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Application of failure mode and effects analysis in a clinical chemistry laboratory

Yuanyuan Jiang, Hongmin Jiang *, Siyi Ding, Qing Liu

Department of Clinical Laboratory, Second Xiangya Hospital, Central South University, Changsha, PR China

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ABSTRACT

Background: Timely delivery of correct results has long been considered as the goal of quality management in clinical laboratory. With increasing workload as well as complexities of laboratory testing and patient care, the traditional technical adopted like internal quality control (IQC) and external quality assessment (EQA) may not enough to cope with quality management problems for clinical laboratories. We applied failure mode and effects analysis (FMEA), a proactive tool, to reduce errors associated with the process beginning with sample collection and ending with a test report in a clinical chemistry laboratory. Our main objection was to investigate the feasibility of FMEA in a real-world situation, namely the working environment of hospital.
Methods: A team of 8 people (3 laboratory workers, 2 couriers, 2 nurses, and 1 physician) from different departments who were involved in the testing process were recruited and trained. Their main responsibility was to analyze and score all possible clinical chemistry laboratory failures based on three aspects: the severity of the outcome (S), the likeliness of occurrence (O), and the probability of being detected (D). These three parameters were multiplied to calculate risk priority numbers (RPNs), which were used to prioritize remedial measures. Failure modes with RPN ≥ 200 were deemed as high risk, meaning that they needed immediate corrective action. After modifications that were put, we compared the resulting RPN with the previous one.
Results: A total of 33 failure modes were identified. Many of the failure modes, including the one with the highest RPN (specimen hemolysis) appeared in the pre-analytic phase, whereas no high-risk failure modes (RPN ≥ 200) were found during the analytic phase. High-priority risks were "sample hemolysis" (RPN, 336), "sample delivery delay" (RPN, 225), "sample volume error" (RPN, 210), "failure to release results in a timely manner" (RPN, 210), and "failure to identify or report critical results" (RPN, 200). The corrective measures that we took allowed a decrease in the RPN, especially for the high-priority risks. The maximum reduction was approximately 70%, as observed for the failure mode "sample hemolysis".
Conclusions: FMEA can effectively reduce errors in clinical chemistry laboratories.

1. Introduction

Laboratory testing plays an indispensable role in health care, as 80–90% of all diagnoses are made on the basis of laboratory test results [1]. The entire testing process is a complex and multi-sector cooperative activity. First, specimens are collected by a nurse and delivered to the laboratory by a courier. Second, the clinical pathologist uses the specimen as a surrogate for the patient to perform the test and returns the results to the requesting physician. Finally, the patient is diagnosed or treated according to the physician's judgment, which is informed by the test results [2]. It is clear that any failure in this series of events may result in delayed or misinformed health care, with the potential for great financial or physical costs to patients. Over the past few decades, many strategies have been employed to reduce mistakes, such as application of internal quality control (IQC) and external quality assessment (EQA) [3]. Such measures focus mainly on monitoring instrumentation failures in the analytic phase, and they only address errors that have already been made. However, as illustrated by many publications, laboratory-related errors occurring in the pre- and post-analytic phases are also important, and they cannot be ignored as a part of efforts to improve quality and reduce adverse events [4]. Therefore, approaches that systematically supervise the whole testing process and identify the causes of all errors, including potential errors, are needed.

In this context, the Clinical and Laboratory Standards Institute (CLSI) document EP18-A2 describes certain techniques to identify risks and to reduce medical laboratory errors [5]. Failure mode and effects analysis (FMEA) is recommended as a proactive risk evaluation technique; this method was first used in industry [6], as the early development of the health care system mainly concentrated on drug manufacture [7]. However, FMEA is now widely used to proactively evaluate complex clinical processes according to a standardized approach, with the intent of

* Corresponding author at: Department of Clinical Laboratory, the Second Xiangya Hospital of Central South University, Renmin Middle Road, Changsha, 410011 Hunan, PR China.
E-mail address: 1026622941@qq.com (H. Jiang).

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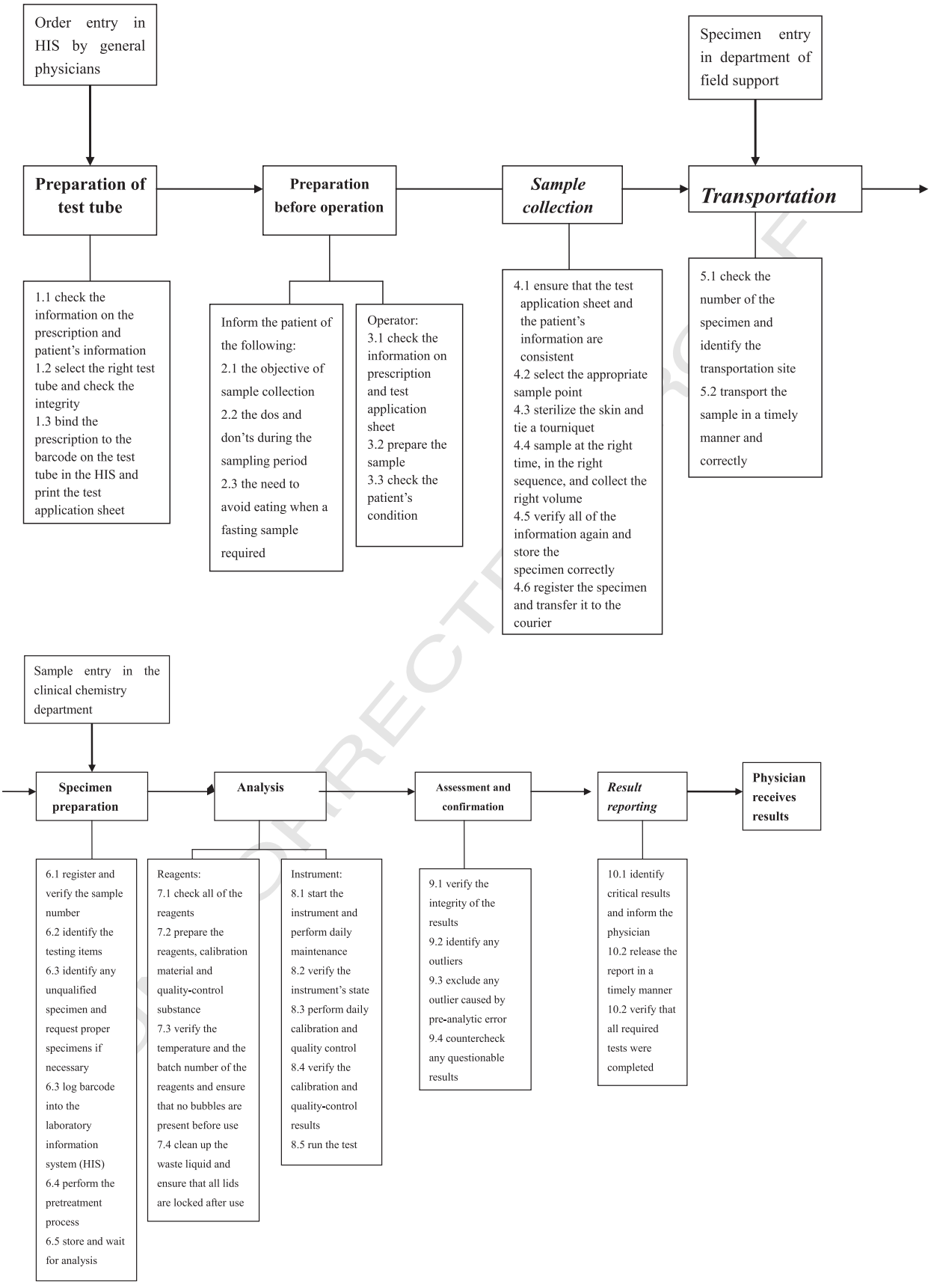

Fig. 1. The flow chart of the current test process in our clinical chemistry laboratory. Critical parts are italicized.

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