Application of Failure Modes and Effects Analysis (FMEA) During the Pre-analytical Phase in a Greek Biochemistry Laboratory

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ABSTRACT

It is well known that the results from clinical laboratories support diagnosis, prognosis and patient treatment. Thus, test results must be relevant, accurate and reliable for patient care. Despite all the automation, errors that are classified as pre-analytical, analytical and post-analytical, are still present. International bibliographic data estimates that approximately 62.0% of the errors made in clinical laboratories are due to errors during the pre-analytical stage. The effect of the pre-analytical errors on the laboratory results has consequences that in many cases can lead to reduction of laboratory quality. In this study, the authors run a failure modes and effects analysis (FMEA) to analyze potential failure risks within the pre-analytical phase, in order to classify them according to severity and likelihood, based on the experience. In the present article, the authors performed an FMEA analysis of the pre-analytical phase of the testing process of a biochemistry laboratory.

KEYWORDS

Biochemistry, FMEA, Pre-Analytica, Risk Assessment

INTRODUCTION

Clinical laboratories produce test results that support diagnosis, prognosis and patient treatment. Test results must be relevant, accurate and reliable for patient care. Laboratory testing of patient samples, beginning from test order to the final interpretation of results by the clinicians, is a complex process. Every step in the total testing process must be correctly performed, thus ensuring valuable decision making and effective patient care. Clinical laboratories have always been forerunners in pursuing quality in their analytical processes, and the practices of quality assessment programs have been a routine in laboratory diagnostics. Automation innovations have also contributed to a significant improvement in the field of laboratory science, but despite all the automation, errors, which can translate to inappropriate patients care decisions, still prevail. These errors are classified as pre-analytical, analytical, and post-analytical. For a patient-centered approach, there is the need to assure that every step of the total testing process is correctly performed, that eventual weaknesses are recognized, and that corrective and preventive actions are designed and implemented (Hammerling,
The risk is defined as the probability of an error occurring in the laboratory that could lead to harm (Njoroge & Nichols, 2014). It can be estimated through a combination of the probability of occurrence of harm, the severity of that harm and the detectability, which is the probability of detecting and preventing errors before they leave the laboratory and reach the patients (Chiozza & Ponzetti, 2009; Njoroge & Nichols, 2014). Risk management is a practice developed in industrial or manufacturer settings. According to ISO 14971, risk management is described as the systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating, controlling, and monitoring risk (International Organization for Standardization, 2007). Recently published guidelines, such as the CLSI document EP18-A2 and the CLSI guideline EP23-A, introduce risk management to the clinical laboratory (Clinical and Laboratory Standards Institute, 2009, 2011). Moreover, the approach to risk reduction has been incorporated into the international standard on Medical Laboratories: Requirements for Quality and Competence (ISO 15189:2012), according to which clinical laboratory staff must identify unwanted events and incidents and adopt improvements systematically, in order to reduce or eliminate risks and minimize consequences to patient care (International Organization for Standardization, 2012; Mourtzikou & Stamouli, 2017; Mourtzikou, Stamouli, & Athanasiadi, 2013; Mourtzikou, Stamouli, Athanasiadi, & Marasidi, 2015; Pouliakis, Athanasiadi, et al., 2014; Pouliakis, Margari, et al., 2014; Vavoulidis et al., 2016a, 2016b, 2016c, 2016d).

Failure modes and effects analysis (FMEA) is a quality tool which identifies potential sources of failure and determines how such failures affect the operation of a system. FMEA, which is considered as a bottom-up approach, involves discovering possible sources of failure, determining the probability and consequences of each failure, and outlining control measures to detect and eliminate such failures (Jiang, Jiang, Ding, & Liu, 2015; Mendes et al., 2013).

The pre-analytical phase of the testing process includes all the procedures before the start of laboratory testing and measurements. Many of these procedures are performed outside the laboratory area, by non-laboratory professionals and thus without direct supervision by the laboratory staff. According to the literature, the majority of the laboratory errors (46%–68%) occur during the pre-analytical phase, including inappropriate test request, wrong order entry, patient or specimen misidentification, sample collected from infusion route, sample collection errors, inappropriate container, wrong handling, storage, or sample transportation, errors in sorting and routing, pour-off, aliquoting, pipetting, labelling, or centrifugation time or speed (Flegar-Mestric et al., 2017; Gimenez-Marín, Rivas-Ruiz, Perez-Hidalgo Mdél, & Molina-Mendoza, 2014; Lippi, Baird, et al., 2017; Simundic et al., 2015; Simundic, Cornes, Grankvist, Lippi, & Nybo, 2014).

Pre-analytical phase is of utmost importance because laboratory results from inappropriate blood specimens are inconsistent and do not allow proper treatment nor monitoring of the patient. Moreover, they lead to increased medical costs, when tests have to be repeated, or patients are misdiagnosed (Flegar-Mestric et al., 2017; Gimenez-Marín et al., 2014; Rana, Naing, & Bothman, 2014). In this study, we performed an FMEA analysis of the pre-analytical phase of the testing process in the biochemistry laboratory of a hospital belonging to the public sector. The laboratory performs more than 4000 tests daily in serum, urine, cerebrospinal fluid and other biological specimens. Each pre-analytical procedure was examined in detail in order to identify possible failure points and control processes that can be implemented to detect and prevent errors. All constituents of the pre-analytical phase were considered in the evaluation of possible failures. FMEA analysis was divided into five subgroups: referral form production, sample collection, sample transportation, sample centrifugation and sample preservation.
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