# Chapter 11
# Detection of Pre-Analytical Laboratory Testing Errors: Leads and Lessons for Patient Safety

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## ABSTRACT

*A Few years later, after the publication of 'To Err is Human: building a Safer Health System', patient safety became the major concern of the medical services and for the public. The clinical laboratory is not completely empty of errors, and these errors may affect the patient's health and the health care service. Evidence from studies indicate that a large percentage of laboratory errors occur in the pre-analytical and post-analytical phases. Based on reliable data, laboratories that established ongoing quality monitoring system have low percentage of errors. Most of laboratory errors are attributed to ineffective systems and less attributed to the individual malpractice, thus the laboratory quality improvement programs should focus more on the system in a holistic manner. This chapter aims to explore the critical issues that underpin laboratory errors and in particular the pre-analytical errors and provides some recommendations of ways to overcome such critical domains.*

## INTRODUCTION

The Institute of Medicine's report (IOM's) 1999, *To Err is Human: Building a Safer Health System*, about medical errors in the United States (U.S), was a driver for the creation of a national agenda to address massive costs in terms of life lost, injury, and the financial burden of medical care required as the result of clinical mistakes, and ultimately the ever increasing burden of medical indemnity. Widespread curiosity about the consequences of medical errors emerged in 1999 when the Institute of Medicine unexpectedly reported that medical errors accounted for up to 98,000 deaths in US hospitals each year. One of the outcomes of the magnitude of these deaths was that they exceeded the annual deaths as the

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results of car accidents, breast cancer, or Acquired Immunodeficiency Syndrome (AIDS), although preventative measures had been highlighted for several years. The IOM report estimated that medical errors cost the U.S. $17-$29 billion a year, and called for huge changes to the health-care system to improve patient safety (Kohn, Corrigan & Donaldson, 1999). The IOM followed their 1999 report with several other reports, including a 2001 report titled, *Crossing the Quality Chasm: A New Health System for the 21st Century*. This report was prepared by the IOM committee on quality of the health care in the United States. As the result of rapid changes, the country's health care delivery system has developed better ability to translate knowledge into practice and applies new technology for patient safety. Crossing the *Quality Chasm* concentrates more extensively on how the health system care can be transformed and improves the delivery of care. Towards this goal, the committee presented several strategies and action plans for the next years (Institute of Medicine, 2001).

## Clinical Decision-Making and Patient Laboratory Results Reporting

The dependence of clinical decision-making and patient management processes on laboratory test reporting must emulate laboratory medicine to set higher quality standards. Timely and accurate laboratory results are the main steps toward effective diagnosis and treatment of patients. Like other medical diagnostic areas, laboratory diagnostic is often delivered under an environment of strenuous pressure with complex technologies and innovation, so that it cannot be considered completely safe (Plebian, 2006). Laboratory practice can be divided into 3 phases; (pre-analytical, analytical, and post-analytical). All the 3 phases of the testing process can be focused on individually for improving quality. In fact, laboratory errors can be defined as "failure of a planned action to be completed as intended, or use of a wrong plan to achieve an aim, occurring at any part of the laboratory cycle, from ordering examinations to reporting results and appropriately interpreting and reacting to them "(International Organization for Standardization, 2005).

Manual results reporting is time consuming with large human error. The computerized system reduces errors and improving patient safety and outcomes. The importance of information system in improving reliability and security of result reporting is widely recognized. Reference range of diseases and medical conditions are important benchmarks for clinical interpretation of laboratory test values. Using the wrong reference range may affect the results interpretation that leads to physicians making errors in their decision-making (Plebian, 2006). This indicates that interpretation provided by laboratory professional with insufficient expertise can be crucial and spotlight the requirement for improvement in standards of interpretation. A study conducted in accident and emergency department to evaluate the delay in clinicians' obtaining emergency biochemistry test results identified unusual events that indicate partial usage of laboratory information system, and 45% of urgent laboratory results have not been accessed (Kilpatrick & Holding, 2001). Sometimes the results released by laboratory may not contain all the needed information or it may contain information considered by clinicians not relevant. However, it has been highlighted that the introduction of new and complex tests might increase the complexity of medical management; this consequently may influence the interpretation of new laboratory tests (Plebian, 2006).

The researcher Lippi and his colleagues published that the errors of total testing process ranges from 0.1% to 3.0% (Lippi, Plebani &Šimundić, 2010). Plebani&Carraro published a paper that described the distribution of mistakes was pre-analytical 68.2%, analytical 13.3% and post-analytical 18.5% (Plebani &Carraro, 1997). In their study on laboratory errors, Plebani and Carraro found that laboratory error rates declined over the 10 years of 1996 to 2006 was 0.47% and 0.33% respectively (Plebani &Carraro, 1997) (Carraro & Plebani, 2007). The decline in the trends of errors rates has been seen more specific