EDUCATIONAL COMMENTARY – PREVENTING PRE-ANALYTIC LABORATORY ERRORS

Learning Objectives
Upon completion of this exercise, you should be able to:

- discuss 4 common sources of errors in the pre-analytic phase of the testing process.
- list and explain 5 strategies to reduce pre-analytic errors.
- discuss 2 sources of pre-analytic errors in testing proficiency samples.

The process of testing a specimen begins when the clinician decides to order a test and ends when he or she interprets and acts upon the result, or in transfusion medicine, when the patient is transfused with a blood product. This broad view of the testing process recognizes 3 phases: (1) the pre-analytic phase, which consists of all activities leading up to actual analysis of the specimen; (2) the analytic phase, which consists of all activities involved in performing the test; and (3) the post-analytic phase, which consists of all activities that occur after the specimen is tested. Most mistakes happen either before or after the specimen is analyzed, and only a minority of laboratory errors occur in the analytic phase, according to Bonini and colleagues and Plebani. Errors in the pre-analytic phase are most frequent, accounting for 46% to 68% of total laboratory errors.

Pre-Analytic Activities and Sources of Error
Pre-analytic steps occur both inside and outside the laboratory and are performed by both laboratory and nonlaboratory personnel. This stage begins outside the laboratory when the clinician decides to order a test. Subsequent steps include completing the requisition, identifying the patient, collecting the sample, labeling and preparing the sample for shipment, and transporting the sample to the laboratory. If the sample cannot be shipped immediately, it must be properly stored until the courier transports it to the laboratory. After the specimen arrives in the laboratory, it must be logged in, centrifuged, aliquotted, labeled, pipetted, diluted, sorted into batches, or otherwise prepared for analysis. Errors can occur in each of these steps.

The most common sources of error in the pre-analytic phase are inappropriate test requests, order entry errors, patient or specimen identification errors, and mistakes in evaluating specimen adequacy. Plebani reported that mistakes in evaluating specimen adequacy occur most often, with more than 60% of pre-analytic errors involving inadequate quantity or unacceptable quality of specimen. Causes of unacceptable quality include collection in the wrong container, improper collection procedure, and improper storage or transportation techniques.

Silverstein noted that another frequent cause of pre-analytical errors is the decision by the clinician to order an inappropriate test. Studies have estimated the percentages of inappropriate test requests at...
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11% to 70% for general chemistry and hematology tests, 5% to 95% for urinalysis and microbiology tests, and 17% to 55% for cardiac enzymes and thyroid tests (Silverstein).

Order entry errors and misidentification of either the patient or the specimen comprise most of the remaining errors. In a study by Valenstein and Meier, 4.8% of outpatient laboratory requisitions contained at least one mistake. These included discrepancies between tests ordered and tests transcribed, discrepancies in patient or physician identification, duplicate ordering, and incorrect test priority. Renner and colleagues’ study of errors on patient armbands found a group average error rate of 5.5%, and 10% of participants had error rates of more than 10%. Misidentification of the specimen can occur outside the laboratory when it is collected or prepared for shipment or inside the laboratory when it is aliquoted for multiple tests.

Strategies To Prevent Errors

A comprehensive plan to prevent pre-analytic errors incorporates 5 interrelated steps:

1. Develop clear written policies and procedures.
2. Provide ample education and training.
3. Integrate automation and information management.
5. Foster interdepartmental cooperation.

Written procedures should clearly explain how to positively identify a patient, collect and label a specimen, and subsequently transport and prepare the specimen for analysis. For each test, specimen collection instructions should include detailed information about the required quantity, proper collection container, storage and transportation conditions, and patient preparation procedures. Equally important, factors that render the specimen unacceptable should also be noted. Finally, written policies should explain how to resolve issues such as improper identification of the patient or specimen and what to do when unacceptable specimens are submitted for testing.

To ensure that written policies and procedures are consistently followed, people who perform pre-analytic activities must understand not only what the proper procedures are but also why these steps are important and how failure to correctly follow instructions can cause serious errors. This requires ongoing training, beginning in the new employee orientation period and continuing in annual proficiency and competency assessments. Also, because many pre-analytic steps are often performed by nonlaboratory personnel, the laboratory’s client relations program should include efforts to educate customers about proper collection procedures and appropriate ordering practices.
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Modern technologies such as robotics and information management systems can also help reduce errors. Robotics can automate some pre-analytic steps and thereby reduce the number of people involved in the pre-analytic phase, and barcodes can simplify specimen routing and tracking. Integrating robotics with information management can further simplify the process and thus reduce potential sources of error. For example, a computer system that simplifies test ordering for the clinician (enabling him or her to directly order a test) eliminates the need for a second person to transcribe the order.

The results of efforts to reduce errors must be monitored in order to assess how well these actions have succeeded. Quality indicators that focus on specific problems should be used for assessment. Examples of possible quality indicators include requisition errors, armband errors, storage or transportation errors, and specimen suitability issues such as hemolysis, clotting, or insufficient quantity.

Finally, the laboratory must foster interdepartmental cooperation. Even though many pre-analytic activities are performed by nonlaboratory personnel, the laboratory cannot dismiss mistakes made by others as “not our problem.” On the contrary, the laboratory must own this issue and lead efforts to reduce errors wherever they are made. This can be done by improving communication, using technology, and expanding training activities to include nonlaboratory personnel. Also, because interdepartmental cooperation is crucial to avoiding errors, improving the pre-analytic process is an excellent subject for interdepartmental quality improvement projects.

Pre-Analytic Errors in Proficiency Testing
As is the case with testing patient specimens, many unacceptable proficiency test results are caused by mistakes made before the sample is analyzed. With proficiency test samples, most pre-analytic errors fall into 2 categories: (1) program enrollment errors and (2) sample handling errors.

Just as ordering the correct test is an important pre-analytic step for a patient, enrollment in the correct program is critical for a successful proficiency test performance. Different analyzers and methods require different types of proficiency samples, so using the wrong sample type can cause unacceptable results. For example, many types of proficiency samples are available for the numerous hematology instruments on the market. If your laboratory uses a 3-part differential Sysmex instrument (Sysmex America, Mendelien, IL), you will need a different set of samples than a laboratory that uses a 5-part differential Coulter instrument (Beckman Coulter, Fullerton, CA). When enrolling in a proficiency-testing program, choose a program that includes the correct sample type for your method.

Specimen handling errors include improper storage, incorrect reconstitution, and testing the wrong sample. When specimens arrive, immediately confirm that they are in acceptable condition and then store them according to the proficiency test provider's instructions. When you are ready to test the
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specimens, follow the provider’s instructions for reconstituting the samples, and test them within the specified time frame. To avoid testing the wrong sample, always match the proficiency sample identifications to those listed on the testing instructions and result forms. Pay particular attention to similar tests, because these may not all use the same sample. For example, even though total creatine kinase (CK), CK-MB, troponin I, and myoglobin are all cardiac markers, they may not all be tested with the same proficiency sample. Similarly, quantitative and qualitative human chorionic gonadotropin (hCG) testing may require different samples. Finally, be sure to review the instructions supplied by the proficiency test provider for every test event. Samples and testing instructions can change from one event to the next, or your method may have special instructions.

Conclusion

Pre-analytic mistakes are a major cause of both erroneous patient test results and unacceptable proficiency test results. Consequently, improving performance in the pre-analytic phase of the testing process is crucial to reducing the number of laboratory errors. Even though pre-analytic mistakes are often made by non-laboratory personnel, ultimately the laboratory is responsible for the quality of its test results and must therefore lead efforts to improve performance.

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**References and Suggested Reading**


