

# A Quality Initiative to Decrease Pathology Specimen–Labeling Errors Using Radiofrequency Identification in a High-Volume Endoscopy Center

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- OBJECTIVES:** Our institution has had problems with mislabeling of tissue specimens in our gastrointestinal and colorectal surgery endoscopy units. Most labeling errors have been due to either the wrong patient label or no label being affixed to a specimen bottle. As a result, an initiative was created to reduce the number of specimen-labeling errors. This initiative involved the application of radiofrequency identification (RFID) technology to specimen bottles, moving to a paperless pathology requisition system and confirmation of the correct site and correct patient by both the endoscopy nursing staff and the endoscopist for each specimen bottle.
- METHODS:** We reviewed the number of specimen-labeling errors from our endoscopy unit for the first 3 months of 2007, before the implementation of the initiative, and for the first 3 months of 2008, 6 months after the initiation of RFID specimen labeling with paperless requisition and two-provider confirmation of correct site, correct patient specimen labeling. The RFID system we used was an off-the-shelf 3M (St. Paul, MN) Library Sciences RFID system modified and installed for our purposes. Specimen-labeling errors were categorized as Class 1 (only typographical with no potential clinical consequences), Class 2 (minor error, unlikely to have clinical consequences) or Class 3 (significant error that has the potential to detrimentally impact patient care). The Fischer's exact test was used to compare the rate of specimen-bottle labeling errors before and after the initiation of this new system.
- RESULTS:** In the first 3 months of 2007, our endoscopy unit sent 8,231 specimen bottles to our pathology laboratory for evaluation; 8,539 bottles were sent in the first 3 months of 2008. There were 646 (7.85%) Class 1 errors in the first quarter of 2007 and 35 (0.41%) in the first quarter of 2008 ( $P < 0.001$ ). There were 112 (1.36%) Class 2 errors in the first quarter of 2007 and 10 (0.12%) in the first quarter of 2008 ( $P < 0.001$ ). Finally, in the first quarter of 2007 there were seven (0.09%) Class 3 errors and in the first quarter of 2008, there were two (0.02%) Class 3 errors. However, with the new system in place, both Class 3 errors in the first quarter of 2008 were recognized and corrected before the processing of the specimens in the pathology laboratory ( $P = 0.001$ ).
- CONCLUSIONS:** These data confirm that the initiation of a new specimen-labeling system that uses RFID technology, a paperless requisition process, and confirmation of the correct site and correct patient by two health-care providers significantly decreased specimen-labeling errors at every level in a high-volume endoscopy center.

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## INTRODUCTION

The Gastroenterology and Colorectal Surgery (GI/CRS) outpatient endoscopy unit at our facility yields over 30,000 specimen bottles that are sent for pathologic review every year. Over the past several years, this unit has had some notable errors with mislabeling of tissue specimens. In one situation, this led to a sentinel event when a wrong site surgery was done because of a mislabeled pathology specimen. Similar reports of mislabeled specimens have come from other institutions (1–3).

In 2005, the Division of Anatomic Pathology at the Mayo Clinic Rochester initiated a proposal to explore a Radio Frequency Identification (RFID) system to help track pathology slides and paraffin-embedded tissue blocks in their laboratory and professional offices. Radio Frequency Identification is a technology often used to automate identification. An RFID tag can be applied to or incorporated into an object for the purpose of identification using radio waves. RFID was originally developed in WWII for use in the identification of aircrafts and is now ubiquitous in a variety of industries including travel, retail, shipping, library science, law and aerospace to track and trace merchandise, parcels, books and paper records. RFID is increasingly being successfully employed in health care, typically for workflow, equipment, drug and inventory management (4–7).

A pilot project in the Division of Anatomic Pathology was the end result of these efforts and focused initially on securing data fidelity. Once the pilot was completed, the focus of the project was shifted to clinical practice with focus on the high-volume GI/CRS outpatient endoscopy unit. The main objective of the clinical practice project was to eliminate paper requisitions that accompany tissue specimens sent to Anatomic Pathology for evaluation and to create a system that would automate specimen bottle tracking. This was accomplished by the application of RFID technology to specimen bottles, the transition from a paper to a paperless electronic requisition system and confirmation of the correct site, correct patient by both the endoscopy nursing staff and the endoscopist on each specimen bottle.

## METHODS

### RFID technology for specimen labeling

An off-the-shelf 3M (St. Paul, MN) Library Sciences RFID system was modified and installed in 41 GI/CRS Endoscopy Suites as well as in the Specimen Processing/Accessioning Laboratory in the Division of Anatomic Pathology in March of 2007. The RFID system employed in our center uses a high frequency range for transmission that is shared only by short-wave and amateur radio transmissions which makes it less vulnerable to interference by everyday technologies such as cell phones or pagers. Prior to the implementation of this system in our facility, our Telecommunications Department tested our system for interference and found none.

RFID sticker tags were placed on the bottom of specimen bottles. The tags were used to uniquely identify each bottle and allow for



**Figure 1.** Specimen bottle with a MERGE database-generated label and RFID tag (on the bottom of the bottle) on RFID pad. RFID, radiofrequency identification.

the passive electronic transfer of information from an institutionally owned and created gastroenterology database named Mayo Electronic Record for Gastrointestinal Endoscopy (MERGE) to the specimen including the patient's name, medical record number, date of procedure, performing endoscopist, requesting physician and the details associated with the specimen such as the site of biopsy and the relevant clinical question (see **Figure 1**).

### Paperless requisition

We continued to use paper requisition forms with our RFID-tagged specimen bottles for the first 6 months of the project. In September of 2007, we transitioned to a completely paperless requisition system. During the programming phase, data are associated with the RFID tags in the 3M database. In the endoscopy suite, patient and specimen data are entered during the endoscopic procedure into the MERGE database by the endoscopy nursing staff with physician input. Upon receipt of the specimen bottles in the Specimen Processing/Accessioning Laboratory in the Pathology Department, the data are transferred to the laboratory information system (CoPath) from the MERGE database with a single key-stroke command from the pathology laboratory personnel.

### Two-provider confirmation of correct site, correct patient

At the time we implemented the RFID system, in March of 2007, we began acquiring two-provider confirmation of the correct specimen source for the correct patient on every specimen bottle. Immediately after the endoscopic procedure is complete, the endoscopy nursing staff fix a MERGE database generated label on to the specimen bottle that has already been programmed with an RFID tag. The label has the patient's name, medical record number and site from where the specimen was obtained. Once the label has been fixed to the specimen bottle, the physician and nursing staff must both initial the bottle confirming that it is from the correct patient and obtained from the site listed on the bottle.

### Classification of labeling errors

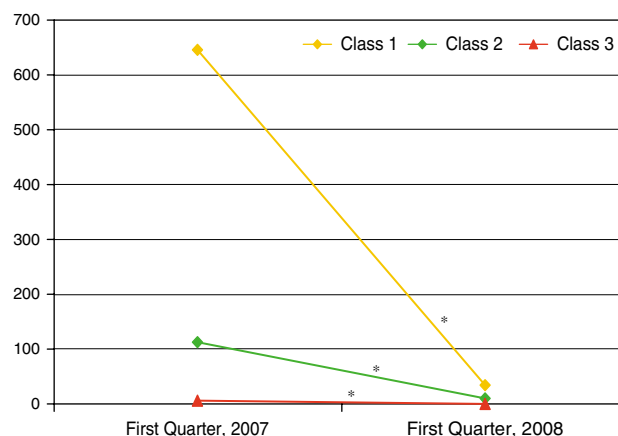
Labeling errors have been measured through the “Specimen Hard Stop Policy,” a Mayo Clinic Rochester (MCR) institutional policy dictating the arrest of a specimen within the laboratory accessioning process when a significant labeling error is detected. Such errors include wrong patient label, no label, or discrepancy between the site of origin of the specimen on the label vs. the MERGE database. Specimen labeling errors were categorized as: Class 1, only typographical errors with no potential clinical consequences; Class 2, a minor error that is unlikely to have clinical consequences, and; Class 3, a significant error that has the potential to detrimentally impact patient care. An example of a Class 1 error is a specimen taken for Barrett’s esophagus surveillance at 36–38 cm beneath the incisors. The MERGE database may say “Barrett’s esophagus, 36–38 cm” and the specimen label may say only “Barrett’s esophagus, 36–38” without “cm” on the label. An example of a Class 2 error is an endoscopy in which biopsies are taken to evaluate for *Helicobacter pylori* and the MERGE database says the biopsy locations are from the “antrum, gastric body and incisura” and the label might say only “gastric antrum and body.” In this situation, though the error was technically the wrong site, it is unlikely to result in an untoward outcome. A Class 3 error would be a completely wrong site such as the database saying “small intestine” and the label saying “esophagus” or no patient label or the wrong patient label affixed to a specimen bottle. In this situation, it is clearly possible that such a mistake could result in a negative patient outcome.

### Statistical analysis

We reviewed and categorized the number of specimen-labeling errors from the GI/CRS outpatient endoscopy unit for the first quarter of the year prior to the project initiation (2007) and the first quarter of the year 3 months after the project had been fully implemented (2008). The Fischer’s exact test was used to compare the rate of specimen bottle-labeling errors before and after the initiation of this new system.

### RESULTS

In the first 3 months of 2007, prior to the initiation of the RFID system, our endoscopy unit sent 8231 specimen bottles to our pathology laboratory for evaluation and 8539 bottles in the first 3 months of 2008, after the system was fully in place. In the first quarter of 2007 there were 765 mislabeled or unlabeled specimens. In the first quarter of 2008 there were 47 mislabeled or unlabeled specimens ( $P < 0.001$ ). Separated by classes, there were 646 (7.85%) Class 1 errors in the first quarter of 2007 and 35 (0.41%) in the first quarter of 2008 ( $P < 0.001$ ). There were 112 (1.36%) Class 2 errors in the first quarter of 2007 and 10 (0.12%) in the first quarter of 2008 ( $P < 0.001$ ). Finally, in the first quarter of 2007 there were seven (0.09%) Class 3 errors and in the first quarter of 2008, there were two (0.02%) Class 3 errors. However, with the new system in place, both Class 3 errors in the first quarter of 2008



**Figure 2.** Reduction in specimen-labeling errors by class, first quarter of 2007 vs. first quarter of 2008.

were recognized and corrected prior to the processing of the specimens in the pathology laboratory ( $P = 0.001$ ) (see **Figure 2**).

### DISCUSSION

These data confirm that the implementation of a pathology specimen labeling system that uses RFID technology, a paperless requisition process and confirmation of the correct site, correct patient by two health care providers significantly decreases specimen labeling errors in a high-volume endoscopy center. This initiative represents an important improvement in the quality of the health care delivery to our patients.

There are some limitations to our study. First, we use an electronic database for our endoscopy unit that is entered real-time during the endoscopy and was developed by and used solely within our institution. As such, our experience may not be easily replicated at other centers. We also created a classification system for specimen labeling errors. To our knowledge, there is no other similar classification system and so there is no information regarding the utility or validity of such a system. For example, it is unknown how often a Class 1, 2 or 3 error results in an untoward patient outcome.

As part of our initiative, we required that specimen labels be verified by both the performing endoscopist and the endoscopy nurse and we transitioned to a completely digital, paperless, requisition for specimens. It might be that this process alone is responsible for the improvement in specimen-labeling errors and has little to do with the RFID technology. We did find that for the most significant errors, Class 3, the RFID system helped us identify the source of pathology specimens that were sent with no labels on them, which suggests that at least in this situation, the RFID system was solely responsible for the prevention of these most serious labeling errors.

Finally, the RFID system we use is not commercially available and was specifically modified from an off-the-shelf library RFID system for our purposes. This particular system has not been evaluated in other similar health care settings. RFID technology is an emerging technology in health care and is rapidly evolving. There have been some reported concerns with RFID in general and in particular in regards to its use in the health care system (8). Most notably, RFID systems use the electromagnetic spectrum and if they are operating at the same frequencies as cell phones, TV broadcasts, GPS etc. (i.e., ultra high frequency) they are prone to electromagnetic interference. If this occurred in a health care system that relies on the technology for tracking patient activities or medication administration it could be crippling. However, the RFID system used in our center uses a frequency range that is shared only by shortwave and amateur radio transmissions (i.e., high frequency) making it less vulnerable to interference by everyday technologies. Nonetheless, our telecommunications department did perform testing on our system to identify if there was any significant electromagnetic interference and found none.

This initiative resulted in some unexpected beneficial outcomes. We found significant improvements in our workflow and staff satisfaction. For example, before implementation the burden of specimen identification and labeling belonged to the endoscopy nursing staff. That is, the endoscopy nurses would fill out the requisition form and label the specimen. This resulted in high levels of nursing staff pressure as there was a looming threat of corrective action with reduced pay and job termination when there were labeling errors or mistakes in specimen identification. With the implementation of the RFID system and the two-provider confirmation, the burden of responsibility has correctly shifted back to the performing endoscopist.

The Pathology laboratory staff has also experienced reduced frustrations given the enhanced standardized accessioning format. There are reduced needs for trouble shooting labeling discrepancies, outside of the hard stop policy, which have been measured at 3.5 min per case and accounts for 0.5 FTE of laboratory staff.

Finally, this project represents a significant advancement in using an established technology in a novel way for a quality improvement initiative in health care delivery. This initiative confirmed the notion that decreasing the “human factor” increases the precision of tracking specimens and results in a significant decrease in mistakes. The success of this project lays important groundwork for future projects using RFID and other automatic identification systems. One could imagine using these types of technologies for a variety of applications such as to track patients throughout their hospital stays and in procedural areas, to obtain specimen samples and to administer medications. We will be working to expand the use of RFID technology in our institution and will continue to report our experiences.

## CONFLICT OF INTEREST

**Guarantor of the article:** Dawn L. Francis, MD, MHS.

**Specific author contributions:** Francis is a gastroenterologist and is the Chair of Quality in the Division of Gastroenterology and Hepatology at the Mayo Clinic Rochester. She assisted in the conduction of the study, the collection of data and drafted the paper. Shalini Prabhakar is the Quality Analyst for the Division of Gastroenterology and Hepatology at the Mayo Clinic Rochester and was instrumental in the operational process of the study in regards to incorporating this project into the endoscopic practice and in collecting and analyzing the data. Sanderson is an anatomic pathologist at Mayo Clinic Rochester and is responsible for the creation of the RFID initiative, its implementation into the endoscopy practice, data collection and drafting the paper.

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## Study Highlights

### WHAT IS CURRENT KNOWLEDGE

- ✓ Many health-care institutions have problems with specimen-labeling errors in many different settings ranging from blood samples to surgical specimens.
- ✓ Taking the “human factor” out of systems that involve repetitive tasks by automation will often reduce errors.
- ✓ RFID is a rapidly evolving technology with many potential applications in the health-care sector.

### WHAT IS NEW HERE

- ✓ This is the first formal study of the use of RFID technology to limit pathology specimen labeling errors.
- ✓ The combination of RFID technology, a paperless requisition process and confirmation of the correct specimen site and correct patient by two health-care providers results in a significant decline in specimen-labeling errors in a high-volume endoscopy center.

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