ORIGINAL ARTICLE

Causes and Counter Measure Analysis of Inpatients Unqualified Clinical Specimens from 2015 to 2019

Yuzhu Huang *, Siqing Mei *, Wen Dai, Jinqu Ma, Yan Li #, Ping-An Zhang #

* Yuzhu Huang and Siqing Mei contributed equally to this work. They are joint first authors
* Yan Li and Ping-an Zhang contributed equally to this work. They are joint corresponding authors

Department of Clinical Laboratory, Renmin Hospital of Wuhan University, Wuhan, China

SUMMARY

Background: To improve the quality of pre-analytical phase and provide targeted suggestions, this study analyzed factors causing unqualified clinical specimens in patients of the Department of Clinical Laboratory of Renmin Hospital of Wuhan University from 2015 to 2019.

Methods: Inpatient specimens from January 2015 to December 2019 were retrospectively analyzed. Unqualified specimens were identified by referring to the general principle of rejection. The analytical indicators included incidence rate of unqualified specimens and constituent ratio of reasons of unqualified specimens. These two indicators were analyzed according to the inpatient wards and types of specimens.

Results: From 2015 to 2019, 21,674 inpatient unqualified specimens were collected, the incidence rate of unqualified specimens was 0.22% (21,674/9,700,869), the number and rate of unqualified specimens decreased year by year. The main reasons of unqualified specimens were insufficient volume (29.67%, 6,430/21,674) and clotting (26.31%, 5,703/21,674). The number of unqualified specimens in the departments of cardiovascular, pediatrics, neurology, oncology, urinary surgery, and intensive care unit ranked the top each year. Clotting (39.29%, 5,682/14,462) was the main reason of unqualified blood specimens while insufficient volume (71.18%, 3,365/4,727) was for urine specimens. Wrong identification caused unqualified feces (62.65%, 728/1,162) and body fluid (40.74%, 539/1,323) specimens.

Conclusions: Clinical laboratory could make effective measures to improve pre-analytical quality by retrospectively analyzing data of unqualified specimens.


KEY WORDS

pre-analytical errors, unqualified specimens, plan-do-check action cycle, quality management, quality improvement

INTRODUCTION

According to the process of specimen analysis, the quality management of clinical laboratory can be divided into three phases: pre-analytical phase, analytical phase, and post-analytical phase [1]. A few studies have demonstrated that about 46.0% - 68.2% of errors occur in the pre-analytical phase, which is the most vulnerable part of the total testing process [2]. The pre-analytical phase starts from clinician’s request, including patients’
preparation and identification, primary specimen collection and transportation, and analytical examination begins [3]. A problem with any part of this process can cause unqualified specimens. Pre-analytical quality control is the important factor to guarantee the quality of test reports. The quality of specimens is the most important factor for assuring the accuracy of test results [4,5]. Poor specimen quality will ultimately lead to patient harm. As a result, laboratory managers must consider the measurement to ensure the qualified rate of specimens. In order to decrease the risks and further improve the quality of pre-analytical phase, identify and avoid potential risk, we collected and analyzed the data of unqualified specimens from 2015 to 2019 to determine the main reason of unqualified specimens.

**MATERIALS AND METHODS**

**Subjects**
Inpatients’ specimens in Department of Clinical Laboratory of Renmin Hospital of WuHan University of China from Jan 2015 to Dec 2019 were collected.

**Methods**
The determination of unqualified specimens based on the general principle of rejection (Table 1) established by the guideline and the reality of our laboratory. The reasons for unqualified specimens were mainly partitioned into several categories, including clotting, hemolysis, insufficient volume, wrong identification, inappropriate container and so on. According to the collected data, we calculated the incidence rate of unqualified specimens, analyzed the reasons of unqualified specimens, and calculated the corresponding constitution ratio. In addition, we figured out the above indicators for each inpatient ward and each type of specimens to facilitate improvement by targeted measurement. The calculation formulas involved in this study were as follows:

The incidence rate of unqualified specimens = the number of unqualified specimens/the total amount of specimens.

The constitution ratio of reason causing unqualified specimens = the number of unqualified specimens caused by this reason/the total number of unqualified specimens.

**Statistical Analysis**
Statistical analyses were performed by Microsoft Excel (Microsoft, Redmond, WA, USA) (2016 version).

**RESULTS**

In total, 9,700,869 inpatient specimens were collected from 2015 to 2019. The number of unqualified specimens was 21,674. The incidence rate of unqualified specimens was 0.22%.

**The incidence rate of unqualified specimens**
The number of inpatient specimens from 2015 to 2019 was 1,445,429; 1,613,446; 1,951,022; 2,145,909; and 2,545,909. Figure 1 showed the incidence rate of unqualified specimens of these five years. Although the quantity of specimens increased with each passing year, the number of unqualified specimens and the corresponding rate was degraded, with a drop from 0.38% in 2015 to 0.13% in 2019. Figure 2 presents the percentage of unqualified specimens in each month of the year. From 2015 to 2017, there was a big decline in the incidence rate of unqualified specimens each year and showed a peak (2015 and 2016) or a trend of continuous increase (2017) from May to September. In 2018 and 2019, the incidence rate of unqualified specimens tended to be stable in each month, remaining around 0.18% in 2018 and 0.13% in 2019.

**The reasons of unqualified specimens**
According to Figure 3, insufficient volume and clotting were the leading reasons for inpatient unqualified specimens, whose constitution ratio was 29.67% (6,430/21,674) and 26.31% (5,703/21,674). Yearly statistics of the reasons for unqualified specimens was presented in Table 2. The main reason from 2015 to 2017 was insufficient volume while clotting was the major factor from 2018 to 2019. From the data of unqualified specimens and corresponding constitution ratio, there was no variation in trend with the year.

**Causes analysis by inpatients wards**
The rate of unqualified specimens for each inpatient ward was shown in Supplemental Table 1. In 2016, the constitution ratio of unqualified specimens of intensive care unit was the highest, which was 9.67% (489/5,055). In addition to that year, the number of unqualified specimens in cardiovascular department accounted for the highest proportion of the total unqualified specimens in the whole year, the proportion was 11.54% (636/5,511), 9.94% (400/4,022), 9.38% (358/3,815), and 9.39% (307/3,270). As for the rate of unqualified specimens for each inpatient ward, it reached the top in 2015, accounting for 0.91% (556/60,588). Except for 2015, the rate of unqualified specimens in the neonatal department was the highest from 2016 to 2019, and the proportion decreased year by year, from 0.79% (143/18,156) in 2016 down to 0.42% (204/48,600) in 2019. Pooled analysis from all the five years of data, the highest proportion of unqualified specimens in the cardiovascular department was 8.94% (2,206/21,674), followed by intensive care unit and pediatric department. The proportion that equaled to unqualified specimens of each ward divided by all the specimens of each ward reached the top for the neonatal department, which was 0.52% (779/149,491) and followed by intensive care unit and general medicine ward.
Table 1. The general principle of rejection for clinical specimens.

<table>
<thead>
<tr>
<th>1. Specimen label is inconsistent with the contents of test application form, or incomplete patient information, or invalid clinicians’ orders</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Patient identification is wrong or unclear</td>
</tr>
<tr>
<td>3. Insufficient volume, so that the entire test cannot be completed. (Definition of insufficient volume: The sampling volume could not meet the minimum testing volume)</td>
</tr>
<tr>
<td>4. Preservative-free for the specimens, which need preservative</td>
</tr>
<tr>
<td>5. Specimens that should not have contact with air have been exposed to air</td>
</tr>
<tr>
<td>6. The anticoagulation specimen has clot, wrong anticoagulants, or incorrect anticoagulant ratio</td>
</tr>
<tr>
<td>7. Inappropriate container, broken specimen container, or specimen loss</td>
</tr>
<tr>
<td>8. Hemolysis, lipid, specimens taken from infusion tubes or blood vessels</td>
</tr>
<tr>
<td>9. Time interval between collection and sending of specimens is too long</td>
</tr>
<tr>
<td>10. Bacterial culture specimens are contaminated</td>
</tr>
</tbody>
</table>

Table 2. Classified statistics for the reasons of unqualified specimens in each year from 2015 to 2019.

<table>
<thead>
<tr>
<th>Reasons</th>
<th>Constitution ratio (The number of unqualified specimens divided by the quantity of unqualified specimens)</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insufficient volume</td>
<td></td>
<td>1,758/31.90%</td>
<td>1,411/27.91%</td>
<td>1,215/30.21%</td>
<td>1,024/26.83%</td>
<td>953/29.14%</td>
</tr>
<tr>
<td>Clotting</td>
<td></td>
<td>1,277/23.17%</td>
<td>1,090/21.56%</td>
<td>1,019/25.34%</td>
<td>1,233/32.31%</td>
<td>1,084/33.15%</td>
</tr>
<tr>
<td>Wrong identification</td>
<td></td>
<td>540/9.80%</td>
<td>695/13.75%</td>
<td>360/8.95%</td>
<td>301/7.89%</td>
<td>190/5.81%</td>
</tr>
<tr>
<td>Hemolysis</td>
<td></td>
<td>504/9.14%</td>
<td>415/8.21%</td>
<td>431/10.71%</td>
<td>321/8.41%</td>
<td>304/9.30%</td>
</tr>
<tr>
<td>Inappropriate container</td>
<td></td>
<td>466/8.46%</td>
<td>547/10.82%</td>
<td>306/7.61%</td>
<td>336/8.80%</td>
<td>224/6.85%</td>
</tr>
<tr>
<td>Improper time of sampling or transfer</td>
<td></td>
<td>345/6.26%</td>
<td>357/7.06%</td>
<td>308/7.66%</td>
<td>235/6.16%</td>
<td>160/4.89%</td>
</tr>
<tr>
<td>Lipid</td>
<td></td>
<td>323/5.86%</td>
<td>307/6.07%</td>
<td>105/2.61%</td>
<td>42/1.10%</td>
<td>16/0.49%</td>
</tr>
<tr>
<td>Leaked or contaminated specimen</td>
<td></td>
<td>137/2.48%</td>
<td>148/2.93%</td>
<td>209/5.20%</td>
<td>100/2.62%</td>
<td>126/3.85%</td>
</tr>
<tr>
<td>Unqualified specimens collected by patients themselves</td>
<td></td>
<td>123/2.33%</td>
<td>43/0.85%</td>
<td>49/1.22%</td>
<td>58/1.52%</td>
<td>51/1.56%</td>
</tr>
<tr>
<td>Specimens with unqualified character or nature</td>
<td></td>
<td>34/0.62%</td>
<td>33/0.65%</td>
<td>17/0.42%</td>
<td>99/2.59%</td>
<td>78/2.38%</td>
</tr>
<tr>
<td>Incorrect specimen type</td>
<td></td>
<td>0/0.00%</td>
<td>6/0.12%</td>
<td>0/0.00%</td>
<td>67/1.76%</td>
<td>82/2.51%</td>
</tr>
<tr>
<td>Improper ratio of specimen to anticoagulant</td>
<td></td>
<td>4/0.07%</td>
<td>3/0.06%</td>
<td>3/0.07%</td>
<td>0/0.00%</td>
<td>2/0.06%</td>
</tr>
<tr>
<td>Quantity of unqualified specimens</td>
<td></td>
<td>5,511</td>
<td>5,055</td>
<td>4,022</td>
<td>3,816</td>
<td>3,270</td>
</tr>
</tbody>
</table>

Statistical analysis showed that between 2015 and 2019, the constitution ratio of unqualified specimens in department of cardiovascular, pediatrics, neurology, oncology, urinary surgery and intensive care unit ranked within the top ten. The detailed analysis for reasons of unqualified specimens of each inpatients ward was shown in Supplemental Table 2. There was no problem of improper ratio of specimen to anticoagulant in these six wards. Insufficient volume and clotting were the major causes of unqualified specimens for the departments of cardiovascular, pediatrics, neurology and oncology, while clotting and hemolysis were the major causes in the intensive care unit. Urinary surgery department had the main problem of insufficient volume and wrong identification. According to the number of unqualified specimens caused by various rea-
Figure 1. The incidence rate of unqualified specimens from 2015 to 2019.

Figure 2. The incidence rate of unqualified specimens in each month from 2015 to 2019.
sons in each year, the departments of cardiovascular, pediatrics, neurology, and oncology had a new problem of incorrect specimen type from 2018. However, some of the problems have improved, for example, problem of inappropriate container in cardiovascular department, insufficient volume in neurology department and urinary surgery department, and lipid in oncology department. The pediatrics department improved the most troubles including insufficient volume, hemolysis, wrong identification and lipid. The next was intensive care unit, which improved hemolysis, wrong identification, and specimens with unqualified character or nature.

**Causes analysis by type of specimens**

The types of clinical specimens included blood, urine, feces, and body fluids (body fluids include pleural fluid, ascites, amniotic fluid, sputum, leucorrhea, etc.). The number of unqualified specimens for each type was 14,462, 4,727, 1,162, and 1,323. Figure 4 presents the analysis of reasons for each type of unqualified specimens from 2015 to 2019. The main cause of blood specimens was clotting (39.29%, 5,682/14,462) while insufficient volume (71.18%, 3,365/4,727) was for urine specimens. Wrong identification caused unqualified feces (62.65%, 728/1162) and body fluid (40.74%, 539/1,323) specimens.

**DISCUSSION**

Quality management of pre-analytical phase is one of the most important prerequisites to determine the authenticity of the test results [6]. Errors from patient preparation, specimen collection, transportation, and pretreatment affect the quality of the test. The characteristics of pre-analytical quality management are uncontrollability of clinical laboratories and the uncertainty of responsibilities [7]. Retrospective analysis with laboratory information systems and strict monitoring of each pre-analytical step do contribute to identify risk factors in pre-analytical phase.
Figure 4. Analysis of reasons for each type of unqualified specimens from 2015 to 2019.
This study retrospectively analyzed the inpatient unqualified specimens from 2015 to 2019, and our laboratory took effective improving measures based on the statistical results. Department of Clinical Laboratory of Renmin Hospital of WuHan University has been adopting PDCA cycle management as a method of pre-analytical quality improvement measure since January 2016. PDCA cycle quality management is a continuous quality improvement method and a target management process.

Since 2016, our laboratory analyzed the data of inpatient unqualified specimens every month. The analytical indicators included incidence rate of unqualified specimens and constituent ratio of reasons of unqualified specimens. These two indicators were analyzed according to the inpatient wards, type of specimens, majors, and test items. Fishbone diagram was used to find problems and summarize the gap between the current situation and the expected goals. After taking targeted measures, we conducted data analysis and comparison and included the incomplete issues in the next PDCA cycle. From the trend of incidence rate of inpatient unqualified specimens from 2015 to 2019, the effect of PDCA cycle management was significant, and the rate reduced year by year. Since 2017, the medical care department has made quality control circles into medical quality management; as a result, the incidence rate of unqualified specimens declined more significantly since that year.

Insufficient volume was the main reason for unqualified specimens, especially for blood specimens, mainly involving pediatric department and intensive care unit that have difficulty in specimen collection. Anticoagulated specimens insufficiently mixed or punctured for a long time could result in clots in specimens, which was the second major cause of unqualified specimens. Nonstandard blood collection procedure, such as repeated tapping of veins during puncture cause capillary hemolysis, will affect the results of some items like potassium, blood ammonia and so on. This situation was common in the neonatal department. The main reason for inappropriate containers was that nurses might use incorrect blood collection tubes during blood collection, for example, nurses used EDTA anticoagulated collection tubes to sample for biochemical items. Another reason was that patients used wrong containers when they collected specimens by themselves. Specimens with unqualified character or nature refers to venous blood used for blood gas analysis or blood collected from the site of infusion. Improper time of sampling or transfer would influence the accuracy of test results. For example, transfer time of blood ammonia should be within thirty minutes. If the time exceeds one hour at room temperature, the concentration of blood ammonia will increase with the time. According to the CLSI H18-A4, blood specimens without pretreatment should be sent to laboratory within two hours under the condition of 10 - 22°C [8]. The investigation found that the factors that caused the unqualified specimens included clinicians and nurses who were unfamiliar with test items and specimens’ collections, nonstandard collecting procedures, documents related to specimen collection had not been updated in time, difficulty in distinguishing specimen collection containers, and inadequate communication between clinical and laboratory departments. In addition, based on the incidence rate of unqualified specimens in each month of five years, the rate from May to September in the 2015 and 2016 reached the top and continually increased in 2017. New employees had just started to work in these months, which had inadequate skill of operations. Consequently, it was necessary to strengthen the training and assessment of new employees. In response to the above problems, we focused on the wards with high incidence rate of unqualified specimens and regularly organized pre-analytical training. Meanwhile, laboratory specialists referred to the latest guideline and compiled the “Specimen Collection Manual”, distributing it to clinical departments. As for test items that were easily confused by clinicians and nurses, laboratories made cue cards and posted them in the inpatient wards. In addition, we communicate monthly with the clinicians and make some improvements based on their feedback. The quality goal of the incidence rate of unqualified specimens set by our laboratory is below 1%. According to statistical results in this study, the rate during these five years was far lower than this target; however, further improvement strategy should be set out.

Clinical laboratories should rely on laboratory information systems to monitor the unqualified specimens, analyze data from multiple perspectives, identify the main reasons and characteristics of unqualified specimens, and take relevant measures. Laboratories also need to strengthen the communication with clinicians and nurses. Only when all the medical personnel cooperate to reduce the number of unqualified specimens will the quality of pre-analytical phases be improved.

Acknowledgment:
All the authors have accepted responsibility for the entire content of this submitted manuscript and approved submission. No competing financial interest exists.

Source of Funds:
There are no source of support in the form of grants, equipment, or drug.

Declaration of Interest:
There was none relevant to the contents of the article for any authors. There was no involvement of company funding. There were no sponsors for this article.
References:


Additional material can be found online at:
http://supplementary.clin-lab-publications.com/200619/