Reporting Standardization in Pathology

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Topics To Cover

- Why standardize reporting?
- Cancer Care Ontario
- LDS Hospital cancer report changes
- HER2 reporting challenges

Why Standardize Reporting?

- Reports are the tangible product of our pathology work
- To be useful, reports must provide
  - Clear, consistent information
  - All elements necessary for decision making
  - Information about validity of process
  - Format allowing for easy retrieval and searching

Pathology Product is Information

- Quality of information defines our competence to others
  - More than our training
  - More than our experience
  - More than our colleague interactions
- Reports document our services
  - For protection against malpractice risk
  - For billing purposes
  - To document “pay for performance” that CMS will implement

Elements of Good Reports

- Includes critical values and how information was communicated.
- Easy for the reader to find information
- Minimum standards for required information met for each report
- Disclaimers when required
- Documentation for billing
- Documentation of consultations
- Appropriate formatting of amendments/addenda for clarity

Cancer Care Ontario

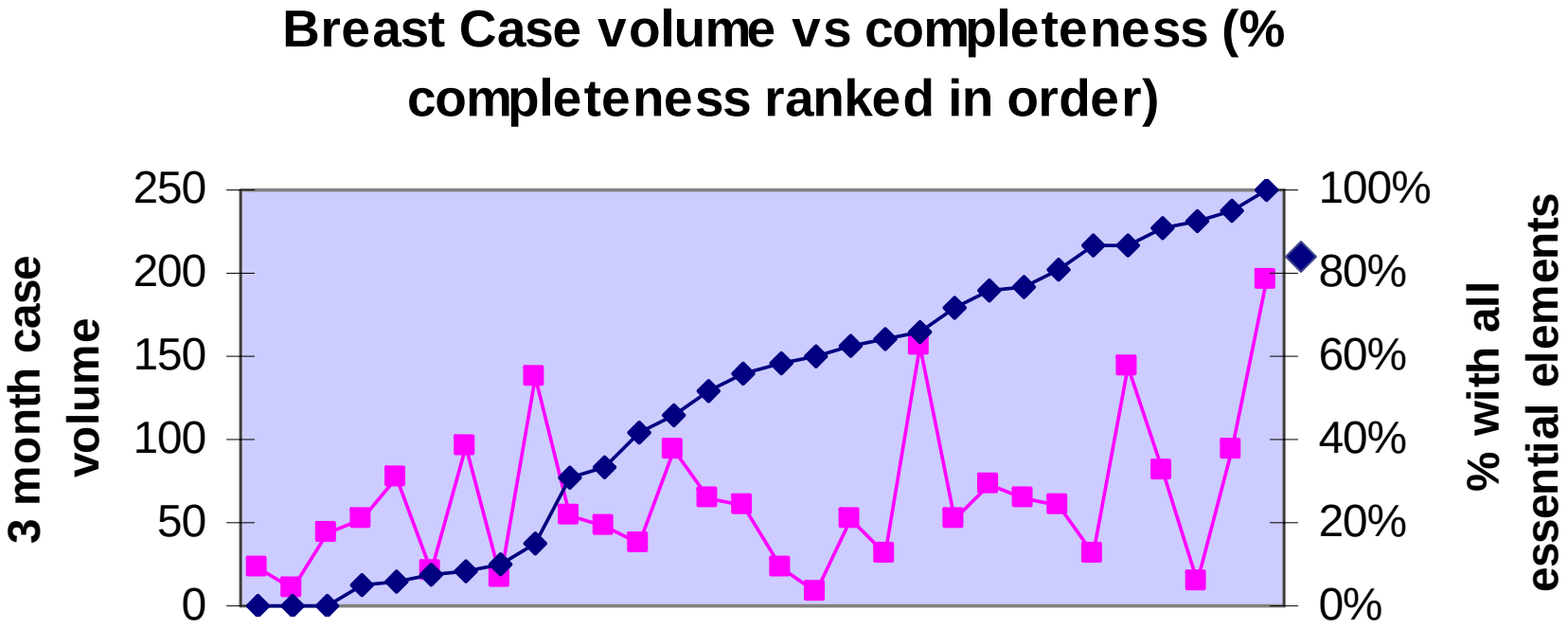
- Full continuum of cancer care
  - Prevention, screening, diagnosis, treatment, supportive care, palliation
- Population $11 million +
- 158 hospitals, 43 community care access centres, 37 public health units and 18 district health councils
- 50,000+ incident cancer cases per year
- Focus on making better use of ~ $2 Billion currently being spent on cancer care

Pilot Study: Breast Cancer

- 692 of total 1,921(36%) breast cancer pathology reports;
- All labs submitting electronically
- Convenience sample; all reports for smaller volume centres and at least 25 for larger volume labs
- May 1 - July 31, 2004
- Detailed analysis of selected CAP checklist elements

30 Institutions – All Elements

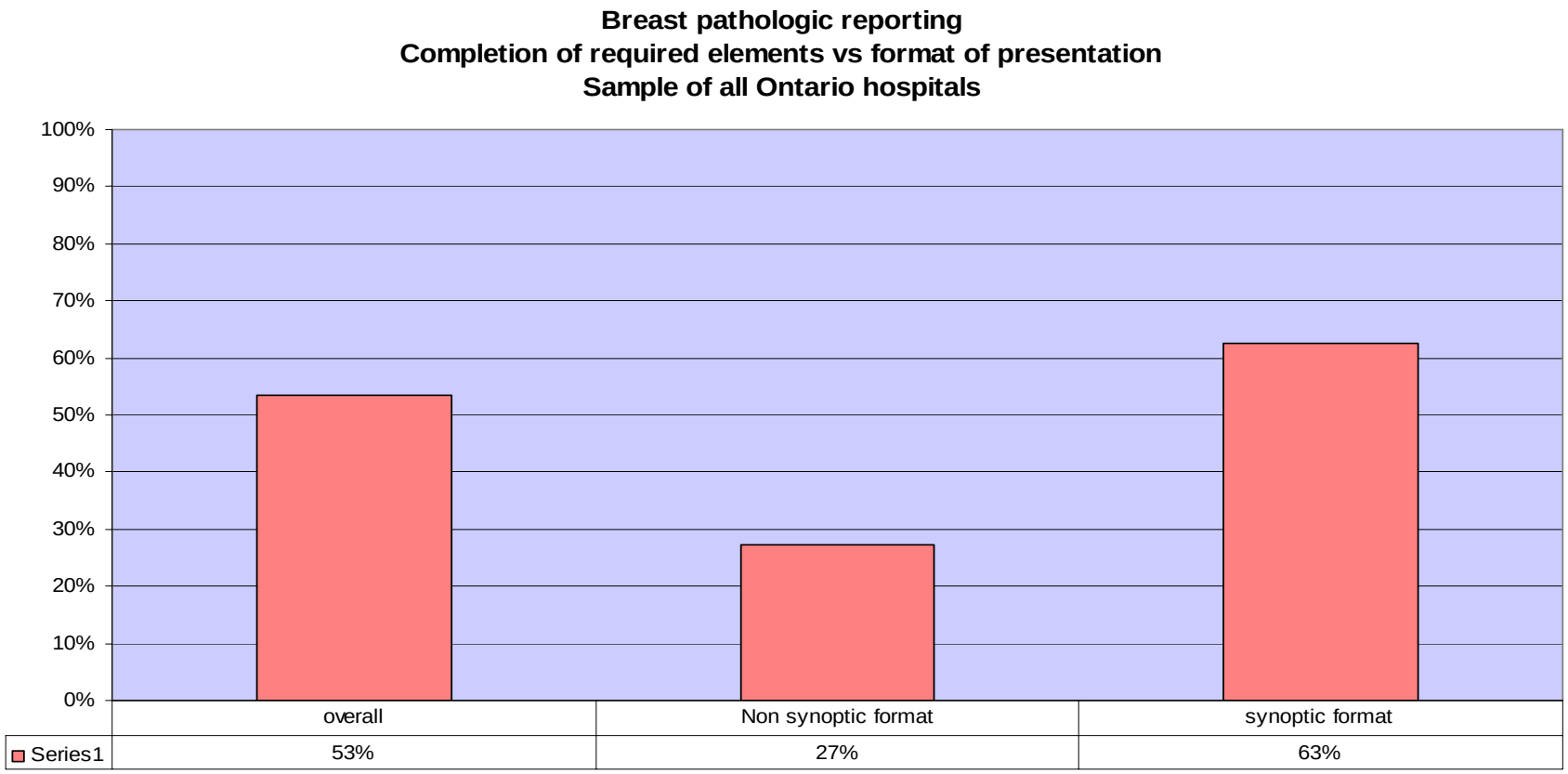
Breast Cancer Pathology Reports, May-July 2004*, Ontario. N=692



Source: Cancer Care Ontario/Ontario Cancer Registry Special Study 2004. * Convenience sample.

Not for distribution.

Breast Pathologic Reporting



Summary

- Completeness is reasonable across the province
- Synoptic format improved completeness levels
- There are significant regional variations
- The interpretation of what cases to apply the full checklist to for breast cancer is variable across the province and has implications for analysis

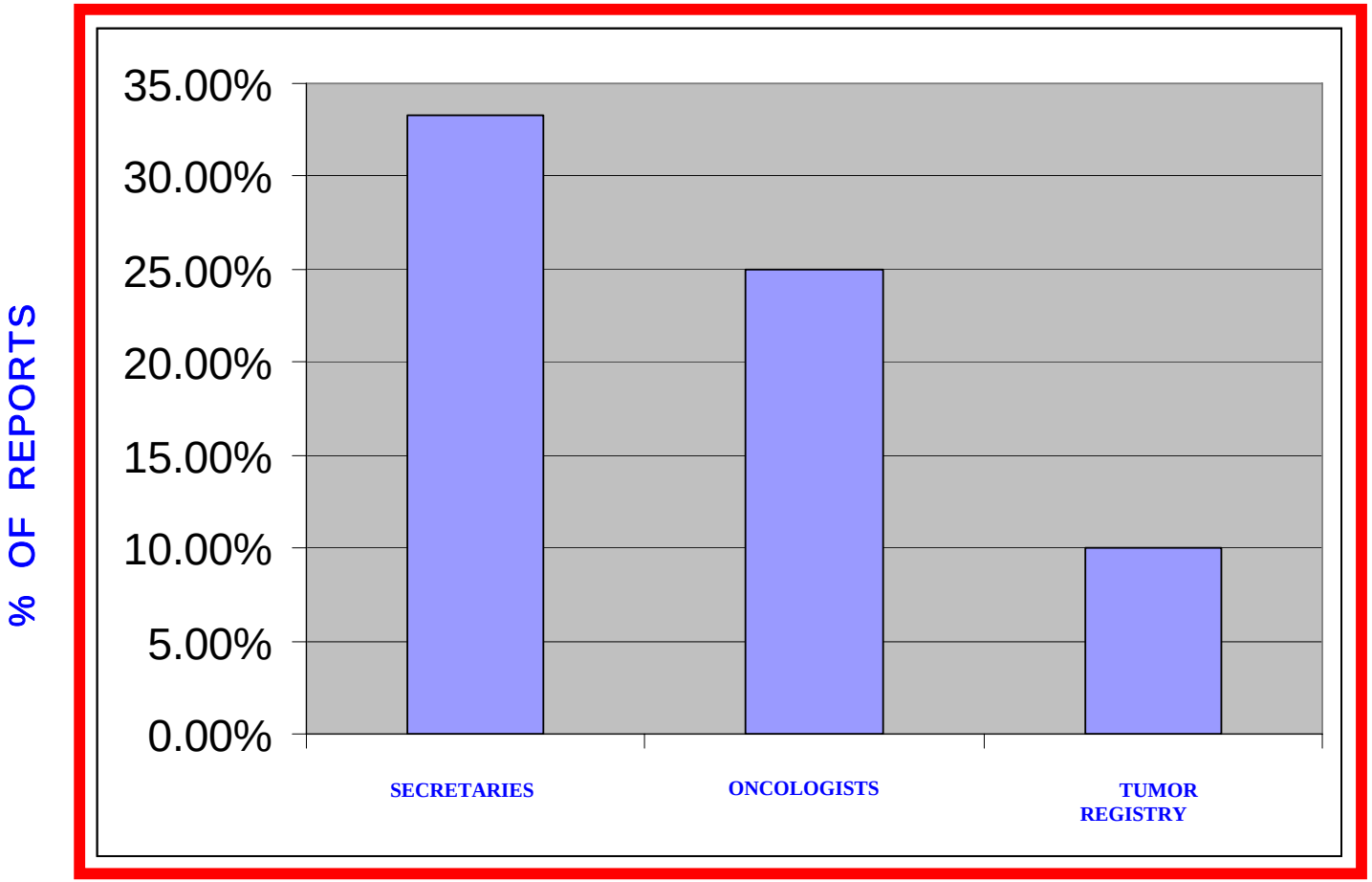
LDS Hospital

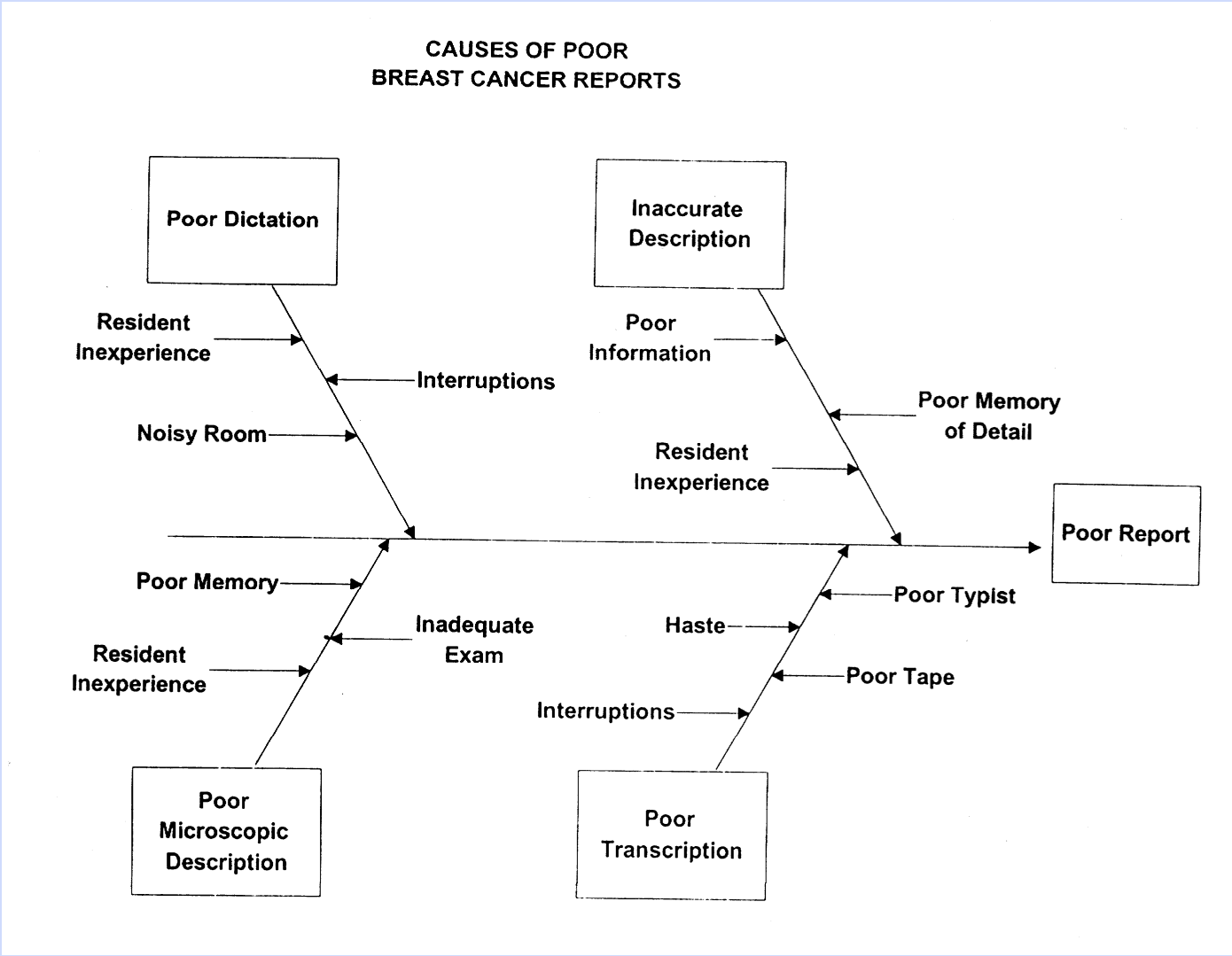
- 550 bed hospital in Salt Lake City
- Provides 60% of cancer care for state
- Flag ship adult hospital for Intermountain Healthcare, a large non profit integrated delivery system in Utah
  - 60% of hospital beds in state
  - 1.2 million of 2 million population covered by health plan
  - Long history of use of computerized health records and associated quality assurance initiatives

Reporting Change at LDS Hospital

- Determined that cancer reports resulted in many disruptive phone calls
- Reviewed extent of problem for breast cancer reports
- Flow charted process and did cause and effect analysis
- Consulted with clinicians about critical report elements
- Implemented synoptic reporting to correct the problem after teaching discussion
- Evaluated the effect on our practice

PHONE CALL FREQUENCY BY SURVEY GROUP




CAUSES OF POOR
BREAST CANCER REPORTS
Poor Dictation
Inaccurate Description
Resident Inexperience
Interruptions
Noisy Room
Poor Information
Poor Memory of Detail
Resident Inexperience
Poor Report
Poor Memory
Inadequate Exam
Resident Inexperience
Haste
Poor Typist
Poor Tape
Interruptions
Poor Microscopic Description
Poor Transcription

Recommendations of NQF

Design work so that it is easy to do it right and hard to do it wrong.

THE NATIONAL FORUM FOR HEALTH CARE QUALITY MEASUREMENT AND REPORTING

We Implemented Synoptic Reporting Format In An Iterative Fashion

- A teaching discussion with pathologists defined how to fill in the required fields in the new report.
- A draft synoptic report was tested for acceptance by pathologists for one month.
- A followup conference was held to modify the form based on suggestions of oncologists and pathologists.
- The form was put in place.

Holding the Gain

	1990	*1993*	*1995*
Total number of reports	356	250	190
Total # complete reports	299	242	188
Total # incomplete reports	32	8	1
# missing gross info	10	8	1
# missing micro info	22	0	0
Total # confusing info	25	0	0

Practice Implications

- Decreased phone calls about cancer reports
- Satisfied clinicians....we even get fan mail!
- Simplified transcription with lessened workload; elimination of ~1 FTE
- Less pathologist interruption
- Less pathologist resistance
- More consistent reporting
- More oncologist satisfaction

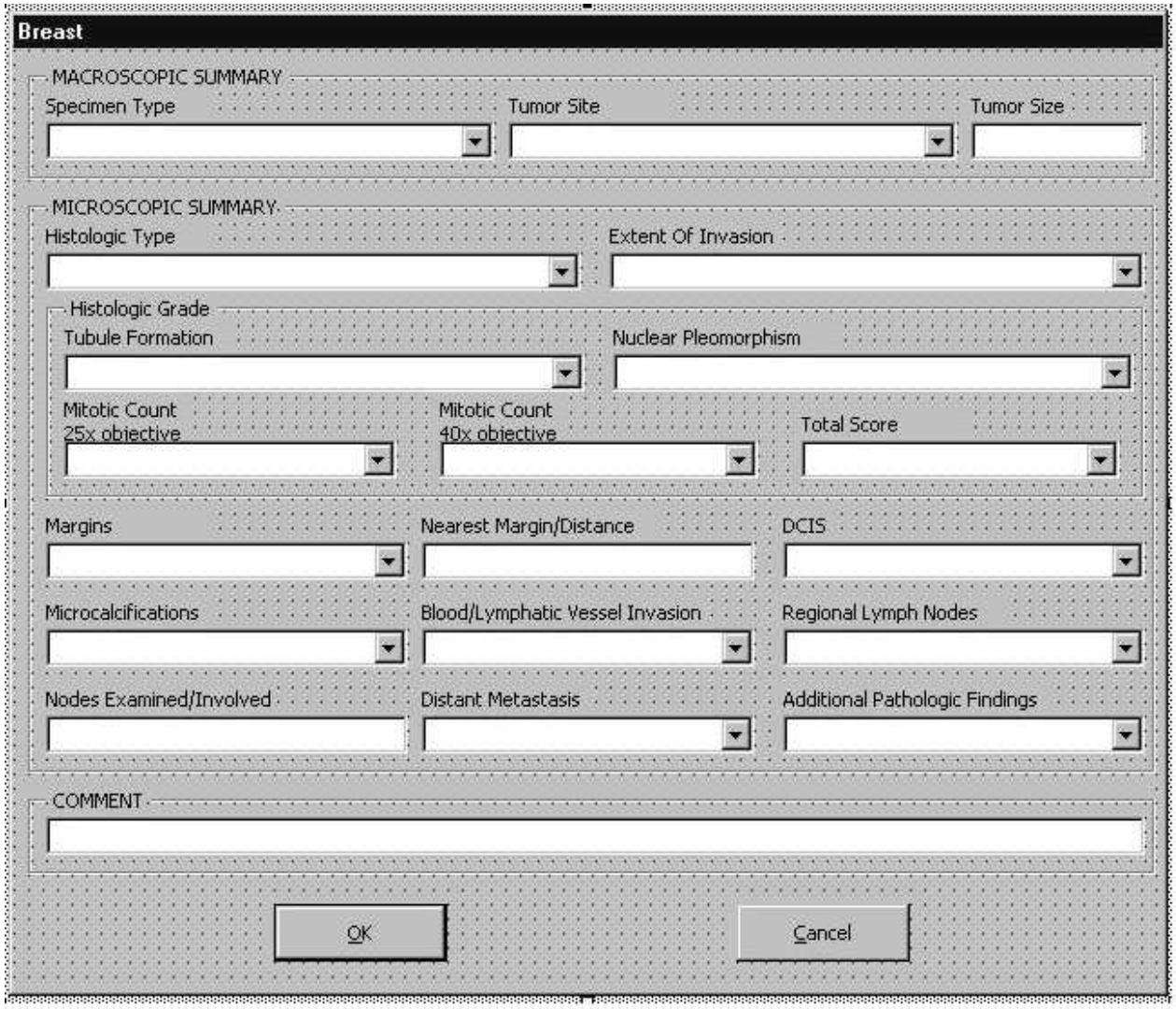
Oncologist Satisfaction (1996)*

- 100% (16/16) reported they were satisfied with the report format
- 100% (16/16) indicated the report was clear and complete
- 94% (15/16) wanted estrogen/progesterone receptor added

* Survey was sent to 31 oncologists. 16 of the 31 (52%) responded. 100% of the medical and radiation oncologists responded.

Followup

- Checklists from CAP were adapted to our clinicians.
- CAP Checklists are approved as ACOS accreditation requirements for cancer hospitals
- Synoptic formats (checklists) implemented as WORD macros with a pick list of choices for each element to standardize data for retrieval.
- WORD macros interfaced with AP computer system and all pathologists trained in use.
- Macros modified by clinician or pathologist suggestion to Informatics Committee
- Information transmitted through HL7 interface to data warehouse for cancer management



Example of IHC Breast Macro Data Entry Screen

IHC Breast Nottingham Score Grading Elements

Tubule Formation

Majority of tumor > 75% (score = 1)
Moderate 10% to 75% (score = 2)
Minimal < 10% (score = 3)

Nuclear Pleomorphism

Small regular nuclei (score = 1)
Moderate increase in size, etc. (score = 2)
Marked increase in size, nucleoli, chromatin clumping, etc. (score = 3)

Mitotic Count 25x Objective

10 mitoses per 10 HPF (score = 1)
10-20 mitoses per 10 HPF (score = 2)
20 mitoses per 10 HPF (score = 3)

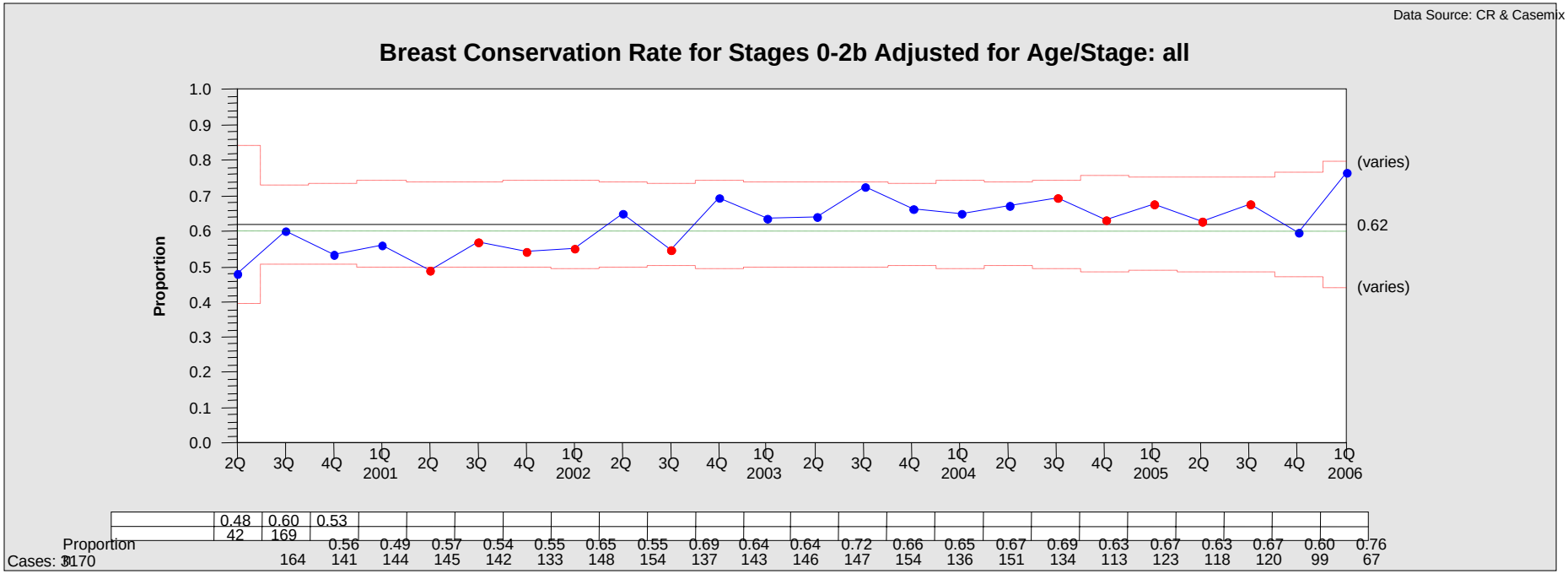
Total Score
Grade I: 3-5 points
Grade II: 6-7 points
Grade III: 8-9 points

IHC Breast Macro Data Elements

Extent Of Invasion

TX: Cannot be assessed
T0: No evidence of primary tumor
Tis: Carcinoma in-situ: Intraductal carcinoma, lobular carcinoma in-situ, or aget's disease of the nipple with no tumor
T1: Tumor < 2 cm. in greatest dimension
T1mic: Microinvasion < 0.1 cm. in greatest dimension
T1a: > 0.1 cm. but < 0.5 cm. in greatest dimension
T1b: > 0.5 cm. but < 1 cm. in greatest dimension
T1c: > 1 cm. but < 2 cm. in greatest dimension
T2: Tumor > 2 cm. but < 5 cm. in greatest dimension
T3: Tumor > 5 cm. in greatest dimension
T4: Tumor of any size with direct extension to chest wall or skin
T4a: Tumor of any size with direct extension to chest wall
T4b: Tumor of any size with edema (including peau d'orange) or ulceration of the skin of the breast or satellite skin nodules confined to the same breast
T4c: Both T4a and T4b

Breast Preservation Rate



Target is 60%
N=3170, 2000-2006

HER2 Testing Standardization

- Surveys of pathologists have shown considerable variation in HER2 reporting practices
- NCCN and ASCO-CAP have produced consensus guidelines to improve HER2 testing in 2006
- Both guidelines enumerate checklist reporting elements which are easily adapted to checklist report formats to improve clarity and avoid missing information.
- New guidelines and resultant education should change this.

Reporting for HER2 in 1998*

- *50% of labs report the HER2 test method that they used.*
- *75% report the degree of overexpression when they report IHC test results.*
- *20% report test as positive or negative without other information*

*Genentech survey. N=110

Reporting Template Requirements

- Standardize report format and language so oncologists and patients understand all important information:
  - Sample identification (block/slide/case)
  - Method used (specifics of test/vendor)
  - Controls used (positive and negative)
  - Assay result and reference ranges
  - If secondary testing will be done, describe how and when it will be reported
  - Provide a comment that describes the laboratory qualifications as an adjunct to the report (optional but desirable)

ER/PR/HER2neu

Pathologic Diagnosis (site, type)

Hosp/Type | Year | Case # | Block ID | Laboratory Extrinsic Controls

Collection time | Time placed in fomalin | Total fixation time | Please note time as military (ie. 5:00 pm is 1700). Total fixation time is noted as minutes.

ERA

Interpretation | Vendor: Dako | % Of Cells | Intrinsic Controls

PgRA

Interpretation | Vendor: Dako | % Of Cells | Intrinsic Controls

HER2

Interpretation | Vendor: Dako Herceptest | % Of Cells | Intrinsic Controls

FISH

Interpretation | Vendor | % Of Cells | Chromosome

Regions Counted | Cells Counted | H&E Section | Control Tissues

COMMENT

Finish | Cancel

Summary

- Synoptic reporting is advantageous for all types of reports
  - Avoid confusion and error
  - Provide clarity and consistency
  - Provide all necessary information for clinical decision making
  - Promotes faster, safer communication about patient results
- Effective changes in reporting require clinician-pathologist consensus
- Implementation has ancillary benefits to systems and regulators