

Procedure to Evaluate Aspects of Clinical Laboratory Services Total Testing Process that Impact Patient Safety

Step #1: Determine Areas of Risk

From the list of Patient Safety Indicators, identify those that pose the greatest risk of harm to patients in your organization.

Identifying the frequency an event occurs in the context of the number of processes performed provides a base-line to compare the effects of interventions implemented for improvement. And it allows each laboratory to compare their laboratory with other laboratories using the same indicators.

Sources to consider for identifying potential harm include: patient safety alerts (national and institutional); review of the published clinical laboratory science literature; your facility's patient safety officer and/or risk management department; phone calls received from providers, nurses, patients; incident reports; and reports of problems from laboratory personnel.

When reviewing events or incident reports, it is important to consider the contributing factors that may affect the situation(s) that occurred. It is also valuable to review data that indicates who was involved in the event, such as by laboratory or non-laboratory personnel, and where the event occurred, such as floor or department. Answer the who, what, where, when, why and how questions with respect to each error or area of risk. This will be important information to consider to understand the root cause of how errors are occurring prior to developing an intervention to resolve the process error.

Step #2: Data Collection

Based on the results of your risk analysis in step 1, select a few of the Patient Safety Indicators, either all in one phase or spread across all three phases of the Total Testing Process. In addition to selecting indicators that represent the three phases of the Total Testing Process, it is also important that the indicators represent the entire scope of testing services (e.g. hematology, chemistry, microbiology, etc.) and spectrum of practice sites (hospital, clinic, outpatient centers). It is important to be selective with the number of indicators monitored. Monitoring too many will be time consuming and ineffective, and monitoring too few may misrepresent the error rate for the laboratory.

Examples of data collection sources include: laboratory information system, hospital information system, event management system, and manual data collection sheets.

Step #3: Determining the Denominator to Calculate the Error Rate

It is critical that a denominator used to calculate error rates is standardized for each patient safety indicator. Converting the absolute number of errors that occur into an error rate is important to compare each laboratory's error rate among other departments in the institution and among other laboratory's and to establish benchmarks. Converting the number of errors to a rate equalizes that frequency based upon patient volume. It allows comparisons to be made among small and large laboratories and it also allows a specific laboratory to monitor its rate over time and as the testing volume changes.

The ASCLS Patient Safety Committee recommends using a patient-centered error rate measurement using the following criteria:

Non-hospital setting (such as public health laboratory, outpatient laboratory, independent laboratory, physician's office laboratory) calculate error rate on an 'event per patient encounter' basis. The denominator for calculating error rates will be the '*number of patient encounters*' for the period evaluated.

Hospital setting (hospitals, skilled nursing facilities) will calculate error rate per adjusted patient day, which takes into account inpatient and outpatient services provided. The denominator for calculating error rates will be '*adjusted patient days*'.

[For very small numbers of errors and large number of adjusted patient days, we recommend using a calculation of '*per 1000 patient days*', so that the error rate can be graphed as a whole number.]

Step #4: Capture data.

Data may be captured by:

Week

Month

Quarter

Year

The period of time that data is collected is dependent upon how often the process error occurs. For an extremely rare event, using the year time frame may be appropriate, whereas something that occurs more frequently, a daily, weekly or monthly time frame would be more appropriate.

Use a mechanism to tabulate collected data, such as a spreadsheet or a database that has the ability for data to be represented as graphs (run charts), bar graphs, pie charts, or other visual representation of the error. These tools are often helpful when sharing this information. Displaying data visually is a valuable tool to use prior to developing an intervention to resolve the process error.

Step #5: Data analysis.

Examine the data using quality or process improvement techniques such as the 5 "whys", and answer the "who, what, where, when, why and how" questions surrounding the process error. Involve individuals who perform the processes and other stakeholders in the process in identifying the root cause of the process error. Contact the quality improvement or process improvement department in your organization for assistance on how to use improvement techniques.

Questions to consider when analyzing data:

Is this rate of errors acceptable?

What do these data mean?

Is the error rate increasing or decreasing? How are the data trending?

Have there been any reports of patient harm as a result of these events?

Were there any near-misses?

Were there any 'never events'?

Step #6: Design an intervention.

Once all the circumstances surrounding the event/error under investigation are understood, an intervention to mitigate the situation may be designed. It is best to only consider one change in a process at a time, in order to determine the effect of that intervention. Prior to implementing the intervention, convene a pilot—or a small study for a short period of time to validate the new process, followed by comparing the data pre and post intervention.

It is critical that an identical measurement tool is used to measure the process prior to, during and post-intervention. Using the same measurement methods before and during the intervention is crucial for determining the effect of the intervention on the error rate.

Step #7: Follow-up

When the error rates for the selected Patient Safety Indicators are at acceptable levels, examine other patient safety indicators. Once an error rate for an Indicator is in an acceptable range, it may be monitored periodically or as a spot check.