
Patient Identification Error Among Prostate Needle Core Biopsy Specimens—Are We Ready for a DNA Time-Out?

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Purpose: Patient identification errors in surgical pathology often involve switches of prostate or breast needle core biopsy specimens among patients. We assessed strategies for decreasing the occurrence of these uncommon and yet potentially catastrophic events.

Materials and Methods: Root cause analyses were performed following 3 cases of patient identification error involving prostate needle core biopsy specimens.

Results: Patient identification errors in surgical pathology result from slips and lapses of automatic human action that may occur at numerous steps during pre-laboratory, laboratory and post-laboratory work flow processes.

Conclusions: Patient identification errors among prostate needle biopsies may be difficult to entirely prevent through the optimization of work flow processes. A DNA time-out, whereby DNA polymorphic microsatellite analysis is used to confirm patient identification before radiation therapy or radical surgery, may eliminate patient identification errors among needle biopsies.

Key Words: malpractice, patient identification systems, prostate, biopsy, DNA

Patient identification errors in surgical pathology are the most rapidly growing category of malpractice claims involving pathologists.^{1,2} Most of these claims involve a switch of specimens between patients and most of these errors involve prostate needle core biopsy or breast needle core biopsy specimens.² We report an analysis of surgical pathology work flow for vulnerability to identification error and suggest a novel method to eliminate these uncommon and yet potentially catastrophic events.

MATERIALS AND METHODS

Root cause analysis, a qualitative method that focuses on discovering the underlying systems that set the stage for error,³ was performed in the aftermath of the cases of prostate needle biopsy identification errors reported. These cases occurred at multiple separate private and university medical centers located in the western, midwestern and eastern United States.

Patient 1

A 51-year-old male was diagnosed with prostatic adenocarcinoma on needle biopsy and subsequently underwent radical prostatectomy. No tumor was identified in the prostatectomy specimen. Tissue blocks from the initial needle biopsy and the radical prostatectomy specimen were submitted for

DNA polymorphic microsatellite analysis.⁴ DNA analysis of the 2 tissue blocks was not consistent with identity.

Subsequently a tissue block from patient 2, who was at the urology clinic the same afternoon as patient 1, was submitted for DNA analysis. The second DNA analysis established that the tissue on which the diagnosis of prostate cancer had been established for patient 1 had in fact come from patient 2. Root cause analysis failed to determine whether the tissue switch had occurred in the pre-laboratory, laboratory or post-laboratory setting. An important contributing factor to the failure of root cause analysis was the inability to retrieve empty specimen containers to determine whether labeling errors had occurred due to a lack of storage space sufficient to retain large numbers of empty specimen containers for lengthy periods.

Patient 2

A 55-year-old male was diagnosed with prostatic adenocarcinoma on needle biopsy and subsequently underwent radical prostatectomy. No tumor was identified in the prostatectomy specimen. Review of prostate needle biopsy slides showed no tumor. Root cause analysis concluded that the pathologist had dictated a report for this patient while performing microscopic examination of slides from a different patient.

Patient 3

A 65-year-old male was diagnosed with prostatic adenocarcinoma on needle biopsy and subsequently he was referred elsewhere for radiation therapy. Review of prostate biopsy slides at the institution where radiation therapy was to be administered showed no tumor. Root cause analysis con-

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cluded that a pathologist had released a report that had been incorrectly transcribed.

RESULTS

The Appendix shows information obtained from our root cause analyses. A partial listing of surgical pathology work flow steps is presented along with the risks of identification error associated with each step. Potential error reduction strategies for each work flow step are also presented.

DISCUSSION

Most patient identification errors in surgical pathology are due to human errors, which cognitive psychologists categorize as slips, lapses (of which each is an error of automatic action) or mistakes (errors of conscious thought).⁵ Patient identification errors in surgical pathology, which may occur at numerous steps during pre-laboratory, laboratory and post-laboratory work flow processes, are usually due to slips or lapses of automatic actions and they are correspondingly difficult to entirely prevent. They do not call attention to themselves at the time of commission and they escape the notice of the operator because a problem is not perceived. They are difficult to detect before an adverse event occurs because the adverse result does not occur in temporal proximity to the error.⁶ Because the processing of surgical pathology specimens is a complex, multistep process, there are many points in the test cycle where identification errors can occur.^{6,7} For these reasons the elimination of patient identification error among prostate needle biopsies may be difficult to achieve through laboratory work flow optimization.

The elimination of patient identification error is a major goal of the patient safety movement. In efforts to prevent wrong site/procedure/person surgery the Joint Commission on Accreditation of Healthcare Organizations and other groups have recognized that a robust approach using multiple, complementary strategies would be necessary and they instituted requirements that include provision for a preoperative time-out procedure.⁸ The goal of the time-out procedure is to perform final verification of the correct patient, procedure and site through active communication among all members of the procedure team. It is consistently initiated by a designated member of the team and is done in a fail-safe mode, ie the procedure is not started until any questions or concerns are resolved.

We suggest that a DNA time-out procedure may eliminate patient identification errors among prostate needle core biopsies. The goal of the DNA time-out would be to perform final verification of correct patient identification through DNA polymorphic microsatellite analysis. To eliminate false-positive malignant diagnoses due to patient identification errors molecular analyses would be performed on malignant prostate needle biopsy specimens in conjunction with a second specimen, eg blood sample or buccal swab, collected from patients in whom cancer had been diagnosed. Definitive treatment would not be administered until any questions or concerns were resolved. Followup molecular analyses would be required to eliminate the possibility that a switching error had occurred during processing of the molecular tests and identify the second patient with whom the biopsy tissue had been switched. Analysis of benign prostate needle biopsy specimens in conjunction with a sec-

ond specimen collected from patients in whom no cancer had been diagnosed would be required to eliminate false-negative diagnoses due to patient identification errors.

Analysis of the Combined DNA Index System loci, a set of 13 microsatellites or STRs, is ideally suited to this purpose.⁹ Commercial kits for the amplification of Combined DNA Index System loci are available, testing can successfully be performed on DNA extracted from peripheral blood as well as from formalin fixed, paraffin embedded tissue biopsy specimens and the loci provide a test result with an extremely high power of discrimination (average more than 10¹²).¹⁰ The cost of the laboratory component of the DNA time-out, not including locality specific charges for overhead such as laboratory space, administration and computer support, would be approximately \$110 per specimen pair in low volume settings and potentially 25% less in high volume settings (see table).

Ours is a limited study that is intended to initiate a discussion regarding the feasibility, desirability and cost-effectiveness of a DNA time-out. To our knowledge no professional societies have taken positions on this issue. Current knowledge of how often patient identification errors occur among prostate needle biopsy specimens is fragmentary. A series of 41 men, similar to the 3 reported, whose prostatectomy specimens harbored pathological findings of no residual cancer or of minute residual cancer that prompted molecular identity testing documented that switching error had occurred in 2.4%.¹¹ This value probably represents an overestimate of the true frequency of such errors because of the increased prior probability of switching error among the cases chosen for review.

The challenging prospective studies that would be required to evaluate the true incidence of switching errors in academic and community settings are beyond the scope of the current study. Formal evaluation of the cost-effectiveness of the DNA time-out may be performed after the true incidence of switching errors has been established. The cost-effectiveness of the proposed intervention may also be addressed through appropriate sensitivity analyses. Future cost analyses would incorporate expenditures for the DNA time-out together with cost savings from the avoidance of under treatment, overtreatment, medicolegal proceedings and liability insurance premium increases. Future cost analyses may also be used to evaluate interventions proposed to decrease patient identification error through work flow optimization. In conclusion, a DNA time-out, whereby DNA polymorphic microsatellite analysis is used to confirm patient identification before radiation therapy or radical surgery, may eliminate patient identification errors among prostate needle biopsies.

Cost estimates for 1 STR analysis

Analytical Step	Cost (\$)	
	Reagent	Technologist
DNA extraction	6.77	8.50
Nucleic acid amplification	15.50	8.50
High resolution separation	6.00	8.50

Costs are presented for a single STR analysis but 2 STR analyses (1 from the initial prostate needle biopsy and 1 from the followup specimen sample) are required for each DNA time-out.

APPENDIX

Surgical Pathology Work Flow and Associated Risks of Patient Identification Error

Work Flow Step	Associated Risks of Error	Potential Error Reduction Strategies
Biopsy specimens are obtained and placed in specimen containers.	Patient is identified incorrectly during enrollment in clinic.	Wristband bracelets, bar codes and radio frequency identification tags may be assigned to patients and medical records.
Biopsy specimens are obtained and placed in specimen containers.	Tissue is placed in mislabeled container.	Specimen containers should be labeled before tissue is placed in container and should be large enough that patient identification labels may be applied prior to the lid being screwed on. Patients (or designated representatives) may sign all biopsy containers to verify that containers bearing their tissue has been correctly labeled. Specimen rejection procedures should be clarified and enforced.
Pathology requisition form is completed.	Incorrect patient identification information is entered onto requisition.	Bar codes may be assigned to specimen containers and requisition forms.
Laboratory assistant arranges requisitions on countertop.	Requisitions of same tissue type but from different patients are placed sequentially on counter.	Requisitions with like specimen types, eg prostate needle biopsies, should be separated by specimens of a different type.
Laboratory assistant writes accession numbers on the patient identification labels of each specimen container.	Incorrect accession number is written on specimen container.	Arrangement of specimen containers on counter should be checked by 2 different people. Accession numbers should be written on specimen identification labels and not on container caps/lids.
Laboratory assistant keyboards information from requisition into laboratory information system.	Laboratory assistant enters information from 1 patient into accession number given to a different patient.	Bar codes and point of care specimen container labels may be printed on prompt from clinician order entry technology. Laboratory information system information may be filled using clinician order entry technology.
Laboratory assistant enters an accession number into tissue cassette labeler.	Laboratory assistant enters an accession number from 1 patient into accession number given to a different patient.	Multicolored cassettes may be used to ensure that cases with successive accession numbers have cassettes with different colors, reducing the possibility of placing tissue from 1 patient into a cassette labeled for a different patient. Bar codes may be assigned to tissue cassettes.
Laboratory assistant places tissue cassettes in cassette racks in sequential alphanumeric order.	Laboratory assistant places cassettes out of order into cassette rack.	Multiple needle core biopsy specimens from multiple patients from prostate, breast and/or other organs sites may be received on the same day. When needle core biopsies from multiple patients are received on the same day, spots of marking ink may be applied to the tissue cassettes that will be used to embed each case. The prosector grossing the case may then mark 1 or more of the tissue threads in each cassette with ink of the color assigned to that case. The color assigned to that case is recorded on the requisition and dictated as part of the gross description
Prosector takes first specimen container, confirms patient identification on container label and opens specimen container.	Prosector takes incorrect specimen container and fails to recognize mismatch between container label and requisition form. Transcriptionist transcribes dictation intended for 1 patient into the pathology report for a different patient.	Holding trays may be used to ensure that specimen requisition forms, matching specimen containers and matching labeled cassettes move through the production process together. Prosectors may begin each dictation with "labeled with the patients name and (last 3 numbers of the medical record number)..." to reduce habituation. Voice command and recognition software may reduce transcription error.
Prosector takes tissue from specimen containers and performs dissection as necessary.	Prosector is interrupted during dissection and forgets which patient tissue on grossing bench belongs to.	Time management policies should be implemented.
Prosector places tissue samples from specimen containers into tissue cassettes.	Prosector carries over tissue from 1 case into the following case. Prosector takes incorrect cassette from cassette rack and places tissue from 1 patient into cassette labeled for another.	Additional tissue forceps may be ordered, so that a different pair of forceps is used for each case, and so each pair of forceps is cleaned prior to being used to gross another case. Forceps should be wiped and washed after each use.
Prosector places cassettes, ideally in numerical order, in a basket immersed in formalin.	Tissue from 1 cassette floats into a different cassette.	Fresh paper towels should be used for each case to ensure a noncontaminated field. Use blue sponge pads or tea bags for bloody or friable tissue in cassettes.
Histotechnologist places the plastic cassette, without any lid, labeled with accession number (with or without letter suffix) onto the embedded specimen and places it on the cooling tray to harden.	Histotechnologist places the wrong plastic cassette on the embedded specimen in the unlabeled embedding mold.	Management policies may limit histotechnologists to working on 1 cassette at a time.

(appendix continued)

APPENDIX continued

Work Flow Step	Associated Risks of Error	Potential Error Reduction Strategies
Histotechnologist cuts a ribbon of thin sections from a tissue block with a microtome and places the ribbon in a warm water bath to soften the paraffin.	Ribbons of tissue from a previous case are still floating in water bath when sections from a new case are placed into waterbath.	Management policies may limit histotechnologists to working on 1 cassette at a time.
Histotechnologist matches the number (with or without letter suffix) on the slide to the number (with or without letter suffix) on the cassette, selects the best cut portion of the ribbon in the water bath and picks the ribbon out of the water bath with the slide.	Histotechnologist uses wrong slides, ie slides labeled for a different patient, to pick up tissue ribbons from waterbath.	Bar codes may be placed on slides and cassettes.
Histotechnologist attaches preprinted adhesive labels onto matching stained slides. The preprinted labels cover the handwritten slide label.	Histotechnologist may place wrong adhesive labels on slides.	Point of care slide etchers may be used.
Pathologist matches the slides for a single case with the requisition, examines the slides under the microscope and dictates findings.	Pathologist takes incorrect slide from slide folder and dictates findings for incorrect patient.	Bar codes may be used on slides with scanners at pathologist desktop computer workstations.
Pathology transcriptionist listens to pathologist dictation and transcribes dictation into pathology laboratory information system.	Transcriptionist may transcribe dictation intended for 1 patient into the electronic record for a different patient.	Voice recognition technology may be used.
Pathologist reviews each report on pathology laboratory information system and signs out each case after verifying that the report is accurate and complete.	Pathologist, in reviewing reports, may not notice that a patient identification error has occurred in transcription.	Voice recognition technology may be used.

Abbreviations and Acronyms

STR = short tandem repeats

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