

# **Tissue procurement quality assurance benefits from shared experience:** Midwestern Division Cooperative Human Tissue Network (CHTN), 2004-2010.

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# Abstract

#### Introduction

Tissue Procurement Service (TPS) is a program of the Midwestern Division, Cooperative Human Tissue Network (CHTN) and the OSU Comprehensive Cancer Center Shared Resource at The James Cancer Hospital and The Ohio State University Medical Center (OSUMC). TPS prospectively procures research tissues from remnant surgical specimens and, when possible, a quality control (QC) block of representative tissue reviewed by pathologists. Quality assurance (QA) in TPS is monitored within the OSUMC Quality Improvement Program of the Department of Clinical Laboratories.

#### Method

Quality indicators have been established to monitor efficiency, accuracy and errors related to tissue procurement process; daily records are maintained. Data is collated and reported in a standard 6 month charting format with a running average. Indicators (with thresholds) currently followed are: 1) tissue procured incorrectly; not meeting protocol expectation (<10 errors/month), 2) negative impact to diagnostic dissection (<10 errors/month), 3) categories of cases where QC was not met: a) small specimens, b) specimen submitted in entirety for research, c) confirmed via frozen section due to small size. Results

In 2010, indicator results were: 92% of procured QC tissues within thresholds and passed; total n=1856, total errors averaged fewer than 1 per month and QC was not met for above categories: a) 273, b) 325, and c) 63 times. (n=661)

### Conclusions

TPS participation in an institutional QA program encourages regular and adequate record keeping and open participation in process improvement along with other high performance laboratory disciplines. Indicators have been added over time and thresholds met. Ongoing QC monitoring underpins the development of best practices for tissue procurement. Sharing this data with other TPS programs provides opportunity for discussion and consensus in developing best practices for quality research tissue procurement.

## Background

The CHTN provides prospective investigator-defined procurement of malignant, benign, diseased and uninvolved (normal adjacent) tissues. The investigator may also choose from several methods to prepare the specimen such as fresh, frozen, or chemically fixed. Tissues are annotated with patient demographics including sex, age, and race. The CHTN also produces tissue microarray (TMA) slides, including surveys of multiple tissue types and disease-specific designs. Additional patient information may be requested where applicable.1

Quality control assessments of tissues are provided by the CHTN principal investigators who are actively involved in the practice of anatomic pathology. The CHTN principal investigators are responsible for proper histopathological characterization, participate in research and understand the importance of quality control in the tissues provided.1

The Ohio State University (OSU) has had an internal tissue procurement service sponsored by their Comprehensive Cancer Center since 1975 and it joined with the CHTN procurement service in 1987. Leona W. Ayers, M.D., is the principal investigator for the Midwestern Division of the CHTN

### Program

Quality Control (QC) is the system of technical activities that measures the attributes and performance of a process, or item, against defined standards, to verify that the stated requirements are fully met.2

From 2004 to January, 2009 QC was a solo activity within Tissue Procurement Service (TPS) established and reviewed within the CHTN research setting. From January, 2009 to present TPS was a member of the institutional Anatomic Pathology Technical Quality Improvement Committee (APTQI) to focus on operational improvements.

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# **APTQI** Participants

### **APTQCI Committee:**

Pathology Administrator

Hospital Administrator

Surgical Pathologist

#### AP/CP Medical Director Supervisors from:

- Autopsy, Neuropathology, Hematopathology, Histology, Immunohistochemistry, Pathology Compliance Officer
  - Renal Pathology, Cytology, Pathology Core Facility, Surgical Pathology Gross
  - Room, Consultations, Transcription **Research Tissue Procurement Service**

APTQI meetings are held monthly and participants present their QA monitors and QC results.



blocks plus [a) small specimens=273, b) specimen submitted in entirety for research=325, and c) confirmed via frozen section=63 (n=661)] passed; total n=1856, total errors averaged fewer than 1 per month.



Figure 2: Procured malignant samples by site (top 15 / other) and by year, 2004 - 2010. In recent years there are increased constraints: 1) tissue availability - impacted by decreasing size of primary tumors due to improved diagnostics; 2) increased boutique request - greater specificity of researcher requests; 3) lack of funding for investigators has not had the major effect that might have been expected; 4) increased pathology restrictions/constraints to assure patient diagnosis. Despite restraints, we are able to serve a large variety of malignancies to a large number of investigators

### Results

### **APTQI** new monitors

- · Detail of tissue quality; monitored reasons for unconfirmed tissue by QC blocks-trends can be assessed from the recorded monitors.
- Specimen QC failure; corrective action plan example: normal adjacent tissue contains malignant tissue: investigate labeling error and/or redesignate tissue as malignant.
- Tissue procured incorrectly; not meeting protocol expectation tied to investigator feedback.
- Tissue procurement errors; communication tool everyone is held more accountable
- Negative impact to diagnostic dissection pathologist/assistants have error log that documents. Log returned to procurement for corrective action.

### **APTQI** enhanced procurement outcomes

- · Improved specimen flow secondary to shared monitor data
- · Stimulated communication interchanges among APTQI participants
- Rapid initiation of corrective actions with feedback
- Improved procurement skills from shared experience and ongoing feedback from pathologists/assistants

# Conclusions

- · Institutional QA programs encourage adequate, regular record keeping and feedback from stake holders: Hospital administration, Pathology administration, Pathology compliance and service area supervisors/leads.
- · Process improvement works best within a context of related laboratory disciplines where all stake holders can meet, review and exchange viewpoints.
- · Quality monitors have been added over time to TPS, thresholds met and regular reviews completed and acted upon.
- Ongoing QC monitoring within a context of guality improvement/assurance underpins the development of best practices for tissue procurement.
- · Sharing our data with other TPS programs provides opportunity for discussion and consensus in developing best practices for quality research tissue procurement.

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