Understanding the True Cost of Bad Quality, Both in Your Lab and throughout Your Parent Hospital or Health Network

LINDA S. FLYNN

PRINCIPAL

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Presentation Goals

- How to identify the impact of failure?
- How lab failures expose the hospital enterprise to scrutiny?
- What happens with loss of CMS deemed status?
- How a CMS inspection differs from other accrediting agencies?
- How to avoid bad quality/failures?

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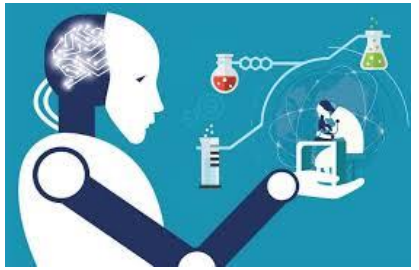
Healthcare Industry Trends

- Increasing number of hospitals "in the news" reporting quality failures
- Focus on quality, but striving for productivity (staff reductions)
- Shortage of qualified leaders
- More complicated regulations
- AO changing the inspection approach
- Increasing number of CLIA validation surveys



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Patient Mortality Rate

According to a recent study by Johns Hopkins, more than 250,000 people in the **United States die** every year because of **medical mistakes**, making it the third leading cause of **death** after heart disease and cancer. Feb 22, 2018

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What are Failures/Bad Quality?

- Unexpected adverse patient outcome as a result of process breakdown or human error
- Sentinel events that are either localized to a specific area or systemic to the enterprise
- Events that create risk to patients, employees, visitors or vendors

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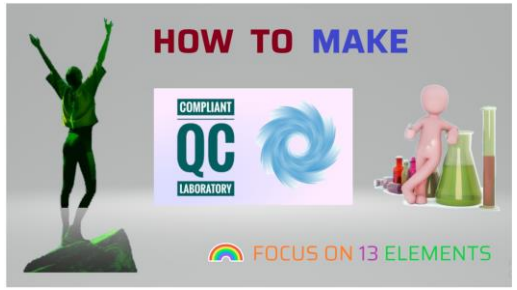
Common Lab-related Reported Failures

- Transfusion-related adverse outcome or fatality
- Unacted upon critical values
- Wrong interpretation of lab results
- Proficiency testing failures
- Specific patient complaints



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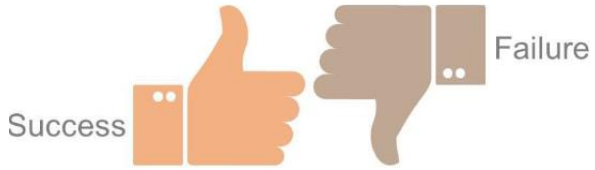
Lab Failures Aren't Always "in the Lab"

- Did nursing mis-label a specimen?
- Did nursing transfuse the wrong blood unit?
- Did nursing fail to report critical results?
- Did the provider fail to react to a critical results?



Lab can do everything "right", but the enterprise may still have a failure

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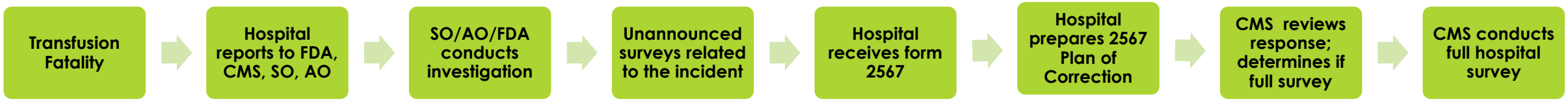
Single Event Can Compromise Enterprise - Example



- Single incident can lead to a full institution-wide survey
- Full CMS surveys will be followed by Life Safety survey
- Full CMS survey can lead to repeat surveys

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Impact of Failure – More Than the $

Media Exposure - Local, State, National

- Local newspapers
- Professional journals
- Web sites/social media
- State government web sites
- CMS-required reporting
  - Error Cause Detail
  - Plan of Correction

Deadly medical errors are less common than headlines suggest
August 3, 2019 9.28pm EDT

Local // Houston
How good is your hospital? New report rates Houston hospitals from worst to best
Peter Dawson , Chron.com / Houston Chronicle
March 7, 2019 Updated: March 11, 2019

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Whistleblowers – Increased Risk

- Once incident is public:
  - Increase in anonymous employee complaints to AO; i.e. CAP
  - Increase in patient complaints
- Enterprise scrutiny – must prove to have merit
- Onus of proof is on healthcare organization

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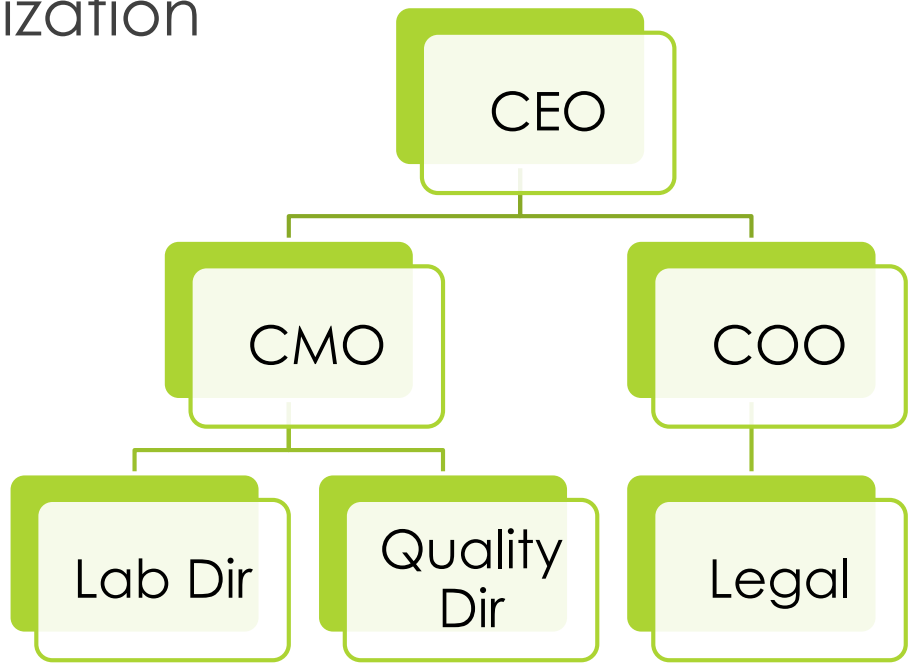
Loss of Key Internal Talent

- Occurs at all levels of a healthcare organization
  - Medical leadership and staff
  - Administrative staff – C-Suite
  - Clinical staff
- Choice or not by choice
- Increases cost of recruitment



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Leadership/Staff Time

How long can a reported single incident impact an organization?

- Nine – twelve months
- Time spent:
  - Communicate with inspection agencies
  - Participate in increased number of inspections
  - Respond to inspection citations; Form 2567
  - Steps to prevent future incidents

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Loss of Confidence – Patient/Providers

- Patient – choice of hospital in a competitive market
- Provider – recruitment of medical specialties
- Employee – increased attrition/hard to recruit
- Industry – lower bond ratings, limits access to capital

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Loss of Deemed Status

- Hospital may be moved from TJC to CMS
- Lab may be removed from CAP to CMS/CLIA
- Changes the inspection cycles, inspection type
- Costs to re-gain deemed status

The Joint Commission

COLLEGE of AMERICAN PATHOLOGISTS

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Increased Inspection Costs

- Each inspection carries a cost
  - CMS
  - FDA
  - State and Accrediting Agencies
  - Facilities/Safety

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Professional Reputation

- Senior administrators or medical directors may lose their job
- Inability to get a new position
- Loss of confidence
- Mental stress
- Personal issues

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Consultant/Legal Expenses/Retainers

- Legal counsel
  - Expertise in medical/regulatory
  - Hourly rates can exceed $500/hour
- Consultants
  - Hospital, laboratory, facilities specialists
  - Hourly rates can exceed $400/hour
- Retainers in effect throughout the incident process

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Malpractice Lawsuits

- Over 17,000 malpractice suits in US annually

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"The True Cost of Medical Malpractice Lawsuits" – Hofstra University, Maurice A. Deane School of Law

Civil Suits/Criminal Suits

State 6256.6 - Civil Suit (New)

CMS may bring suit in the appropriate U.S. District Court to enjoin continuation of any specific activity that is causing a significant hazard, or to enjoin the continued operation of the laboratory itself, including a CLIA-exempt laboratory, if CMS believes that continuation of the specific activity or laboratory operations would constitute a significant hazard to the public health.

6256.7 - Criminal Sanctions (New)

An individual who is convicted of intentionally violating any CLIA requirement may be imprisoned or fined. An intentional violation is knowing and willful noncompliance with any CLIA requirement. The RO refers suspected instances of intentional violations to the Office of Inspector General (OIG).

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Calculated Cost of Failure

- Varies significantly for each organization

Costs	Estimate	Range
Legal	$1M	$500K - $2M
Consulting/Interim	$1M	$500K - $3M
Staff Overtime	$1M	Depends on size
Recruiting	$500K	Depends on size
Sanctions	$???	Depends on size and complexity

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CMS/CLIA Inspections

How Does AO Differ from SO Inspection?

AO - CAP, TJC

- More collegial
- Volunteer inspectors from similar hospital labs
- More lenient to making "on the spot" corrections
- Uses detailed checklist with advice to meet the stated requirement
- Deficiencies checked next inspection

SO - CMS/CLIA

- Issued from state agency
- Uses career inspectors
- Inspections based upon CLIA regulations – Appendix C State Operation Manual
- Deficiencies checked 45 days after POC submittal

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What is a D-tag?

D-tags are the numbering system used to identify

- Individual requirements
- Conditional level requirements
- Based on CLIA regulations (CFR)

State Operations Manual Appendix C -Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services

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Levels of CLIA Deficiencies?

Standard

- Based upon Individual D-tags
- Similar to CAP requirement numbers
- Easiest to resolve

Condition

- Several D-tags "rolled up" to warrant a condition
- Crosses over multiple areas of lab (systemic)
- May impact reimbursement

Immediate Jeopardy

- High risk to patient safety
- Can require stoppage of testing for a specific analyte
- Can close part or entire laboratory
- Impacts reimbursement

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Higher Levels of Scrutiny

What is a CMS condition level deficiency?

Condition level when non-compliance represents a severe or critical health or safety breach. ... A full **CMS** survey will follow to review the facility for compliance with all Conditions of Participation

What is immediate jeopardy in CMS?

"Immediate Jeopardy means 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.

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Removal of Immediate Jeopardy

Removal of IJ Removal

In CLIA labs - requires the removal of past, present, and future jeopardy. Ceased testing by the laboratory removes the present and future IJ, but does not address past IJ. The laboratory must address how patients were affected, or likely affected, by the deficient practice which triggered IJ prior to its removal (i.e., past jeopardy)

Must do Patient Look-back

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Termination Notices

Regulations for providers require CMS to notify the public of Medicare terminations prior to date of the termination. All notices of termination for facilities will be posted for three months on the public website.

- Arkansas: De Queen Medical Center - 05/02/2019 [PDF, 192KB]
- California: Central Valley Specialty Hospital - 04/09/2019 [PDF, 139KB]
- California: Hacienda HealthCare - 06/20/2019 [PDF, 73KB]
- Colorado: Kindred Hospital Denver South - 05/23/2019 [PDF, 66KB]
- Florida: Golden Glades Nursing and Rehabilitation Center - 04/30/2019

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Responding to a CMS/CLIA Inspection

CMS Form 2567

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
		A. BUILDING _____ B. WING _____	

NAME OF FACILITY	STREET ADDRESS, CITY, STATE, ZIP CODE

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY SHOULD BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERRED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. *(See reverse for further instructions.)* Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE

FORM CMS-2567 (02/99) Previous Versions Obsolete

If continuation sheet Page _____ of _____

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CMS/CLIA Resources

State Operations Manual Appendix C – Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services

- 418 page document
- Released in 2004, **last updated in September 2019**
- Provides detailed information on how inspection should occur
- List mandatory citation events
- Lists all Standards and Conditions by D-tag

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Link to Latest CLIA Release

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO-19-20-CLIA.pdf

Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-19-20-CLIA **DATE: September 26, 2019**

TO: State Survey Agency Directors

FROM: Director Quality, Safety & Oversight Group

SUBJECT: Revisions to State Operations Manual (SOM), Chapter 6 – Special Procedures for Laboratories

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Committing to a Culture of Quality

How Can Lab Contribute?

- Communicate, educate, and train staff (lab, nursing, physicians, other providers, etc.)
- Create Evidence Binders to ensure that regulatory requirements are addressed (and staff know where to find evidence)
- Take responsibility for pre-analytical and post-analytical processes – get out of the lab!
- Know how to conduct a root cause analysis
- Be inspection-ready

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