

# Implementing an Improved Tracking Management and Oversight System For Clinically Generated Tissue, Blocks, and Slides

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## **Abstract**

Pathology departments are the recognized legal guardians of tissue obtained from a patient for the purpose of a medical diagnosis. At Mayo Clinic, all paraffin-embedded tissue, blocks, and slides are retained and permanently stored at Tissue Registry Archives. These materials are important for future clinical, research, and educational studies, and therefore are constantly being borrowed and returned. A quality metric used at Tissue Registry is the percentage of borrowed material that is returned, and over the past several years, it had become evident that the existing processes and tracking database in use were not sufficient for growing demands.

Using continuous improvement methods, a root cause analysis was performed to identify various factors as to why borrowed material was not being returned. In response to the findings, Tissue Registry developed several new standards that outlined specific criteria for borrowing and returning material, and also acquired a commercial tracking management system. The new process design was implemented in January 2008.

Data was collected to determine the return rate of slides and blocks in 2005. It was found that only 47% of blocks and 61% of slides sent out in 2005 were returned. Data collected for 2008 determined that 94% of blocks and 91% of slides sent out were returned. After identifying areas for improvement, Tissue Registry implemented a new tracking management and oversight system that has improved the success rate for the return of borrowed

## Introduction

Tissue that is obtained from a patient during the course of a biopsy for the purpose of a medical diagnosis is sent to a pathology laboratory or department, where it is processed for histological examination and diagnosis. All of this material, including formalin fixed, paraffin embedded blocks and tissue slides, becomes part of the patient's medical records and must be maintained and preserved to meet compliance with regulations set forth by federal laws and professional institutions such as CLIA, CAP and TJC. At Mayo Clinic, all formalin-fixed paraffin embedded blocks and tissue slides are permanently retained, along with formalin fixed tissue which is retained for 10 years (Table 1).

#### Table 1

	Retention Requirements (length of time in yrs) according to *:					
Type of Record	CLIA	CAP	TJC (JCAHO)	NYS	Mayo Clinic Tissue Registry	
Glass Slides	10	25	10	20	Permanently	
Paraffin Blocks	2	10	2	20	Permanently	
Tissue in Formalin	Not Specified	2 weeks from final report	1 week from final report	Not Specified	10	

\*CLIA: Clinical Laboratory Improvement Amendments; CAP: College of American Pathologists; TJC: The Joint Commission, formerly the Joint Commission on Accreditation of Healthcare Organizations (JCAHO); NYS: New York State Department of Health

## Introduction (continued)

This material must also be maintained and preserved for further clinical examination, "second" diagnostic opinion or treatment by other pathology departments, medico-legal purposes, quality programs, educational purposes, and research use. To ensure blocks and slides are available for these activities, the Mayo Clinic Tissue Registry Archives Warehouse was created to guarantee prolonged storage and physical integrity of the material (Figure 1).

#### Figure 1



ignated as the Tissue Registry Archives Warehouse, which is under the supervision of the Division of Anatomic Pathology, within the Department of Laboratory Medicine and Pathology. Tissue Registry is a stand alone, temperature controlled 12,000 square foot facility that stores all clinically generated pathology material dating back to 1907.

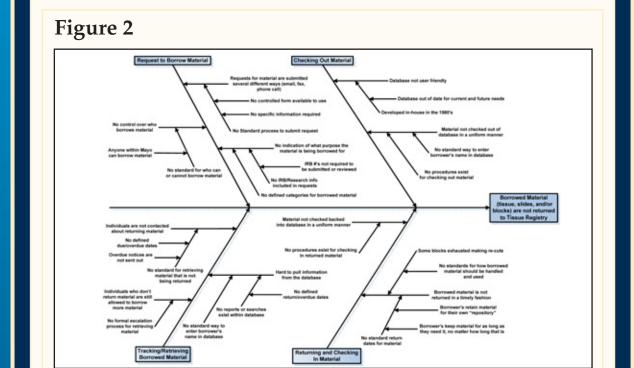
A tissue archive is not static and material is constantly being requested, borrowed, and returned. Therefore, it is necessary to have the ability to track these activities in order to offer proper oversight. Over the past several years, it had become evident that the current tracking and management system developed in-house at Tissue Registry in the 1980's, and used to track borrowed material, was not sufficient for growing demands.

## Materials and Methods

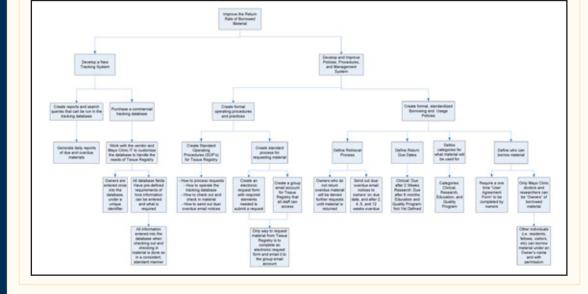
At the start of 2007, a cross-functional team was developed to work on creating and implementing an improved tracking and management oversight program at Tissue Registry. Members of the team included representatives from Tissue Registry, Pathology, Project Management, Quality, Process Engineering, and IT. The current practices at Tissue Registry were reviewed and several aspects of the system were identified as being lacking or completely absent. A process classification type cause and effect fishbone diagram was created to illustrate the issues that were identified (Figure 2).

The team identified the primary goal: Improve the return rate of borrowed material, as well as the major "means" by which the goal could be achieved: 1) Develop or improve policies, procedures, and an overall management system, and 2) Develop a new tracking system. A Tree Diagram was created to map out the levels of detailed actions that needed to be accomplished in order to achieve

## Materials and Methods (continued)

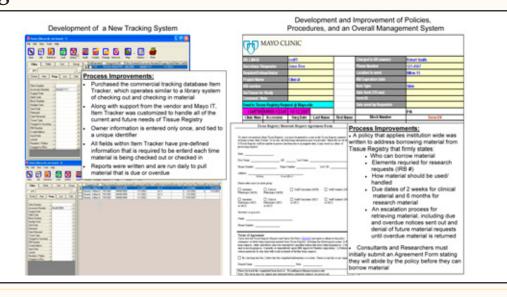


## Figure 3



The team worked diligently throughout 2007 and all aspects of the improved tracking management and oversight system for clinically generated tissue, blocks, and slides at Tissue Registry were completed and implemented on January 1, 2008. An overview of the process improvements that were achieved are highlighted below (Figure 4).

### Figure 4



## Results

We selected the year 2005 as a baseline year to illustrate the problem of borrowed material not being returned to Tissue Registry. The number of glass slides and paraffin blocks borrowed and returned were tracked in the old tracking system, but tissue was not (Table 2).

#### Table 2

2005	Glass Slides	Paraffin Blocks		
	Borrowed Returned (%)	Borrowed Returned (%)		
Total	155,373 94,762 (61)	57,701 27,144 (47)		

Borrowed material is tracked in Item Tracker by tissue, blocks, and slides. The reason material is borrowed is broken down into 4 categories and tracked by Clinical, Research, Education, and Quality Program. The number of glass slides, paraffin blocks, and tissue in formalin that were borrowed and returned to Tissue Registry was pulled from Item Tracker for the year 2008, to illustrate improvements following implementation of the improved tracking management and oversight system (Table 3).

#### Table 3

2008	Glass Slides		Paraffin Blocks		Tissue in Formalin	
	Borrowed	Returned (%)	Borrowed	Returned (%)	Borrowed	Returned (%)
Research	122,965	109,172 (89)	36,778	33,707 (92)	185	168 (91)
Clinical "send away"	35,121 * 5,835	34,430 (98) 5,686 (97)	12,608	12,548 (99)	154	150 (97)
Education	15,474	14,567 (94)	1,428	1,408 (99)	30	25 (83)
Quality Program	2,873	2,127 (74)	602	422 (70)	4	4 (100)
Total	182,268	165,982 (91)	51,416	48,085 (94)	373	347 (93)

Represents the number of slides forwarded to outside pathology departments for second opinion and/or because the patient is being seen or treated at an outside institution.

Comparison between material return rates in 2005 and 2008 were observed and the percentage of improvement between the two years was calculated (Table 4).

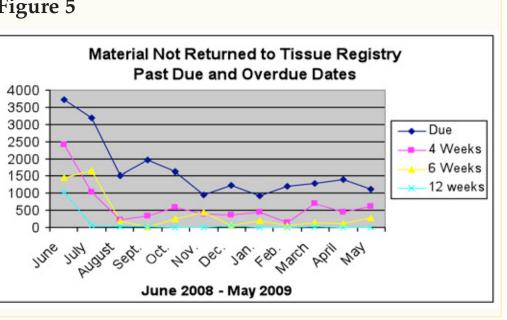
#### Table 4

	2005	2008	% Improvement
Glass Slides Borrowed % Returned	155,373 61	182,268 91	49
Paraffin Blocks Borrowed % Returned	57,701 47	51,416 94	100

In June 2008, Tissue Registry began sending out email notices for due and overdue material at 4 defined intervals: on the due date, 4 weeks overdue, 6 weeks overdue, and 12 weeks overdue. It was found that the number of borrowed material not returned prior to due dates and past due dates fell sharply in response to these email notices (Figure 5). Feedback from borrowers has been that they check out material, use it for the purpose needed, and return it right

## Results (continued)

#### Figure 5



## Conclusion

A thorough review of the practices at Tissue Registry found significant deficiencies in processes, policies, and procedures, as well as a tracking system that could no longer adequately protect the integrity of the pathology materials stored there. In response to this problem, we have been able to develop and implement processes, policies, and procedures for enhanced oversight of clinical or diagnostic tissue, blocks, and slides. In addition, we identified requirements necessary for a tracking and management system that protects this material. Finally, we reviewed a number of commercially available systems, and identified and customized Item Tracker, a system that meets current and future needs for tracking of linically generated tissue, blocks, and slides. Following implementation data showed that between 2005 and 2008, the percentage of borrowed blocks that were returned increased from 47% to 94% and the percentage of borrowed slides that were returned increased from 61% to 91%. This accounts for an improvement rate of 100% for blocks and 49% for slides. Through the implementation and enforcement of new policies and procedures, improved communication and education, and implementation of a new, robust commercial tracking system we believe we have successfully reached all of the process improvement goals set for Tissue Registry.

# Bibliography

- Harty-Golder B. Retention and ownership of blocks. MLO Med Lab Obs, 2004; 36:37 2. Dry S. Who owns diagnostic tissue blocks? Lab Medicine, 2009: 40:69-73.