Laboratory Errors and Patient Safety (WG-LEPS), with the goal of reducing laboratory medicine-associated errors. The WG-LEPS’s most promising initiative has been establishing standardized quality indicators (QIs) to help labs monitor all three phases of testing.

QIs measure how well the laboratory meets the needs and requirements of users and the quality of all operational processes. Monitoring the total number of samples lost or not received normalized to the total number of samples received is an example of a QI for the pre-analytical phase. Adopting QIs to track and improve performance is essential: what a laboratory does not measure, it cannot improve. Only by monitoring the performance of the TTP can labs reliably identify and manage these potential variations.

**Sources of Pre-analytical Variability**

There are four general categories of pre-analytical variability, including: test ordering, patient preparation, specimen collection, and specimen processing, transportation, and storage (5). In this article, we discuss for each category the sources of variation, potential solutions, and appropriate QIs.

**Test ordering**

Test ordering, the first step of the pre-analytical process, is often referred to as the pre-pre-analytical phase. Ordering the wrong test not only is wasteful but also potentially harmful to patients. Providers order inappropriate tests for a variety of reasons, including confusion over tests with similar names (such as 25-hydroxyvitamin D versus 1,25-dihydroxyvitamin D), unnecessary duplicate orders, transcription errors during order entry, and misinterpreted verbal orders, which occur when physicians do not place test orders themselves.

To deal with problems in this phase of testing, labs must engage hospital staff to promote appropriate test utilization. This is typically done through a laboratory formulary committee or test utilization committee that draws from hospital-wide resources and influences physicians’ test ordering behavior. Institutions lacking the resources or structure to set up a formulary committee should focus on areas that will have the biggest impact, such as monitoring expensive sendouts and duplicate orders. Labs must ensure that such efforts are data driven and closely monitored with QIs that can track inappropriate test orders, duplicate orders, and errors in test input (Table 1).

**Patient preparation**

Patient preparation is one of the most challenging among the pre-analytical phases because it encompasses variables that typically occur before the individual arrives for his or her sample collection. Patient preparation factors include:

**Diet**

Food ingestion is a significant source of pre-analytical variability. This effect varies based on the analyte and the time between meal ingestion and blood collection. For example, glucose and triglycerides significantly increase after meals with high carbohydrates and fat, respectively. An overnight fasting period of 10 to 14 hours prior to blood collection is optimal for minimizing variations. However, some meals may have longer-lasting effects and particular foods should be prohibited before performing certain tests. For example, bananas are high in serotonin and can affect 5-hydroxyindoleacetic acid excretion testing. Caffeine, alcohol, vegetarianism, malnutrition, and starvation are also known to have a significant impact on commonly measured analytes. Communicating these requirements to patients is important to ensure appropriate preparation for testing and has been recognized in ISO 15189:2012.

**Posture/exercise**

A change from lying to standing can cause within 10 minutes an average 9% elevation in serum concentrations of proteins or protein-bound constituents. This occurs because