Research Article

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Approach to pre-analytical errors in a public health laboratory

Halk sağlığı laboratuvarında preanalitik hatalara yaklaşım

DOI 10.1515/tjb-2016-0197
Received October 31, 2015; accepted June 14, 2016; previously published online December 10, 2016

Abstract

Background and objective: We aimed to investigate the effect of "training about the pre-analytical phase" and "technological arrangements in laboratory information systems (LISs) and tube barcoding system", on decreasing PEs.
Materials and methods: PEs in 2013 and 2014 were obtained from the LIS retrospectively in order to evaluate the effect of improvements. Ten quality indicators (QIs) described for pre-analytical phase were calculated. We compared QIs of the "improved year" with the past year. Four quality specification criteria were defined as "unacceptable", "minimum", "desirable" and "optimum" for each quality indicator.
Results: There was a reduction in all types of PEs related to the improvement strategies. When QIs were considered as quality specifications (QSs), QI-14 (number of samples damaged in transport) and QI-16 (samples improperly stored) were "unacceptable", QI-8 (samples lost-not received) and QI-12 (samples with insufficient sample volume) were "minimum" and QI-9 (samples collected in inappropriate container) was "desirable" in 2013; QI-10a, 10b (samples hemolyzed), 11a (samples clotted) and 13 (samples with inadequate sample-anticoagulant) were all "optimum" in 2 years.
Conclusion: It was shown that continuous education on pre-analytical phase and improvements of the technological infrastructures are the main factors that will enable the control of this phase.

Keywords: Pre-analytical errors; Training; Technological arrangements; Public health laboratory.

Özet

Amaç: Preanalitik hataları azaltmak amacı ile yapılan eğitimin ve Laboratuvar Bilgi Sistemi ile tüp barkotlama sisteminde yapılan teknolojik yeniliklerin etkisini ortaya koymak çalışmamızda amaçlanmıştır.
Gereç ve Yöntem: İyileştirmelerin sonuçlarını değerlendirmek için 2013 ve 2014 yıllarına ait preanalitik hatalar Laboratuar Bilgi Sisteminden (LBS) geriye dönük olarak alınmıştır. Preanalitik faz için on kalite indikatörü hesaplanmıştır. İyileştirme yapılmış yıl ile geçmiş yıl karşılaştırılmıştır. Kabul edilemez, minimum, kabul edilebilir ve optimal olmak üzere dört kalite spesifikasyon ölçütü tanımlanmıştır.
Bulgular: İyileştirme çalışmalarından sonra tüm preanalitik hata tiplerinde azalma görülmüştür. Kalite indikatörleri spesifikasyon ölçütü olarak değerlendirildiğinde, 2013 yılında QI-14 (taşıma sırasında hasarlanmış örnekler) ve QI-16 (yanlış saklanan örnekler) kabul edilemez, QI-8 (kayıp örnekler) ve QI-12 (yetersiz hacimli örnekler) minimum ve QI-9 (yanlış kaptaki örnekler) kabul edilebilir iken, 2014 yılında tümünün optimal düzeyde olduğu görülmüştür. QI-15 (hatalı etiketlenmiş örnekler) kabul edilebilir iken 2014 yılında kabul edilemez olarak değerlendirilmiştir. QI-10a, b (hemolizli örnekler), 11a (pıhtılı örnekler)

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ve 13 (yetersiz hacimli örnekler-antikoagülanlı tüplerde) her iki yılda da optimal düzeyde değerlendirilmiştir.
Sonuçlar: Preanalitik faz ile ilgili eğitimlerin sürekliliğinin sağlanması ve teknolojik alt yapının güçlendirilmesi bu evrenin kontrolünü sağlayacak temel faktörlerdir.

Anahtar kelimeler: Preanalitik hatalar; Eğitim; Teknolojik iyileştirme; Halk sağlığı laboratuvarı.

Introduction

Most laboratory errors occur in the pre-analytical phase of the total testing process. This is especially important for public health laboratories. The pre-analytical phase, during which most of the errors occur in the total test process [1–3], is also the process that requires most of the work in public health laboratories (PHL). Samples that are collected from family health centers (FHC) are transported to the PHL at certain times. The use of vehicles in transportation of samples causes problems which are different than those that are experienced in hospitals. These include breaking of cold chain principles during sample transportation, obtaining of samples by different health care professionals in each FHC, and this causes problems in controlling errors in the pre-analytical phase and standardization. Studies on detecting and improving problems in the pre-analytical phase were mostly done in secondary and tertiary care health centers [1, 4]. But as yet, no pre-analytical studies are encountered in the literature for laboratory services provided by family health centers, which have begun to occupy a major place in health care services and which is the first address that patients are admitted at. For reducing errors in laboratory testing, the IFCC Working Group on Laboratory Errors and Patient Safety (IFCC WG-LEPS) aimed to develop a series of quality indicators, specifically designed for clinical laboratories. They also determined quality specifications (QSs) for each QI. For the pre-analytical phase 16 quality indicators were determined [5]. QSs were described as optimum, desirable, minimum and unacceptable. Our aim in this study is to determine pre-analytical process errors based on 10 quality indicators and to emphasize the effects of education and technological developments on minimizing these errors.

Materials and methods

The study was carried out in the PHL of Uşak City, where 180,000 people reside. There were 21 FHCs localized in different regions of the city. The samples are ordered by family physicians working at FHCs, the tubes are labeled and samples are collected by family health nurses and all of them accepted by transfer vehicle employees. Distance between the FHCs and PHL were varied between 2 and 60 km. Transferring of all samples to the PHL was carried out nine times a day.

The PHL approved approximately 2500 samples which were transferred from the FHCS by ring vehicles in appropriate sample transport containers according to cold chain principles. The sample transport containers' temperatures were followed by digital thermometers and the acceptable temperature of a container was between + 4 and 8°C.

Biochemistry parameters (glucose, creatinine, urea, uric acid, total cholesterol, trigliserit, HDL-cholesterol, ALT, AST, GGT, ALP, total and direct bilirubin, ASO, CRP, RF, iron, iron binding capacity, total protein, albumin, amylase, calcium, creatine kinase, LDH, lipase, sodium, potassium, chloride) on a Beckman Coulter Unicell Dxc 800 Synchron (Beckman Coulter, CA, USA) hormone parameters (free T3 and T4, TSH, ferritin, folate, vitamin B12, beta-HCG, total PSA, 25-OH vitamin-D, insulin) on an Abbott Architect isr2000 Immunology Analyzer (Abbott Diagnostics, USA), hematology (whole blood count, sedimentation, HbA_{1c} and thalassemia screening) on a Coulter LH 780 Hematology Analyzer (Beckman Coulter, CA, USA), Alifax (ESR Line, PD, Italy), and an Ultra² Resolution Variants Analyzer (Trinity Biotech, USA), respectively, serology tests (anti-HIV, anti-HCV, HbsAg, anti-HbsAg, *Treponema pallidum* hemaglutination anticore, anti-rubella Ig M and G, anti-CMV Ig M and G, anti-*Toxoplasma* Ig M and G) on an Abbott Architect I 2000 Immunology Analyzer (Abbott Diagnostics, USA) and urine analysis on an Iris iQ200 Elite (Beckman Coulter, CA, USA) and urine cultures were conducted in the Uşak Public Health Medical Laboratory. Approximately 2500 sample tubes belonging to approximately 500 patients were received at our laboratory from 21 family health centers located in the city center and in surrounding towns. Centrifuges of the samples taken from family health centers were performed in the family health centers. The quality indicators in our study included all the tests conducted in our laboratory.

From June to December 2013, there were technological developments in the barcoding system and the laboratory information system (LIS) and we provided training on the pre-analytical phase.

Education includes:

a. The technological improvement about the barcoding system and LIS.

   From June to September 2013, tube labeling system with four pieces (biochemistry/ELISA/

hormone – urine – complete blood cell count/thalassemia/HbA_{1c}/blood group – culture) was changed to a tube labeling system including 10 pieces (biochemistry – hormone/ELISA – serology – complete blood cell count – HbA_{1c} – blood group – thalassemia – sedimentation – urine – culture). That application prevented from the entrance of the wrong tubes to the device. A system for tracking the samples was implemented, which included the time when the test was ordered by the physician, the time when the transport staff received the sample, the time when the sample was received by the laboratory and the time when the sample was put into the device, approval by the technician and approval by the specialist.

b. Training on the pre-analytical phase:

Family physicians and health care staff of the family health centers were trained about the pre-analytic phase during December 2013 for eight sessions. Visual training aids were used for appropriate collecting of samples, sample drawing and barcoding techniques, with demonstrations on sample collecting by making use of power point presentations. Appropriate centrifugation conditions and key points were highlighted by the educators.

Tests covered under the same headline but which were analyzed with different devices were separated under different headlines. By using a mobile barcode reader, a system was set up for tracking the sample from the time of collection to its approval. The sample rejections were screened retrospectively in the LIS for the years 2013 and 2014. The causes of rejection for each rejection type were grouped under the heading of PEs for 2 years. Based on these errors and preliminary data from the IFCC WG-LEPS, quality indicators were determined [5]. Pre-analytical phase errors were related to identification, collection, handling and transport of samples and the error data obtained from LIS. There was no considerable technological infrastructure in 2013 with the four piece barcode system and the staff did not receive training. However, percentages for every type of error have been calculated for 2013 and 2014, separately and evaluated according to the QIs developed by the IFCC WG-LEPS and 2014 showed a dramatic improvement. QI calculations were shown in Table 1. Our laboratory performance category was classified as optimum, desirable, minimum and unacceptable in accordance with IFCC WG LEPS quality targets [5]. The study was approved by the Ethics Committee of the Pamukkale University School of Medicine.

Results

According to data obtained retrospectively from the LIS; the number of tubes received at our laboratory in 2013 was 267,140, reaching 275,580 in 2014. A decrease was observed in orders for urine and sedimentation, with an increase in orders for routine chemistry, hormone, and serology and ELISA tests. Hemolysis and clotting were undetectable causes of rejection in tubes containing citrate and in urine tubes containing polystyrene thus; calculations could not be done for these tubes. QI levels designed for pre-analytical phase are shown in Table 2 for 2-year period.

Considering the quality specifications, QI-14 and QI-16 were unacceptable, QI-8 and QI-12 were minimum; QI-9 was desirable in 2013, and after improvements all these quality indicators were accepted as the optimum in 2014. QI-15 became desirable from unacceptable. QI-10a, QI-10b, QI-11a and QI-13 were all optimum in 2 years.

Table 1: Quality indicators of the pre-analytical phase for identification, collection, handling and transport of samples [5].

Quality indicator	Calculation formula
QI-8	Percentage of ''Number of samples lost-not received/total number of samples''
QI-9	Percentage of ''Number of samples collected in inappropriate container/total number of samples''
QI-10a	Percentage of ''Number of samples hemolyzed (hematology)/total number of samples''
QI-10b	Percentage of ''Number of samples hemolyzed (chemistry)/total number of samples''
QI-11a	Percentage of ''Number of samples clotted (hematology)/total number of samples with anticoagulant''
QI-12	Percentage of ''Number of samples with insufficient sample volume/total number of samples''
QI-13	Percentage of ''Number of samples with inadequate sample-anticoagulant/total number of samples with anticoagulant''
QI-14	Percentage of ''Number of samples damaged in transport/total number of samples''
QI-15	Percentage of ''Number of samples improperly labeled/total number of samples''
QI-16	Percentage of ''Number of samples improperly stored/total number of samples''

Table 2: Quality indicators of 2 years and their specifications.

	Year 1	Year 2
QI-8 Percentage of ''Number of samples lost-not received/total number of samples''	0.49 (minimum)	0.01 (optimum)
QI-9 Percentage of ''Number of samples collected in inappropriate container/total number of samples''	0.05 (desirable)	0.01 (optimum)
QI-10a Percentage of ''Number of samples hemolyzed (hematology)/total number of samples''	0.006 (optimum)	0.005 (optimum)
QI-10b Percentage of ''Number of samples hemolyzed (chemistry)/total number of samples''	0.09 (optimum)	0.05 (optimum)
QI-11a Percentage of ''Number of samples clotted (hematology)/ total number of samples with anticoagulant''	0.22 (optimum)	0.17 (optimum)
QI-12 Percentage of ''Number of samples with insufficient sample volume/total number of samples''	0.085 (minimum)	0.024 (optimum)
QI-13 Percentage of ''Number of samples with inadequate sample-anticoagulant/total number of samples with anticoagulant''	0.17 (optimum)	0.04 (optimum)
QI-14 Percentage of ''Number of samples damaged in transport/ total number of samples''	0.0006 (unacceptable)	0.0002 (optimum)
QI-15 Percentage of ''Number of samples improperly labeled/total number of samples''	0.060 (unacceptable)	0.012 (desirable)
QI-16 Percentage of ''Number of samples improperly stored/total number of samples''	0.099 (unacceptable)	0.032 (optimum)

Year 1, 2013 QI (IFCC WG LEPS Quality Specification).
Year 2, 2014 QI (IFCC WG LEPS Quality Specification).

Discussion

In our study it was aimed to launch training programs for family physicians and phlebotomists upon the increase in the number of sample rejections caused by pre-analytical errors. We also aimed to decrease the number of errors to minimum by making technological improvements in the LIS and sample barcoding system. The QI-14 and QI-16 were at an unacceptable level, QI-8 and QI-12 were at the minimum level and QI-9 was at the desirable level in 2013, however, all these quality indicators reached the optimum level with training and technological improvements.

Harmonizing the pre-analytical phase requires the use of standardized operating procedures for correct test selection, sample collection and handling [6]. In this study, we considered all these factors based on quality indicators, it was shown that training on the pre-analytical phase, improvements in the tube labeling systems and LIS and developing better communication between family physicians and the laboratory have decreased the frequency of tube rejections. Aykal et. al. suggested that education and its follow-up were important in reducing the rejection tubes ratio in their study [7].

While the specifications of QI-14, QI-15 and QI-16 were unacceptable in 2013, after improvements they were classified as optimum in 2014. Similarly, QI-8 and QI-12 were evaluated as optimum whereas their specifications were minimum in 2013. A partial improvement was detected for QI-10a, QI-10b, QI-11a, QI-13 and they were all considered as optimum in 2 years. Far-reaching training activities and new technological arrangements for a tube labeling system should be developed for QI-15 to have better results.

Samples lost-not received (QI-8) is the most frequent cause of rejections in the study by Adolfo Romero and also in our study [8]. These researchers claimed that they could improve the pre-analytical process by a thorough investigation, new strategies towards all health care professionals that play a role in this chain. They first planned a continuous training financed by their Regional Health Services for the preventive medicine health care professionals (primary care nurses). Similar to our study, in their study comparing errors in these 2 years, the number of lost-not received samples were 755 (3.02%) in biochemistry, 1108 in hematology (3.99%) and 1567 (8.3%) in urine samples in 2007, and these figures decreased to 635 (2.47%) in biochemistry, 843 (3.12%) in hematology and 1256 (6.6%) in urine samples, respectively, in 2009 (all $p < 0.001$). In our study while QI-8's percentage was considered 0.49 in 2013, after training activities and technological arrangements it was detected as 0.01, similar to Romero's findings. Ashakiran et al. had formulated six articles in their study that they have planned to determine the percentage of errors, categorize and reduce them as we planned [9]:

1. Phlebotomy staff: Adequate and appropriate health care professionals to maintain collection standards.
2. Phlebotomy training: Phlebotomists should complete a standard academic course in phlebotomy and undergo thorough on-the-job training under supervision.
3. Continuing training: Phlebotomists should participate in regular educational competency assessments, which gives them an opportunity to recognize their errors.
4. Evacuated tubes: The use of evacuated tube system will overcome errors pertaining to sample volume and will provide appropriate sampling for anticoagulants.
5. Prompt transport: Training should be given to transport personnel to enable the transportation of the specimens promptly to the laboratory.
6. Technology: Incorporation of barcode scanners for personal identification.

There are points on which we were still not successful in our study; we aimed to decrease our errors by applying these solutions.

Salinas et al. have shown that training, communication and arrangements in the LIS base have decreased inappropriate requests for 1,25$(OH)_2$D in the diagnosis of vitamin D deficiency [10]. In this study "inappropriate requests" were not evaluated.

Recently, the model of QIs has been updated on the basis of the recent Consensus Conference "Harmonization of Quality indicators in Laboratory Medicine: Why, How and When?", held in Padova in the October 2013. QIs in this study and in ours were in substantial agreement. But this model was designed to highlight the value of the individual QI for assessing not only the quality of the service and possible effects on patient safety, but also the feasibility of data collection [11].

All other studies and our study have shown that errors can never totally be prevented [12], however, training, the use of visual training materials and improvements in the technological infrastructure will considerably decrease errors. Managing a model of QIs would provide all laboratories especially public health laboratories with a tool to monitor and control the pre-analytical phase [13].

Another point that we consider as important is that the improvement in communication between family physicians and the laboratory and control of this communication with feed-back mechanisms will yield positive results.

We believe that decreasing errors will require continuous training and a network of communication. In this way, we aim to make positive contributions to the country's economy.

Conflict of interest statement: The authors have no conflict of interest.

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