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Causes and impact of specimen rejection in a clinical chemistry laboratory

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ABSTRACT

Background: Pre-analytical errors necessitate specimen rejection and negatively affect patient safety. Our purpose was to investigate the factors leading to specimen rejection and its impact.
Methods: Specimen rejections in a clinical chemistry laboratory during a 1-year period were reviewed retrospectively and analyzed for frequency, cause, circumstances, and impact.
Results: Of the 837,862 specimens received, 2178 (0.26%) were rejected. The most common reasons for specimen rejection were contamination ($n = 764$, 35.1%), inappropriate collection container/tube ($n = 330$, 15.2%), quantity not sufficient (QNS) ($n = 329$, 15.1%), labeling errors ($n = 321$, 14.7%), hemolyzed specimen ($n = 205$, 9.4%), and clotted specimen ($n = 203$, 9.3%). The analytes most often affected were glucose ($n = 192$, 8.8%); calcium ($n = 152$, 7.0%), magnesium ($n = 148$, 6.8%), potassium ($n = 137$, 6.3%), creatinine ($n = 100$, 4.6%), and blood urea nitrogen ($n = 97$, 4.4%). Outpatient service and blood draw by phlebotomists were associated with low rejection rates (536/493,501 or 0.11% and 368/586,503 or 0.06%, respectively). Recollection due to specimen rejection increased the turnaround time by an average of 108 min. The total cost for the recollection was around $43,210 USD with an average cost around $21.9 USD.
Conclusions: The factors associated with rejection are remediable by improved training and quality assurance measures. Policies and procedures specific to specimen collection, transportation, and preparation should be strictly followed.

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1. Introduction

Clinical laboratories play an important role in healthcare services. Physicians rely on accurate and timely laboratory test results to make appropriate decisions for delivery of effective patient care. Therefore, providing results with high quality and short turnaround time has become the major goal of clinical laboratories. In the past few decades, a variety of concepts and approaches have been developed to improve the quality of clinical laboratory services [1] such as establishment of total quality management, including internal quality control, external quality assessment, and proficiency testing programs [2–4], and implementation of the Clinical Laboratory Improvement Amendments (CLIA) [5]. Especially in the clinical chemistry laboratory, notable advances in laboratory instrumentation and automation have enabled more reliable, timely, and accurate test results.

Despite the many efforts made to improve the overall quality of clinical chemistry laboratory service, errors still occur, increasing healthcare costs and jeopardizing patient safety. Laboratory errors can originate at any point in the testing process, from test ordering (pre-pre-analytical phase), collection of diagnostic specimens (pre-analytical phase), and sample analysis (analytical phase) to results reporting (post-analytical phase) or interpretation (post-post-analytical phase) [6]. While most attention has been focused on the quality of the analytical phase, the majority of laboratory errors have been reported to arise in the pre-analytical phase, including specimen collection, handling, transportation, preparation, and storage [7,8]. Of those, improper specimen identification and inadequate quality/quantity are the two main types of pre-analytical errors. According to the Key Incident Management and Monitoring System Quality Assurance Program, the main specimen identification errors are lack of labeling, mislabeling, or insufficient labeling, unclear or incorrect patient identification, and irregularities in transfusion product labeling. The major quality and quantity errors include factors that affect specimen integrity, such as hemolysis, icterus, lipemia, or clotting; inappropriate specimen type; incorrect filling level; insufficient specimen quantity; contamination; and specimens lost or not received [9]. Once detected, specimens with identification or quality/quantity errors should be rejected to ensure high-quality test results.

Abbreviations: CLSI, Clinical and Laboratory Standards Institute; TPN, total parenteral nutrition; QNS, quantity not sufficient; SRR, specimen rejection rate; LIS, laboratory information system.

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2. Materials and methods

2.1. Source of data

The laboratory information system (LIS) at MD Anderson Cancer Center was searched retrospectively for records of all blood specimens processed by the clinical chemistry laboratory during the 1-year period from January 1 to December 31, 2013. The specimens were received from the outpatient service and the inpatient services, including the emergency department (ED) and the adult intensive care units (ICUs), at the center.

2.2. Laboratory specimen acceptance and rejection criteria

Elements required for specimen acceptance included appropriate specimen type for test(s) performed, appropriate collecting container/tube, sufficient labeling, complete order entry information, adequate specimen volume, appropriate patient preparation, appropriate additives, completed paperwork (e.g., requisitions), appropriate specimen transportation, appropriate timing of specimen collection, and adequate specimen integrity. Specimens that were considered suboptimal were given special handling to determine whether they would be accepted or rejected and possibly recollected. The criteria for specimen rejection in this study are categorized as follows: a. contaminated specimen, which mainly means contamination by intravenous (IV) fluid or total parenteral nutrition (TPN) solution; b. specimen collected in inappropriate container/tube; c. specimen with labeling errors, including lack of labeling, mislabeling, and inappropriate labeling. Proper specimen labeling includes: patient's first and last name, patient's medical record or unique identification number, date and time of collection, specimen collector's computer identification number or initials, specimen type of source; d. specimen with insufficient quantity; e. hemolyzed specimen. Even mild or almost undetectable hemolysis by visual inspection (serum hemoglobin <0.6 g/L) can lead to statistically significant difference of the results in clinical chemistry testing [10]. Mild hemolysis in serum or plasma specimen after centrifugation can be detected visually, and invisible hemolysis can be identified by spectrophotometric detection of serum indices [11]; f. clotted specimen, which has a red cell clot in whole blood or a fibrin clot in plasma; and g. other reasons such as specimen in broken or leaking tubes, specimen too old to process, or lost specimen. Once the specimen was determined to be rejected, clinical personnel responsible for the patient's care were notified, and all actions taken on theses specimens were documented electronically, including date, time, and name of person handling the problem, name of physician/nurse contacted, and a summary or resolution of the problem.

2.3. Data analysis

All pre-analytical errors that caused specimen rejection in our clinical chemistry laboratory in the study period were investigated. The frequency of each type of error was calculated, the distribution of the sources of the errors was analyzed, and the impact of the errors was assessed. To study the impact of the pre-analytical errors, the frequency of each affected analyte was quantified, the average delay time per test from recollection order placed to results completed was measured, and the total cost and average cost of specimen recollection due to pre-analytical errors was estimated.

2.4. Statistical analysis

Data collected from this assessment were analyzed using GraphPad Prism ver 6.05. Groups were compared by the χ^2 test and/or Fisher's exact test, and $P < 0.05$ was considered statistically significant.

3. Results

3.1. Analysis of causes for specimen rejection

Of the 837,862 clinical chemistry specimens received in our clinical chemistry laboratory during the study period, 2178 specimens were rejected according to our rejection criteria with a specimen rejection rate (SRR) of 0.26%. The most common reasons for specimen rejection are shown in Fig. 1. Among the specimens rejected, 35.1% ($n = 764$) were rejected because of contamination by IV fluid or TPN solution, the most frequent reason for rejection. Inappropriate collection container/tube was the second most frequent cause of rejection, accounting for 15.2% of rejected specimens ($n = 330$). 15.1% of specimens ($n = 329$) were rejected because of quantity not sufficient (QNS). Labeling errors accounted for 14.7% of rejected specimens ($n = 321$). Another 9.4% ($n = 205$) were rejected because of hemolyzed specimen, 9.3% ($n = 203$) because of clotted specimen. Excluded from the above analysis, 1% specimens ($n = 26$) were rejected for other reasons such as received in broken or leaking tubes, too old to process, or lost.

3.2. Analysis of specimen rejection according to collection site and personnel

To identify the locations of these errors, the frequencies of the errors from different clinical services were analyzed and compared (Fig. 2 a&b). The results showed that considerably more specimen rejections were associated with the inpatient services (75.4% of all rejections, $n = 1642$) compared to the outpatient service (24.6%, $n = 536$) ($P < 0.01$) (Fig. 2a). Even more importantly, the error rate was much higher for inpatients (1642/344,361 or 0.48%) than outpatients (536/493,501 or 0.11%) ($P < 0.01$). Of the inpatient services, ICUs (17.2%, $n = 375$) and ED (11.0%, $n = 240$) were the two sites with high pre-analytical errors occurred (Fig. 2a). Specifically, the rejection rates were 0.93% for ICUs (375/40217), 0.64% for ED (240/37704), and 0.39% for all other inpatient units (1027/266440) (Fig. 2b). Of all the specimens, 70.0% ($n = 586.503$) were collected by laboratory personnel (phlebotomists), and 30.0% ($n = 251,359$) were collected by other in-hospital personnel groups (nursing and other medical staff). The phlebotomists submitted fewer rejected specimens at a significantly lower rate (368/586,503 or 0.06%) than other in-hospital personnel groups (1810/251,359 or 0.72%) ($P < 0.01$) (Fig. 3).

3.3. Impact of specimen rejection and recollection

To investigate the impact of specimen rejection and recollection, the tests affected, the turnaround time, and the cost of specimen recollection were analyzed. The most commonly affected test analytes are shown in Fig. 4. The analyte most affected was glucose (8.8%, $n = 192$), followed by calcium (7.0%, $n = 152$), magnesium (6.8%, $n = 148$), potassium (6.3%, $n = 137$), creatinine (4.6%, $n = 100$), and blood urea nitrogen (BUN; 4.4%, $n = 97$). Of the 2178 specimens rejected, 1971 (90.5%) were recollected. Recollection added an average of 108 min to the turnaround time of the test. The total cost of specimen recollection and reanalysis was around $43,210 USD, and the average cost for the recollection and reanalysis was around $21.9 USD.

4. Discussion

In this retrospective study of blood specimen rejection by our clinical chemistry laboratory, we detected a SRR over a 1-year period of 0.26%, which is consistent with the prevalence of 0.2% reported in a recent Q-Probe analysis of 78 clinical laboratories [12]. The SRR reported over the past 5 years are shown in Table 1. The reported rejection rates may not be comparable, however, because of variations in healthcare settings and/or methods used to detect the errors necessitating rejection.

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