



# Highs and Lows Propelled Our Anatomic Pathology Department's Journey to Transform the Culture with Lean, Six Sigma and ISO 15189

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## Wake Forest Baptist still reviewing thousands of pathology cases

POSTED → APRIL 13, 2018, BY [NC HEALTH NEWS](#)



Wake Forest Baptist Medical Center in Winston-Salem. Courtesy of NC Health News

By Mark Toszak, [North Carolina Health News](#)

Wake Forest Baptist Medical Center is reviewing more than 9,000 cases from its pathology lab, seeking to uncover any additional instances of errant cancer diagnoses.

# Immediate Jeopardy (IJ)

- “a situation in which the provider’s noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident.”
- Once a hospital or healthcare organization gets an IJ rating, it’s given a time frame to fix the deficiency. If not, CMS will terminate the facility’s Medicare and Medicaid funding.

# Timeline

- **8/1/2017 Start at WFBMC**
- **9/13/2017 assume interim chair role**
- **Risk Management becomes aware of concerns**
- **Self reporting to NC DHSR**
- **2/5/2018 first inspections**

# Index Cases

- Lumpectomy with radiation (2)
- Bilateral mastectomy



COLLEGE of AMERICAN  
PATHOLOGISTS

The College of American Pathologists recognizes

## North Carolina Baptist Hospital Inc

**Anatomic Path**

1395801-05

As a laboratory demonstrating continuous improvement in quality through participation in the 2017 CAP Surveys, and/or Anatomic Pathology Education Programs.

R. Bruce Williams, MD, FCAP  
CAP President

Rec'd 2/5/2018

# Alphabet soup of inspection agencies

ASCT, CAP, CLIA, CMS, DHSR, JC, OSHA  
(several agencies, multiple times)





**You Can't  
Make This Up**



# Work Flow

- Case identification
- Cases reviewed by external pathologist
- WFBMC pathologists review flagged cases
- Obtain additional clinical information from EMR
- 'Tumor Board'
- Medical Review Committee
- Physician Notification/Patient Notification
- Revised report issued
- Risk Management

## Clinical Leadership & Infection Control

# Arkansas VA hospital reviews 7K patients for misdiagnosis by impaired physician

[Click Here to Access The  
Infection Control Products  
to Know Database](#)

*Written by Megan Knowles* | August 21, 2018 | [Print](#) | [Email](#)

[in](#) [Share](#) Fayetteville, Ark.-based Veterans Health Care System of the Ozarks reviewed 7,482 cases for misdiagnosis after an investigation found an impaired pathologist had treated patients, [KNWA](#) reports.

[Tweet](#)

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[f](#) [Share](#) VA pathologists reviewed 2,925 of the cases, and non-VA pathologists reviewed the rest.

[G+](#)

A Veterans Health Care System of the Ozarks pathologist was found to be "impaired" in March 2016, according to Kelvin Parks, interim director of the VA medical center. The hospital immediately removed the pathologist from clinical care.

# Some Lessons Learned

- The importance of CULTURE
  - Patient comes first
  - Safety & quality
- FPPE/OPPE matter (focused/ongoing professional practice evaluation)
- Leadership...the Laboratory Director & others
- Hire the appropriate staff
- Policies & Procedures
- Validation

# **A Path to Change**

# Email From Michael Cohen:

Read  
Below:

I need your  
help



SPRING COLLECTION  
In a variety of vibrant colors

## In wake of incorrect cancer diagnoses, Wake Forest Baptist has open-ended deadline for fixing problems

By Richard Craver Winston-Salem Journal Apr 4, 2018 (3)

### Clinical Leadership & Infection Control

## Case review reveals more erroneous cancer diagnoses at Wake Forest Baptist

Written by Avla Ellison (Twitter | Google+) | April 16, 2018 | Print | Email



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## WAKE FOREST BAPTIST LAB'S PATH ERRORS TEACH LESSONS

*CMS inspection uncovered multiple serious deficiencies in histology and pathology departments*

By Joseph Burns | From the Volume XXV No. 7 – May 7, 2018 Issue



← Cleveland Clinic Lab Has Multi-year Test Utilization Success

May 7, 2018 Intelligence: Late Breaking Lab News →

**CEO SUMMARY:** For medical directors and pathologists interested in improving their labs' compliance with CLIA regulations, a report from federal and state inspectors of an inspection of the pathology lab at the Wake Forest Baptist Medical Center offers insights into what issues caught the inspectors' attention. During their visit in February, the government lab inspectors found multiple, serious diagnostic errors in the medical center's academic pathology department.



Volume XXV No. 7 – May 7, 2018

### TABLE OF CONTENTS

COMMENTARY & OPINION BY R. LEWIS DARK

# Leadership Support

- President of Health System
- Senior Vice President of Business Service
- Pathology leadership

**What do you want your lab to look like?**

- ✓ **Lean**
- ✓ **Standardization**
- ✓ **ISO15189**

**We need Lean and we need it now**



Conrad Emmerich  
Senior Vice President of Business  
Services

# Consultation Goal

## Understand the current state:

1. Cultural characteristics and challenges
2. Production bottlenecks
3. Waste and inefficiencies
4. Opportunities for improvement

Recommend efficient business transformation





# Visit at Wake Forest Pathology

Going back in time to 2005

Pathologist  
frustrations



- Lack of standardization
- Bottlenecks
- Missing patient information
- Defects corrected before sign out



# Staff Interviews

Q1. What keeps you up at night?

Q2. What would you change?

Q3. What would you improve and what would you do?



**The most common response was the lack of space, equipment, and personnel**

# Wake Forest Pathology AP Accessioning Value Stream Map

**Supplier:**  
Accessioning  
(specimens from  
CP - Clinical Labs,  
OR)

**Customer:**  
Grossing PAs/  
Residents

No accessioning  
internal data summary,  
huddle to root cause

Specimens  
waiting in CP

No Shift  
Stagger

Clinic Lean issues  
(longer term)

No feedback to Clinics  
of summarized QC  
issues weekly from  
Accessioning

All manual  
input

Specimen containers/cassettes/  
requisitions  
on cart and transport trays not  
lean



Current State (OR)

**Step 1:**  
Verify Patient  
Information  
matches labels

**Step 2:**  
Generate Accession  
number and add to  
containers (manual)

**Step 3:**  
Select part type,  
number, and color of  
cassettes (from  
specimen type)

**Step 4:**  
Print cassettes  
(accession number, part,  
number/color of cassettes)

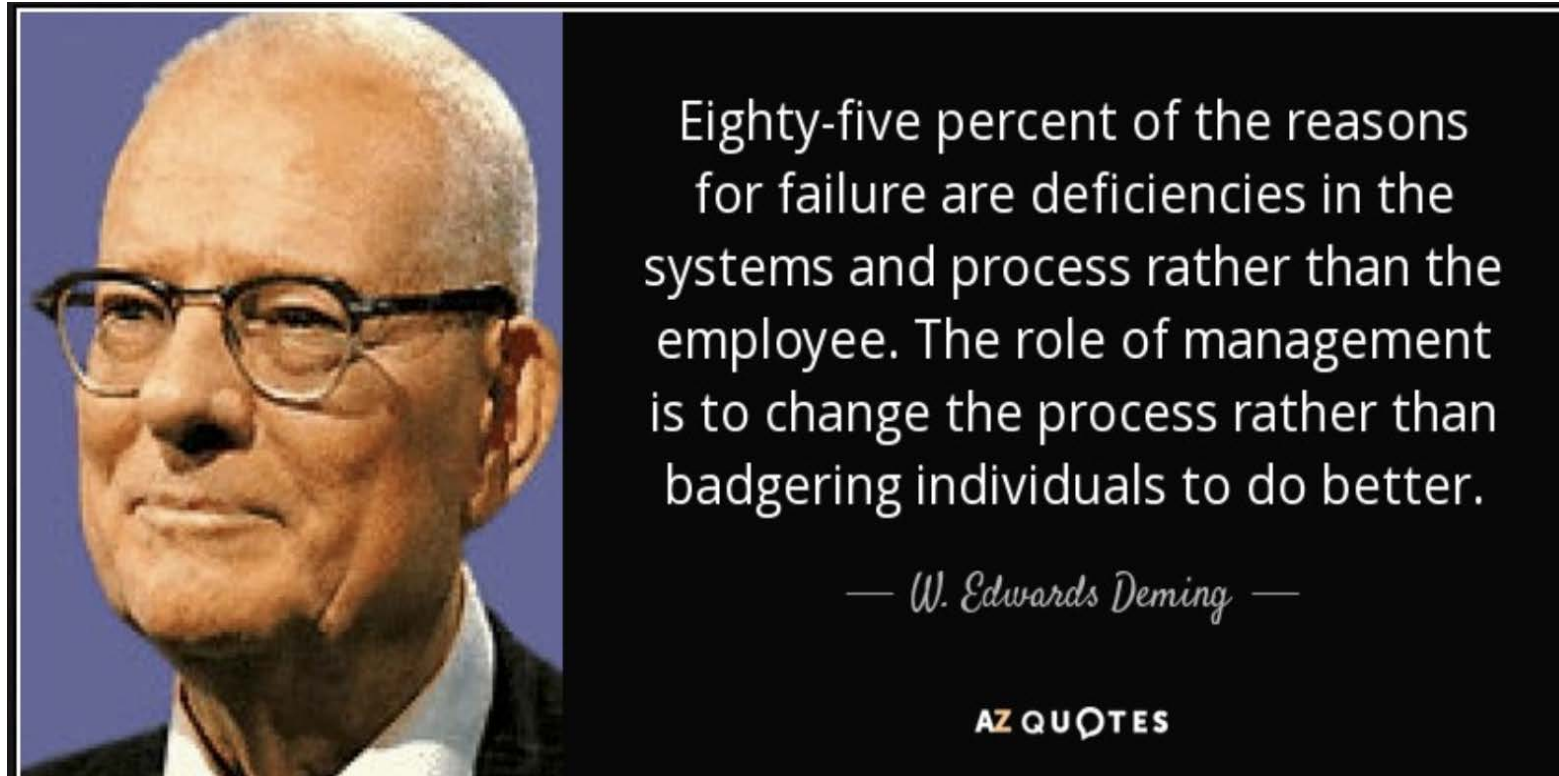
**Step 5:**  
Assemble cassettes,  
tape to specimen  
container (only when more  
than one) with  
requisitions stacked  
on top

Specimens waiting in CP (up to 12 hr. c

No requisition (1 to 5 day delay)

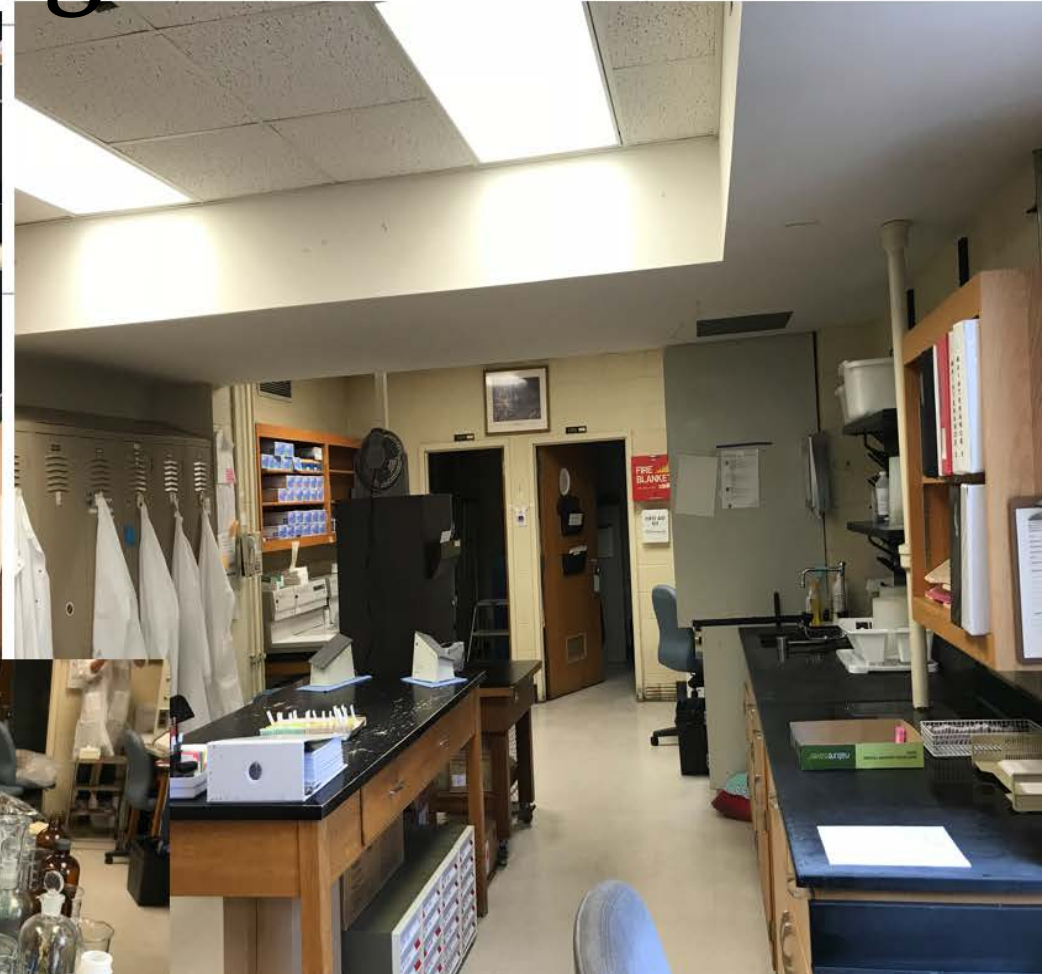
## WFBMC Pathology:

Ordinary people doing extraordinary things in a historic outdated laboratory





# First things First



- Clean and organize the anatomic pathology labs
  - 5 S workplace organization

# Culture Change

- **Transformative Leadership:** encourage, inspire and motivate employees to innovate and to create change
- **Transformation:** Change from I to Team
- **Performance Goals:** Staff goals aligned to strategic goals
- **Empowerment:** Employee participation





# The Beginnings of Lean

- Leader provided a message at the start of each training session
- Objectives were defined and assigned to all employees
- Created a structure for change
- Empowered the employees



**Anatomic Pathology Faculty, Staff, Residents**



# Improving Employee Morale

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Yi Zhou M.D., Ph.D.



# Future of Wake Forest Pathology

- Continuation of Lean Management as a system initiative
- Pathology - grass roots approach
- Lean implementation in the Clinical Labs
- Standardization initiative for incoming specimens from all clinical sites



