

Content Sheet 14-1: Overview of Occurrence Management

Role in quality management systems

Occurrence management, or dealing with laboratory errors, is important in assuring good service from the laboratory. It is one of the twelve quality essentials, and must be addressed in laboratory quality management.

This module will describe and explain basic elements that are essential for developing an effective occurrence management program.



Overview of the process

Occurrence management is a central part of continual improvement. It is the process by which errors, or near errors (also called near misses) are identified and handled. The goal of an occurrence management program is to correct the errors in either testing or communication that result from an event, and to change the process so that the error is unlikely to happen again.

Well managed laboratories will also review their systems and detect process problems that could possibly cause error at some time in the future, allowing for prevention of these errors.

Definition

An occurrence is any event that has a negative impact on an organization, including its personnel, the product of the organization, equipment, or the environment in which it operates. All such events must be addressed in an occurrence management program.

Content Sheet 14-2: Sources and Consequences of Laboratory Error

Causes of laboratory error

Some of the common causes of error in the laboratory are easily identifiable, and are also readily correctable.

For example, some errors may occur because staff are unclear about who is responsible for carrying out a particular task, so it may remain undone. To prevent these types of errors, individual responsibilities must be clearly defined and communicated.

Other errors occur when procedures are not written or followed, and staff are not adequately trained. Written procedures serve as a guide for all staff, and help to assure that everyone knows what to do. It is essential to ensure that these written procedures are followed correctly. Staff need to be trained on how to conduct the procedures, and if this training is neglected errors can result.



There are many other sources of error, in addition to these which are frequently observed. While they often occur during pre- and post-examination processes, errors can occur throughout the testing process.

Two useful studies for understanding sources of laboratory errors:

¹Retrospective data collection found Australian pathology laboratories had a transcription-error rate of up to 39% and an error rate of up to 26% for analytical results.

²A report from the College of American Pathologists in collaboration with the CDC Outcomes Working Group describes error stratification in the working process for clinical laboratories. In more than 88 000 defects, 41% were observed in the preexamination phase of testing, 55% in the post-examination phase, and only 4% in the examination phase.

Pre-examination errors

Some examples of pre-examination errors that are frequently seen include:

- collecting the wrong sample;
- mislabeling or failing to label the sample;
- storing the sample incorrectly prior to testing, so that the sample deteriorates;
- transporting the sample under conditions that damage the sample or that endanger staff and public safety;
- damaging the reagents or test kits by storing them improperly.

¹ Khoury M, Burnett L, Mark A Mackay MA. Error rates in Australian chemical pathology laboratories. *Medical Journal of Australia*. 1996; 165: 128-130. Available at URL: <http://www.mja.com.au/public/issues/aug5/khoury/khoury.html>

² Bonini P, Plebani M, Ceriotti F, Rubboli F. Errors in laboratory medicine. *Clinical Chemistry*; 2002;48:691-698. Available at URL: <http://www.clinchem.org/cgi/content/full/48/5/691> See Table 1 in this reference.

Examination errors

A list of common errors that occur during the testing process include:

- failing to follow an established algorithm; as an example, for HIV testing;
- reporting of results when the quality control material tests out of range;
- incorrect measuring of the sample or reagents; usually these are dilution or pipetting errors;
- using reagents that have been improperly stored, or after their expiration date.

Post-examination errors

Many of the common laboratory errors occur following the testing of the sample, and some of these may be more difficult to detect. Common examples of these kinds of errors include:

- making a transcription error when preparing the report;
- producing a report that is illegible, usually caused by poor handwriting, but sometimes by damage to the report form;
- sending the report to the wrong location, which often results in complete loss of the report;
- failing to send the report.

Consequences of laboratory error

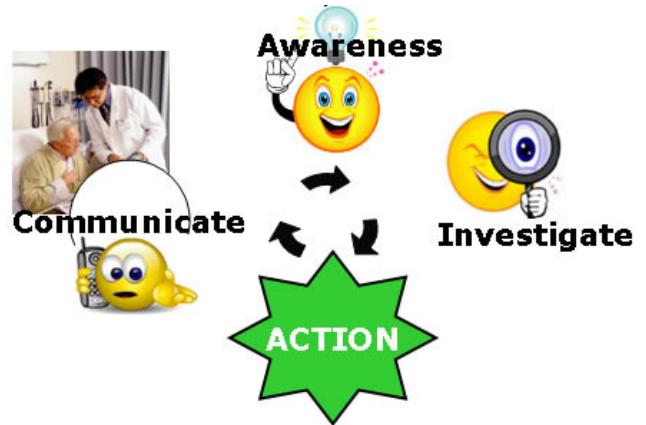
The laboratory is a critical partner in all health systems, and it must perform its functions well in order to help ensure good outcomes of health programs and interventions. A failure in the laboratory role can have significant effect, producing:

- inadequate or inappropriate patient care;
- inappropriate public health action;
- undetected communicable disease outbreaks;
- wasting of resources;
- death of an individual.

Content Sheet 14-3: Investigation of Occurrences

Occurrence cycle includes investigation

A cycle of events reflects the process of occurrence management. When occurrences are found, they must all be investigated to find the causes of the problem. The investigation will help to identify the actions needed to correct the problem and to ensure that it does not occur again. All necessary communication must take place, including informing any health care providers whose clients are affected.



Detecting occurrences

Occurrences are detected through a variety of investigative techniques. Monitoring of complaints and satisfaction surveys will yield much information. Once the laboratory establishes and monitors quality indicators, deficits will be noted. The tools of external assessment, such as proficiency testing, external quality assessment, accreditation and certification processes, will be very useful in occurrence management. A very valuable tool is the use of the internal audit, which can be performed at any time in the laboratory. The laboratory's process improvement efforts will identify opportunities for improvement.



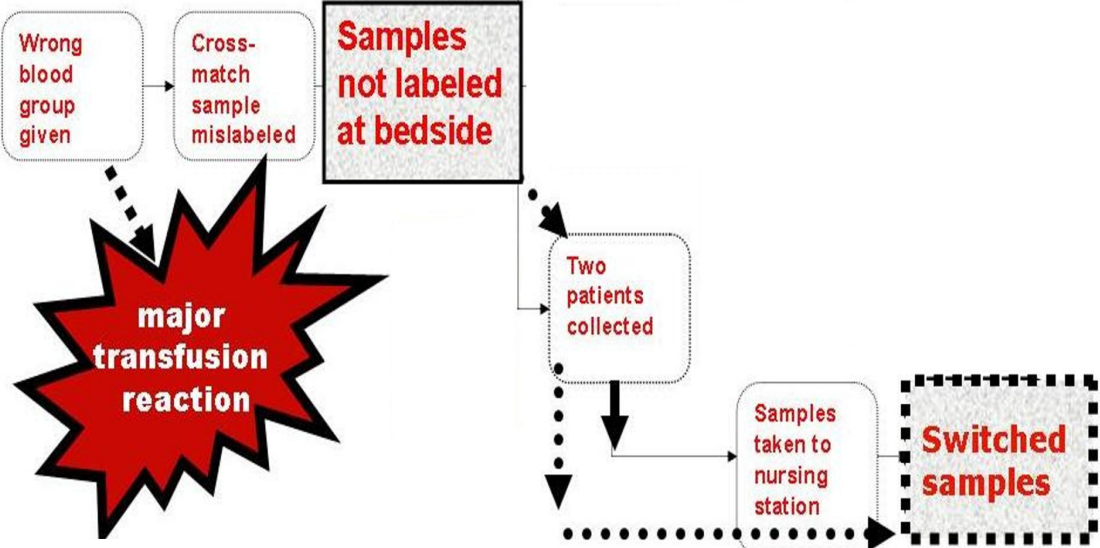
It is the responsibility of management to review all the information that results from use of these tools, to look for underlying patterns and potential causes for persistent or repeated error.

Investigation involves gathering complete and detailed information about events that led to a problem, and a thorough analysis to determine all the factors that contributed to the problem occurrence.

Root cause analysis

The most aggressive and complete approach to addressing occurrences is to seek the root cause of the problem. This is more than just a thorough examination, but is a planned and organized approach toward finding not only the superficial causes of a problem, but also the deeper, or core problems. With some occurrences, they are likely to occur and reoccur until such time as the true root causes are discovered, and addressed.

The example shown illustrates how root cause analysis was used to determine how a major blood transfusion reaction could occur.



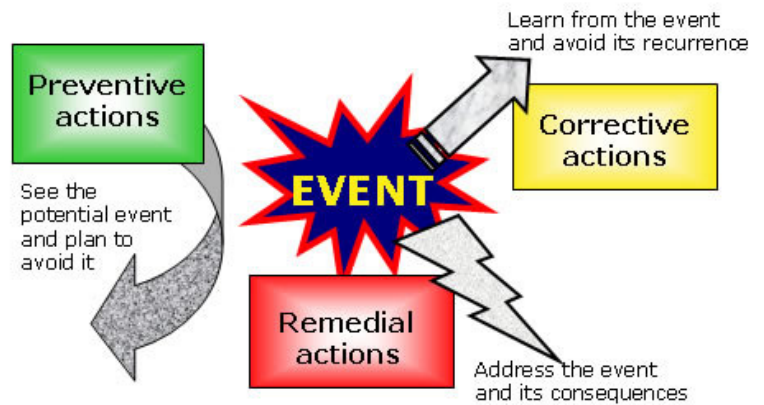
Content Sheet 14-4: Rectifying and Managing Occurrences

Correction of occurrences

As a reminder, an occurrence is any event that has a negative impact on an organization, which includes personnel, product, equipment, or the environment.

There are several levels of action that may be undertaken to rectify occurrences, including the following.

- Preventive actions involve a planned and organized evaluation of processes and procedures to identify potential error points, so action can be taken to prevent the errors from ever occurring. Preventive actions require planning and team participation.
- Remedial action, or remediation, is the fixing of any consequences that result from an error. For example, if an erroneous result has been reported, it is essential to immediately notify all persons concerned about this error, and to provide the correct result.
- Corrective actions address the cause of the error. If a test was done incorrectly, resulting in an incorrect result, corrective actions sort out why the test was not performed properly, and steps are taken so that the error does not happen again. As an example, a piece of equipment may have been malfunctioning, and the corrective actions would be to recalibrate, repair, or otherwise address the equipment problem.



Occurrence management process

The management process for dealing with errors or occurrences involves several steps. The laboratory should develop a system for prompt investigation of every laboratory problem and error.

1. Establish a process to detect all problems, using the tools that are available. Remember that problems may go undetected unless there is an active system for looking for them.
2. Keep a log of all problem events that records the error, any investigation activities, and any actions taken.
3. Investigate the causes of any problem that is detected, and carefully analyze the information that is available.

4. Take the necessary action—remedial and corrective, and if the problem is detected before the error actually occurs, preventive action.
5. Monitor and observe for any recurrence of the original problem, keeping in mind that there may be a systemic problem.
6. Provide information to all those who need it, and to those who are affected by the error.

Responsibilities The responsibility for monitoring for occurrence belongs to everyone in the laboratory. It is important, however, that someone be designated as the person responsible for marshalling the energies and activities of all staff into an effective management process. In many instances, this is the responsibility of the laboratory director, or laboratory manager, or the quality manager.

Content Sheet 14-5: Summary

Summary

Occurrence management is an integral component of laboratory quality management. It establishes the methods for finding errors and preventing them from occurring again, and also seeks to identify potential errors and prevent them from happening.

The laboratory should employ an active process for occurrence management and take a positive approach. Make an effort to detect problems as early as possible, and then take immediate remedial and corrective action. Be proactive, and see opportunities to identify potential error, thus preventing an occurrence. And finally, keep good records of all problems, investigations, and actions taken.

Key messages

The difference between a quality-managed laboratory and laboratories with no system in place is that the quality laboratory detects the problem, investigates, and takes actions.