LabGuide 71

Incident Management: Developing a Plan

INTRODUCTION

In light of the Institute of Medicine studies focusing on reducing medical errors, COLA developed Accreditation criterion QA 20 to focus the laboratory's attention on 1.) those activities that produce clinically significant consequences, and 2.) negative outcomes that may occur as a result of laboratory processes.

The intent of this criterion is to assist laboratories as they expand their efforts to focus on incident management, as an extension of their on-going Quality Assessment (QA) Program. QA 20 promotes the identification and resolution of all types of laboratory related errors.

QA 20 is a two-part question (See Table 1). To be in compliance, the laboratory must be able to answer "yes" to both questions.

In addition, the laboratory must address incidents that occur as a result of:

- non-compliance with expected laboratory policies and procedures resulting in a significant negative impact on patient care or the safety of patients or staff; and
- errors, accidents, or unexpected events that have caused, or have the potential to cause, death or serious injury to patients or staff.

By "address" we mean that the laboratory must develop policies and procedures to identify, evaluate, manage, and correct these occurrences. The laboratory must then follow through by implementing those policies and procedures when needed. Part of the action includes documenting the use of the Incident Management Plan to investigate and determine the root (true) cause of the incident and to prevent future occurrences.

Table 1
COLA QA 20

QA 20.1
Has the laboratory developed and implemented written policy and procedures to identify, evaluate, manage, and correct and incidents resulting from non-compliance with stated policies and procedures?

QA 20.2
Does the laboratory have procedures for the identification, evaluation, management, and correction of any unexpected event which has caused, or has the potential to cause, death or serious injury to patients or laboratory staff?

Definitions Section

Incident: an event that results in or has the potential to result in death or serious injury to patients or laboratory staff.

Incident Management Plan: written policies and procedures that describe the actions to be taken in response to an incident. The plan is a supplement to the overall laboratory Quality Assessment (QA) Plan.

Systemic Non-compliance: a condition where recurring non-compliance with the stated policies and procedures in several phases of related laboratory activities has the potential to seriously impact laboratory testing.

Root Cause Analysis: steps taken to investigate the incident and determine the true or underlying cause of the occurrence.

Incidents

In this context, an incident is an event that results in, or has the potential to result in, death or serious injury for patients or staff. Your routine QA reviews may identify areas of non-compliance or problems that need to be resolved, but the impact does not create the potential for death or serious injury. Those types of quality assessment issues still need correction, but they would not be considered incidents.

As stated previously, the intent of this criterion is to focus attention on the most serious consequences and outcomes that may occur as a result of laboratory activities.

Systemic Non-Compliance

Systemic non-compliance with stated policies and procedures has the potential to cause errors in all phases of laboratory testing. Systemic non-compliance is observed when several laboratory systems (for example, quality control performance, calibration, reagent use, and adherence to testing procedures) are

Requirements for good laboratory practice and COLA Laboratory Accreditation programs are underlined.

not performing as expected. The combination of repetitive problems in these testing systems results in an intertwining condition that is considered to be systemic non-compliance.

When these systems combine to produce errors that have a significant impact on the accuracy and reliability of test results, and they lead to negative outcomes for patients, they become incidents. For example, repeated failure to recognize that reagents are out of date and that the controls are out-of-range for a critical assay, such as prothrombin time or digoxin, could impact the accuracy of patient results. Treatment decisions based on inaccurate results could have disastrous results for the patient.

When Errors Become Incidents

The following are examples of when laboratory errors can lead to incidents:

- Analytical processes, such as incorrect test results, leading to misdiagnosis or improper treatment.
- Safety issues, such as accidents or improper disposal of contaminated waste, causing injury to staff or patients.
- Test tracking errors, such as reporting a result on the wrong patient or mislabeling of a specimen, leading to disastrous results.
- Recurring complaints, such as patients who report excessive pain, burning, numbness or severe hematoma from phlebotomy, indicating an injury from the procedure.

HOW QA CAN HELP IDENTIFY INCIDENTS

An effective QA process can be instrumental in recognizing potential incidents. Even though they occur infrequently, incidents that result in, or have the potential to result in, death or serious injury to patients or staff must be anticipated and carefully evaluated when they occur to eliminate the chance for recurrences.

Learn to expect the unexpected. Have policies and procedures in place to address how staff should respond and specific actions to take when faced with an incident. The laboratory can identify, learn from and prevent incidents from occurring by developing and implementing an Incident Management Plan that is an extension of the overall QA Plan.

DEVELOPING AN INCIDENT MANAGEMENT PLAN

The laboratory must have written polices and procedures that describe the actions to be taken in response to an incident. These policies and procedures must be followed whenever an incident occurs. Develop forms to document incidents when they occur and retain all documentation regarding incidents. The laboratory must ensure that the following processes and their underlying elements are addressed by its incident management policies and procedures:

- **Identification of Incidents**
  Define in general terms what would be considered an incident in your laboratory. Describe how you would determine if an event /error constitutes an incident. Further clarify by listing the types of incidents that could possibly occur, even if they seem unlikely. Remember, the key here is to expect the unexpected. Don't dismiss a potential incident by thinking, "It couldn't happen here." Collect and verify the facts when an incident is identified. Be specific and include dates and details.
- **Evaluation of the Incident to Determine the Root Cause**
  State the steps you will take to investigate the incident and determine the root cause. (See Written Investigation Procedure on next page.) Each incident should be reviewed on a case-by-case basis and discussed promptly so that the problem can be addressed immediately. Identify who will be responsible for each step in the process. Determinations will need to be made about the medical significance of the incident and whether testing should be stopped.
- **Correction of Incidents**
  Develop a corrective action plan and implement the corrections. Some actions might include writing or revising policies and retraining staff. If testing was stopped, verify an effective resolution before resuming patient testing.
- **Management of Incidents**
  Ensure that personnel involved in the investigation of incidents have the necessary technical knowledge and authority to evaluate and resolve the incident. Determine the medical significance of the incident by evaluating the impact on clinical diagnosis and treatment of patients. Consider the effect on results:
  - prior to the identification of the incident (past)
  - during the investigation, correction, and resolution of contributing factors (present)
  - once the incident is resolved and a follow-up of corrections is performed (future).

Establish procedures for recall, re-testing, re-evaluation, and release of affected results. Identify and notify affected parties (patients, staff, referring physicians, and regulatory agencies).

- **Documentation of Incidents**
  Develop a form specifically for documenting the investigation of incidents and potential incidents. Be sure to document each step of the process, including the incident description, evaluation, correction, notifications, reporting, and resolution of the incident. Describe your plan for prevention of future incidents. Include the initials of those involved in each step and the date each step is performed and completed. The final step should include the signature of the Laboratory Director indicating approval of the overall process.

STAFF TRAINING

Ensure each employee receives training on Incident Management. Include guidance on how to recognize potential incidents and how to report them. Make sure all staff have read and understand the laboratory incident management policies and procedures.

WRITTEN INVESTIGATION PROCEDURE

A written investigation procedure for evaluating incidents might include the following steps:

1. Immediately report the incident to the Laboratory Director. Retain any materials that could be involved in the incident.
2. The Laboratory Director will determine if any outside agency reporting requirements apply to the incident (e.g., a transfusion related fatality must be reported to the FDA and the laboratory's accrediting agency within five days). In addition, the ordering physician will be notified of the situation.
3. The director or designated manager or supervisor will perform the evaluation and investigation of the incident. Unlike a routine QA review, the serious nature of the incident makes it important that someone with appropriate technical knowledge and experience evaluates the incident. This individual must have the authority to recommend changes in policy, procedure, and process to effectively resolve and prevent a recurrence of the incident.
4. The designated incident investigator will analyze the impact of the incident during the time prior to the initial report of the incident, during the investigation of the incident, and for future testing. It may be prudent to suspend testing or make other treatment decisions until the true cause has been determined and corrected. There may be a need to notify affected patients and re-evaluate their medical care.
5. The incident investigator will perform a root cause analysis (See Table 2). Ask "what happened, when did it happen, who was involved, where did it happen, how did it happen, and why did it happen." Continue to ask "why" at least five times to discover the true underlying cause.
6. The incident investigator documents the facts, findings, and conclusion, and the report is given to the laboratory director for review and signature.
7. Based upon the findings, the laboratory director determines the appropriate corrective actions that will be taken to prevent a recurrence of the incident. A timeline for implementation of corrective actions should be established. The laboratory should document the date that each corrective action step is completed.
8. The investigation findings and outcome are communicated to the staff. Complete any necessary policy or procedure revisions or retraining of personnel.
9. Within a pre-determined amount of time, the laboratory director or designee will perform a follow-up evaluation of the corrective actions to ensure that they were effective.

Requirements for good laboratory practice and COLA Laboratory Accreditation programs are underlined.

Table 2
ROOT CAUSE ANALYSIS

A simple "root cause analysis" is performed by repeatedly asking "why." Continuing to ask "why" at least five times will dig progressively deeper to reach the true underlying cause of the situation. During the analysis, many contributing factors may be uncovered while striving to identify the true cause of the incident.

A root cause analysis is the investigation into the causal factors that lead to the outcome of an event. Causal factors include equipment problems, control problems, environmental factors or human errors. Often a root cause analysis simply identifies these causal factors and makes recommendations to correct them. This may prevent the same event from recurring, but if the "true" cause is not addressed, the event is likely to recur in the future.

Root causes are the weaknesses in the system that allow the causal factors to occur. Systems are the processes an organization has in place to ensure patient safety and to encourage personnel to take the appropriate actions and discourage them from taking inappropriate actions. The focus should be on the systems and processes, not individual performance. Examples include written procedures and instructions, maintenance and calibration, and standards and policies.

The root cause analysis could be performed by mapping or flowcharting the events and circumstances surrounding the event. All causal factors, barriers, and system issues are identified with an indication of how each impacted the incident. Once all of the facts of the case are known and the root cause is identified, a corrective action plan is developed and implemented. The final step is to follow-up within a determined amount of time to ensure that the corrective action plan is effective. All steps in the analysis must be thorough and credible.

Resources:

1. QuIC: Understanding Medical Errors and Patient Safety Report of the Quality Interagency Coordinated Task Force, 2000 (www.quic.gov/report/errors6.pdf).
2. "Sentinel Events Workbook – Health & Disability Sector to Learn from Mistakes", Gillian Bohm, Senior Advisor Quality Improvement, Ministry of Health, New Zealand, September 2001 (www.moh.govt.nz - under publications).
3. Statewide Sentinel Event Reporting, Department of Human Services, Australia, 2002-2003 (http://clinicalrisk.health.vic.gov.au/sentin.htm).
4. Agency for Healthcare Research & Quality (AHRQ) - Medical Errors & Patient Safety (www.ahcpr.gov/qual/errorsix.htm).

Incident Management Investigation Report Form

Facility Information: *(Complete all information)*

Facility Name _____ Laboratory Director _____
Address _____ Phone _____
_____ Fax Number _____
City, State, ZIP _____ _____

Person Reporting Event: _____ **Date:** _____

Reporting Information: *(Complete all information)*

Date of Incident		**Number of Persons Affected**	
Incident:		Patient(s):	
Time:		Staff:	
		Other(s):	

Event Type: *(Check all appropriate event types)*

Death related to treatment		Death related to medication error based on lab result	
Injury due to treatment		Failure in safety procedure	
Mis-identification of specimen		Hemolytic blood transfusion reaction	
Mis-identification of report		Procedures involving the wrong patient	
Misdiagnosis based on laboratory report		Procedures involving the wrong body part	
Instruments or materials retained in the patient following a procedure		Recurring complaints about phlebotomy or specimen collection	
Physical attack or abduction		Other catastrophic event *(describe)*	
Instrument & methodology failures			

Patient/Staff Information of Person Affected by Event: *(Complete all information)*

Name: Last _____ First _____ Middle _____
D.O.B: _____ Patient Identification Number: _____
Treatment Date: _____ Current status: *(circle)* Discharged Hospitalized Deceased Unknown

Person Responsible for Investigation of Event: _____
Date of Investigation Report: _____
Regulatory Agency to be Notified of Incident: _____
Date of Notification: _____
Ordering Physician to be Notified of Incident: _____
Date of Notification: _____
Person to be Notified of Incident: _____
Date of Notification:

Brief Summary of Incident: *What happened and how was it handled? What area is affected?*

Incident Management Investigation Report Form

Report of Investigation Findings: *What did the true cause investigation and analysis find?*

a. What factors are involved in the event? (e.g., Human, Equipment, Controllable Environment, Uncontrollable External factors)

b. What systems or processes underlie these factors? (e.g., Human resource issues, Information Management issues, Emergency & Failure-Mode responses, Leadership issues, Uncontrollable factors)

Patient Outcomes:

Correction Action to be Taken as a Result of Investigation Findings: *What will you do to prevent reoccurrence of the incident?*

Action Plan

Root Cause / Opportunity for Improvement	Action to Reduce Reoccurrence	Person(s) Responsible for Implementation	Date of Implementation	Result Expected

Person Responsible for Reviewing the Findings: _____
Date of Review of Report: _____
Person Responsible for Communicating the Findings to Staff: _____
Date of Communication Report: _____

Follow-Up Actions to be Taken: *(Check all appropriate actions)*

	No action required		Development of new policy / procedure		Cease patient testing
	Communication of findings to staff		Revision of policy / procedure		Refer patient testing
	Staff training and in-service		Staff competency assessment		Resume patient testing
	Corrective action monitoring				
	Corrective action follow-up and review by (date):				
	Findings inconclusive -- monitor process. Review by (date):				
	Information is incomplete; follow-up to be completed by (date):				

Notes/Comments:

Report Submitted by: _____ **Date:** _____
Report Approved by: _____ **Date:** _____

Incident Management Investigation Report Form

Facility Information: *(Complete all information)*

Facility Name	*State Circle Testing, Inc*	Laboratory Director	*Dr. John Smith*
Address	*State Circle*	Phone	*555-555-1212*
		Fax Number	*555-555-1213*
City, State, ZIP	*Statesville, XX, 99999*		

Person Reporting Event: *Sue Tech* **Date:** *01/11/2010*

Reporting Information: *(Complete all information)*

Date of Incident		Number of Persons Affected	
Incident:	*01/04/2010*	Patient(s):	*4*
Time:	*unknown*	Staff:	
		Other(s):	

Event Type: *(Check all appropriate event types)*

Death related to treatment		Death related to medication error based on lab result	
Injury due to treatment		Failure in safety procedure	
Mis-identification of specimen	✓	Hemolytic blood transfusion reaction	
Mis-identification of report		Procedures involving the wrong patient	
Misdiagnosis based on laboratory report		Procedures involving the wrong body part	
Instruments or materials retained in the patient following a procedure		Recurring complaints about phlebotomy or specimen collection	
Physical attack or abduction		Other catastrophic event *(describe)*	
Instrument & methodology failures			

Patient/Staff Information of Person Affected by Event: *(Complete all information)*

Name: Last *See attached list of all Pts* First _____ Middle _____

D.O.B: *See attached list of all Pts* Patient Identification Number: _____

Treatment Date: *01/04/2010* Current status: *(circle)* Discharged Hospitalized Deceased Unknown

Person Responsible for Investigation of Event:	*Ellen Jonson, Phlebotomy Supervisor*
Date of Investigation Report:	*01/11/2010*
Regulatory Agency to be Notified of Incident:	*Not applicable*
Date of Notification:	
Ordering Physician to be Notified of Incident:	*Yes, see attached list.*
Date of Notification:	*01/12/2010*
Person to be Notified of Incident:	*See attached list*
Date of Notification:	*01/12/2010*

Brief Summary of Incident: *What happened and how was it handled? What area is affected?*

On 01/04/2010, four oncology specimens were mislabeled. The lab receptionist usually verifies orders and inputs patients into the LIS, which then generates lab labels. She called in sick and Sue Tech, the phlebotomist, then had to perform these duties in addition to her own. To keep the patients' wait time to a minimum, Sue decided to draw the patients prior to inputting the data into the LIS. She hand-labeled the tubes of the 25 patients she drew, with their first initial and last name. All patients were drawn for CBCs, prior to chemotherapy. After the morning rush was over, Sue entered the orders into the LIS. Then, she put the appropriate labels on the specimen tubes. However, M. Frankel was switched with M. Franklin and D. Compton was switched with D. Hampton. The physicians questioned the discrepancies in the patients' results from the last draw. All four patients had to return to the clinic for a redraw.

Incident Management Investigation Report Form

Report of Investigation Findings: *What did the true cause investigation and analysis find?*

a. What factors are involved in the event? (e.g., Human, Equipment, Controllable Environment, Uncontrollable External factors)

1. *The phlebotomist took a short cut in labeling patients' specimens and did not use two unique identifiers.*
2. *The phlebotomist was rushed when attaching computer generated labels to specimen tubes and did not allow sufficient time to properly identify tubes.*
3. *The phlebotomist failed to communicate with supervisor that additional help was needed.*

b. What systems or processes underlie these factors? (e.g., Human resource issues, Information Management issues, Emergency & Failure-Mode responses, Leadership issues, Uncontrollable factors)

1. *Review of specimen collection procedure did not clearly state the need to use two patient identifiers.*
2. *Review of QA occurrence log identified six previous events in the past three months, where specimen labeling issues had been identified by testing staff, but no follow up or corrective actions were performed.*

Patient Outcomes: *Four patients had to be called back to the clinic to be redrawn and administration of chemotherapy was delayed for 24 hours for each patient.*

Correction Action to be Taken as a Result of Investigation Findings: *What will you do to prevent reoccurrence of the incident?*

Recommend Corrective Action:

1. *Verify that all phlebotomy staff understand labeling procedure.*
2. *Rewrite and clarify procedure for identifying patients and labeling of patient samples.*
3. *Provide in-service to all staff*
4. *Implement a process to ensure all occurrences have corrective actions performed and follow-up reviews completed.*

Action Plan

Root Cause / Opportunity for Improvement	Action to Reduce Reoccurrence	Person(s) Responsible for Implementation	Date of Implementation	Result Expected
Staff not labeling specimens with two identifiers, which did not allow for accurate identification of the patients' samples.	*Revise procedure, retrain staff, and ensure all occurrences are fully investigated and corrective actions taken.*	*Laboratory Director*	*April 1, 2010*	*100% compliance with revised communication policy*

Person Responsible for Reviewing the Findings: _____

Date of Review of Report: _____

Person Responsible for Communicating the Findings to Staff: _____

Date of Communication Report: _____

Follow-Up Actions to be Taken: *(Check all appropriate actions)*

	No action required	✓	Development of new policy / procedure		Cease patient testing
	Communication of findings to staff	✓	Revision of policy / procedure		Refer patient testing
✓	Staff training and in-service	✓	Staff competency assessment		Resume patient testing
	Corrective action monitoring				
✓	Corrective action follow-up and review by (date): *5/15/10*				
	Findings inconclusive -- monitor process. Review by (date):				
	Information is incomplete; follow-up to be completed by (date):				

Notes/Comments:

Report Submitted by: *Ellen Johnson, Phlebotomy Supervisor* **Date:** *01/11/2010*

Report Approved by: *Fred Jones, Hematology Supervisor* **Date:** *01/11/2010*

Attach additional information if necessary, including all applicable laboratory reports. -