis

The diagnosis is made on the basis of clinical examination, radiological investigations (bilateral mammography and ultrasound, in particular cases magnetic resonance imaging or other imaging techniques may be of value) and pathomorphological assessment. Pathologic diagnosis with fine needle aspiration (limited to cases with small nodules or suspicious areas) or core needle biopsy should be obtained before any surgical procedure. Final pathological diagnosis should be made according to the World Health Organization classification and the tumor–node–metastasis (TNM)

Determination of estrogen receptor (ER) and progesterone receptor (PgR) status is mandatory, preferably by immunohistochemistry [III, B]. Reports of immunohistochemical results for ER and PgR should include the percentage of ER- and PgR-positive cells. According to the St Gallen Consensus, hormone receptors are no longer included among the prognostic factors but are the most relevant predictive factor for the choice of treatment. Immunohistochemical determination of HER2 receptor expression should be carried out at the same time for treatment planning. When semiquantitative results of immunohistochemistry are ambiguous (++), *in situ* hybridization (FISH or CISH) to determine HER2 gene amplification should be carried out. It is possible to directly carry out a gene amplification study (FISH or CISH) and not carry out the HER2 immunohistochemistry at all.

Routine staging examinations include physical examination, full blood counts, routine chemistry including liver enzymes, alkaline phosphatase, calcium and assessment of menopausal status. This staging is needed for all patients and it can be acceptable for patients with small clinical tumors (T1) and without palpable nodes. For all other cases and in particular for candidates to preoperative treatment, the conduct of additional investigations should be considered prior rather that after surgery.

In patients with higher risk (pathological N2 with four or more positive axillary nodes or T4 tumors or with laboratory signs or clinical signs or symptoms suspicious for the presence of metastases), chest X-ray, abdominal ultrasound and isotopic bone scan are appropriate [III, B].

nt decisions are based primarily on endocrine ness of the tumor and secondarily on risk of . Risk stratification has been revised and currently hree risk groups: low, intermediate and high risk Vascular invasion has been described as an important factor, particularly in node-negative disease.

### ent plan

planning should be done by a multidisciplinary team including a surgical, a medical and a radiation oncologist, and if possible a pathologist in order to integrate local and systemic therapies as well as their sequence [III, B].

The possibility of hereditary cancer should be explored and counseling of relatives should be considered [IV, D].

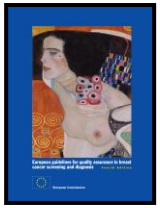
### local therapy

#### invasive carcinoma

Generally, operable breast cancer is initially treated by surgery, using breast-conserving surgery or mastectomy, both in combination with axillary dissection or a sentinel node biopsy. Contraindications to breast-conserving surgery include multicentric tumors, large tumors (>3–4cm) in small breasts, possibly retroareolar localization and tumor-involved margins after resection. Sentinel node biopsy should only be carried out

*Correspondence to:* ESMO Head Office, Via La Santa 7, CH-6962 Viganello-Lugano, Switzerland

Approved by the ESMO Guidelines Working Group: May 2003, last update December 2006. This publication supersedes the previously published version—Ann Oncol 2005; 16 (Suppl 1): i7–i9



review

*Annals of Oncology* 19: 614–622, 2008
doi:10.1093/annonc/mdm481
Published online 5 February 2008

# European guidelines for quality assurance in breast cancer screening and diagnosis. Fourth edition—summary document

N. Perry[1], M. Broeders[2], C. de Wolf[3], S. Törnberg[4], R. Holland[5]

## surgical aspects

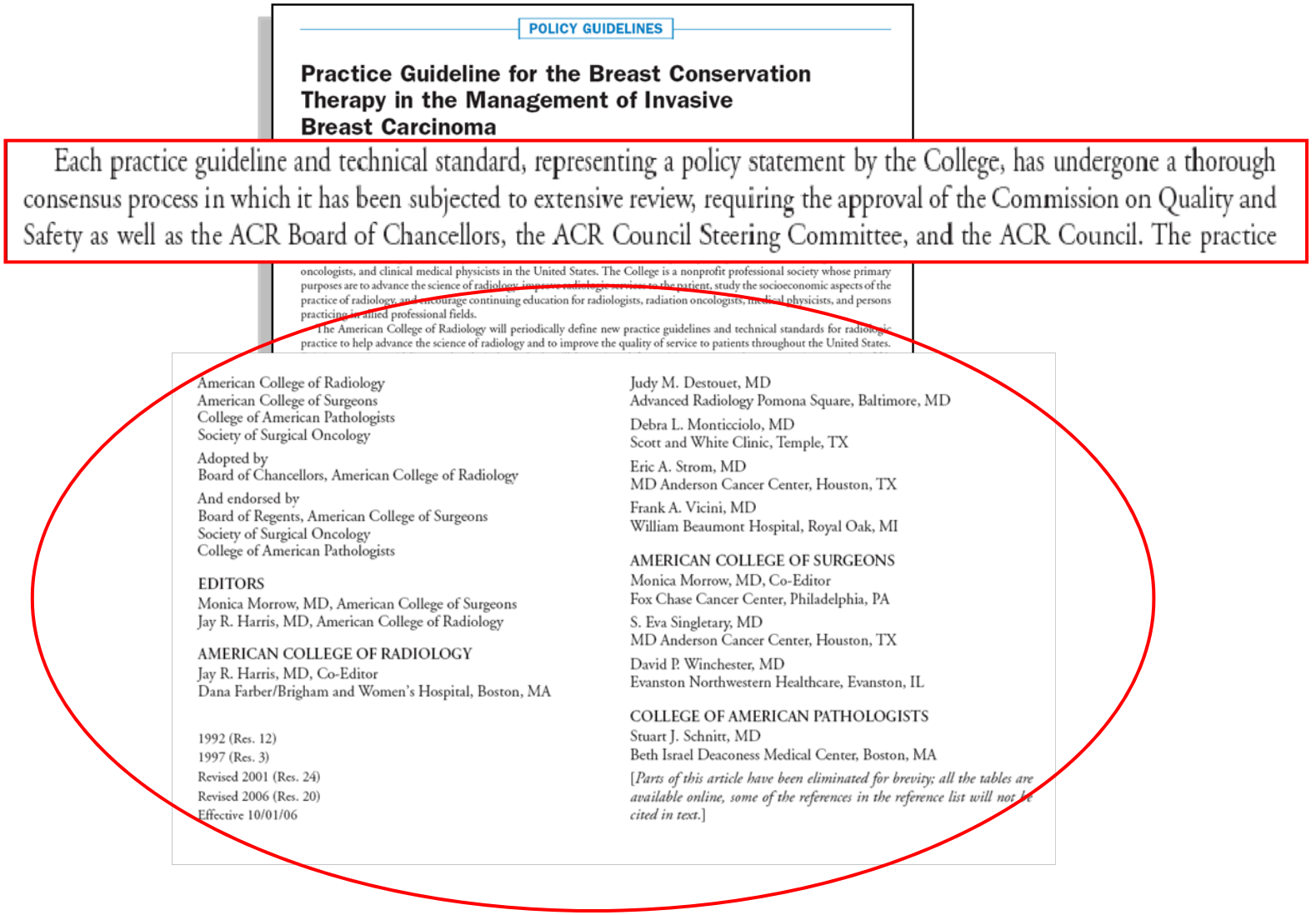
- The surgeon is a member of the multidisciplinary team and should always personally assess and examine a woman before accepting her for surgery. The lead surgeon should ensure that important activities and decisions are not delegated to unsupervised trainees.
- The surgeon must have access to all support services including radiology and cytology/histopathology, which conform to established quality assurance guidelines.
- Management of cases coming to surgery from screening programmes should be carried out only by surgeons with specialist knowledge and expertise, having undergone specific formal multidisciplinary programme training which include courses in communication and counselling.
- Specified target figures must be observed for successful removal of mammographic abnormalities and definitive surgical treatment of those cases following a clear malignant diagnosis at the first operation. Unnecessary surgical excision and benign biopsy rate should be minimised.
- Accurate marking procedures must be available to the surgeon in order to improve postoperative cosmesis for those women having an impalpable lesions. Its aim is to allow full excision of the tumour with uniform margins. A full report of the localisation procedure and relevant images must be provided by the radiologist for the surgeon in the operating theatre.
- Specimen radiography is essential for lesions such as microcalcification visible on X-ray to confirm excision in theatre, before skin closure. Such images must also be available to the pathology department.
- Frozen sectioning is generally inappropriate in the assessment of clinically impalpable lesions.
- The surgeon must ensure that women receive information on treatment options and be aware that breast-conserving surgery is the treatment of choice for the majority of small screen-detected cancers. Where appropriate, patients should be offered a choice of treatment including immediate or delayed breast reconstruction should mastectomy be required.
- Surgeons undertaking axillary sentinel node procedures should receive specific training and validation.
- Mastectomy should be carried out in patients who do not satisfy criteria eligibility for breast-conserving treatment or in those patients who express a preference for it. Patients with high risk factors for local recurrence should be offered adjuvant chest wall radiation treatment.
- Preoperative (neo-adjuvant) chemotherapy must be offered if appropriate in order to downstage large tumours to allow breast-conserving treatment.
- Patients with locally advanced breast cancer should be offered combined modality treatment to ensure lasting locoregional control.
- Follow-up after treatment for breast cancer is mandatory for the measurement of outcomes, assessment of recurrences and screening for second primaries.

Annals of Oncology

persons are needed per unit. They must be available to counsel, offer practical advice and emotional support.
- The unit must possess suitable and up-to-date imaging and therapeutic equipment.
- Adjuvant therapies such as radiotherapy or cytotoxic therapy may be given at separate clinics or hospitals to the breast unit but such treatment must be supervised by the main breast unit and all decisions made by the unit's multidisciplinary

### pathology

# LINEE GUIDA TRATTAMENTO



POLICY GUIDELINES

**Practice Guideline for the Breast Conservation Therapy in the Management of Invasive Breast Carcinoma**

Each practice guideline and technical standard, representing a policy statement by the College, has undergone a thorough consensus process in which it has been subjected to extensive review, requiring the approval of the Commission on Quality and Safety as well as the ACR Board of Chancellors, the ACR Council Steering Committee, and the ACR Council. The practice

oncologists, and clinical medical physicists in the United States. The College is a nonprofit professional society whose primary purposes are to advance the science of radiology, improve radiologic services to the patient, study the socioeconomic aspects of the practice of radiology, and encourage continuing education for radiologists, radiation oncologists, medical physicists, and persons practicing in allied professional fields.

The American College of Radiology will periodically define new practice guidelines and technical standards for radiologic practice to help advance the science of radiology and to improve the quality of service to patients throughout the United States.

American College of Radiology
American College of Surgeons
College of American Pathologists
Society of Surgical Oncology

Adopted by
Board of Chancellors, American College of Radiology

And endorsed by
Board of Regents, American College of Surgeons
Society of Surgical Oncology
College of American Pathologists

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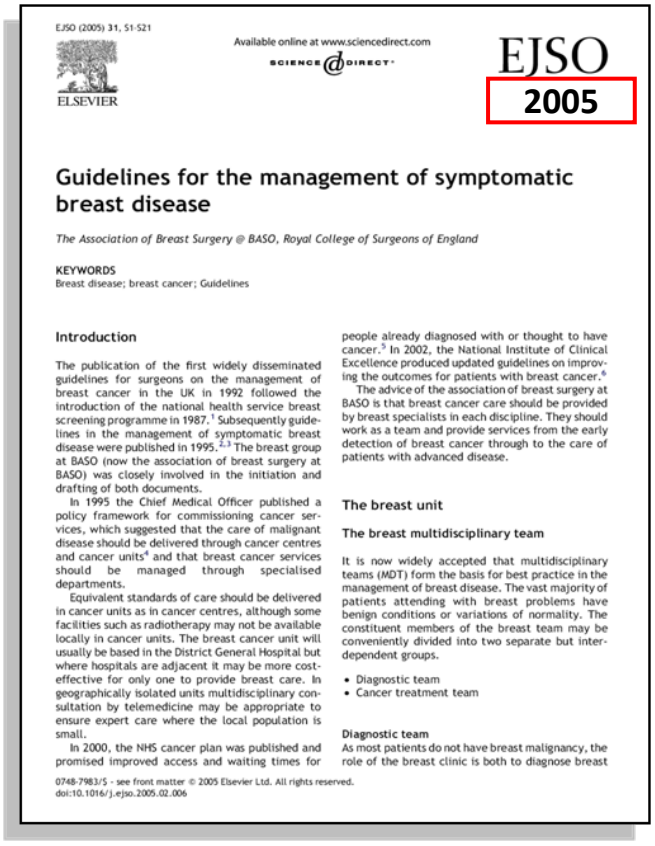
[*Parts of this article have been eliminated for brevity; all the tables are available online, some of the references in the reference list will not be cited in text.*]

# LINEE GUIDA



EJSO (2005) 31, 51-521

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## Guidelines for the management of symptomatic breast disease

*The Association of Breast Surgery @ BASO, Royal College of Surgeons of England*

KEYWORDS
Breast disease; breast cancer; Guidelines

### Introduction

The publication of the first widely disseminated guidelines for surgeons on the management of breast cancer in the UK in 1992 followed the introduction of the national health service breast screening programme in 1987.[1] Subsequently guidelines in the management of symptomatic breast disease were published in 1995.[2,3] The breast group at BASO (now the association of breast surgery at BASO) was closely involved in the initiation and drafting of both documents.

In 1995 the Chief Medical Officer published a policy framework for commissioning cancer services, which suggested that the care of malignant disease should be delivered through cancer centres and cancer units[4] and that breast cancer services should be managed through specialised departments.

Equivalent standards of care should be delivered in cancer units as in cancer centres, although some facilities such as radiotherapy may not be available locally in cancer units. The breast cancer unit will usually be based in the District General Hospital but where hospitals are adjacent it may be more cost-effective for only one to provide breast care. In geographically isolated units multidisciplinary consultation by telemedicine may be appropriate to ensure expert care where the local population is small.

In 2000, the NHS cancer plan was published and promised improved access and waiting times for people already diagnosed with or thought to have cancer.[5] In 2002, the National Institute of Clinical Excellence produced updated guidelines on improving the outcomes for patients with breast cancer.[6]

The advice of the association of breast surgery at BASO is that breast cancer care should be provided by breast specialists in each discipline. They should work as a team and provide services from the early detection of breast cancer through to the care of patients with advanced disease.

### The breast unit

#### The breast multidisciplinary team

It is now widely accepted that multidisciplinary teams (MDT) form the basis for best practice in the management of breast disease. The vast majority of patients attending with breast problems have benign conditions or variations of normality. The constituent members of the breast team may be conveniently divided into two separate but interdependent groups.

- Diagnostic team
- Cancer treatment team

#### Diagnostic team

As most patients do not have breast malignancy, the role of the breast clinic is both to diagnose breast


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- **Figure pofessionali / processi / struttura**
- **Livelli evidenza**
- **Obiettivi di qualità**

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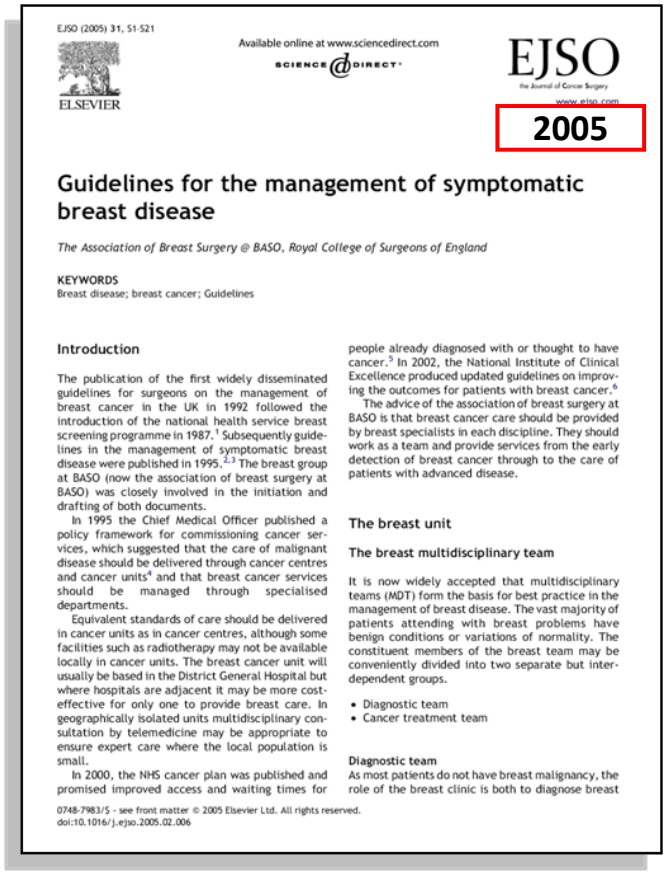

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Risulta uno dei più importanti documenti ai fini dell'elaborazione degli indicatori sia FONCaM che GISMa

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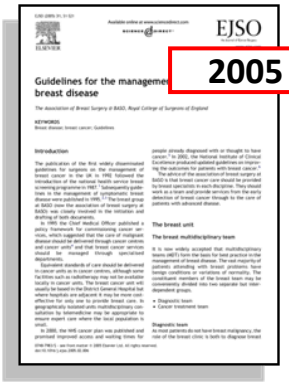
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Guidelines for the management of breast disease

The Association of Breast Surgery at BASO, Royal College of Surgeons of England

KEYWORDS

Introduction

The breast unit

The breast multidisciplinary team

Diagnostic team

Cancer treatment team

Diagnostic team

**Patient waiting times**

Patients, whom the GP suspects of having breast cancer, should be seen within 2 weeks of referral. Breast units should inform general practitioners how they may rapidly access breast clinics.

The association of breast surgery at BASO recommends that all patients are seen as soon as possible to relieve anxiety and because a small proportion of breast cancers are detected in patients with a seemingly benign presentation. The published results of the effect of delays in diagnosis are conflicting,[31,32] but delays of more than 6 months may lead to impaired survival[31] (Level 2 evidence).

Surgical, radiological and pathological findings should usually be discussed at multidisciplinary team meetings before diagnostic results are confirmed to patients.

of symptomatic breast disease S9

| | Outcome measures |
|---|---|
| ld be managed by staff se in breast disease to | Every breast unit must have a written protocol for the management of breast disease |

cts of having breast 2 weeks of referral. eneral practitioners reast clinics. urgery at BASO recen as soon as possible a small proportion of in patients with a The published results s are conflicting,[31,32] onths may lead to dence). pathological findings at multidisciplinary stic results are con-

Following diagnosis, patients must be given adequate time, information and support in order to make a fully informed decision concerning their treatment. This must include discussion of suitable treatment options with the surgeon in liaison with the breast care nurse. The treatment options offered should be agreed at a multidisciplinary meeting and the decisions agreed with the patient should be recorded. In the event of a patient refusing the recommended treatment options this should be recorded (Table 6).

Close communication must be maintained between surgeons and oncologists to plan primary treatment and to facilitate subsequent adjuvant therapy. A care plan for each patient must be drawn up. It must take account of factors predictive of both survival and of local or regional recurrence, the age and general health of the patient, the social circumstances and p should enable reco women who wish

**Communication with the patient**

- Patients should be encouraged to bring a partner or friend with them when the results are being discussed.
- Breaking bad news should be done in a professional way. The person conducting the consultation must be a member of the multidisciplinary breast team and the breast care nurse would usually be present. It should take place in an appropriate environment with adequate privacy.
- The follow-up arrangements should be clear and the patient must know how to access the breast care nurse and other relevant components of their care plan.

**Surgery**

Surgical treatment o must be carried ou interest and training evidence). Breast su teams, which have facilities for a multi

**Avoidance of dela**

When a decision has treatment, patients operation rather tha Reconstruction proc planning but should n diagnostic and thera An operation for d within 2 weeks of maximum wait for th month from the dat treatment is planned plan[5] states that pat wait of 1 month fro 2002, this standard months wait from ur

**Treatment**

**Treatment planning**

Each breast unit will have written protocols on the treatment of breast cancer, which were formulated and agreed by the breast multi-disciplinary team. The treatment of patients should usually follow these protocols, although it is accepted that there may be reasonable exceptions. The reasons for not following guidelines should be documented.

**Avoidance of delay in surgical treatment**

When a decision has been reached to offer surgical treatment, patients should be offered a date for operation rather than be placed on a waiting list. Reconstruction procedures will require logistical planning but should not lead to significant delay. All diagnostic and therapeutic operations are urgent. An operation for diagnostic purposes should be within 2 weeks of the decision to operate. The maximum wait for therapeutic surgery should be 1 month from the date of diagnosis, except where treatment is planned to be delayed. The NHS cancer plan[5] states that patients should have a maximum wait of 1 month from diagnosis to treatment. In 2002, this standard was extended to a maximum 2 months wait from urgent GP referral to treatment.

# CONSENSUS CONFERENCE TRATTAMENTO

CONSENSUS PROCEEDINGS

## Consensus Conference on Breast Conservation

Gordon F Schwartz, MD, MBA, FACS, Umberto Veronesi, MD, FACS(Hon), Krishna B Clough, MD, J Michael Dixon, MB, ChB, FRCS(Eng), FRCS(Edin), Ian S Fentiman, MD, DSc, Sylvia H Heywang-Köbrunner, MD, Roland Holland, MD, PhD, Kevin S Hughes, MD, FACS, Robert E Mansel, MB, MS, FRCS, Richard Margolese, MD, Ellen B Mendelson, MD, Ivo A Olivotto, MD, FRCPC, Juan P Palazzo, MD, Lawrence J Solin, MD, the Consensus Conference Committee*

In a single generation, treatment of most women with early-stage breast cancer has changed dramatically. Clinical trials with more than 20 years followup have documented that, for appropriately selected patients, breast-conserving operations followed by whole-breast irradiation have outcomes equivalent to mastectomy. The appropriate selection of patients remains controversial. Questions remain about the role of new diagnostic imaging modalities, radiation therapy techniques, achieving optimal cosmesis, and the choice and timing of adjuvant chemotherapy.

To address these issues, the Fifth International Consensus Conference of the Breast Health Institute, co-sponsored by the European Institute of Oncology, was convened in Milan, Italy, April 29 through May 1, 2005, inviting a group of experts in breast cancer and breast conservation, representing each of the disciplines involved in the care of these patients. From recorded transcripts of the discussion, these proceedings were written to summarize the opinions and conclusions of the entire group. The conference dealt only with invasive cancer; ductal carcinoma in situ was intentionally not discussed.

### DEFINITION

Breast-conserving therapy (BCT) implies complete removal of the breast tumor with a concentric margin of surrounding healthy tissue performed in a cosmetically acceptable manner (lumpectomy) usually followed by radiation therapy. Surgical evaluation of the axillary lymph nodes is customarily part of breast conservation; the panelists agreed that treatment of the breast and axilla should be considered separately; presence of pathologically positive axillary lymph nodes is not a contraindication to breast conservation.

### OUTCOMES AFTER BREAST CONSERVATION

BCT and mastectomy offer equivalent longterm survival for appropriately selected patients. Breast conservation does imply risk for "in-breast" recurrence or a new primary cancer in the same breast. Unlike local recurrence after mastectomy, usually a forerunner of systemic disease, most panelists agreed that in-breast recurrence after BCT can be an isolated event treated successfully by additional operation, usually mastectomy. Nevertheless, there was unanimous support for every effort being made to achieve optimal local control.

The goal of BCT should be a 10-year local recurrence rate between 5% and 10%; <1% per year. Demographics of the treated population might produce variations in these observations, but the group unanimously supported these 10-year benchmarks.

Treatment of in-breast recurrence is traditionally by mastectomy, with or without reconstruction. Several panelists championed local excision alone for recurrence as ductal carcinoma in situ or for small invasive tumors, but acknowledged that a second attempt at breast conservation is associated with increased risk of additional recurrence. Use of accelerated partial breast irradiation (APBI; discussed later) to treat an in-breast recurrence was discussed; there was no agreement on appropriate indications for such an approach. All agreed that a short interval between initial treatment and recurrence (<2 years) implies radioresistance, and APBI would be inappropriate in those patients. All concurred that a second course of whole-breast irradiation is not appropriate, irrespective of the time between events.

Occurrence and treatment of axillary recurrence was

*See Appendix for full list of committee members and their affiliations.

Sponsored by the Breast Health Institute, Philadelphia, PA, and the European School of Oncology, Milan, Italy, April 28 to May 1, 2005.
Reprinted with permission from *Cancer*, Volume 107, Issue 2, July 15, 2006.


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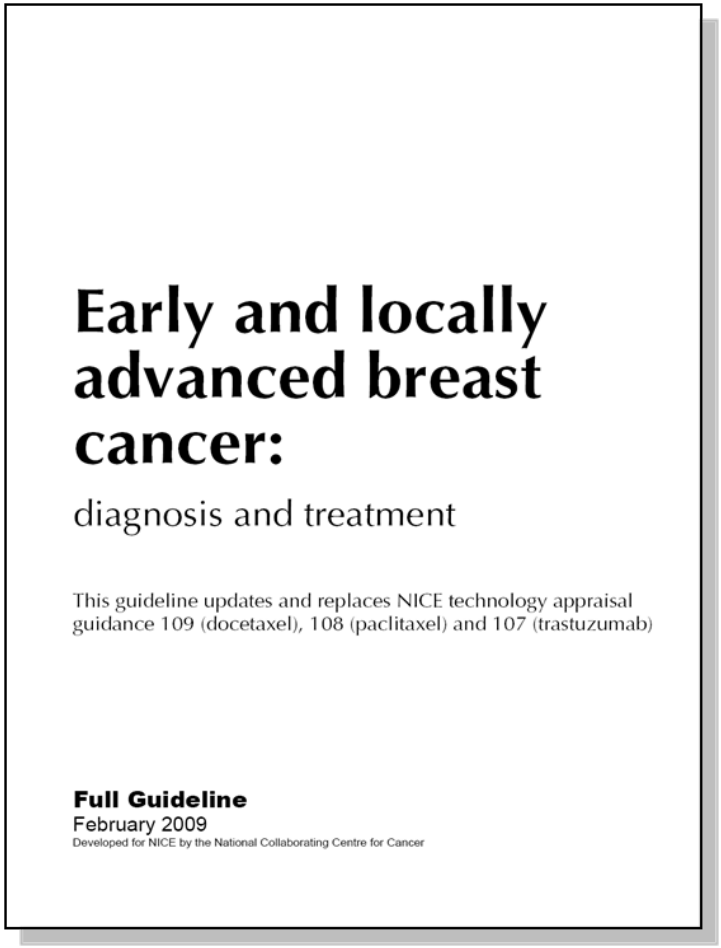
# LINEE GUIDA NICE

# NICE GUIDELINES SHORT VERSION




## Assessment of the axilla

### Patients with DCIS

| Patient group | Actions |
|---|---|
| Having breast conserving surgery and not considered at high risk of invasive disease. Patients at high risk include those with a palpable mass or extensive microcalcifications | • Do not perform SLNB routinely. |
| Having mastectomy | • Offer SLNB. |

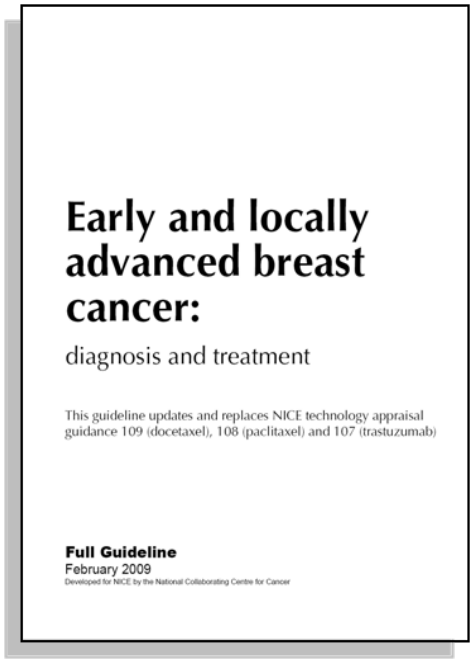
### Patients with early invasive breast cancer

| Patient group | Actions |
|---|---|
| All being investigated | • Perform pretreatment ultrasound evaluation of the axilla.<br>• If morphologically abnormal lymph nodes are identified, offer ultrasound-guided needle sampling. |
| No evidence of lymph node involvement on ultrasound, or negative ultrasound-guided needle biopsy | • Perform minimal surgery, rather than lymph node clearance. SLNB is the preferred technique.<br>• SLNB should only be performed by a team that is validated in the use of the technique, as identified in the NEW START training programme[5].<br>• Perform SLNB using the dual technique with isotope and blue dye. |
| Macro- or micrometastases shown in SLN, or preoperative ultrasound-guided needle biopsy with histologically proven metastatic cancer | • Offer further axillary treatment. Axillary lymph node dissection (ALND) is the preferred technique because it gives additional staging information. |
| Only isolated tumour cells in SLNs | • Do not offer further axillary treatment. Regard as lymph node-negative. |
| All | • Breast units should audit their axillary recurrence rates. |

[5] NEW START Sentinel Lymph Node Biopsy Training Programme, Royal College of Surgeons of England (www.rcseng.ac.uk/education/courses/new_start.html)

Issue date: February ***2009***. ***Early and locally advanced breast cancer***. Diagnosis and treatment.

# LINEE GUIDA: MODALITA' DI RACCOMANDAZIONI




**Recommendations**

- For all patients treated with breast conserving surgery for DCIS a minimum of 2 mm radial margin of excision is recommended with pathological examination to NHSBSP reporting standards. Re-excision should be considered if the margin is less than 2 mm after discussion of the risks and benefits with the patient.
- Enter patients with screen-detected DCIS into the Sloane Project (UK DCIS audit).
- All breast units should audit their recurrence rates after treatment for DCIS.

**Qualifying statement:** The evidence is from observational studies shows that there is no single size of clear margin that is the optimum for reduced local recurrence rate. These recommendations are based on GDG consensus.

**Recommendations**

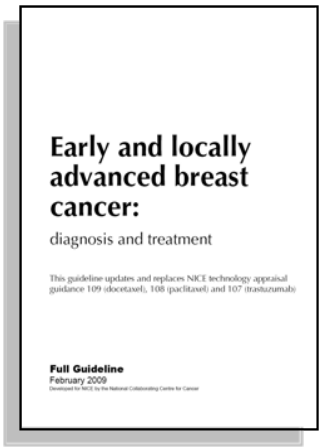
- Do not perform SLNB routinely in patients with a preoperative diagnosis of DCIS who are having breast conserving surgery, unless they are considered to be at a high risk of invasive disease[1].

**Qualifying statement:** There was insufficient evidence to support the routine use of SLNB in patients with DCIS. There was GDG consensus that patients at a high risk of having unsuspected invasive disease would benefit from SLNB.

- Offer SLNB to all patients who are having a mastectomy for DCIS.

**Qualifying statement:** This recommendation was based on GDG consensus.

# LINEE GUIDA: MODALITA' DI RACCOMANDAZIONI



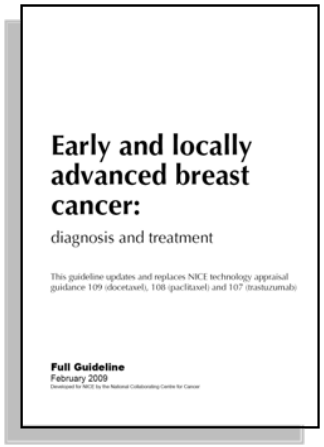

## Research recommendation

- In the absence of good data about differences in clinical outcome between axillary radiotherapy and completion ALND, entry into appropriate clinical trials, e.g. AMAROS, is recommended for early breast cancer patients when the axilla has been found by SLNB to contain metastasis.

## Health Economic Evaluation

A joint systematic review of the evidence was conducted to assess the cost effectiveness of using SLNB as the staging procedure for patients with invasive breast cancer (compared to ALND or axillary node sampling), and of using SLNB for patients with DCIS; comparing SLNB to either ALND or no ALND. The volume of economic evidence identified was limited and referred to patients with invasive breast cancer only. From a total of 80 references obtained from the search, six studies were identified that were related in some way to the cost effectiveness of SLNB in patients with invasive breast cancer: one of these studies was a full economic evaluation (Jeruss *et al.*, 2006), two of them were partial economic evaluations (Fortunato *et al.*, 2004 and Ronka *et al.*, 2004), and three of them were cost studies (Chirikos *et al.*, 2001, Gemignani *et al.*, 2000 and Perrier *et al.*, 2004).

# LINEE GUIDA: MODALITA' DI RACCOMANDAZIONI



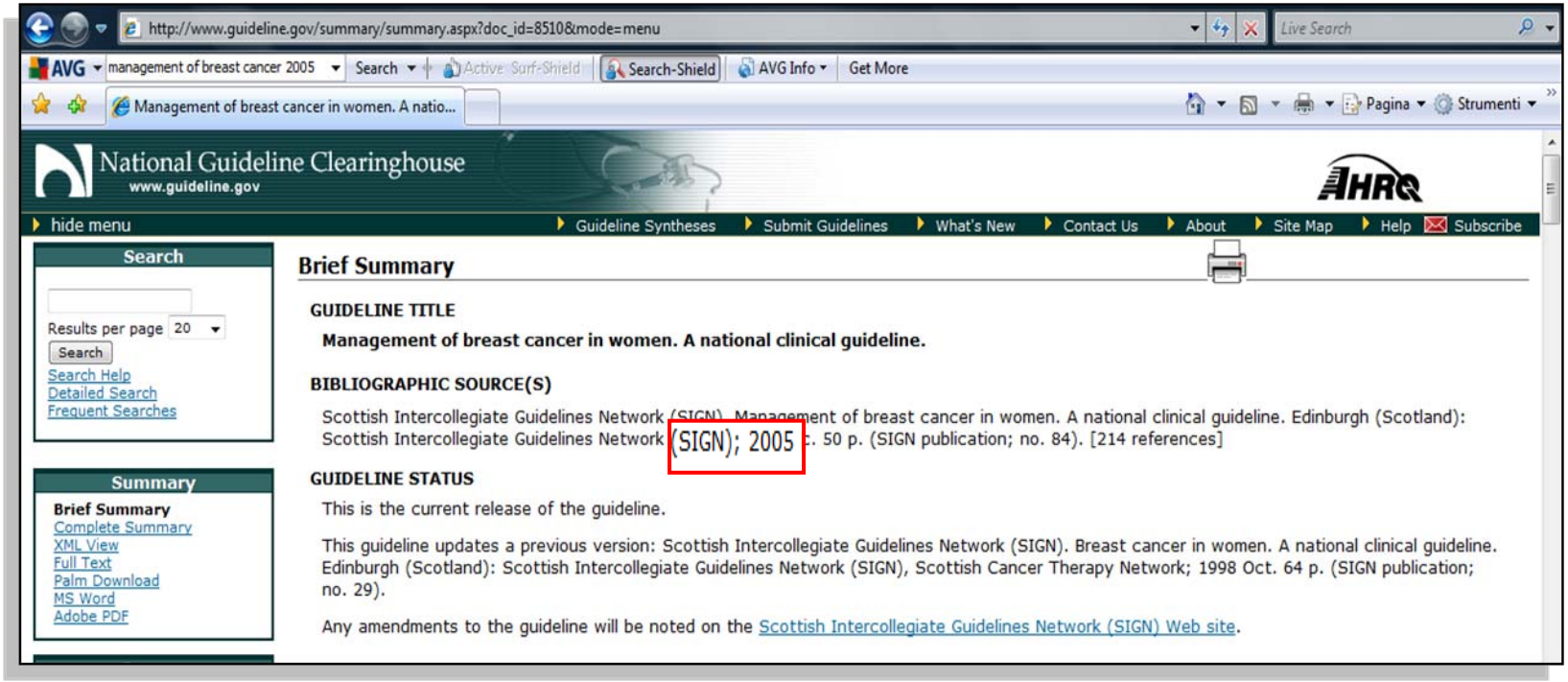

## Breast Reconstruction

**Recommendation**

- Discuss immediate breast reconstruction with all patients who are being advised to have a mastectomy, and offer it except where significant comorbidity or (the need for) adjuvant therapy may preclude this option. All appropriate breast reconstruction options should be offered and discussed with patients, irrespective of whether they are all available locally.

**Qualifying statement:** These recommendations are based on limited clinical evidence from observational studies and on GDG consensus that immediate reconstruction is an acceptable procedure that does not disadvantage patients compared to delayed reconstruction.

# LINEE GUIDA




**Breast Reconstruction after Mastectomy**

**C** - The possibility of breast reconstruction should be discussed with all patients prior to mastectomy. **(SIGN 29)**

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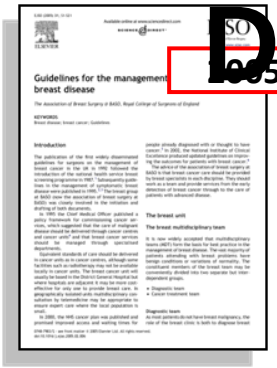

Guidelines for the management of breast disease

2005

## Ductal carcinoma in situ

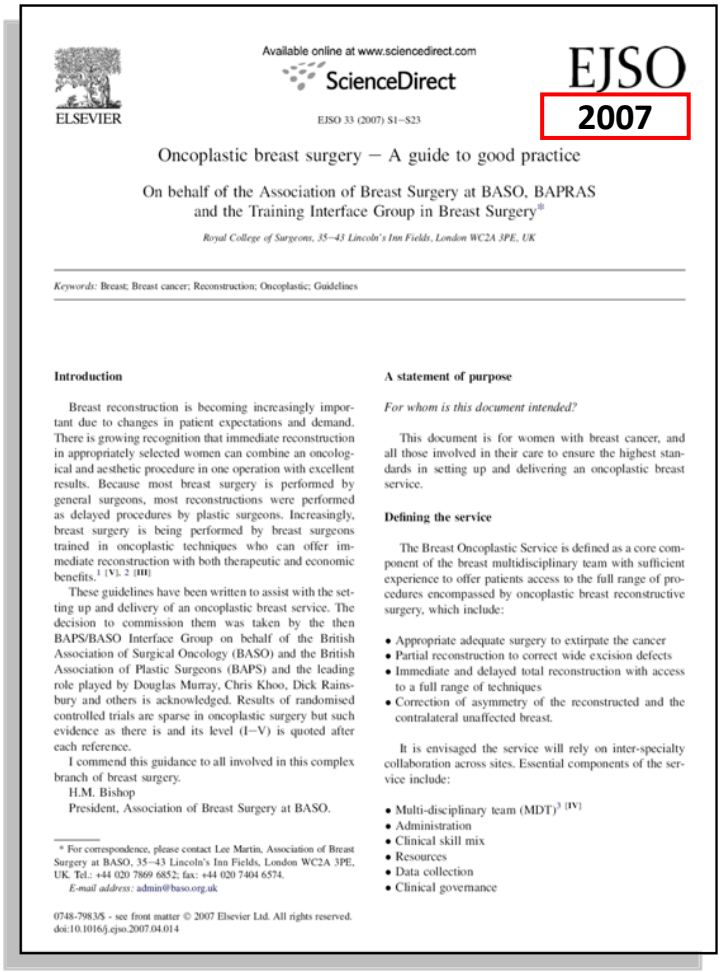
Ductal carcinoma in situ (DCIS) is a malignant precursor of invasive breast cancer. The aim of surgery is to achieve complete excision of the in situ tumour and to minimise local recurrence. Tumour multifocality is not uncommon and can lead to high local failure rates.[57] Approximately, 50% of local relapses after treatment for DCIS are invasive and not in situ. The indications for mastectomy are uncertain but extensive micro calcification on the pre-operative mammogram is a risk factor for local recurrence after conservation surgery. Observational studies suggest that high local recurrence rates occur after conservation surgery for diffuse in situ carcinoma. The grade of the tumour[58] and the width of the resection margin[59] are important factors in the management of DCIS.

Two published randomised trials of local excision alone vs excision and radiotherapy have demonstrated a significant reduction in the risk of ipsilateral invasive and non-invasive recurrence in the radiotherapy group at 5 years[60,61] (Level 1 evidence). These data suggest that local recurrence after local excision of DCIS and radiotherapy is

Lymph node staging is not normally required in DCIS. However, in cases where DCIS is high grade, appears extensive or presents as a mammographic or palpable mass lesion, invasive cancer may

or palpable mass lesion, invasive cancer may

# DOCUMENTO RACCOMANDAZIONI



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2007

## Oncoplastic breast surgery – A guide to good practice

On behalf of the Association of Breast Surgery at BASO, BAPRAS and the Training Interface Group in Breast Surgery*

*Royal College of Surgeons, 35–43 Lincoln's Inn Fields, London WC2A 3PE, UK*

*Keywords:* Breast; Breast cancer; Reconstruction; Oncoplastic; Guidelines

### Introduction

Breast reconstruction is becoming increasingly important due to changes in patient expectations and demand. There is growing recognition that immediate reconstruction in appropriately selected women can combine an oncological and aesthetic procedure in one operation with excellent results. Because most breast surgery is performed by general surgeons, most reconstructions were performed as delayed procedures by plastic surgeons. Increasingly, breast surgery is being performed by breast surgeons trained in oncoplastic techniques who can offer immediate reconstruction with both therapeutic and economic benefits.[1] [V], 2 [III]

These guidelines have been written to assist with the setting up and delivery of an oncoplastic breast service. The decision to commission them was taken by the then BAPS/BASO Interface Group on behalf of the British Association of Surgical Oncology (BASO) and the British Association of Plastic Surgeons (BAPS) and the leading role played by Douglas Murray, Chris Khoo, Dick Rainsbury and others is acknowledged. Results of randomised controlled trials are sparse in oncoplastic surgery but such evidence as there is and its level (I–V) is quoted after each reference.

I commend this guidance to all involved in this complex branch of breast surgery.

H.M. Bishop
President, Association of Breast Surgery at BASO.

* For correspondence, please contact Lee Martin, Association of Breast Surgery at BASO, 35–43 Lincoln's Inn Fields, London WC2A 3PE, UK. Tel.: +44 020 7869 6852; fax: +44 020 7404 6574.
*E-mail address:* admin@baso.org.uk


doi:10.1016/j.ejso.2007.04.014

### A statement of purpose

*For whom is this document intended?*

This document is for women with breast cancer, and all those involved in their care to ensure the highest standards in setting up and delivering an oncoplastic breast service.

### Defining the service

The Breast Oncoplastic Service is defined as a core component of the breast multidisciplinary team with sufficient experience to offer patients access to the full range of procedures encompassed by oncoplastic breast reconstructive surgery, which include:

- Appropriate adequate surgery to extirpate the cancer
- Partial reconstruction to correct wide excision defects
- Immediate and delayed total reconstruction with access to a full range of techniques
- Correction of asymmetry of the reconstructed and the contralateral unaffected breast.

It is envisaged the service will rely on inter-specialty collaboration across sites. Essential components of the service include:

- Multi-disciplinary team (MDT)[3] [IV]
- Administration
- Clinical skill mix
- Resources
- Data collection
- Clinical governance

# DOCUMENTO RACCOMANDAZIONI


2007



thrombosis, skin and flap necrosis, wound infection and delayed healing.[11–19] [II–IV]

*Intraoperative management: general principles*

Particular attention should be paid to correct positioning of the patient with the appropriate operating table attachments thereby preventing pressure sores, maintaining perfusion pressure and the avoidance of hypothermia.[20] [II]

*Post-operative care*

All staff should be aware of the importance of observation, especially of changes in colour and temperature of a transposed flap (see Appendix E for flap monitoring chart). Appropriate physiotherapy should be started postoperatively (see Appendix D on physiotherapy).

*Discharge process*

implants and the use of corrective surgery to the opposite breast.

*Breast-conserving surgery and reconstruction*

*Rationale*

Poor planning in breast-conserving surgery can result in unacceptable deformity. Thought must be given to the likely cosmetic result and the impact and timing of additional treatment. Plastic surgery techniques can be used to remodel the conserved breast and surgery to the opposite breast can be anticipated to achieve better symmetry.[21] [V] The use of implants to correct volume deficiency can lead to bad results.[22] [IV]

Oncoplastic techniques extend the scope for breast-conserving surgery by combining an extensive local excision of the breast parenchyma with a simultaneous reconstruction of the defect to avoid local deformity.[23] [V]

*Indications*

nd reconstruction should be
here adequate local excision
nificant risk of local defor-
urs after:

of the breast volume;
le resections;
mpectomy incision;
ior quadrants;
breast parenchyma to allow

women considering a breast
.25 [III]
o have had poorly planned
ten severe and difficult to
onstruction of these defor-
complications and recurrent
oved in 50% of patients.
easily accepted by these pa-
ade to avoid these late defor-
al surgery.

ction is contraindicated:

be assured without perform-
ing a mastectomy;

- in patients with T4 tumours;
- in those patients with multicentric disease;
- in patients with extensive malignant mammographic microcalcification;
- in patients with inflammatory carcinoma.

*Timing of procedure*

Breast-conserving surgery and reconstruction can be performed as a one-stage procedure, or as a two-stage

**Selection of breast reconstruction techniques**

Historically, the goals of breast reconstruction were to improve the appearance when clothed and to avoid an external prosthesis. Surgical advances and increased patient expectations have modified these goals. The current aim is to produce symmetry that satisfies the patient's wishes within the limits of technical feasibility, whilst matching the remaining breast in terms of its contour, dimension and position. This may involve the use of breast

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# LINEE GUIDA CANADESI TRATTAMENTO/CHIRURGIA

**Clinical practice guidelines for the care and treatment of breast cancer: 3. Mastectomy or lumpectomy? The choice of operation for clinical stages I and II breast cancer (2002 update)**

Hugh Scarth, Jacques Cantin, Mark Levine, for the Steering Committee on Clinical Practice Guidelines for the Care and Treatment of Breast Cancer*

Dr. Scarth is Assistant Professor in the Department of Surgery, Dalhousie University, and is with the Atlantic Health Sciences Corporation, Saint John, NB. Dr. Cantin is Associate Professor in the Department of Surgery, University of Montreal, and is with the Centre hospitalier de l'Université de Montréal, Montreal, Que. Dr. Levine is Professor in the Departments of Clinical Epidemiology and Biostatistics and of Medicine and is the Buffet Taylor Chair in Breast Cancer Research, McMaster University, Hamilton, Ont.

*The Steering Committee is part of Health Canada's Canadian Breast Cancer Initiative.

**Abstract**

**Objective:** To assist women and their physicians in making the most clinically effective and personally acceptable decision regarding the choice of primary surgery for potentially curable breast cancer.
**Options:** Breast-conserving surgery (BCS; also referred to as lumpectomy or wide local excision) or mastectomy.
**Outcomes:** Local recurrence, disease-free survival, overall survival, cosmetic results.
**Evidence:** Systematic computerized search of MEDLINE (1980 to May 2001) and CANCERLIT (1985 to May 2001). Nonsystematic review of breast cancer literature to December 2001.
**Benefits:** Minimization of disfigurement offered by BCS.
**Harms:** The need for radiotherapy and the greater costs associated with BCS.
**Recommendations:**

- For patients with stage I or II breast cancer, BCS followed by radiotherapy is generally recommended. In the absence of special reasons for selecting mastectomy, the choice between BCS and mastectomy can be made according to the patient's circumstances and personal preferences.

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NCCN National Comprehensive Cancer Network® The Oncology Report
Highlights of the NCCN 13th Annual Conference

# NCCN GUIDELINES FOR BREAST CANCER

## Is radiation therapy necessary for DCIS?

One major change in the breast cancer guidelines was incorporation of the option of lumpectomy without lymph node surgery and RT for essentially all women with DCIS, which received a category 2B recommendation (lower quality of evidence and nonuniform consensus). For the primary treatment of these women, it joins lumpectomy without lymph node surgery with whole-breast RT (category 1) and total mastectomy with or without sentinel node biopsy (SNB).

Data from two large randomized clinical trials—NSABP (National Surgical Adjuvant Breast and Bowel Project) B-17 (*Fisher B et al. J Clin Oncol 1998;16:441–452*) and an EORTC (European Organization for Research on the Treatment of Cancer) study (*Bijker N et al. J Clin Oncol 2006;24:3381–3387*)—support the use of RT in the treatment of patients with DCIS. Both trials showed reduced local failure rates in women treated with breast-conserving surgery (with negative margins) and RT compared with women undergoing breast-conserving surgery alone, with about a 50% reduction in the risk of l

**DCIS treatment recommendations**

- Lumpectomy without lymph node surgery plus whole-breast radiation

However, these benefits did not extend to overall survival. "I would chall
show that the treatment of DCIS with radiation or without radiation, by maste
surgery, with or without hormonal therapy provides any survival advantage,"
Roswell Park Cancer Institute.

In both of these trials, the researchers "were unable to identify any subs
reduction in the risk of local recurrence with RT," Dr. Edge reported. Howev
define subsets of women with "low- risk" DCIS for whom the risk of local fail
omit RT, he asserted. In two trials evaluating the use of lumpectomy without
small, low-grade disease with wide margins or negative margins following r
*Clin Oncol 2006;24:1031–1036)* or women with either low- or intermediate
grade DCIS < 1 cm *(Hughes L et al. 2006 San Antonio Breast Cancer Sy*
local recurrence rates of 12% in the former trial and 6.8% and 13.7%, respe

"The question is whether these numbers represent figures that are low
predict the likelihood of local recurrence for women with DCIS based on tun
has been developed (*Silverstein MJ, Lagios MD. J Surg Oncol 2007;95:6*
retrospective analysis.

According to the NCCN breast cancer outcomes database for women
obvious that a large fraction of women in the United States who were treate
admitted. Therefore, the updated NCCN guidelines include a statement refl
be appropriately treated by lumpectomy alone, saying that whole-breast RT
It mentions factors that affect the risk of recurrence, indicates that some low
appears to be no difference in patient survival among the local treatments.

"So the updated recommendations really place the onus back on the p
when making decisions regarding the use of RT," Dr. Edge summarized.

## Axillary staging in DCIS?

On the issue of axillary nodal staging in patients with DCIS, Dr. Edge said that he was "surprised by how many people do SNB for all women with DCIS in the community." A study evaluating results of two trials from the NSABP (B-17 and B-24; *Julian TB et al. Ann Surg Oncol 2007;14:2202–2208*), which addressed whether SNB is advised for these women, does not support the use of SNB in patients with conservatively treated, localized DCIS, he said.

"The large majority of patients with DCIS who have positive nodes have disease detectable only by immunohistochemistry (IHC)," remarked Dr. Edge, and studies have shown that overall disease-specific survival did not differ for patients with DCIS who had IHC-detected nodes versus those who did not *(El-Tamer M et al. Ann Surg Oncol 2005;12:254–259)*. Based on these and other data, the 2008 NCCN guidelines recommend that women with DCIS being treated with lumpectomy do not undergo lymph node surgery; however, the recommendation for women with DCIS being treated by mastectomy includes SNB. The latter recommendation is based on the unlikelihood that a subsequent SNB could be performed if invasive cancer was detected after mastectomy, said Dr. Edge.

## Role of postmastectomy radiation therapy

Another change in the 2008 guidelines regarding RT was made for women with invasive breast cancer. Based on evidence from randomized trials showing a survival advantage with RT after mastectomy for women with early-stage invasive breast cancer characterized by one to three positive axillary lymph nodes, the NCCN Breast Cancer Guidelines Panel strengthened the recommendation for the use of RT in this group of patients. The guidelines now state that postmastectomy RT to the chest wall and supraclavicular area should be "strongly considered" for these women. A recommendation for consideration of RT to internal mammary nodes is also included in the guidelines for patients with one to three positive nodes following mastectomy, although this suggestion was more controversial.

"A shortcoming of our guidelines over the past years has been the absence of a guideline covering techniques of RT," Dr. Edge explained. So, for the first time, the 2008 NCCN guidelines offer an outline on the principles of RT, including best practices, doses, the fields, and mention of the investigational use of partial breast irradiation.

## Breast reconstruction guidance

Principles of breast reconstruction are described in another new guideline included this year. It focuses on reconstruction following mastectomy, including information on skin-sparing mastectomy and the sequencing of reconstruction with respect to RT. Dr. Edge emphasized the importance of a multidisciplinary evaluation within a breast program on the use of reconstruction and of including patients in the discussion with careful counseling.

Furthermore, "reconstruction has the potential for affecting the delivery of RT," he said. For instance, according to an M. D. Anderson Cancer Center series (*Motwani SB et al. Int J Radiat Oncol Biol Phys 2006;66:76–82*), 52% of women who underwent reconstruction and received RT had "compromised" RT, either in terms of delivery of radiation or dosing to underlying structures. In addition, women considering reconstruction with autologous tissue should strongly "consider delaying reconstruction until after RT," Dr. Edge suggested, since pre-irradiation reconstruction may lead to a worse cosmetic outcome. However, pre-irradiation breast reconstruction is preferred if an implant is used, he added, because it can allow sparing of skin and expansion of non-radiated skin.

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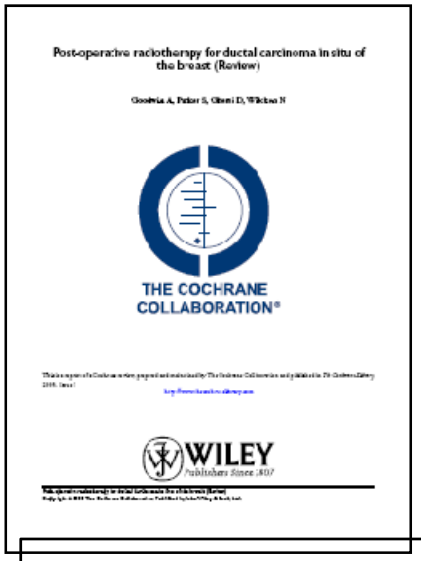

Post-operative radiotherapy for ductal carcinoma in situ of the breast (Review)

Goodwin A, Parker S, Ghersi D, Wilcken N

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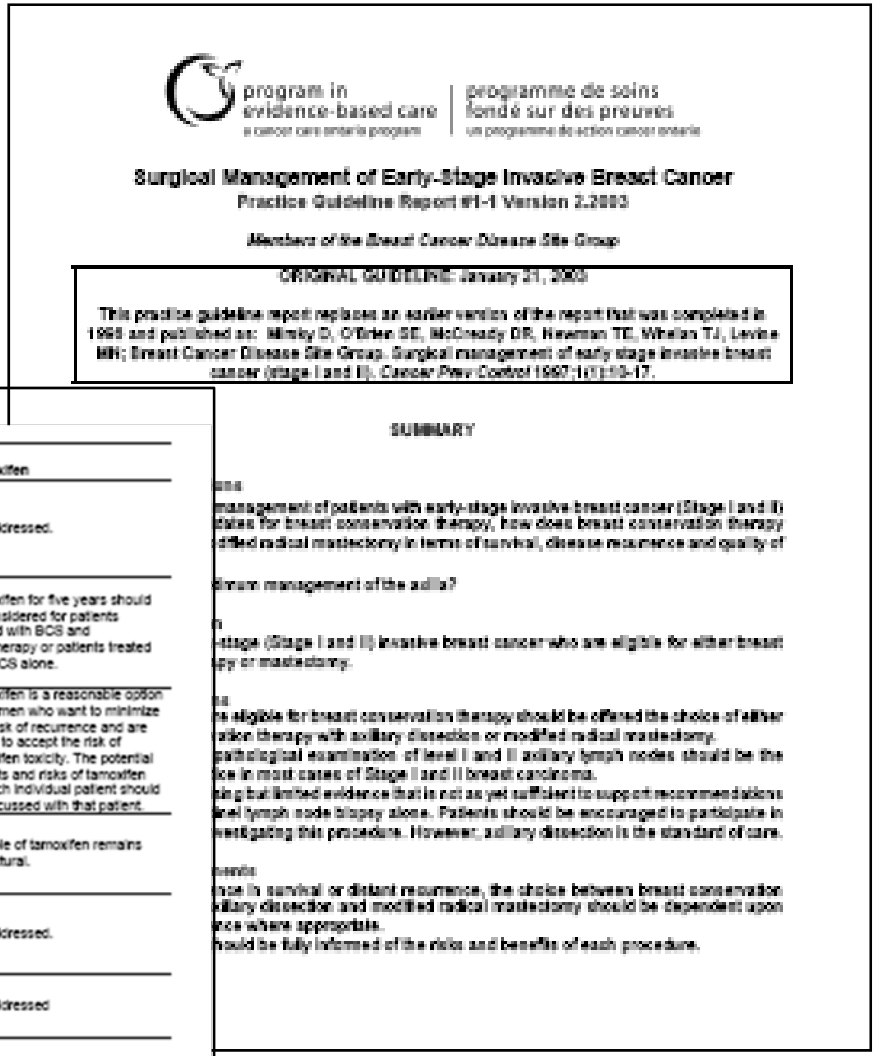

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Surgical Management of Early-Stage Invasive Breast Cancer
Practice Guideline Report #1-1 Version 2.2003

*Members of the Breast Cancer Disease Site Group*

ORIGINAL GUIDELINE: January 31, 2003

This practice guideline report replaces an earlier version of the report that was completed in 1998 and published as: Mirsky D, O'Brien SE, McCready DR, Hnewman TE, Whelan TJ, Levine MN; Breast Cancer Disease Site Group. Surgical management of early stage invasive breast cancer (stage I and II). *Cancer Prev Control* 1997;1(1):10-17.

SUMMARY

anne

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ussion

ase in survival or distant recurrence, the choice between breast conservation illary dissection and modified radical mastectomy should be dependent upon nce where appropriate.

should be fully informed of the risks and benefits of each procedure.

Table 8: Clinical practice guidelines relevant to the management of DCIS.

| Source (reference) | Country of Origin | Date last updated | Recommendation/statement Surgical | Radiation | Tamoxifen |
|---|---|---|---|---|---|
| National Breast Cancer Centre (18) | Australia | 2003 | Excision must obtain clear margins. If margins are involved, further excision is required. | Radiotherapy after complete local excision reduces invasive recurrence. For women with good prognostic features, the overall clinical benefit may be small. | Not addressed. |
| National Comprehensive Cancer Network (19) | USA | 2003 | Women with DCIS that is not amenable to margin-free excision should receive mastectomy; otherwise BCS is recommended. | Whole breast irradiation with boost to tumour bed is recommended for women with negative margins. Selected patients with DCIS may be appropriately treated with BCS without irradiation. | Tamoxifen for five years should be considered for patients treated with BCS and radiotherapy or patients treated with BCS alone. |
| Canadian Breast Cancer Initiative (20,21) | Canada | 2001 | Mastectomy is recommended for those with large lesions where BCS would produce an unacceptable cosmetic effect or where there is persistent margin involvement after 2 or more attempts at excision. | BCS should usually be followed by radiotherapy, but in cases of small low-grade lesions with clear margins, radiotherapy may be omitted, after a careful discussion with the patient regarding options and risks. | Tamoxifen is a reasonable option for women who want to minimize their risk of recurrence and are willing to accept the risk of tamoxifen toxicity. The potential benefits and risks of tamoxifen for each individual patient should be discussed with that patient. |
| The Royal College of Radiologists (22) | United Kingdom | 1999 | Extensive or multifocal DCIS should be treated by mastectomy. | Radiotherapy after BCS reduces the rate of local recurrence, particularly in women with high-grade lesions or positive margins. | The role of tamoxifen remains conjectural. |
| The Scottish Intercollegiate Guideline Networks (23) | Scotland | 1998 | Mastectomy is recommended for patients with DCIS greater than 4cm or those with disease affecting more than one quadrant. | Radiotherapy should be considered following BCS with wide local excision. | Not addressed. |
| New Zealand Guidelines Group (24) | New Zealand | 1997 | Excision with clear margins is the treatment goal. To achieve this, either mastectomy or BCS may be performed. | Radiotherapy should normally be given following BCS. | Not addressed |

Abbreviations: BCS, breast conserving surgery; DCIS, ductal carcinoma in situ.

SYSTEMATIC REVIEW – page 13

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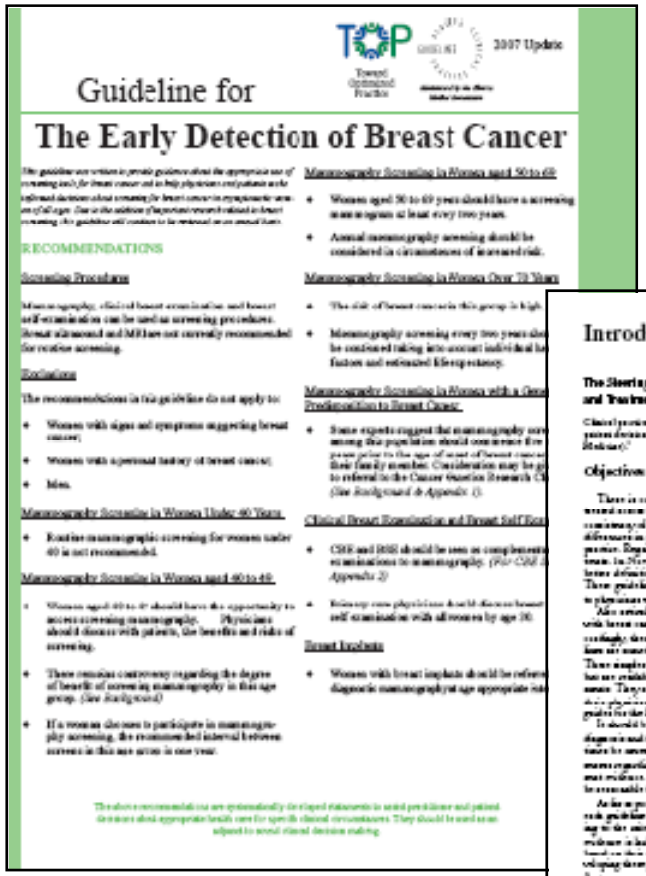


Guideline for

## The Early Detection of Breast Cancer

2007 Update

RECOMMENDATIONS

Screening Procedures

Exclusions

The recommendations in this guideline do not apply to:

- Women with signs and symptoms suggesting breast cancer;
- Women with a personal history of breast cancer;
- Men.

Mammography Screening in Women Under 40 Years

- Routine mammographic screening for women under 40 is not recommended.

Mammography Screening in Women aged 40 to 49

- Women aged 40 to 49 should have the opportunity to access screening mammography. Physicians should discuss with patients, the benefits and risks of screening.
- There remains controversy regarding the degree of benefit of screening mammography in this age group. *(see Background)*
- If a woman chooses to participate in mammography screening, the recommended interval between screens in this age group is one year.

Mammography Screening in Women aged 50 to 69

- Women aged 50 to 69 years should have a screening mammogram at least every two years.
- Annual mammography screening should be considered in circumstances of increased risk.

Mammography Screening in Women Over 70 Years

- The risk of breast cancer in this group is high.
- Mammography screening every two years should be continued taking into account individual health factors and estimated life expectancy.

Mammography Screening in Women with a Genetic Predisposition to Breast Cancer

- Some experts suggest that mammography screening among this population should commence five years prior to the age of onset of breast cancer in their family member. Consideration may be given to referral to the Cancer Genetics Research Clinic. *(See Background & Appendix 1).*

Clinical Breast Examination and Breast Self-Examination

- CBE and BSE should be seen as complementary examinations to mammography. *(See CBE & Appendix 2)*
- Every woman should be encouraged to practice breast self-examination with all women by age 30.

Breast Implants

- Women with breast implants should be referred for diagnostic mammography at age appropriate risk.

The above recommendations are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances. They should be used as an adjunct to sound clinical decision making.

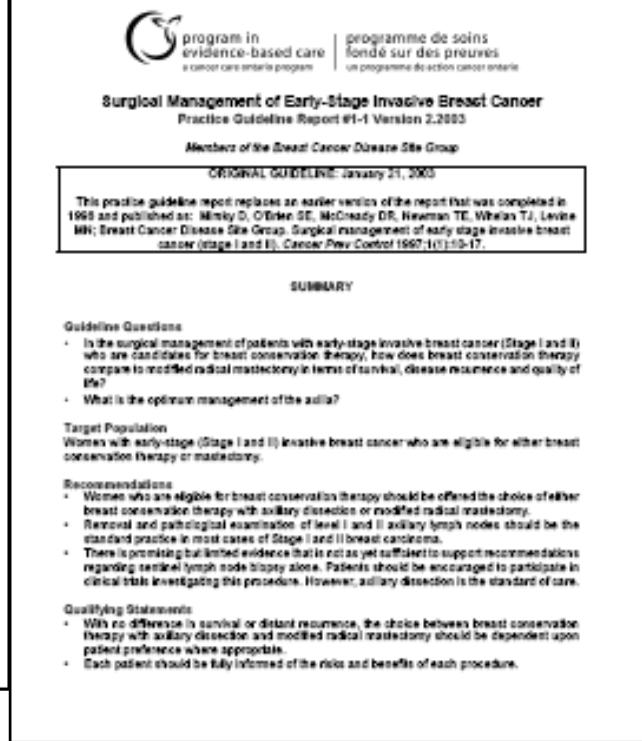
## Introduction

**The Steering Committee on Clinical Practice Guidelines for the Care and Treatment of Breast Cancer**

*Special Supplement*

### Objectives

### Method



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a cancer care ontario program | un programme de action cancer ontario

## Surgical Management of Early-Stage Invasive Breast Cancer

Practice Guideline Report #1-1 Version 2.2003

*Members of the Breast Cancer Disease Site Group*

ORIGINAL GUIDELINE: January 21, 2003

This practice guideline report replaces an earlier version of the report that was completed in 1998 and published as: Minsky D, O'Brien SE, McCready DR, Newman TE, Whelan TJ, Levine MN; Breast Cancer Disease Site Group. Surgical management of early stage invasive breast cancer (stage I and II). *Cancer Prev Control* 1997;1(1):10-17.

SUMMARY

Guideline Questions

- Is the surgical management of patients with early-stage invasive breast cancer (Stage I and II) who are candidates for breast conservation therapy, how does breast conservation therapy compare to modified radical mastectomy in terms of survival, disease recurrence and quality of life?
- What is the optimum management of the axilla?

Target Population

Women with early-stage (Stage I and II) invasive breast cancer who are eligible for either breast conservation therapy or mastectomy.

Recommendations

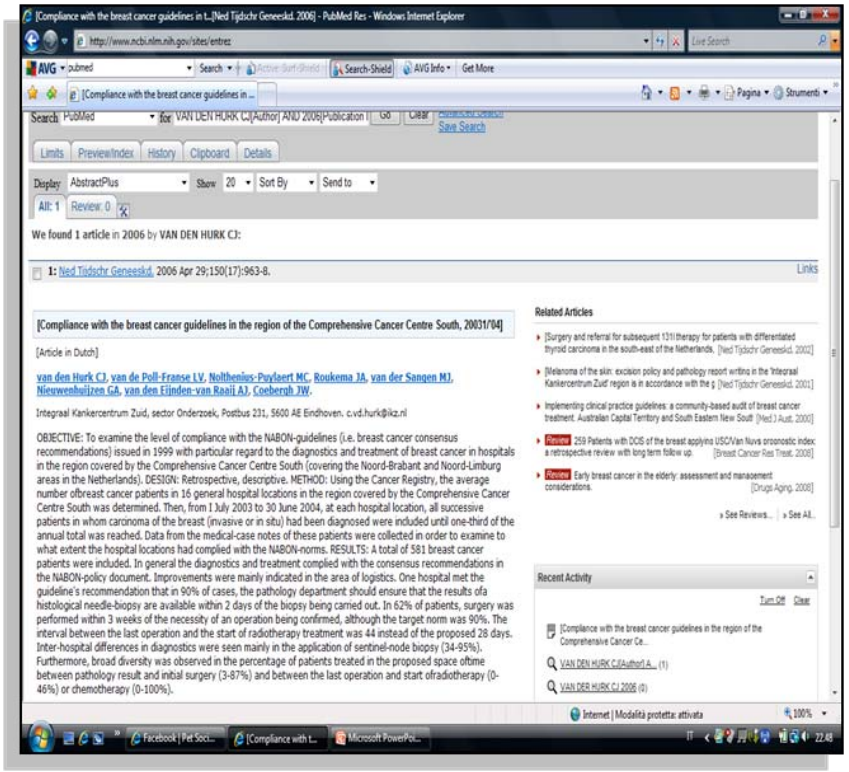
- Women who are eligible for breast conservation therapy should be offered the choice of either breast conservation therapy with axillary dissection or modified radical mastectomy.
- Removal and pathological examination of level I and II axillary lymph nodes should be the standard practice in most cases of Stage I and II breast carcinoma.
- There is promising but limited evidence that is not as yet sufficient to support recommendations regarding sentinel lymph node biopsy alone. Patients should be encouraged to participate in clinical trials investigating this procedure. However, axillary dissection is the standard of care.

Qualifying Statements

- With no difference in survival or distant recurrence, the choice between breast conservation therapy with axillary dissection and modified radical mastectomy should be dependent upon patient preference where appropriate.
- Each patient should be fully informed of the risks and benefits of each procedure.

# LINEE GUIDA E MONITORAGGIO INDICATORI

## ESPERIENZA OLANDESE




Su valutazione intra-ospedaliera e inter-ospedaliera.

<u>Parametri accettabili</u>:

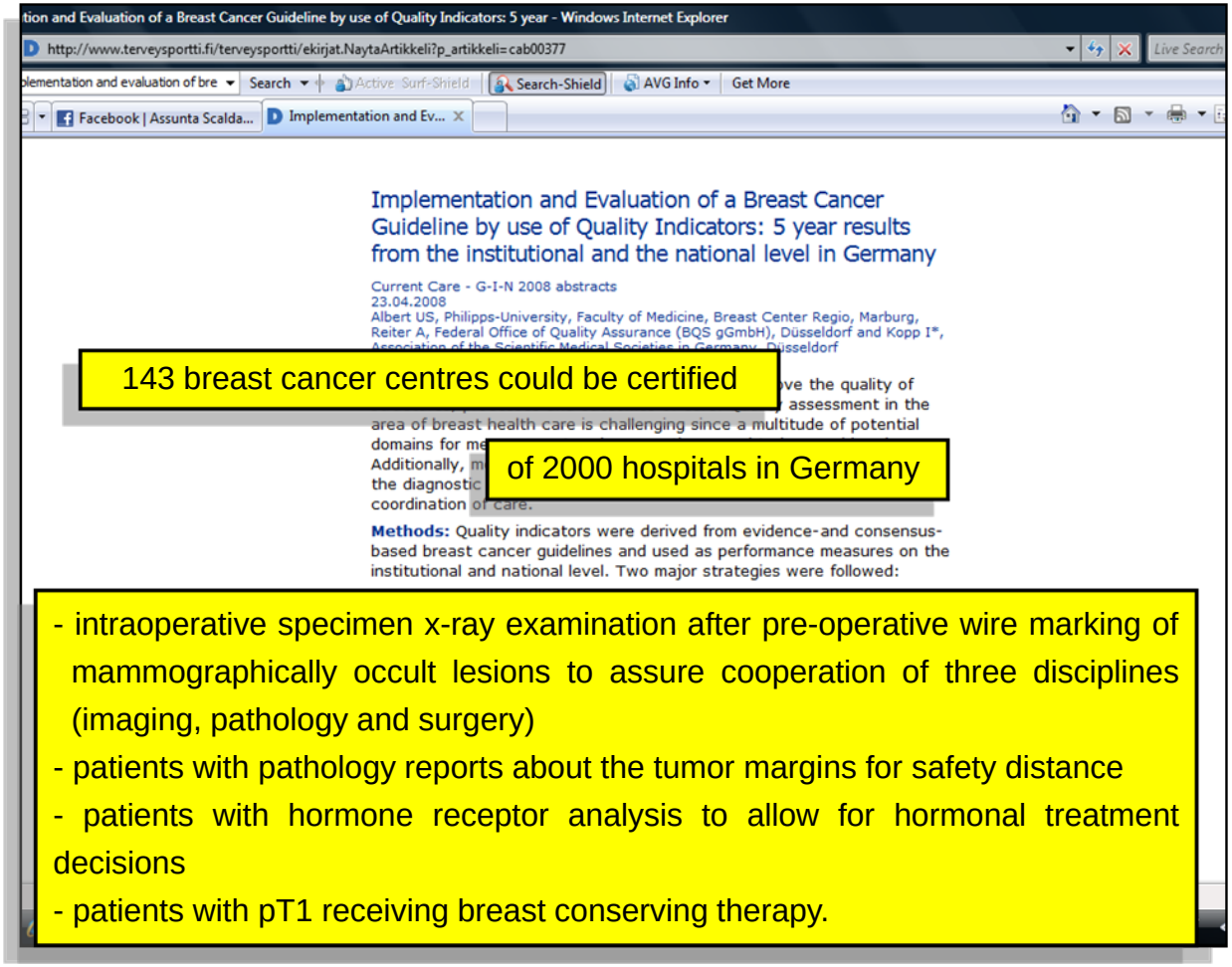
- Intervallo per esito cito-istologico preoperatorio di 2 giorni dalla data di esecuzione dell'esame
- Intervallo tra esito istologico ed intervento chirurgico di 3 settimane

<u>Parametri non accettabili</u> per range troppo ampio:

- Applicazione SB Biopsy
- Inizio RT/CHT dopo 44 giorni dal trattamento chirurgico.

# LINEE GUIDA E MONITORAGGIO INDICATORI

# ESPERIENZA TEDESCA



# LINEE GUIDA E INDICATORI

## ESPERIENZA CANADESE


Canadian Breast Cancer Network

CBCN Groups Resources News Bulletin Boards Community Links How You Can Help

The National Network & Voice of Breast Cancer Survivors

Top ↳News ↳Breast cancer news in Canada

**2007.03.13 Canadian breast cancer guidelines: Have they made a difference?**

2007 Canadian Medical Association or its licensors Research Canadian Breast cancer guidelines: Have they made a difference?

From the Department of Surgical Oncology (Latosinsky) and the Epidemiology and Cancer Registry (Fradette, Hildebrand, Turner), CancerCare Manitoba; and the Departments of Surgery (Latosinsky) and Community Health Sciences (Latosinsky, Lix, Turner), University of Manitoba, Winnipeg, Man. Correspondence to: Dr. Steven Latosinsky, Department of Surgery, Health Sciences Centre, Rm.

We studied a population-based cohort of 7022 women living in Manitoba in whom breast cancer was diagnosed from (1995 to 2003).

We examined 4 measures of care: breast-conserving surgery, axillary assessment in invasive disease, axillary node dissection in noninvasive disease and the adequacy of axillary node dissection.

**Interpretation: Our results suggest that the Canadian breast cancer guidelines are not meeting their stated objective. New strategies for guideline dissemination and implementation may be required.**

*BMJ* 1997;315:1109-1110 (1 November)

**Editorials**

# Medicine based evidence, a prerequisite for evidence based medicine

*Future research methods must find ways of accommodating clinical reality, not ignoring it*

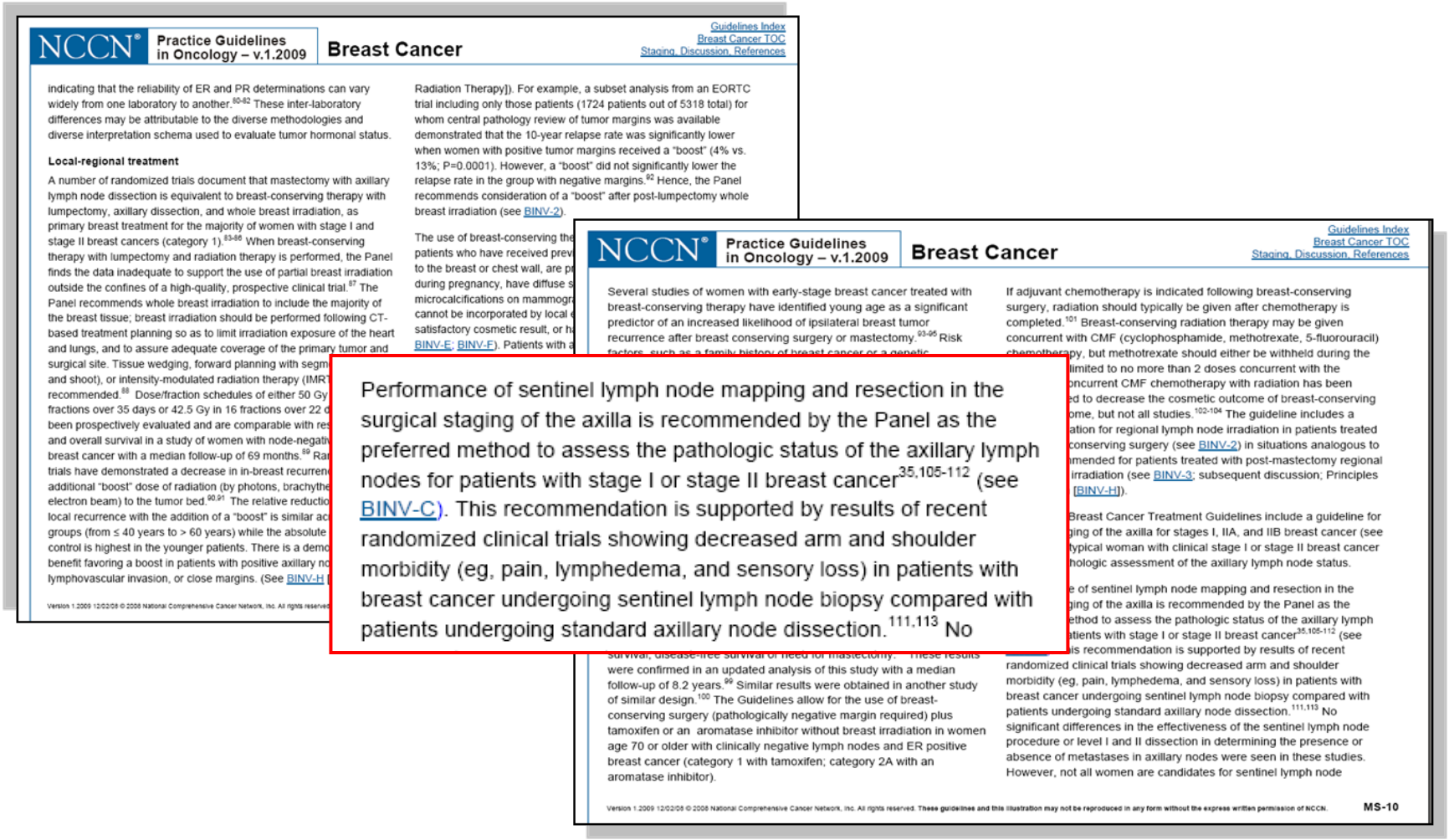
**…IL MONITORAGGIO DI QUALITA' DEVE AVERE COME OBBIETTIVO LA CORREZIONE DEGLI STANDARD NON RISPETTATI…**

**…DEVE INOLTRE INDIVIDUARE QUALI INDICATORI RICHIEDONO ULTERIORE FORMAZIONE…**

Strada proposta dal progetto di formazione:

- ***individuare*** (attraverso il monitoraggio degli indicatori) gli eventuali problemi nelle diverse realtà
- ***proporre*** correttivi, sia incrementando la formazione teorico-pratica ove carente, sia segnalando le carenze delle strutture agli organi competenti.

# NCCN GUIDELINES FOR BREAST CANCER



NCCN® Practice Guidelines in Oncology – v.1.2009 **Breast Cancer**

Guidelines Index
Breast Cancer TOC
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indicating that the reliability of ER and PR determinations can vary widely from one laboratory to another.[80-82] These inter-laboratory differences may be attributable to the diverse methodologies and diverse interpretation schema used to evaluate tumor hormonal status.

**Local-regional treatment**

A number of randomized trials document that mastectomy with axillary lymph node dissection is equivalent to breast-conserving therapy with lumpectomy, axillary dissection, and whole breast irradiation, as primary breast treatment for the majority of women with stage I and stage II breast cancers (category 1).[83-86] When breast-conserving therapy with lumpectomy and radiation therapy is performed, the Panel finds the data inadequate to support the use of partial breast irradiation outside the confines of a high-quality, prospective clinical trial.[87] The Panel recommends whole breast irradiation to include the majority of the breast tissue; breast irradiation should be performed following CT-based treatment planning so as to limit irradiation exposure of the heart and lungs, and to assure adequate coverage of the primary tumor and surgical site. Tissue wedging, forward planning with segm
and shoot), or intensity-modulated radiation therapy (IMRT
recommended.[88] Dose/fraction schedules of either 50 Gy
fractions over 35 days or 42.5 Gy in 16 fractions over 22 d
been prospectively evaluated and are comparable with re
and overall survival in a study of women with node-negati
breast cancer with a median follow-up of 69 months.[89] Ra
trials have demonstrated a decrease in in-breast recurren
additional "boost" dose of radiation (by photons, brachythe
electron beam) to the tumor bed.[90,91] The relative reductio
local recurrence with the addition of a "boost" is similar ac
groups (from ≤ 40 years to > 60 years) while the absolute
control is highest in the younger patients. There is a demo
benefit favoring a boost in patients with positive axillary no
lymphovascular invasion, or close margins. (See BINV-H

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Radiation Therapy]). For example, a subset analysis from an EORTC trial including only those patients (1724 patients out of 5318 total) for whom central pathology review of tumor margins was available demonstrated that the 10-year relapse rate was significantly lower when women with positive tumor margins received a "boost" (4% vs. 13%; P=0.0001). However, a "boost" did not significantly lower the relapse rate in the group with negative margins.[92] Hence, the Panel recommends consideration of a "boost" after post-lumpectomy whole breast irradiation (see BINV-2).

The use of breast-conserving the
patients who have received prev
to the breast or chest wall, are p
during pregnancy, have diffuse s
microcalcifications on mammogr
cannot be incorporated by local
satisfactory cosmetic result, or h
BINV-E; BINV-F). Patients with a

Performance of sentinel lymph node mapping and resection in the surgical staging of the axilla is recommended by the Panel as the preferred method to assess the pathologic status of the axillary lymph nodes for patients with stage I or stage II breast cancer[35,105-112] (see BINV-C). This recommendation is supported by results of recent randomized clinical trials showing decreased arm and shoulder morbidity (eg, pain, lymphedema, and sensory loss) in patients with breast cancer undergoing sentinel lymph node biopsy compared with patients undergoing standard axillary node dissection.[111,113] No

NCCN® Practice Guidelines in Oncology – v.1.2009 **Breast Cancer**

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Several studies of women with early-stage breast cancer treated with breast-conserving therapy have identified young age as a significant predictor of an increased likelihood of ipsilateral breast tumor recurrence after breast conserving surgery or mastectomy.[93-95] Risk
factors, such as a family history of breast cancer or a genetic

were confirmed in an updated analysis of this study with a median follow-up of 8.2 years.[99] Similar results were obtained in another study of similar design.[100] The Guidelines allow for the use of breast-conserving surgery (pathologically negative margin required) plus tamoxifen or an aromatase inhibitor without breast irradiation in women age 70 or older with clinically negative lymph nodes and ER positive breast cancer (category 1 with tamoxifen; category 2A with an aromatase inhibitor).

If adjuvant chemotherapy is indicated following breast-conserving surgery, radiation should typically be given after chemotherapy is completed.[101] Breast-conserving radiation therapy may be given concurrent with CMF (cyclophosphamide, methotrexate, 5-fluorouracil)
chemotherapy, but methotrexate should either be withheld during the
limited to no more than 2 doses concurrent with the
oncurrent CMF chemotherapy with radiation has been
ed to decrease the cosmetic outcome of breast-conserving
ome, but not all studies.[102-104] The guideline includes a
ation for regional lymph node irradiation in patients treated
conserving surgery (see BINV-2) in situations analogous to
mended for patients treated with post-mastectomy regional
irradiation (see BINV-3; subsequent discussion; Principles
[BINV-H]).

Breast Cancer Treatment Guidelines include a guideline for
ging of the axilla for stages I, IIA, and IIB breast cancer (see
typical woman with clinical stage I or stage II breast cancer
hologic assessment of the axillary lymph node status.

e of sentinel lymph node mapping and resection in the
ging of the axilla is recommended by the Panel as the
ethod to assess the pathologic status of the axillary lymph
atients with stage I or stage II breast cancer[35,105-112] (see
is recommendation is supported by results of recent
randomized clinical trials showing decreased arm and shoulder
morbidity (eg, pain, lymphedema, and sensory loss) in patients with
breast cancer undergoing sentinel lymph node biopsy compared with
patients undergoing standard axillary node dissection.[111,113] No
significant differences in the effectiveness of the sentinel lymph node
procedure or level I and II dissection in determining the presence or
absence of metastases in axillary nodes were seen in these studies.
However, not all women are candidates for sentinel lymph node

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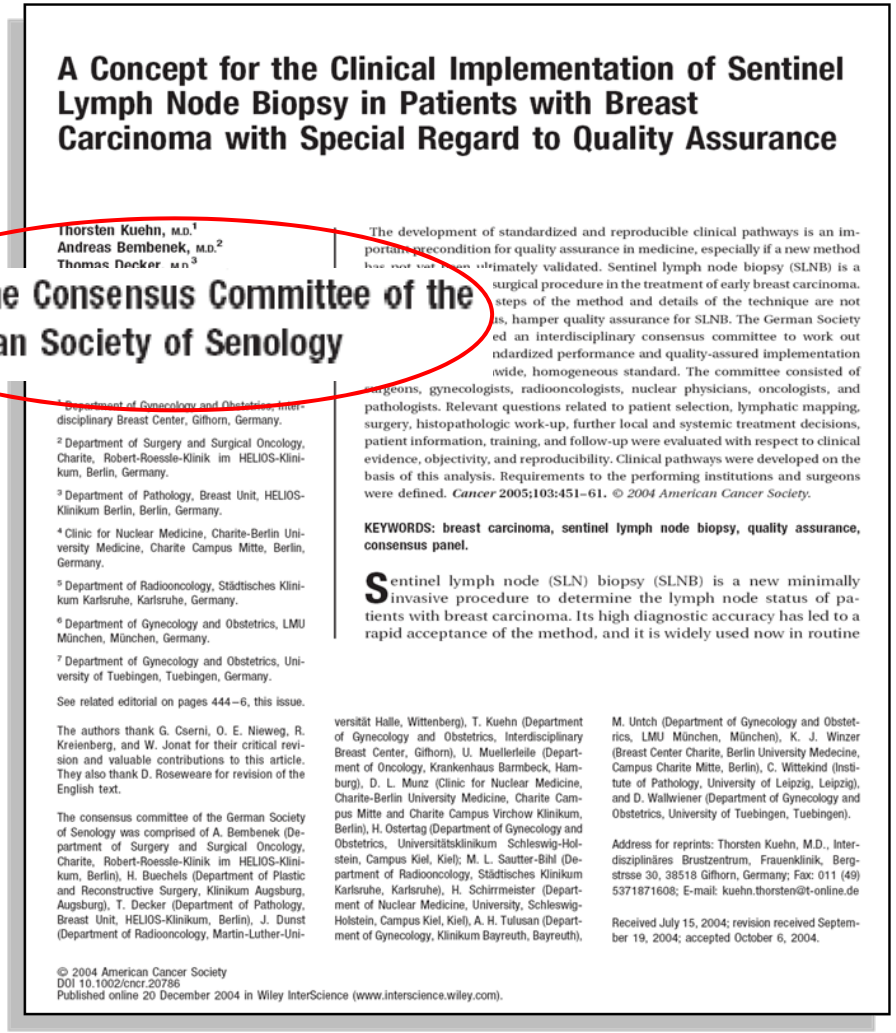
MS-10

# CONSENSUS CONFERENCE TRATTAMENTO CHIRURGIA (SENTINELLA)

## ESPERIENZA TEDESCA



A Concept for the Clinical Implementation of Sentinel Lymph Node Biopsy in Patients with Breast Carcinoma with Special Regard to Quality Assurance

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Andreas Bembenek, M.D.[2]
Thomas Decker, M.D.[3]

For the Consensus Committee of the German Society of Senology

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See related editorial on pages 444–6, this issue.

The authors thank G. Cserni, O. E. Nieweg, R. Kreienberg, and W. Jonat for their critical revision and valuable contributions to this article. They also thank D. Roseweare for revision of the English text.

The consensus committee of the German Society of Senology was comprised of A. Bembenek (Department of Surgery and Surgical Oncology, Charite, Robert-Roessle-Klinik im HELIOS-Klinikum, Berlin), H. Buechels (Department of Plastic and Reconstructive Surgery, Klinikum Augsburg, Augsburg), T. Decker (Department of Pathology, Breast Unit, HELIOS-Klinikum, Berlin), J. Dunst (Department of Radiooncology, Martin-Luther-Universität Halle, Wittenberg), T. Kuehn (Department of Gynecology and Obstetrics, Interdisciplinary Breast Center, Gifhorn), U. Muellerleile (Department of Oncology, Krankenhaus Barmbeck, Hamburg), D. L. Munz (Clinic for Nuclear Medicine, Charite-Berlin University Medicine, Charite Campus Mitte and Charite Campus Virchow Klinikum, Berlin), H. Ostertag (Department of Gynecology and Obstetrics, Universitätsklinikum Schleswig-Holstein, Campus Kiel, Kiel); M. L. Sautter-Bihl (Department of Radiooncology, Städtisches Klinikum Karlsruhe, Karlsruhe), H. Schirrmeister (Department of Nuclear Medicine, University, Schleswig-Holstein, Campus Kiel, Kiel), A. H. Tulusan (Department of Gynecology, Klinikum Bayreuth, Bayreuth), M. Untch (Department of Gynecology and Obstetrics, LMU München, München), K. J. Winzer (Breast Center Charite, Berlin University Medecine, Campus Charite Mitte, Berlin), C. Wittekind (Institute of Pathology, University of Leipzig, Leipzig), and D. Wallwiener (Department of Gynecology and Obstetrics, University of Tuebingen, Tuebingen).

Address for reprints: Thorsten Kuehn, M.D., Interdisziplinäres Brustzentrum, Frauenklinik, Bergstrsse 30, 38518 Gifhorn, Germany; Fax: 011 (49) 5371871608; E-mail: kuehn.thorsten@t-online.de

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DOI 10.1002/cncr.20786
Published online 20 December 2004 in Wiley InterScience (www.interscience.wiley.com).

The development of standardized and reproducible clinical pathways is an important precondition for quality assurance in medicine, especially if a new method has not yet been ultimately validated. Sentinel lymph node biopsy (SLNB) is a surgical procedure in the treatment of early breast carcinoma. steps of the method and details of the technique are not s, hamper quality assurance for SLNB. The German Society ed an interdisciplinary consensus committee to work out ndardized performance and quality-assured implementation wide, homogeneous standard. The committee consisted of rgeons, gynecologists, radiooncologists, nuclear physicians, oncologists, and pathologists. Relevant questions related to patient selection, lymphatic mapping, surgery, histopathologic work-up, further local and systemic treatment decisions, patient information, training, and follow-up were evaluated with respect to clinical evidence, objectivity, and reproducibility. Clinical pathways were developed on the basis of this analysis. Requirements to the performing institutions and surgeons were defined. *Cancer* 2005;103:451–61. © *2004 American Cancer Society.*

**KEYWORDS: breast carcinoma, sentinel lymph node biopsy, quality assurance, consensus panel.**

Sentinel lymph node (SLN) biopsy (SLNB) is a new minimally invasive procedure to determine the lymph node status of patients with breast carcinoma. Its high diagnostic accuracy has led to a rapid acceptance of the method, and it is widely used now in routine

# DBCG ACHIEVEMENTS

- A multidisciplinary approach to diagnosis and treatment of breast cancer

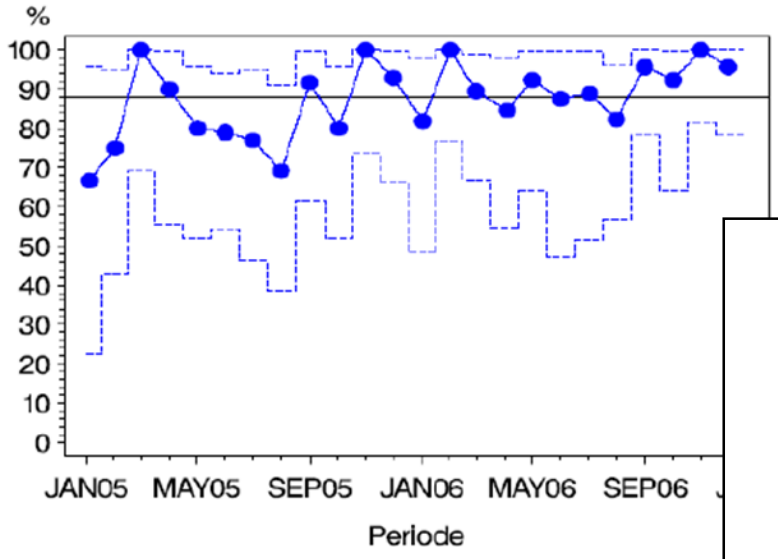
- National evidence based treatment guidelines
  - Rapid implementation of new treatment strategies

- Overview of the status and treatment of early breast cancer
  - Quality assurance of diagnostic and treatment procedures
  - Identification of indicators fit for monitoring quality outcome measures

**2005**: description of 11 quality indicators

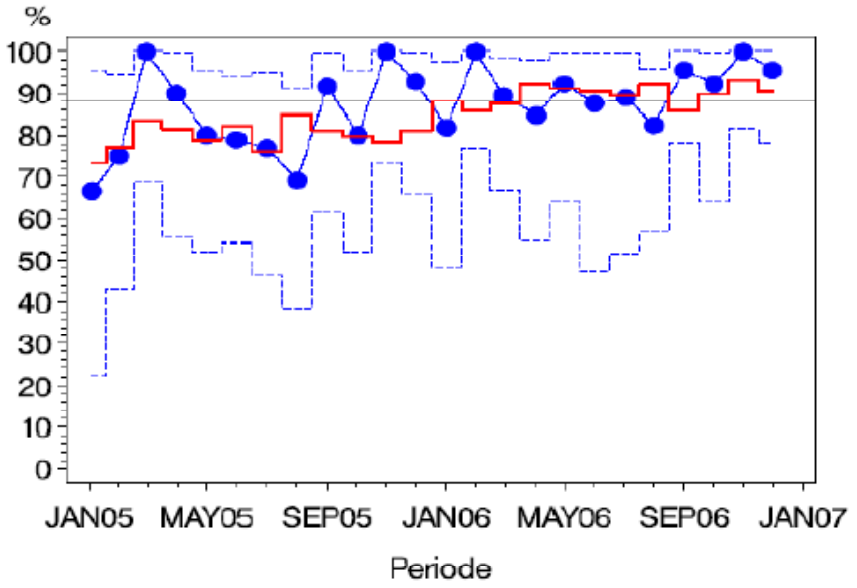
**2008**: data accessible on the web
(Analyseportalen

## Rate of node negative patients, suitable for SN methods, whose nodal status is determind by SN for a single unit vs. total mean for the same units according to time.




2. may 2008, SM

## Rate of node negative patients, suitable for SN methods, whose nodal status is determind by SN for a single unit vs. nationwide means according to time.



# RACCOMANDAZIONI

## TEMPI TRA DECISIONE DI INTERVENIRE E INTERVENTO CHIRURGICO

**Rationale**

Non vi sono dati certi sulla correlazione tra sopravvivenza e tempi del trattamento chirurgico, in quanto non sempre è facile definire il momento in cui la malattia insorge, né distinguere l'origine di un eventuale ritardo che può dipendere dalla paziente (che tarda a recarsi dal medico), o che può effettuarsi al momento della richiesta della visita specialistica chirurgica oppure al momento di fissare la data dell'intervento. Da punto di vista strettamente clinico il trattamento chirurgico per il carcinoma mammario non è da considerarsi una urgenza e un intervallo fino a 3 mesi tra diagnosi e trattamento non influenza la prognosi.

Dal punto di vista della qualità dell'assistenza è però riconosciuto che un'attes
decisione di intervenire chirurgicamente e intervento chirurgico può essere u
di stress per le pazienti. La necessità di limitare il tempo di attesa per il tratta
è essenzialmente legata all'obiettivo di contenere l'ansia della paziente.

**Obiettivo generale:**

Limitare il più possibile lo stato ansioso delle pazienti affette da tumore del
intervento chirurgico e salvaguardare il più possibile lo stato di salute in gene
brevi i tempi che intercorrono tra indicazione all'intervento chirurgico e dat
*(difficilmente misurabile)*

**Benefici attesi:**

assicurare che le pazienti per le quali è indicato un intervento chirurgico a
terapeutici non siano inserite in una lista di attesa *(misurabile)*

assicurare che le pazienti per le quali è indicato un intervento chirurgico a
terapeutici siano sottoposte a intervento entro i tempi massimi definiti *(misura*

**Raccomandazioni**

**Al momento della prescrizione del trattamento chirurgico (sia d
terapeutico) alla paziente deve essere fornita una data per l'interven
posta in una lista di attesa *(buona pratica)***

***Chirurgia diagnostica***

**L'intervento dovrebbe avere luogo entro due settimane dal r
indicazione *(livello di prova VI – consenso)***

11

***Chirurgia terapeutica***

**L'intervento dovrebbe aver luogo entro quattro settimane dal momento della prescrizione chirurgica (*livello di prova VI - consenso* )**

**Indicatori, strumenti di rilevazione e risultati attesi**

**Dati e informazioni da rilevare: data della indicazione e della prescrizione al trattamento chirurgico; data di prenotazione dell'intervento; data dell'intervento; sistema di prenotazione interventi.**

| Tipologia | Indicatore | Metodo di rilevazione | Risultati attesi |
|---|---|---|---|
| Processo | %di pazienti che ricevono un intervento chirurgico diagnostico entro 2 settimane dalla indicazione | Data base ad hoc | ≥ 80% |
| | % di pazienti che ricevono un intervento chirurgico terapeutico entro 4 settimane dalla indicazione | | ≥ 80% |
| struttura | % di pazienti a cui viene fornita data di intervento al momento della prescrizione chirurgica | Data base ad hoc | + 50% |

# L'evoluzione della specie Oncology

Cancer Treatment Reviews (2008) 34, 701–709

available at www.sciencedirect.com

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ELSEVIER

ANTI-TUMOUR TREATMENT

# Evaluation of international treatment guidelines and prognostic tests for the treatment of early breast cancer

**Summary** The clinical decision to treat early-stage breast cancer with adjuvant chemotherapy is sometimes a difficult one because 70–80% of patients who receive chemotherapy would probably have survived without it. To help clinicians in this decision-making process, different tools or 'decision aids' have been developed for the treatment of early breast cancer over the years. Some of these tools include clinical treatment guidelines and computer-based programs as well as different prognostic and/or predictive tests such as those based on gene expression profiles or the presence minimum invasive disease. All of these tools try to individualize as much as possible the estimation of the risk of breast cancer relapse and death and to facilitate the clinical decision about giving additional treatment, and ultimately the most appropriate treatment to be given.

Thus, it is important for clinicians to be aware of not only the existence of these tools or 'decision aids', but also to know how they have been developed, how frequently there are revised and if they have been validated. In order to address all these concerns, we have carried out a critical review of the most important prognostic tests and clinical guidelines for the treatment of early breast cancer. Information regarding their development process as well as frequency of

and if they have been validated. In order to address all these concerns, we have carried out a critical review of the most important prognostic tests and clinical guidelines for the treatment of early breast cancer. Information regarding their development process as well as frequency of

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0305-7372/$ - see front matter 
doi:10.1016/j.ctrv.2008.04.002

# CONSENSUS CONFERENCE TRATTAMENTO (ONCOLOGIA)

## ESPERIENZA SPAGNOLA

Clin Transl Oncol (2008) 10:552-559
DOI 10.1007/s12094-008-0250-y

SPECIAL ARTICLE

2007

**Diagnosis and me of breast cancer. Cordoba Consensus of 2007**

**Juan De la Haba-Rodríguez · Emilio Alba · Agustí Barnadas · Eloisa Bayo · Antonio Llombart · Ana Lluch · Miguel Martín · José Andrés Moreno-Nogueira · Gumersindo Pérez Manga · Álvaro Rodríguez-Lescure · Enrique Aranda**

Received: 3 July 2008 / Accepted: 20 July 2008

**Abstract** Many important studies have changed the perspective from which breast cancer is approached, and they may change what have to date been the standards applicable to the diagnosis and treatment of breast cancer. In 2007, just over 200 oncologists from all over Spain met in Cordoba in order to review the latest evidence related to breast cancer and reach a consensus on the most important aspects of its diagnosis and treatment in different clinical situations: neoadjuvance, adjuvance and advanced disease. In view of these important changes, opinions on some specific aspects may be varied and all are justified. This document represents a review of the current state of the evidence.

**Keywords** Breast cancer · Diagnosis · Prognostic factors · Treatment

The affiliations are listed at the end of the article

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**Prognostic factors**

Expression profiles as decision-making criteria in the treatment of breast cancer

To date, clinical and pathological factors (size, degree of differentiation, age or whether nodes are affected) have been used to predict the likelihood of relapse and thus establish the possible therapeutic indication of adjuvance. This risk estimation system has also been fundamental in the design of clinical trials in the last few decades, establishing different therapeutic indications. This way of classifying breast cancer, however, involves treating a very important percentage of patients who will not relapse and therefore do not need treatment, or ineffectively treating another important group.

In the last few years, we have witnessed, on the one hand, the development of prognostic platforms based on tumour gene expression studies (Oncotype®, Mammaprint®), retrospective studies of which have shown their discriminatory capacity to select, within the moderate- and low-risk subgroups (according to classic criteria), a group with a very good prognosis not requiring chemotherapy and another with a poor prognosis which would have to be treated [1–3].

On the other hand, this array analysis technology has enabled a new breast cancer classification considering biological parameters [4, 5]. The importance of this new classification lies in the fact that it groups together different types of breast cancer with very different biological behaviour [6, 7].

This new breast cancer classification establishes at least 4 different subgroups: luminal A, luminal B and C, HER2 and basal-like.

The *luminal A phenotype* (50%) has a pattern of expression similar to luminal epithelial cells, with high gene expression for the oestrogen receptor and genes associated to

# RAPPORTO ISTISAN INDICATORI RT

Pubblicazioni

Settore Attività Editoriali

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pubblicazioni@iss.it

**Rapporti ISTISAN: 05/3**

***Audit* clinico su Indicatori di Qualità in Radioterapia**
**patologia.**
A cura del Gruppo di lavoro dell'Unità Operativa 1 del Proge
in radioterapia"
2005, ix, 151 p.

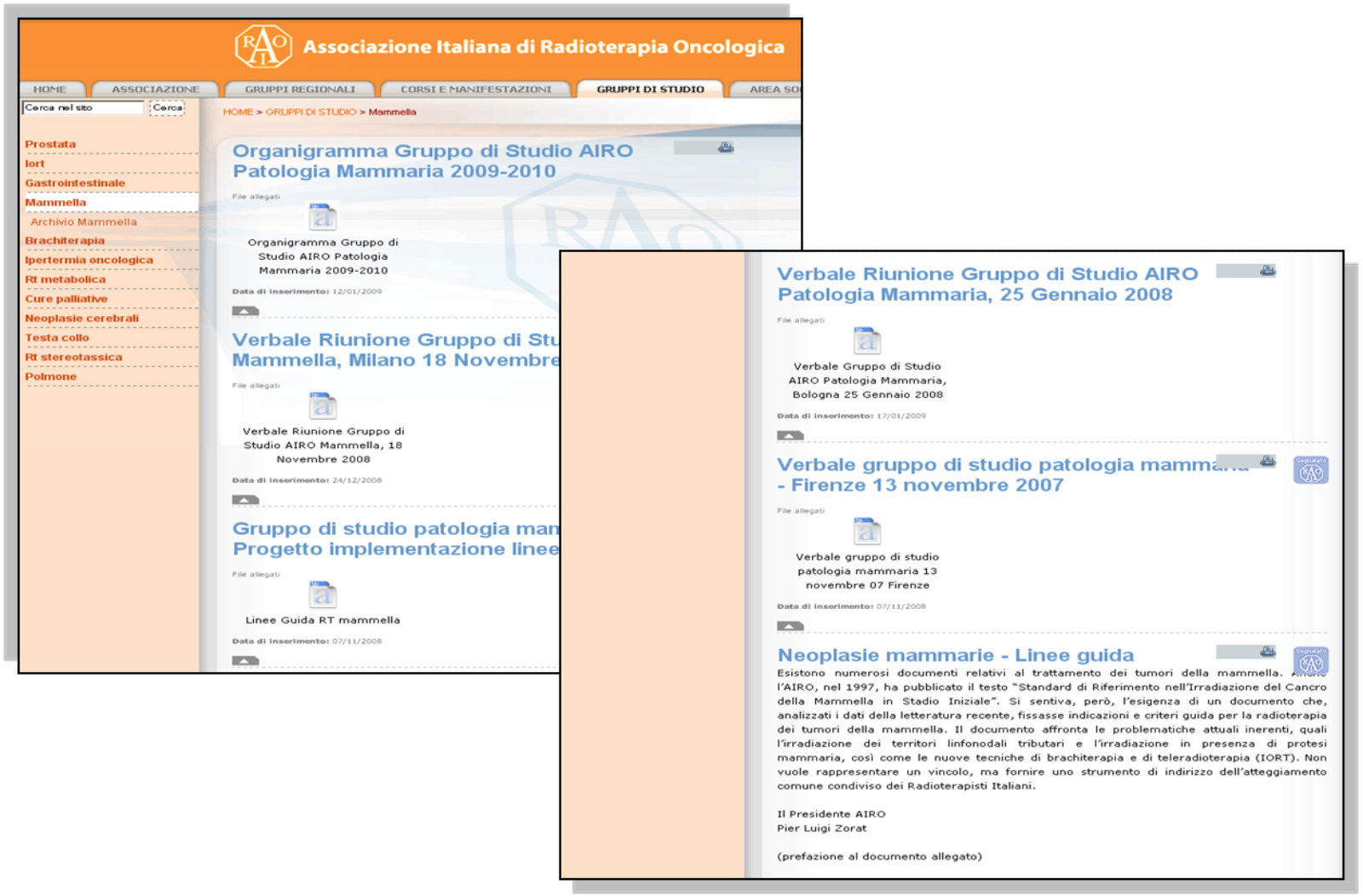
All'interno del progetto di ricerca nazionale dell'Istituto Sup
"Indicatori di qualità in radioterapia" una delle unità operat
qualità in radioterapia selezionati per patologia) si è occupa
indicatori di struttura, processo ed esito per sette patologie
tumori della mammella, metastasi ossee, tumori del polmo
prostata, tumori del retto e tumori del testa collo. Alla defi
hanno partecipato 30 Centri con i relativi Servizi di fisica sa
delle patologie è stato sviluppato un insieme di 6-7 indicato
stati rilevati da un numero di centri variabile da 8 a 16. Sor
degli indicatori e una prima analisi dei risultati ottenuti. Sor
le modifiche degli indicatori suggerite dalla rilevazione.
*Parole chiave*: Radioterapia, Indicatori professionali, Tumo
della mammella, Metastasi ossee, Tumori del polmone, Tu
Tumori del retto e Tumori del testa collo

### 2.2.2. Indicatore MAM 02: Dose agli organi critici

| MAMMELLA | MAM 02 |
|---|---|
| Nome Indicatore | Dose agli Organi Critici - DOC |
| Argomento | Valutazione della dose agli organi critici nella RT dei tumori della mammella dopo chirurgia conservativa. |
| Razionale | La valutazione della dose agli organi critici (*Organs At Risk*, OAR), e la sua conseguente riduzione, consente il contenimento di effetti acuti e tardivi |
| Tipo | Processo |
| Numeratore | Punteggio complessivo (somma dei punteggi attribuiti alle pazienti) |
| Denominatore | Numero totale delle pazienti considerate |
| Soglia/Valore di Conformità | Da definire / Tendente a 5 |
| Definizioni | Modalità di valutazione della dose agli organi critici:<br>a) nessuna valutazione o valutazione basata su formule di letteratura (es. CLD) con misure bidimensionali: 1 punto<br>b) mediante istogrammi DVH calcolati per interpolazione a partire solamente da alcune sezioni: 3 punti<br>c) mediante DVH(*): 5 punti |
| Responsabile rilevazione | Direttore dell'UO o persona la lui designata |
| Responsabile analisi e interpretazione | Direttore dell'UO o persona la lui designata |
| Rilevazione | Su popolazione |
| Durata rilevazione | |
| Note | Per organi critici si intendono polmoni e cuore (grossi vasi inclusi)<br>(*) Il calcolo del (DVH) in questo caso deve basarsi sul contornamento dell'intero organo.Per la mammella destra non è necessario contornare il cuore |
| Bibliografia | 1) Gabor G, *et al.* Myocardial damage in breast cancer patients treated with adjuvant radiotherapy: a prospective study. *Int J Radiat Oncol Biol Phys* 1996;36:899-905.<br>2) Fuller, *et al.* Cardiac doses in postoperative breast irradiation. Radiother Oncol 25:19-24.3) Cazzaniga LF, *et al.* Radiological findings when very small lung volumes are irradiated in breast and chest wall treatment. *Radiat Oncol Invest* 1998;6:58-62.4) Gagliardi G, *et al.* Long-term cardiac mortality after radiotherapy of breast cancer-application of the relative seriality model. *Brit J Radiol* 1996;69:839-46.5) Gabor G, *et al.* Evaluation of irradiated heart volumes in stage I breast cancer patients treated with postoperative adjuvant radiotherapy. *J Clin Oncol* 1997;15:1348-53.<br>6) Gagliardi G, *et al.* Prediction of excess risk of long-term cardiac mortality after radiotherapy of stage I breast cancer. *Radiother Oncol* 1998;46:63-71.<br>7) Eriksson f, *et al.* Radiation pneumonitis after breast cancer irradiation: analysis of the complication probability using the relative seriality model. *Radiother Oncol* 2000;55:153-62.8) Rancati T, *et al.* Factors predicting radiation pneumonitis in lung cancer patients: a retrospective study. *Radiother Oncol* 2003;67:275-83.<br>9) Bornstein BA, *et al.* Can simulation measurements be used to predict the irradiated lung volume in the tangential fields in patients treated for breast cancer? *Int J Radiat Oncol Biol Phys* 1990;18:181.<br>10) Linee guida AIRO sulla mammella 2005 |
| Risposta Centri | Hanno risposto 16 Centri sui 16 che si erano impegnati a raccogliere dati su questa patologia |

Associazione Italiana di Radioterapia Oncologica

# LINEE GUIDA



# NUOVI INDICATORI ?? DIAGNOSI E TERAPIA

- IMPIEGO RM MAMMARIA

- IMPIEGO PARTIAL BREAST IRRADIATION

# NUOVI INDICATORI ?? CHIRURGIA ONCOPLASTICA E RICOSTRUTTIVA

Workshop sugli indicatori biosistemici per la ricostruzione mammaria

Milano, 18 Aprile 2005

Direttori del Corso
Dr.ssa Gemma Marino – Dr. Maurizio Nava

Sede del Corso : Sala Convegni Melis – Corso Buenos Aires, 64 Milano

Obiettivo del Corso:

Attraverso un lavoro teorico-pratico si vogliono aumentare le abilità dei chirurghi ricostruttori sulla semeiotica biomeccanica e sistemica in grado di portare ad una scelta ottimale degli interventi protesici e ricostruttivi nelle donne che hanno avuto diagnosi di tumore al seno.
Il Corso è da ritenersi propedeutico ad una formazione più approfondita sulla semeiotica e l'approccio biosistemico.
Il corso è riservato esclusivamente ai soci della Scuola di Oncologia Chirurgica e Ricostruttiva ed ad un numero ristretto di 30 partecipanti.

Relatori:

| | |
|---|---|
| Dr. Hubert Godard | Parigi |
| Dr.ssa Gemma Marino | Milano |
| Dr Maurizio Nava | Milano |
| Livia Sedodi | Milano |
| Raffaella Sensi | Milano |

Segreteria Organizzativa:

Scuola di Oncologia Chirurgica e Ricostruttiva via Venezian,1 Milano

Telefono 0223902797

Fax 0223902602

Email: info@scuolaonco.com

E' in corso la pratica ECM per il conseguimento dei crediti formativi

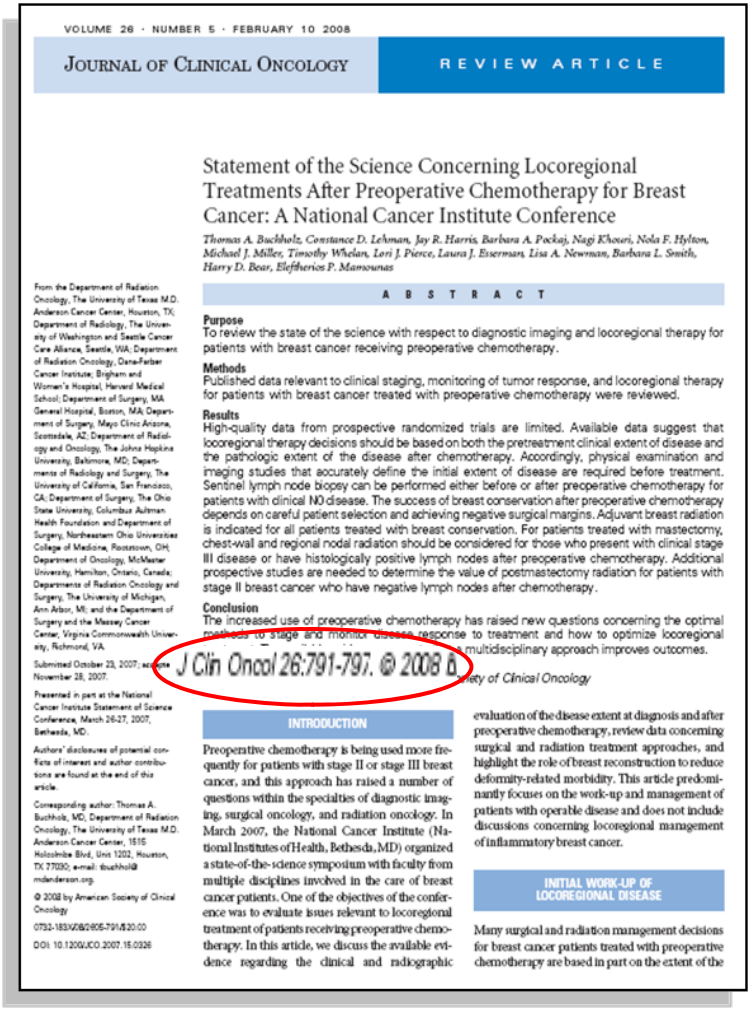
INTEGRAZIONE INDICATORI SULLA RICOSTRUZIONE POST-MASTECTOMIA

- ***IMPIEGO SKIN SPARING***
- ***MPIEGO NIPPLE SPARING***
- ***ESITI IN BASE A TIPOLOGIA DI RICOSTRUZIONE***

INDICATORI SU ONCOPLASTICA (COLLEGATI AD ESITI ESTETICI )

# NUOVI INDICATORI ??

## INDICAZIONI ALLA TERAPIA NEOADIUVANTE (VALUTAZIONE POST-NAD)



VOLUME 26 · NUMBER 5 · FEBRUARY 10 2008

JOURNAL OF CLINICAL ONCOLOGY

REVIEW ARTICLE

# Statement of the Science Concerning Locoregional Treatments After Preoperative Chemotherapy for Breast Cancer: A National Cancer Institute Conference

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Authors' disclosures of potential conflicts of interest and author contributions are found at the end of this article.

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A B S T R A C T

**Purpose**
To review the state of the science with respect to diagnostic imaging and locoregional therapy for patients with breast cancer receiving preoperative chemotherapy.

**Methods**
Published data relevant to clinical staging, monitoring of tumor response, and locoregional therapy for patients with breast cancer treated with preoperative chemotherapy were reviewed.

**Results**
High-quality data from prospective randomized trials are limited. Available data suggest that locoregional therapy decisions should be based on both the pretreatment clinical extent of disease and the pathologic extent of the disease after chemotherapy. Accordingly, physical examination and imaging studies that accurately define the initial extent of disease are required before treatment. Sentinel lymph node biopsy can be performed either before or after preoperative chemotherapy for patients with clinical N0 disease. The success of breast conservation after preoperative chemotherapy depends on careful patient selection and achieving negative surgical margins. Adjuvant breast radiation is indicated for all patients treated with breast conservation. For patients treated with mastectomy, chest-wall and regional nodal radiation should be considered for those who present with clinical stage III disease or have histologically positive lymph nodes after preoperative chemotherapy. Additional prospective studies are needed to determine the value of postmastectomy radiation for patients with stage II breast cancer who have negative lymph nodes after chemotherapy.

**Conclusion**
The increased use of preoperative chemotherapy has raised new questions concerning the optimal methods to stage and monitor disease response to treatment and how to optimize locoregional [illegible] multidisciplinary approach improves outcomes.

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[illegible]ety of Clinical Oncology

## INTRODUCTION

Preoperative chemotherapy is being used more frequently for patients with stage II or stage III breast cancer, and this approach has raised a number of questions within the specialties of diagnostic imaging, surgical oncology, and radiation oncology. In March 2007, the National Cancer Institute (National Institutes of Health, Bethesda, MD) organized a state-of-the-science symposium with faculty from multiple disciplines involved in the care of breast cancer patients. One of the objectives of the conference was to evaluate issues relevant to locoregional treatment of patients receiving preoperative chemotherapy. In this article, we discuss the available evidence regarding the clinical and radiographic evaluation of the disease extent at diagnosis and after preoperative chemotherapy, review data concerning surgical and radiation treatment approaches, and highlight the role of breast reconstruction to reduce deformity-related morbidity. This article predominantly focuses on the work-up and management of patients with operable disease and does not include discussions concerning locoregional management of inflammatory breast cancer.

## INITIAL WORK-UP OF LOCOREGIONAL DISEASE

Many surgical and radiation management decisions for breast cancer patients treated with preoperative chemotherapy are based in part on the extent of the

# LINEE GUIDA E INDICATORI PER UNITA' DI SENOLOGIA E OPERATORI

"Non c'è qualità se non è qualità per tutti i soggetti coinvolti nel processo"

Crozier, 1988

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Position Paper

## Guidelines on the standards for the training of specialised health professionals dealing with breast cancer

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**Cos'è**

La Forza Operativa Nazionale sul Carcinoma Mammario (FONCaM) è stata costituita da Umberto Veronesi nel 1977 con gli obbiettivi principali di:
- stabilire linee-guida condivise volte a favorire un'uniforme diffusione degli interventi diagnostico-terapeutici per i tumori della mammella in tutto il territorio del Paese.
- favorire la creazione di una rete nazionale di centri per la diagnosi e/o la cura dei tumori della mammella e migliorare i collegamenti tra quelli già esistenti.
- favorire l'aggiornamento professionale e svolgere opera di educazione sanitaria della popolazione femminile per consentire una più intensa partecipazione alle attività di diagnosi precoce.

La FONCaM è stata fino al 1996 supportata dal CNR nell'ambito di tre consecutivi Progetti Finalizzati dedicati all'oncologia (*Controllo della crescita neoplastica, Oncologia, Applicazioni Cliniche della Ricerca Oncologica*). Successivamente la FONCaM, diventata con oltre 2.500 aderenti un importante punto di riferimento per molti medici italiani, si è strutturata in modo autonomo pur mantenendo le peculiarità che l'hanno da sempre caratterizzata:

- adesione libera (scheda di adesione).
- ricerca del consenso attraverso il confronto di esperienze e competenze professionali interdisciplinari
- utilizzo prevalente della metodologia dei gruppi di lavoro

**La struttura**

La FONCaM non ha uno statuto ne prevede cariche elettive anche se al suo interno sono individuate alcune figure di riferimento (Coordinatore Nazionale, Segretario Scientifico, ecc) per la gestione scientifica ed organizzativa (organigramma).
Come già ricordato l'adesione è libera e non vincolata alla sottoscrizione di alcuna quota associativa. Dal 1996 la segreteria è accorpata con quella della Scuola Italiana di Senologia

**Come opera**

Cardini dell'attività sono i Gruppi di Lavoro: alcuni sempre attivi si occupano delle tematiche di più ampio respiro (es: diagnosi, trattamento, ecc) altri sono invece costituiti in funzione della necessità di dare risposte a problematiche emergenti o più particolari (es: familiarità). Definiti gli obbiettivi i Gruppi, formati da specialisti di diverse discipline, nominano al proprio interno uno o più coordinatori ed operano indipendentemente attraverso incontri periodici. Il lavoro dei Gruppi viene quindi presentato e discusso in occasione delle riunioni

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# Sintesi delle Attività

Produzione e diffusione documenti di Linee Guida:

- prima edizione 1979
- aggiornamento biennale
-ultima edizione"globale" novembre

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# Linee Guida(???) - Peculiarità

- Verosimilmente a livello nazionale hanno rappresentato il primo punto di partenza e di stimolo aggregativo multispecialistico finalizzato alla formulazione di linee comportamentali condivise per l'approccio diagnostico terapeutico dei tumori del seno

# Peculiarita'/Limiti

- particolare rilievo di alcuni temi innovativi in linea con impronta chirurgica e indirizzo conservativo dell'approccio al tumore al seno (v. messa a punto biopsia del lfn sentinella )

- punto di incontro tra standard di buona pratica clinica e proposte di approcci clinici "sperimentali "

•INTRODUZIONE INDICATORI DI QUALITA' A PARTIRE DALL'EDIZ .2003

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**Indicatori sulla diagnosi e indicatori di processo dell'Unità di senologia (tabella 3)**

| Indicatori | Obiettivo |
|---|---|
| **Numero di sessioni diagnostiche**<br>Per le donne operate è il numero di sessioni necessarie a completare gli accertamenti diagnostici, che deve essere inferiore o uguale a 3. | ≥95% |
| **Diagnosi preoperatoria**<br>Indica la proporzione di lesioni mammarie sottoposte prima dell'intervento chirurgico ad agoaspirato o a biopsia percutanea con diagnosi preoperatoria citologica o istologica positiva per cancro (C5 o B5), sul totale delle lesioni mammarie operate (palpabili o impalpabili) con diagnosi istologica definitiva di carcinoma invasivo o *in situ*. Il totale, al denominatore, comprende i casi per i quali non sono stati effettuati né agoaspirato né biopsia percutanea. | ≥90%<br>(desiderabile)<br><br>≥70%<br>(accettabile) |
| **Referti citologici mammari con risultato inadeguato (C1)**<br>Indica la proporzione di esami citologici con reperto inadeguato per giudizio diagnostico (C1), sul totale dei referti citologici (C1-C5) di agoaspirati su guida strumentale. | ≤15%<br>(≤10% nei cancri) |
| **Sensibilità della diagnosi preoperatoria positiva per cancro (C5)**<br>Indica la proporzione di esami citologici con referto "positivo per cellule neoplastiche (C5)", sul totale delle lesioni mammarie operate con diagnosi istologica definitiva di carcinoma invasivo o *in situ* per le quali è stato effettuato un agoaspirato preoperatorio. Questo indicatore viene denominato "absolute sensitivity" nelle linee guida in lingua inglese. Il denominatore include gli esiti citologici inadeguati (C1). Ciò allo scopo di valutare la qualità della diagnosi preoperatoria nel suo complesso e non soltanto della lettura citologica. Inoltre si assume che le lesioni refertate C5 e non operate siano effettivamente cancri. | ≥80% |
| **Grado disponibile**<br>Indica la proporzione di pazienti operate per carcinoma mammario invasivo (esclusi i microinvasivi) in cui sia stata fornito il grado istopatologico. | ≥95% |
| **Recettori ormonali disponibili**<br>Indica la proporzione di pazienti operate per carcinoma mammario invasivo (esclusi i microinvasivi) in cui sia stata fornita la misurazione dei recettori ormonali. | ≥95% |

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Estratto degli Indicatori di qualità dell'Unità di senologia, linee guida FONCaM 2003.[4]

**Indicatori di struttura dell'Unità di senologia**

| | |
|---|---|
| Volume annuo di nuovi casi trattati ≥150 | |
| Uso di protocolli interni | |
| Incontri multidisciplinari per la discussione dei casi clinici: | < nella fase preoperatoria<br>< nella fase postoperatoria<br>< in occasione di recidive e complicanze |
| Completezza del gruppo di specialisti | |
| Possibilità di eseguire la ricostruzione della mammella entro l'Unità | |
| Tempi e spazi dedicati: | < ambulatori<br>< sala operatoria |
| Adozione della tecnica del linfonodo sentinella | |
| Adozione della ricostruzione | |
| Adeguato livello di formazione degli operatori | |
| Unità impegnata in attività di formazione | |
| Partecipazione a trial clinici | |
| Follow up coordinato | |
| Raccolta dei dati e monitoraggio degli indicatori di qualità | |

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L’istituzione di unità di senologia specialistiche multidisciplinari con sessioni operatorie dedicate, la discussione pre- e postoperatoria di tutti i casi trattati e il volume di attività raccomandato dalle linee guida è necessario per poter diminuire i tempi di attesa fornendo cure di qualità adeguata

DA M. TOMATIS RAPPORTO ONS SU DATI GISMA 2006

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“.....Un’altra limitazione di questo studio è il fatto che, per quanto i casi studiati rappresentino una fetta consistente (il 50% circa) delle lesioni operate a seguito di screening, non si può escludere che il reclutamento sia selettivo in quanto le Regioni e i programmi dotati di maggiori risorse e migliori qualità potrebbero essere quelle maggiormente in grado di contribuire.....

**Questo aspetto richiama la necessità di concepire una modalità di monitoraggio più semplice e pertanto più esaustiva di tutte le realtà presenti a livello nazionale**.

SQTM potrebbe essere utilizzato **per tutti i nuovi casi e in tempo reale, durante la gestione clinica della paziente e il follow up e in occasione delle riunioni multidisciplinari di discussione dei casi.....**

DA M. TOMATIS RAPPORTO ONS SU DATI GISMA 2006

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all in the same boat

# CONCLUSIONI 1 !!!

**«Quasi sempre conosciamo con precisione il tipo di assistenza che dovremmo erogare. Ne abbiamo le prove e ne possediamo le misure. Ciò malgrado, siamo lontani dall'ottenere la performance.**

**Sopratutto ora siamo in grado di osservare le variazioni di qualità tra un presidio ed un altro, tra una regione ed un'altra.**

**Penso che stia avvenendo un sostanziale cambiamento. E che il cambiamento dipenderà da ciò che abbiamo imparato e da ciò che abbiamo fatto in termini di misura della qualità».**

**Carolyn M. Clancy, M.D., Director of the Agency for Healthcare Research and Quality (AHRQ)**

# CONCLUSIONI 2 !!!!

" La qualità dell'assistenza è come lo Spirito Santo : è invisibile ai più e rappresenta la ragione di vita di alcuni ( pochi ) che ne divengono esclusivi ed incompresi cultori ! "

*Sanità-Management Gennaio 2002*

**Grazie**

**ugualmente per l'attenzione**