Do No Harm, Miss No Diagnosis

The Importance of Patient Safety in the Anatomic Pathology Laboratory
Patient Safety Challenges in Tissue Diagnostics
Preventable errors in healthcare

98K people die each year from medical errors

440K people die if you include medical record errors

Common errors in tissue diagnostics

- Up to 8% of patient tissue slides are contaminated.
- 1 in 1000 patient tissue slides is mislabeled.

Why do we care?
Patient 1

- 34 yr. old female
- Diagnosed with a rare cancer
- Jaw removed
- 22 reconstructive surgeries

NEVER HAD CANCER
Patient 2

- Female, mid 40's
- Double mastectomy
Hospitals Move to Cut Dangerous Lab Errors
Improved Specimen Collection And Efficiency Help Increase Accuracy of Medical Testing

By Lauren Landry

Diagnosed with a deadly breast cancer at age 44, [Patient Name] was about to lose her beauty. After four estrogen to treat breast cancer that has recurred in her liver, she was told she was about to lose her beauty. She called her friend, the oncologist who had treated her, to ask if there was anything else she could do. He explained that the only way to treat her cancer was to remove the tumor from her liver. She said, "I will not die of breast cancer, but I will die of beauty." She died of breast cancer a few weeks later.

For patients, one of the most frustrating medical errors can exist in the lab. When a diagnosis is delayed, it can lead to more serious conditions and even death. In many cases, these errors can be prevented.

New hospitals and health care providers are working to reduce errors in the lab. The goal is to make sure that testing is accurate and that patients receive the right treatment.

In the largest effort, a group of major medical associations and labs are participating in a national collaborative to reduce errors in the lab. The goal is to make sure that testing is accurate and that patients receive the right treatment.

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That’s why even one error is unacceptable!
How do these errors occur?
The journey of a tissue specimen
Diagnostic steps

- Pre-Analytical
- Analytical
- Post-Analytical
Specimen removal

- Inappropriate quality of specimen
- Incorrect place of origin
- Improper handling

Pre-Analytical: Step 1
Specimen placed in fixative

- Insufficient volume of fixative
- Inappropriate fixative type (alcohol vs saline vs formalin)
- Inappropriate fixative state (cold vs room temperature)
Treatment isn’t a one size fits all solution

It’s a targeted strategy
Treatment isn’t a one size fits all solution

It’s a targeted strategy

50% increase in the number of new cancer drugs entering clinical testing

Clinical success rates for new cancer drugs double while more enter testing. Tufts Center for the Study of Drug Development. Impact Report, 15 (May/June 2013)
“To be effective and reliable, the fixative process needs to be standardized and uniform. It is important that tissue specimens be placed in fixative immediately after their removal from the body…”

40% ERROR RATE

Commission of Inquiry on Hormone Receptor Testing
Government of Newfoundland and Labrador. Published 2009
Kinase pathway testing represents 1/3 of oncology drugs in development.
Rapid two-temperature formalin fixation

“...This new protocol preserves histomorphology and yields tissue that is compatible with an expanded set of downstream clinical and research assays, including immunohistochemistry for phosphorylated epitopes...”

Specimen placed in fixative

Pre-Analytical: Step 2

• Insufficient volume of fixative
• Inappropriate fixative type (alcohol vs saline vs formalin)
• Inappropriate fixative state (cold vs room temperature)

Better results for certain biomarkers

Chafin D, Theiss A, Roberts E, Taft J, Grogan T, Otter M. 2+2 Fixation Leads to Better Preservation of Phosphomarkers in FFPE. Poster presented at: Pre-Analytics-Symposium; 2013 Mar 20; Berlin, Germany.
Container labeled and transported to lab

- Wrong patient ID
- Incorrect labeling
- Specimen is lost

Pre-Analytical: Step 3
Container labeled and transported to lab

Pre-Analytical: Step 3

• Wrong patient ID
• Incorrect labeling
• Specimen is lost

9% ERROR RATE

“Before the RFID system was adopted, the lab utilized an entirely manual process for tracking specimens, from the collection area to the AP laboratory.”
Container is accessioned

Pre-Analytical: Step 4
"As many as 3.5% of prostate biopsy specimens were contaminated or inadvertently switched with that of another patient."

Gross Examination

- Extraneous tissue contamination
- Specimen swap/provenance complications
- Inadequate tissue selection (not representative of tumor)
“unlike other areas of a hospital the sharing of unsterilized instruments between patients is considered to be normal”
Tissue placed in cassette and processed

- Specimen swap/provenance complications
- Lack of formalin diffusion throughout tissue
- Over and under-specimen fixation

Pre-Analytical: Step 6
Embedding

• Extraneous tissue contamination
• Specimen swap/provenance complications
Microtomy

• Extraneous tissue contamination
• Specimen swap/provenance complications

Pre-Analytical: Step 8
Water bath contamination

In the 13 water baths examined...

only 1 tissue fragment was identified
H&E staining

- Extraneous tissue contamination
- Inconsistent staining
80% of cancers diagnosed from H&E alone

“All patients suspected of having cancer have H&E and that 80% cancers are diagnosed from the H&E alone.”
Contaminants in histology lab

Up to 25% of blank slides showed contamination

Tissue Floaters and Contaminants in the Histology Laboratory
Eric Platt, BS; Paul Sommer; Linda McDonald, MT, ASCP; Ana Bennett, MD; Jennifer Hunt, MD
(Arch Pathol Lab Med. 2009;133:973–978)
Can you “read through” contaminants?

Most pathologists say… Yes
Can you “read through” contaminants?

A recent study says… No
Common mitigation strategies?

Of 72 stainers analyzed… 100% were contaminated

Measurement of stainer bath contamination and evaluation of common mitigation strategies
Common mitigation strategies?

Up to 36.4% of blank detector slides contaminated

Measurement of stainer bath contamination and evaluation of common mitigation strategies
Common mitigation strategies?

Up to 3,018 tissue fragments found in representative samples of reagent bath

Measurement of stainer bath contamination and evaluation of common mitigation strategies
### Quality and safety within the lab: Chemistry

<table>
<thead>
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<th>Quality and Safety Features</th>
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<th>Today</th>
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*Analytical: Step 9*
Quality and safety within the lab: **Histology**

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Analytical: Step 9
Pathologist interpretation

Technology inadequacies to mitigate
- Reporting error
- Excessive turnaround time
- Inaccurate diagnosis
- Improper data entry
- Failure or delay in reporting critical values

Post-Analytical: Step 10
Automated reporting of positive results...

40% of notifications were missed or ignored

One error is unacceptable!
How can we avoid errors?
The Ventana Patient Safety Initiative
Our Goals

1. **Raise awareness** regarding the risks involved in current tissue diagnostics practices.

2. **Effect positive change** with regulatory bodies in the space to increase patient safety.

3. **Develop and launch technologies** that reduce or eliminate the risk of cross contamination and misidentification.
Because of the diagnostic issues that contaminants can cause, the AP laboratory has a responsibility to reduce potential for error in every way possible.

-Eric Platt, et al.

"Tissue Floaters and Contaminants in the Histology Laboratory"^2

The concern: cross contamination

In many labs today, the primary staining process is completed manually through "dipping and dunking" slides into shared reagent baths.

The potential for cross contamination presents itself at multiple points in the process:

- Tissue can detach from a slide inside the reagent bath
- Extraneous tissue floating in the reagent bath can re-attach to another patient’s slide
- On one slide, two patients’ tissue can coexist

Sometimes, cross contamination is something a pathologist can "read through" or detect on his/her own because of obvious differences in tissue structure.
Other times, the tissue fragments are too similar to tell the difference.
Members of the advisory board were compensated by Ventana for their participation in the advisory board.
Our Principles

1. All patients around the globe deserve standardized, high quality pathology services.
As patient advocates, to support accurate diagnosis and enable personalized medicine, the Ventana International Pathology Patient Safety Advisory Board identifies significant opportunities to improve patient safety by developing and implementing solutions to enhance:

- tissue preservation
- specimen/slide identification and tracking
- prevention of tissue contamination
Our Principles

We, the members of the Ventana International Pathology Patient Safety Advisory Board, find further opportunity to define standardized parameters for data collection and sharing in the assessment of these processes leading to quality measures for laboratory improvement.
Our Principles

We call upon the pathology profession to collaborate with laboratory and hospital administrative partners, clinician colleagues, and the laboratory diagnostics industry to address these opportunities to achieve excellence in patient care.
Next Steps

1. Increase awareness and broaden the dialogue among stakeholders outside the lab.
2. Establish common quality metrics with our advisers.
3. Gather real error rate data from labs.
4. Drive toward the establishment of guidelines to help prevent errors in the lab.
Improving the lives of all patients affected with cancer.
One error

...is one too many
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