

The Future of Quality Improvement in Small Biopsy and Cytopathology Tissues

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Quality

- ▶ Quality is the product and or service that meets the requirements of a wide number of individuals and or groups
- ▶ Quality is optimal patient care
- ▶ Quality is what the customer wants
- ▶ QI is an effort to improve the quality of a product beyond its current state

Institute of Medicine domains of quality

- ▶ Safety – avoiding injuries to patients
- ▶ Timeliness – reducing waits and delays
- ▶ Effectiveness – providing care based on scientific knowledge
- ▶ Patient centeredness – providing care based on patient needs
- ▶ Efficiency – decreasing waste
- ▶ Equity – equal access

Levels of Care

- ▶ To improve care, change must occur at four levels:
 - The experience of patients (level A)
 - Microsystems (small units of care) (level B)
 - Organizations that support microsystems (level C)
 - Environment of policy, payment regulation, accreditation and other factors that shape the behavior, interests and opportunities of organizations (level D)

Current care

- ▶ High rates of inappropriate care
- ▶ Large variation in clinical practice delivery
- ▶ High frequency of patient harm related to medical error
- ▶ High level of waste, resulting in astronomical costs

Models of care delivery

- ▶ Bottom up versus top down
 - Individual practitioners versus teams
 - Control versus empowerment
 - Motivate/incentives versus create work that is easy to perform
 - Unlimited time and resources versus tools built into workflow

Brent James

- ▶ Current state secondary to:
 - Reliance on the craft of medicine
 - Clinical uncertainty
 - ▶ Complexity
 - ▶ Absence of knowledge of best treatment
 - ▶ Subjective judgment

Brent James

▶ Craft based medicine

- Individual physicians
- Customized solution for each patient
- Core ethical commitment to patient
- Vast personal knowledge

▶ Profession based medicine

- Groups of peers treating similar patients
- Coordinated care delivery
- Individual clinicians adapt to patient needs

Phases of diagnostic testing

- ▶ Pre-pre-analytic phase – choice of the test
- ▶ Pre-analytic phase – performance of the test
- ▶ Analytic phase – processing and analysis of the specimen
- ▶ Post-analytic phase – reporting of the test result
- ▶ Post-post-analytic phase – use of the test result in patient care

Characteristics of cytopathology and small tissue biopsy

- ▶ FNA/non-gynecologic cytology (FNGC) and small tissue procurement procedures (STPP) generally are less invasive/performed on ambulatory patients
- ▶ FNGC/STPP often used for patient management triage
- ▶ Marked increase in FNGC/STPP for primary diagnosis (without follow-up excisions)

Characteristics of cytopathology and small tissue biopsy

- ▶ Conflict with traditional pathology model of subspecialty (based on organ) and clinician/pathologist roles
- ▶ Pathology practitioners (of FNA, at least) tend to function at the intersection of care levels A and B
- ▶ FNGC/STPP tissues intersect with the rapid growth of personalized/molecular medicine (prognosis)

Types of quality improvement implementation (QII) in FNGC/STPP

- ▶ Evidenced-based: shown to improve quality through systematic testing and/or evaluation research
- ▶ Theory-driven: when, how, why QIIs work, relationship of context and setting, content of QIIs, delivery of QIIs, understanding of effectiveness
- ▶ Quality domains ALWAYS overlap

Safety

- ▶ Medical error is the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim (Institute of Medicine)
- ▶ A diagnostic testing error occurs when the "result" does not correctly describe the disease process in the patient (i.e., the intended action (the test) does not achieve the correct aim (making a correct diagnosis))

Error frequency by phase

- ▶ Stroobants et al. Clinica Chimica Acta 2003;333:169-176.
 - Pre-analytic phase: 2.0% frequency of occurrence
 - Analytic phase: 0.2%
 - Post-analytic phase: 2.2%
 - Pre-pre-analytic: 12.0%
 - Post-post-analytic: 5.0%
 - Overall: 20.0%

Part A.

Quality of specimen

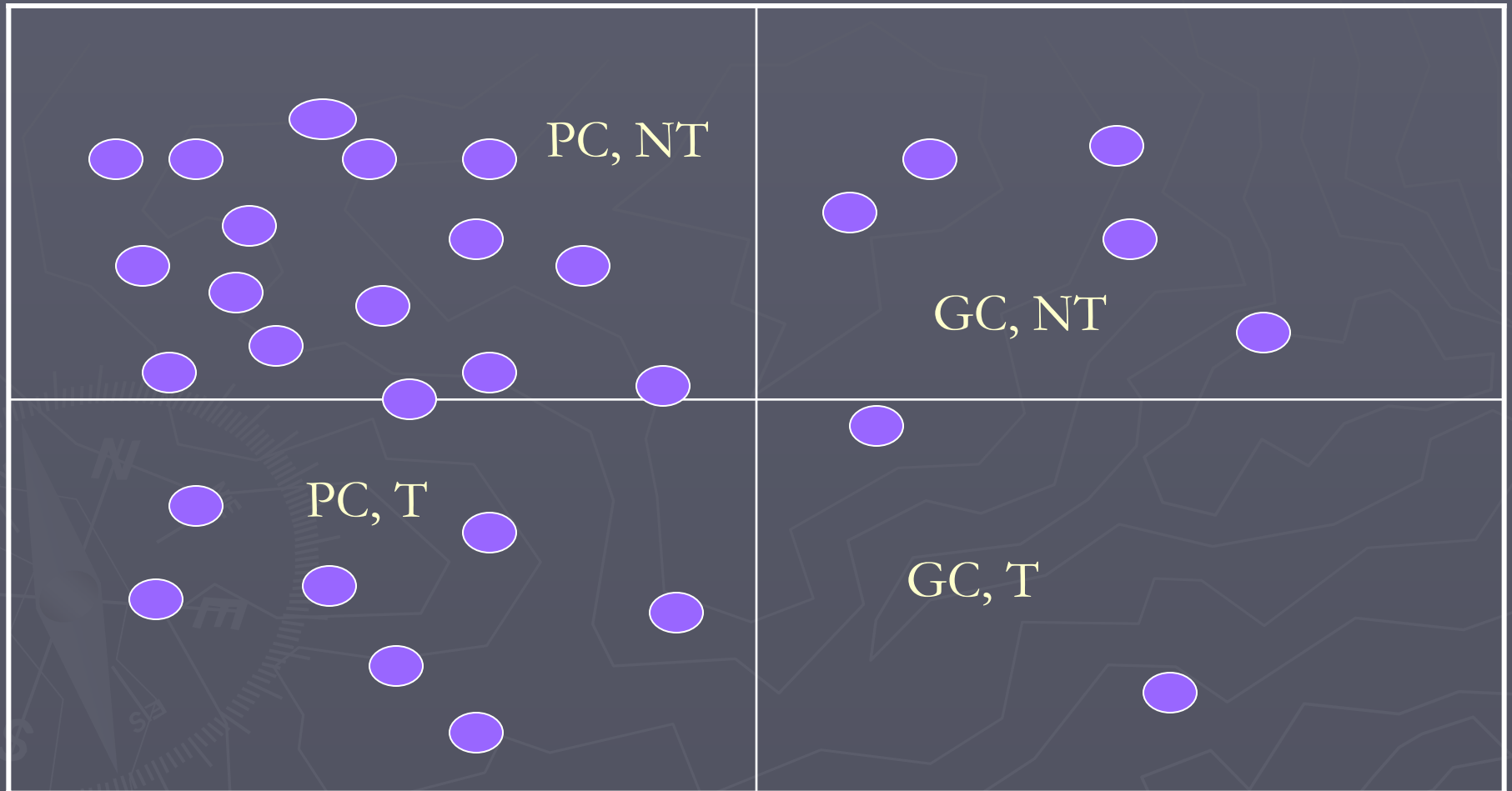


Amount of tumor

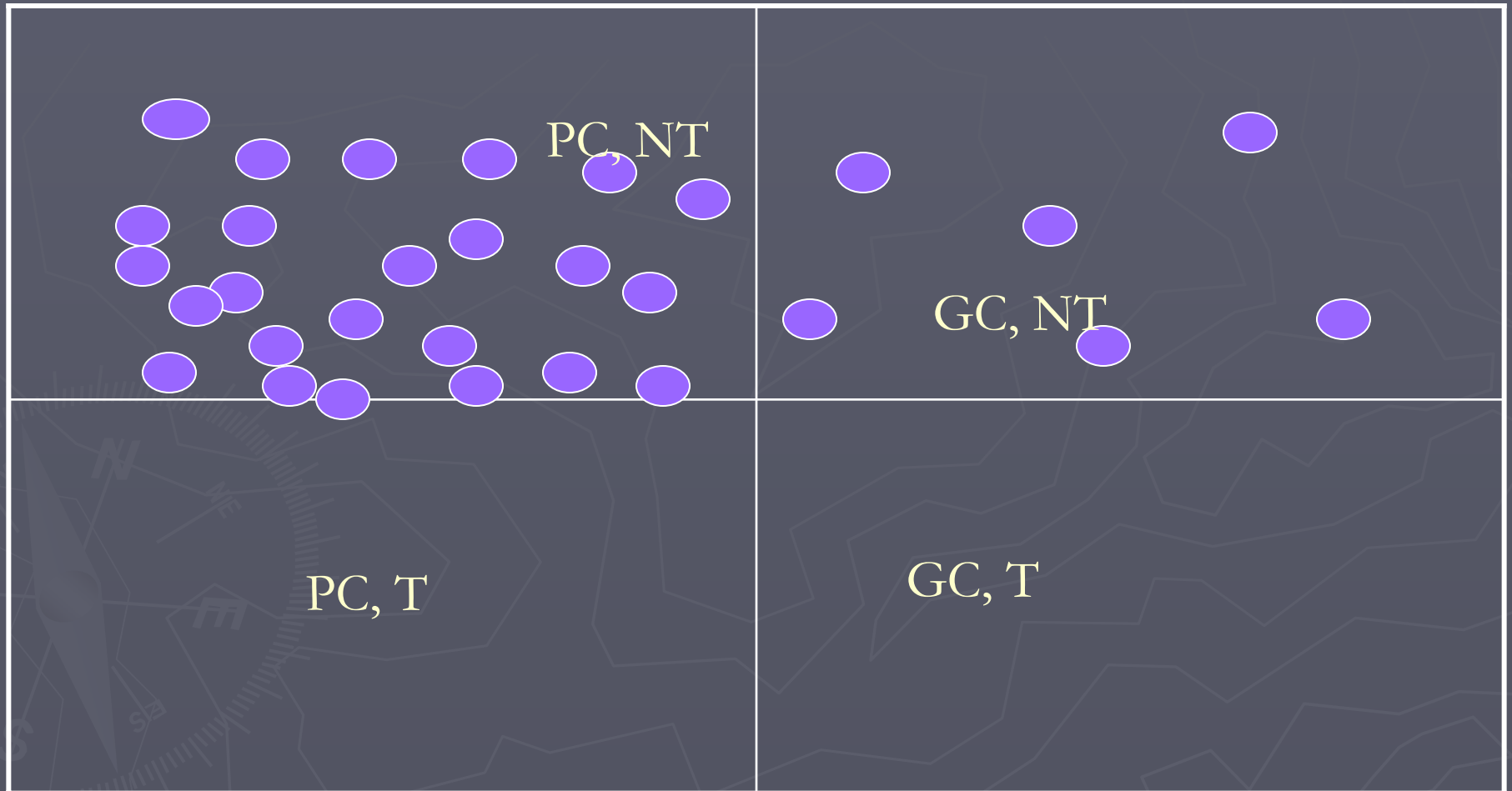


| | |
|---|--|
| <p>A.</p> <p>Poor quality specimen</p> <p>No tumor identified</p> | <p>B.</p> <p>Excellent quality specimen</p> <p>No tumor identified</p> |
| <p>C.</p> <p>Poor quality specimen</p> <p>Tumor identified</p> | <p>D.</p> <p>Excellent quality specimen</p> <p>Tumor identified</p> |

Categorization of 30 thyroid gland false negatives



Categorization of 30 thyroid gland false positives



Modified Eindhoven root cause analysis

- ▶ Latent (System) sources
 - Technical
 - Organizational
- ▶ Active (Human) sources
 - Knowledge-based
 - Rule-based

Modified Eindhoven root cause analysis

▶ Latent Error

■ Technical

- ▶ TM: Material defect found
- ▶ Example: poor slide staining from expired stain

■ Organizational

- ▶ OC: Culture, A collective approach to risk and error rather than the behavior of one individual
- ▶ Example: accepting inadequate specimens due to clinician pressures not to reject

▶ Active Error

- Rule-based, Qualification: the incorrect fit between an individual's qualifications, training or education and a particular task

- ▶ Example: a junior resident making slide smears on the first day of a cytology rotation

Active and latent errors

► For 18 Gynecologic cases:

- 52 pre-analytic latent errors
- 4 pre-analytic active errors
- 11 analytic latent errors
- 20 analytic active errors

► For 31 Non-gynecologic cases

- 107 pre-analytic latent errors
- 7 pre-analytic active errors
- 48 analytic latent errors
- 39 analytic active errors

Timeliness

- ▶ Time to breast surgical procedure decreased when immediate information (TP or FNA) provided (5-7 days, depending on the diagnosis)
- ▶ As part of a Lean QII to improve Pap test quality, immediate feedback from cytotechnologist to gynecologist improve Pap test quality

Effectiveness

- ▶ Use of a standardized terminology scheme in thyroid gland FNA
 - Sensitivity: Pre-intervention: 70.2%; post intervention: 92.3% ($P < 0.001$)
 - False negative rate: Pre-intervention: 41.8%; post intervention: 18.2% ($P = 0.006$)
- ▶ Use of double viewing services

Patient Centeredness

- ▶ Patient satisfaction: survey showed that >95% of patients would like immediate information following a FNGC/STPP
- ▶ More than >90% of patients want information even if told the incorrect diagnosis
- ▶ FNGC/STPP specimens are amenable to “fast” tissue processing – results in 3-4 hours

Efficiency

- ▶ QII of a standardized terminology scheme (similar to NCI scheme) and an immediate interpretation service of thyroid gland FNA resulted in fewer repeat FNAs (12.7% to 3.7%)
- ▶ Lean QII in a histology laboratory processing FNGC/STPP tissues showed improvement in lab productivity (pre and post-QII productivity ratio: 3,439 and 4,074 work units/FTE, respectively ($P < 0.001$))

Equity

- ▶ FNAB in developing nations (Andrew Field)
- ▶ Interdisciplinary care models (e.g., College of American Pathologists: See, Test, and Treat™ events)
 - Use FNGC/SPTT services
 - Fast tissue processing
 - Immediate feedback/care planning

Future

- ▶ Team approach
 - Practitioners of procurement
 - ▶ Rapid diagnosis
 - ▶ Patient centeredness
 - ▶ Clinical interactions
 - Signs out with subspecialties
- ▶ QII focus on all portions of the testing pathway

Future

- ▶ Remodeling of reimbursement (level D)
- ▶ Information technology adoption/process improvement
- ▶ Data sharing
- ▶ Health service research training and practice
- ▶ Transformational leadership

Future

- ▶ Standardization and subspecialty
 - Pathologist model based on individual practitioner
 - Necessity for outcome data
 - Develop best practice model
 - Leadership by existing societies/organizations/government

Future of practice research

- ▶ CDC 2007 Institute on Critical Issues in Health Laboratory Practice: Managing for Better Health
- ▶ Development of a health laboratory research agenda using an electronic modified Delphi method
 - Evaluate the frequency of laboratory test misinterpretation by clinicians and the negative impact on health outcomes
 - Develop standardized measures of error in anatomic pathology
 - Develop evidence based laboratory performance measures

“I am sorry for you, young men (and women). You will do great things. You will have great victories, and standing on our shoulders, you will see far, but you can never have our sensations. To have lived through a revolution, to have seen a new birth of science, a new dispensation of health, reorganized medical schools, remodeled hospitals, a new outlook for humanity, is not given to every generation.”

Reid EG. The Great Physician: A Life of Sir William Osler. New York, NY: Oxford University press, 1931 (p. 241)

Questions

