Patient Sample Management and Chain of Custody: Modern Practices for Modern Demands

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30 plus years of experience in histology

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Red Fox Histology Solutions

Consider these questions…

- **Have you ever experienced a misplaced or lost patient sample?**

- **Do you feel that your chain of custody practices for your lab's patient tissue assets are secure?**

- **What vulnerabilities or liabilities do you see in your current practices?**

- **Is an increased volume of asset requests causing pain points for your staff or workflow?**

Introduction

- Laboratory managers are the custodians of assets

- Biopsied tissue is the primary source of data that determines pathology analysis, disease diagnosis, and treatment plans.

- Many rules and regulations dictating asset management practices

Four forces combined are complicating and placing increased pressure on laboratories' sample management practices:

Aging Boomer generation

Workforce shortages and turnover rates

"Personalized medicine"

Legal and regulatory demands

- Boomer generation is the largest in the USA and Canada.

- Aging and ailing boomers need more tests than younger, smaller generations, increasing sample volume

- Advances in medicine keeping people alive longer

- Shift from "one size fits all treatment" to individualized treatment driven by:
  - Advances in genomics
  - Value-based medicine
  - Patients as medical "consumers"

- Rapid advances in personalized cancer diagnosis and treatment in particular
- Corresponding sharp increase in number and availability of clinical trials
- More trials = more sample check out requests

- Federal, state and local mandates

- Patient samples considered a part of the medical record

- CAP guidelines on patient samples provide timelines for sample storage

- Need to show continuous improvement per CAP guidelines

Cancer Research UK Report 2020:

- The report, *[Estimating the cost of growing the NHS cancer workforce in England by 2029](#)* by Cancer Research UK indicates that a 45% staff increase is needed across seven cancer-related professions to meet Health Education England's (HEE) aim to provide world-class services for cancer patients by 2029.

- Without targeted action and investment, the number of histopathologists is forecast to reduce from the existing shortfall by an additional 2% by 2029.

Patient sample chain of custody is a crucial consideration for all histology and pathology laboratories

Factors that affect sample chain of custody are:

Labeling of samples:

- Handwritten vs. barcode

- Complexity of label information

- LIS documentation and tracking of labeled samples

Tracking systems:

- Plentiful options exist, but not standardized and mixed results on their performance and how often they are even used.

- Most tracking systems fail to consider archiving

- Standalone tracking systems can be seen as "middleware"

Archiving of samples:

- Retrieval and replacement of samples in an archive

- Manual vs. automated vs. third party archiving systems

From the moment tissue or fluids are taken from a patient, the samples must be properly labeled.

Consequences of poor labeling practices

- Patient record errors
- Inefficiency
- Need to "re-sample" or "re-biopsy"
- Incorrect diagnosis

Handwritten vs Barcode

Handwritten issues:

- Human error
- Readability issues
- The amount of info on the slide
- Traceability and label correctness

Barcoding:

- Quality issues (drift, registration)
- If it's a poor barcode, it won't scan
- Advantages of automation
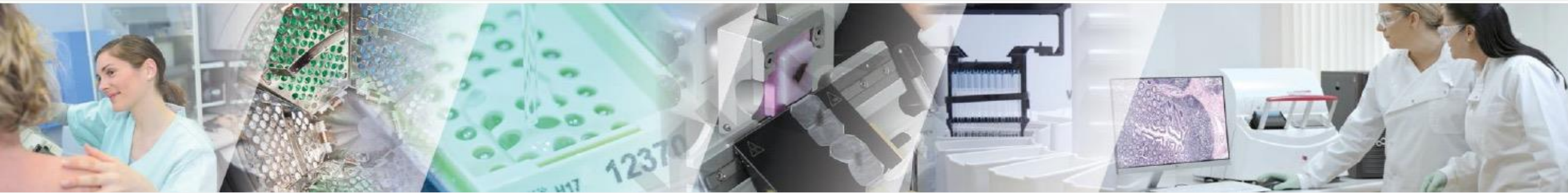
Sample collection

Archiving

Grossing

Imaging

Tissue processing

Staining

Embedding

Sectioning

- **Ease of organization and cataloging**

- **Protocols for check in, check out**

- **Security of sample environment**

In-house manual

Pros:

- Little technical knowledge needed to establish system

Cons:

- Human error
- Not scalable
- Not secure

In house automated

Pros:

- Scalable,
- Highly secure
- Reduce burden on staff for reminders and organization
- LIS integrated

Cons:

- Learning curve
- IT demands
- Expense

Offsite, third-party management

Pros:
- Scalable
- Reduces burden

Cons:
- Increases paperwork
- Longer turnaround times
- Expense
- Liability

Denise Bland

Senior Technical Director Histopathology

Massachusetts General Hospital

Laboratory Overview:

- Central service to all MGH locations

- Approximate throughput /
  ~ 800,000 / year

- Department / Staff size
  ~ 45 staffers

Asset archiving challenge:

"There are state regulations and federal regulations governing that we be responsible custodians of this tissue for the patients, while improving our process on an annual basis to ensure that we are doing what we can to retain these valuable assets."

Mass General lab using old, manual system:

"It was a very laborious system. It left room for error, because there wasn't a lot of traceability and accountability. I've wanted automation for a while, but I hadn't seen a system that I thought was truly going to meet all our needs."

- **Check out / Check in process in a manual system did not put Denise in a position of secure gatekeeper.**

MGH lands on a new sample archiving solution: a proprietary automated, digitized system

This new automated system has many benefits:

- Asset management software logs exact location of samples

- Samples can be added as completed (non-alpha or chronologic order).

- Group samples in this system by year only

- Only approved users can access system and locate assets

- Software alerts to missing blocks, gives reminders

- Accommodates pathologists' needs for dedicated block towers while maintaining security

MGH
1811

Results:

"Since implementing this system, we have not lost one block or slide."

Labs need robust asset management practices to accommodate the increased demands

Best practices in labeling:
- Barcode printers for cassettes and slides to reduce reading errors and mislabeling and increase efficiency and data capturing capabilities

Best practices in archiving:
- Automated slide and tissue block asset archiving for secure chain of custody and efficient/secure accommodating of asset sign in/sign out needs