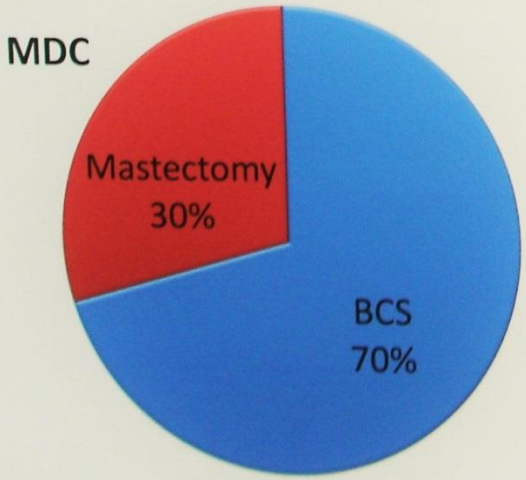
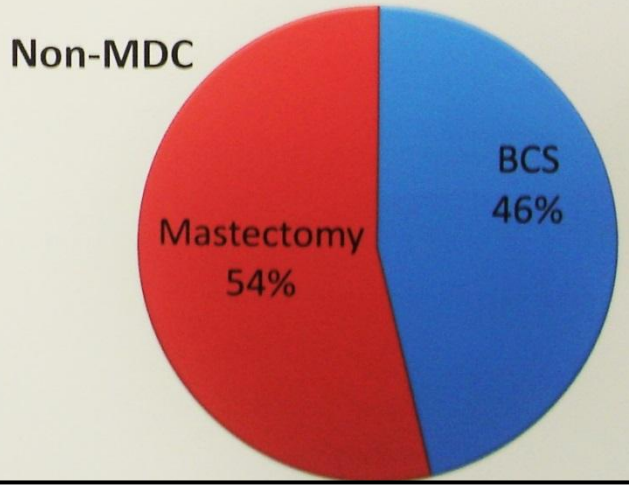
Breast Conservation Surgery

Table 2. Breast Conservation Rates

	Multidisciplinary Clinic (n = 213 breasts)		Non-Multidisciplinary Clinic (n = 145 breasts)		
	N	**%**	**N**	**%**	**P**
All Patients	140	66%	61	42%	**< 0.0001**
Neoadjuvant Chemotherapy Pathway	11	37%	2	12%	0.08
Surgery Pathway	129	70%	59	46%	**< 0.0001**





Multidisciplinary Clinic | Individual surgeon

Gomez C, Wang P et al. poster at SABCS 2014 UCLA / Santa Monica

Quality Certification . . .

- Has created a higher and more uniform level of breast care
- Has taught us how to work in a truly multidisciplinary fashion
- Has taught us how to measure ourselves and compare ourselves with others
- Has shown that measures must adapt to the continuous transformation of new ideas and treatments

Debate on quality of breast surgery: A forgotten item?

From Theory to Practice

Cary S. Kaufman MD, FACS
Associate Clinical Professor of Surgery
University of Washington

We want to choose quality measures that will help us do the right thing!

Concept: we want to identify the

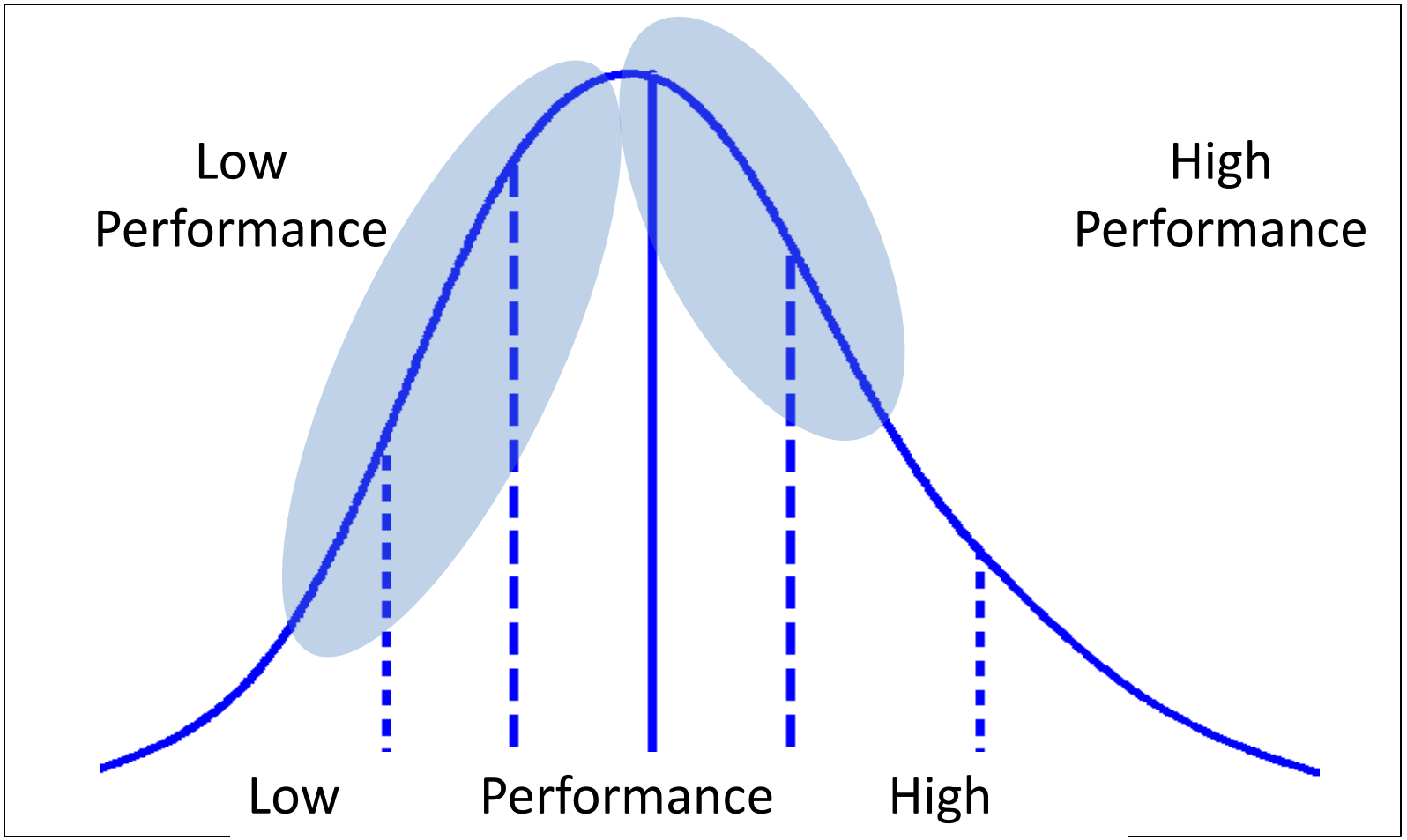
- right person with the
- right diagnosis to provide the
- right treatment to be given at the
- right time by the
- right people with the
- right safety concerns using the
- right compassion to get the
- right outcome

But, there are many hurdles that stand in our way

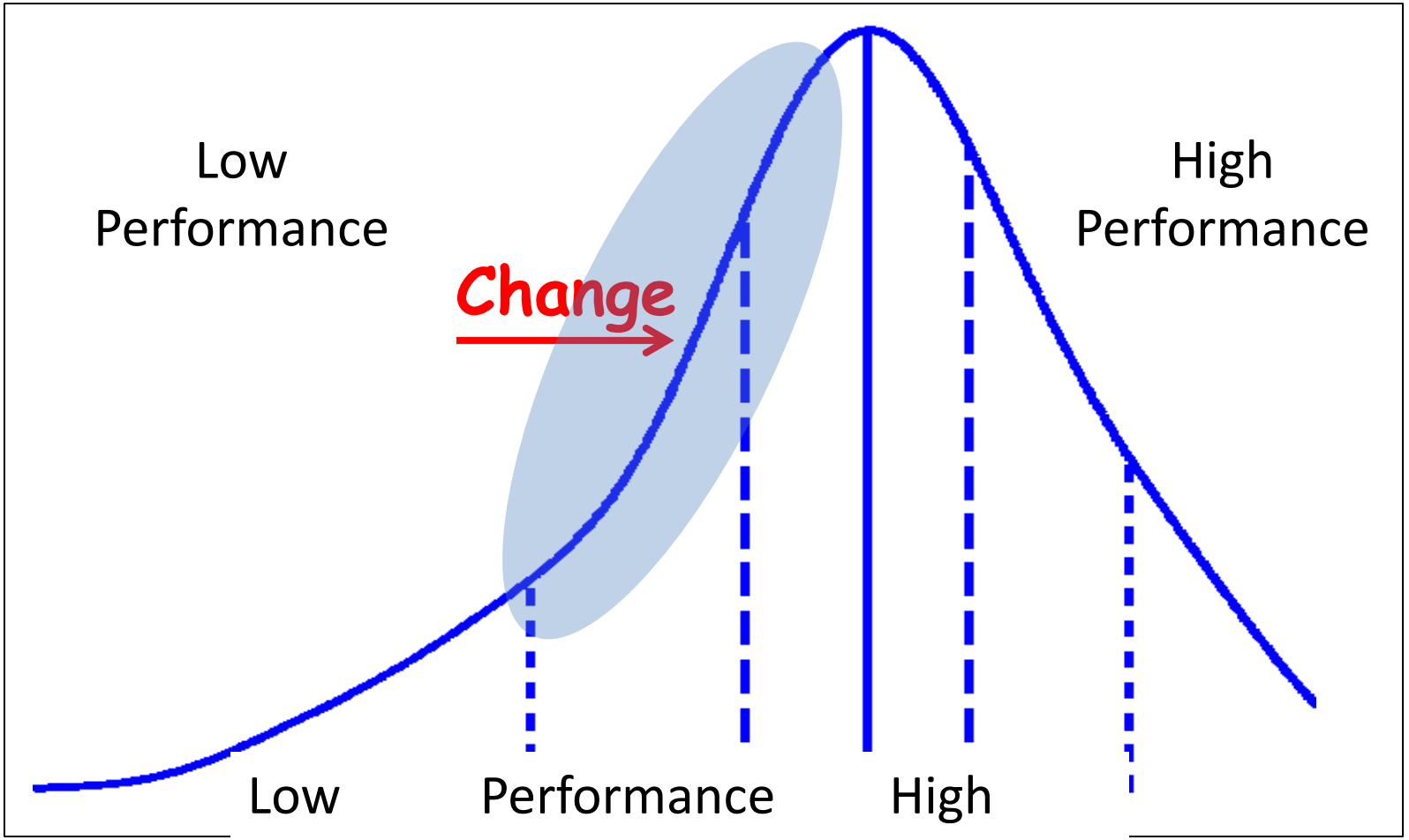
Choosing quality measures

- Must be **important**
  (improvement makes a difference in outcomes)
- Must be **appropriate** to study
  (value as compared with other measures)
- Must have **variation** in care provided
  (lack of uniform performance)
- Must be **feasible** to obtain data
  ($ to abstract, access to data, accurate)
- Must consider **theory vs practice**

Target for Improving Care



Target for Improving Care



Theory to Practice

- Timeliness of care
- Margins
- Re-excision surgery
- Axillary surgery

Timeliness of Initial Care

US

- Time between (NQMBC):
  - Screening mammogram and diagnostic imaging
  - Diagnostic imaging and needle biopsy
  - Needle biopsy and initial surgical procedure
  - Pathology specimen to report
- **Benchmarks not requirements**

German

- Time between:
  - Screening mammogram and biopsy: max 2 weeks
  - Pathology result and surgery: 3-14d
  - Surgery and radiation: max 4 weeks
- **Requirements not benchmarks**

From Theory to Practice

NQMBC – Structure

- Web Based = **universal access**
- **“Snapshot of care”** submissions q 6 months
- **Confidential** (access by breast center only)
- **Comparison reports** immediately available
- **“Like-centers”** defined by demographics
- Routine and random **audits performed**
- **No fee**/ NCBC membership **NOT** required

National Quality Measures for Breast Centers – NQMBC

Time from Needle Biopsy to Initial Surgery

First Tier Variables
"Theory"

- Timely pathology report
- Communication with primary care provider
- Explanation to the patient
- Consultation with Surgeon
- Surgery scheduling

National Quality Measures for Breast Centers – NQMBC

Time from Needle Biopsy to Initial Surgery

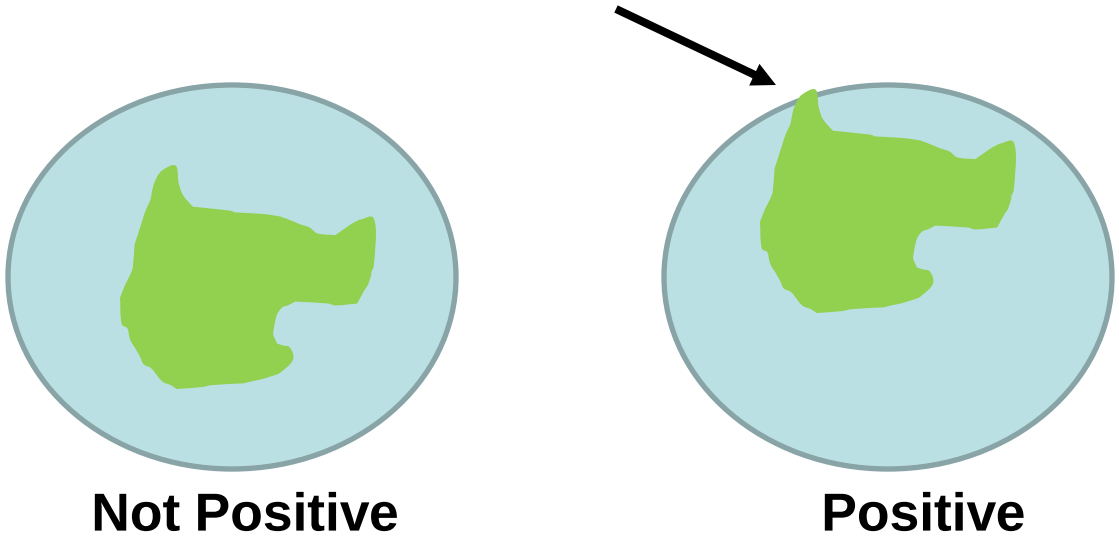
First Tier Variables
"Theory"

- Timely pathology report
- Communication with primary care MD
- Explanation to the patient
- Consultation with Surgeon
- Surgery scheduling

Second Tier Variables
"Practice"

- Need for MRI
- Second surgical consultation
- Genetic testing / high-risk counseling
- Plastics consultation
- Payer issues
- Patient refusal / alternative treatments

What is a positive margin?

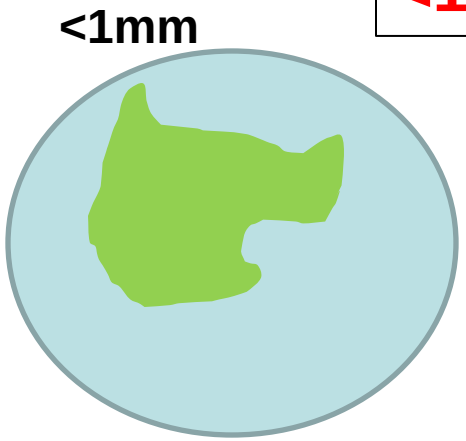


Not Positive

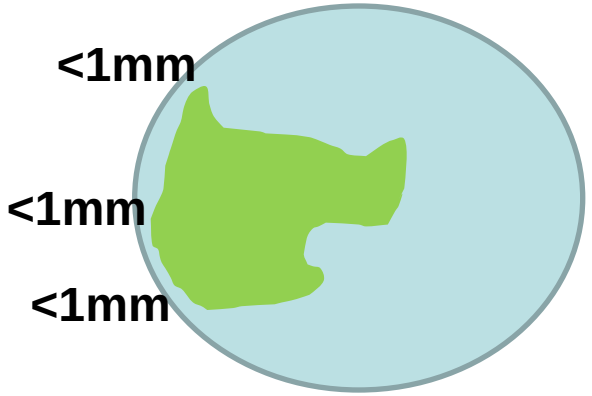
Positive

What is a close margin?

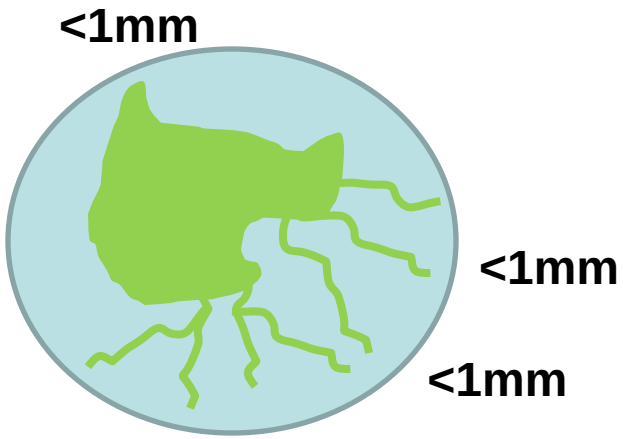
<1 mm Margin



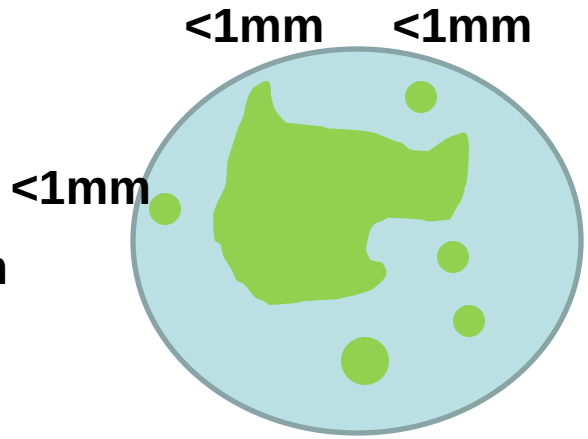
Focal close margin



Broad close margin



Extensive Intraductal Component (EIC)



Multifocality/ Satellites

NCCN Guidelines for Margins Invasive Breast Cancer

- **Cases with a positive margin should undergo further surgery. “Breast-conserving therapy is contraindicated for patients who have positive pathologic margins”**

- No comment on **width of negative margin**

What do Surgeons think?

What is a Close Margin?

	American		Canadian	
• > 1 mm	52%	88%	59%	88%
• > 2 mm	36%		29%	
• > 5mm	12%		11%	

Parvez E, et al. Breast J 2014; 20:481-488

SSO – ASTRO Consensus on Invasive CA
meta-analysis 28,162 pts

- **Cases with a positive margin should undergo further surgery.**
- **Negative margin is defined as “no ink on tumor”**
- **Close margins are considered “no ink on tumor”**

Have we examined the tumor?
“no ink on tumor”

Standard processing 84% of margin NOT examined

- 8 cm specimen totally embedded
- Sliced into 5 mm sections
- 16 blocks
- 4 microns section each block

- 16% of margins examined

Tucker FL, Internat J Breast Ca. 2012;2012:1-16.

SSO – ASTRO Consensus on Invasive CA
meta-analysis 28,162 pts

TABLE 4 Summary of selected results of margins meta-analysis[13]

Relationship between IBTR and margin status

	No. of studies	No. of participants	Adjusted OR	95% CI
Margin category (model one)		28,162		
Close/positive	33	6,178	1.96	1.72–2.24
Negative	33	21,984	1.0	—
Margin category (model two)		13,081		
Positive	19	1,641	2.44	1.97–3.03
Close	19	2,407	1.74	1.42–2.15
Negative	19	9,033	1.0	—

18%

Consensus Recommendation

Positive	??	????	???	
Close/Negative	??	????	???	

SSO – ASTRO Consensus on Invasive CA

meta-analysis 28,162 pts

Their Bottom Lines:

- Positive margins require re-excision
- Negative margins wider than no ink on tumor did not translate to lowered recurrence rate
- Excludes pure DCIS, partial breast irradiation, neoadjuvant chemo, or lumpectomy alone
- Underscored inaccuracies of pathologic evaluation of margins but did not suggest corrections.
- Meta-analysis studies did not all use “no ink on tumor” definition for re-excision.
- Consider re-excision in some “negative” margins (e.g. young patients, large tumors with EIC, close margins over broad area).

“Margins are like money,

the more you have

the better you like it”

– Mel Silverstein 2011

Re-excision Rates

US

- Not measured
- Data suggests 20% on average (NQMBC graph)

German

- Not measured

National Quality Measures for Breast Centers – NQMBC

Re-excision Rate for lumpectomy for CA

First Tier
"Theory"

- Adequacy of Imaging
- Radiologist – Surgeon communication
- Surgical wide excision
- Specimen imaging
- Marking surgical margins
- Unified definition of a clear margin

National Quality Measures for Breast Centers – NQMBC

Re-excision Rate for lumpectomy for CA

First Tier
"Theory"

- Adequacy of Imaging
- Radiologist – Surgeon communication
- Surgical wide excision
- Specimen imaging
- Marking surgical margins
- Unified definition of a clear margin

Second Tier
Variables
"Practice"

- Adequacy of Margin Analysis
- Preop Needle Biopsy
- Extensive DCIS
- Young patient,
- Patient Choice (rather re-excision than mastec)
- Cosmesis

Potential Unintended Consequences

- Larger lumpectomies
- Decreased cosmesis
- More mastectomies to avoid re-excision
- MRI type reaction (overdiagnosis)
- Avoidance of re-excision despite close/positive margin

Perhaps the quality metric should be frequency of positive margins post initial breast cancer surgery

Axillary Dissection

US

- Z-11 study acceptance decreased the number of axillary dissections
- Minimum 8 nodes expected at ALND*
- No minimum number of nodes require repeat surgery

German

- Z-11 accepted
- Lymphadenectomy invasiv BC: at least 95% (SNB depending on stage)
- Lymphadenectomy in DCIS: less than 5%
- Min 10 nodes

*https://clinicaltrials.gov/show/NCT01901094

Clarity Among Guidelines and Benchmarks

- **AXILLARY SURGERY**
- Do all positive sentinel node patients need axillary dissection? Z-11? AMAROS? *
- Does a patient with a clinically negative, ultrasound positive lymph node with +FNA need an axillary dissection?
- How many nodes must be removed during an adequate axillary dissection?

* Donker M, et al. Lancet Oncol 2014 15:1303
Guiliano A et al. JAMA 2011;305:569
Louis-Sylvestre et al. J Clin Oncol 2004; 22:97

Summary: From Theory to Practice

- A large group of clinicians who represent the lower portion of the bell curve are not involved in quality measures
- Improvement in overall quality may be best viewed as improving the low outliers rather than improving the top performers
- Despite well intentioned attempts, it is difficult to identify quality measures that are simply applicable across all groups
- Benchmarks, requirements and guidelines must take into account the real world and issues that are out of the control of the physician.

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