Clinical Biochemistry xxx (2014) xxx–xxx

Contents lists available at ScienceDirect

Clinical Biochemistry

journal homepage: www.elsevier.com/locate/clinbiochem

Classification of reasons for rejection of biological specimens based on pre-preanalytical processes to identify quality indicators at a university hospital clinical laboratory in Turkey

Incilay Sinici Lay *, Aslı Pınar, Filiz Akbıyık

Hacettepe University Faculty of Medicine, Department of Medical Biochemistry, Turkey
Hacettepe University Hospitals, Clinical Pathology Laboratory, Ankara, Turkey

ARTICLE INFO

Article history:
Received 8 April 2014
Received in revised form 22 April 2014
Accepted 23 April 2014
Available online xxxx

Keywords:
Clinical laboratory
Patient safety
Pre-preanalytical errors
Specimen rejection
Quality indicator

ABSTRACT

Objectives: Specific types of error should be identified and corrected in each laboratory to ensure quality results. The objectives of this study were:

- to identify and classify the causes of biological specimen rejections,
- to determine the specimen rejection rates (SRRs) in terms of pre-preanalytical errors and with respect to collection areas, and
- to identify an appropriate quality indicator (QI) for the preanalytical phase in a university hospital clinical laboratory.

Design and methods: Data on rejected biological specimens in the laboratory information system from January 2013 to January 2014 were analyzed. SSRs according to the type of pre-preanalytical error and collection area were determined.

Results: In total, 971,780 biological specimens were received during the period and 26,070 (2.7%) specimens were rejected based on our laboratory rejection criteria. The most frequent reason for the rejection was the clotted specimen (55.8% of total rejections), followed by inadequate volume (29.3% of total rejections). Most of the clotted specimens were received from adult hospital inpatient services (54.3%), followed by pediatric hospital inpatient services (26.8%). High rates of inadequate volume were also observed in samples originating from adult and pediatric hospital inpatient services, especially in the premature, neonatal, intensive care, and oncology units.

Conclusions: The SSR of clotted specimens was selected as the QI for the preanalytical phase in our laboratory. The selected QI will help to define the effects of our specific interventions and corrective actions, and thus allow monitoring of quality improvement in our hospitals.

Introduction

Clinical laboratories have a direct impact on patient diagnoses and treatments and thus have important roles in patient management and safety [1]. Given that 70–80% of all diagnoses are made, at least in part, based on laboratory tests, laboratory errors have consequences: misdiagnoses, diagnostic delays, inappropriate therapies, increased risks to patient safety, increased costs, and time lost [2]. The laboratory "total testing process" (TTP) includes three main phases: the preanalytical, analytical, and postanalytical phases. Approximately 70% of laboratory errors originate in the preanalytical phase [3–5]. The preanalytical phase consists of pre-preanalytical phase and 'true' preanalytical phase. The processes of selecting appropriate tests by clinicians, ordering, collecting, identifying and labeling, handling, transporting are known as pre-preanalytical phase. The processes of accepting samples by the laboratory, centrifuging, aliquoting, diluting, and sorting the biological specimens for analysis are known as 'true' preanalytical phase [6]. Errors can occur during each step, mostly in processes performed outside the laboratory before the acceptance of biological specimens by the laboratory, referred to as the pre-preanalytical phase. The processes of 'true' preanalytical phase which are undertaken within the laboratory are less prone to errors compared with processes performed outside the laboratory.

In terms of quality, over time, with the remarkable advances in instrument technology, automation, computer science, reliable quality indicators, internal quality control rules, and external quality assessment programs, in the analytical phase quality is largely assured. Thus, further

* Corresponding author at: Hacettepe University Hospitals, Clinical Pathology Laboratory, 06100 Ankara, Turkey. Fax: +90 312 3052084.
E-mail addresses: lincilay@gmail.com, isinici@hacettepe.edu.tr (I. Sinici Lay).

http://dx.doi.org/10.1016/j.clinbiochem.2014.04.024
0009-9120/

quality improvements are focused on additional sources of variation, such as preanalytical errors. The ISO 15189:2012 standard for laboratory accreditation defines the preanalytical phase, and points out the need to evaluate, monitor, and improve all procedures and processes in the initial phase of TTP [7]. Quality indicators (QIs) are objective measures that enable the quantifying, documenting, monitoring, and improving of quality, and are now required for the accreditation of a clinical laboratory [8]. Several national and international programs have developed and used QIs as sample collection, erroneous requests, erroneous samples, samples not taken, hemolysis, blood re-collection and productivity, and misidentifications and specimen quality [9–12]. In particular, identification and sample problems are the most commonly used QIs for the preanalytical phase in clinical laboratories. Recently, the Working Group on Laboratory Errors and Patient Safety (WG-LEPS) of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) attracted attention to test requests by including test requests and request forms as QIs for the preanalytical phase [1,13].

In this study, we sought to identify, classify, and document the causes of biological specimen rejections, to assess the specimen rejection rates (SRRs) in terms of pre-preanalytical errors, evaluate SRRs with respect to collection areas, and determine the best QI for the preanalytical phase according to conditions at Hacettepe University Hospitals, Clinical Pathology Laboratory, Turkey.

Methods

Hacettepe University Hospital is one of the largest university hospitals in Turkey, consisting of the Adult Hospital, Ihsan Dogramaci Children's Hospital, and the Oncology Hospital, with 76 clinical departments providing services to inpatients and outpatients. Laboratory testing of biological specimens using 187 different parameters is performed by the central Hacettepe University Hospitals Clinical Pathology Laboratory. The hospital information system (HIS) enables electronic test requests with the necessary medical information at our university hospitals. All of the biological specimen collection areas have a system of barcode labeling, as does the Clinical Pathology Laboratory. Access to the HIS is restricted to clinical staff members and is limited and monitored closely. The Clinical Pathology Laboratory has its own laboratory information system (LIS) connected to HIS. The LIS enables acceptance and log-in, assignments, scheduling, tracking, associated analytical workload, inspection, approval, and reporting results for the biological specimens, as well as other sophisticated features. In total, 130 technical staffs perform laboratory tests and all have limited access to LIS according to their laboratory section areas.

In this study, data regarding rejected biological specimens were obtained from the LIS for the 1-year period from January 2013 to January 2014. Biological specimens were rejected at the acceptance of biological specimens by our laboratory according to the laboratory rejection criteria available on HIS and LIS. The criteria for rejection were as follows:

1) Biological specimens without barcodes or unsuitable barcodes
2) Incorrect test requests (e.g., incomplete, duplicate, wrong patient's requests, errors in test input, inconsistent information)
3) Unsuitable container or tube
4) Unspecified or inappropriate biological specimen
5) Incomplete volume or excess volume
6) Incorrect timing of sample
7) Incorrect preservation, storage
8) Inappropriate transport conditions (e.g., cold chain, light protection, delayed transport time)
9) Lipemic specimen
10) Hemolytic specimen
11) Clotted specimen
12) Absence of necessary preliminary preparation for specific tests (such as urinary VMA measurement)

Rejection reasons were recorded systematically in the LIS for each rejected specimen. The reasons for rejection and origins of rejected biological specimens were investigated. Rejection reasons were classified into five groups based on pre-preanalytical processes. These five major groups were subdivided to detail the pre-preanalytical processes. Analysis of the SRRs in terms of pre-preanalytical errors was performed by calculating the percentages in total and in each category. To evaluate SRRs with respect to collection areas, the percentages of rejected specimens from different collection areas were calculated. The areas that rejected the highest numbers of biological specimens were identified.

Results

In total, 971,780 biological specimens were received between January 2013 and January 2014 and 26,070 specimens were found to have been rejected according to our rejection criteria. The SRR was thus 2.7%. Clotting of specimens was the most frequent reason for rejection (55.8% of total rejections), followed by inadequate volume (29.3% of total rejections). Although all rejections were recorded at the time of acceptance of specimens by our laboratory, rejection reasons were classified into five groups as improper request, incorrect labeling (barcode errors), improper collection, inappropriate transport, and rejection reasons at acceptance according to pre-preanalytical processes (Table 1). These five main groups were subdivided to identify the problematic issues. Table 1 shows that the most common reasons for rejection were clotting of specimens and inadequate volume; the least common reason was incorrect labeling. The most common origins of clotted specimens were the adult and pediatric hospital inpatient services (Table 2). The highest rates of inadequate volumes were in specimens from the adult and pediatric hospital inpatient services, particularly the premature, neonate, intensive care, and oncology units (Table 3). Documenting the rates of rejections in these groups enabled us to identify the pre-preanalytical errors, target the problematic processes in our hospitals, and finally select the appropriate QI.

Discussion

The SRR was found to be 2.7% in our laboratory, reflecting the pre-preanalytical error frequency in our hospitals. Studies of biochemistry and hematology specimens have reported SRRs from 0.3 to 1.4% [14–17]. Thus, the high SRR in our study prompted us to classify the rejection reasons in terms of pre-preanalytical errors to facilitate establishment of specific, targeted corrective actions and to implement an appropriate QI.

The clotted specimen was the most frequent reason for rejection (55.8% of total rejections and 93% of specimen rejection reasons at acceptance). At a university hospital in Porto Allegre with 60 specialty areas and 750 beds, similar to our university hospitals, a high prevalence of clotted specimens (43.8%) was also reported [15]. Another study also indicated that clotting of specimens was the most common rejection reason, at 51.2% [14]. Inappropriate mixing of blood with the anticoagulant after collection may explain the clotted samples. Clotted specimens were most frequently received from adult hospital inpatient services (54.3%), followed by pediatric hospital inpatient services (26.8%). Biological specimens are obtained by phlebotomy teams, physicians, and nurses from assisting units in our hospitals. While collection of specimens from outpatients in clinics is performed by trained phlebotomy teams in blood-collection centers, these procedures are performed by nurses and physicians in inpatient clinical services. The reason for the high rates of clotted specimens originating from inpatient services is most likely the lack of trained phlebotomy teams, high turnover of staff, particularly physicians, and the busy schedules of nurses and physicians. The laboratory director has a responsibility to bring these results to the attention of hospital management to emphasize the importance and need for phlebotomy teams with specially trained personnel. In the meantime, laboratory professionals recalled the

Please cite this article as: Sinici Lay I, et al, Classification of reasons for rejection of biological specimens based on pre-preanalytical processes to identify quality indicator..., Clin Biochem (2014), http://dx.doi.org/10.1016/j.clinbiochem.2014.04.024