

# Direct cost analysis for 32,783 samples with preanalytical phase errors

## Pinar Eker

Department of Biochemistry, Maltepe University Faculty of Medicine, Istanbul, Turkiye

### **ABSTRACT**

**OBJECTIVE:** Errors in the laboratory process often occur in the preanalytical phase (PA). The study aims to calculate the direct cost elements of PA errors, including material, logistics, transfer, personnel workforce, and medical waste.

**METHODS:** Medical laboratory PA phase errors were retrospectively reviewed using the Laboratory Information Management System. We evaluated the whole 2019 laboratory data of the 836-bed Health Sciences University Umraniye Training and Research Hospital (UTRH). We assessed the direct cost elements of PA errors, such as those related to material, logistics, transfer, human resources, and waste. We performed the procedure for both samples analyzed in the hospital and transferred to the central laboratory.

**RESULTS:** We analyzed 1,939,650 patient samples and 46,534,532 parameters studied in 2019 for UTRH. The rates for rejected tests and rejected samples (tube) for UTRH were noted as 0.32% and 1.7%, respectively. The total direct cost for PA errors was TRY 438,284.51 (68,918.07 euros) for 32,783 patient samples and 147,893 tests. We calculated the total cost for PA test errors detected in the hospital as TRY 390,238.06, while the total cost for PA test errors detected in the central laboratory was TRY 48,046.45. 89% of the total cost was for PA errors detected in the hospital, and 11% was for the errors detected in the central laboratory. The 2019 direct PA error cost we calculated based on our hospital's data was 0.153% of the 2019 hospital operating cost. We calculated the direct cost per rejected sample as TRY 13.37 (2.1 Euro).

**CONCLUSION:** Providing reliable laboratory service with the least possible financial loss is one of the main goals in terms of laboratory medicine. In achieving this goal, the prevention of error costs is a priority. The direct cost elements for the PA phase, where laboratory errors are concentrated, can be easily identified. The amount of PA phase error direct cost will attract the attention of health policy decision-makers and field professionals and inspire further research. Therefore, we tried to determine a threshold cost regarding interventions and practices required to prevent PA phase errors.

Keywords: Direct cost; error cost analysis; medical laboratory; patient safety; preanalytical phase.

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Evaluating all approaches to managing many diseases reveals that clinical laboratory medicine plays a central role [1]. As an essential part of qualified healthcare services, *in vitro* diagnostic (IVD) tests have been numerically increasing in the past 10 years. It appears that this trend of increase will continue in the future [2]. It has been reported that IVD based expenditures constitute 1.4–2.3% [3], while hospital operating costs constitute less than 5% of total healthcare expenditures [4]. Despite their seemingly low cost, laboratory tests have a significant share in terms of their effects on medical decisions [5]. Unfortunately, the increase in health-care expenditures cannot be directly associated with benefit production. Evidence shows that expenditures arising from excessive use, errors, unnecessary or inappropriate testing requests, and unnecessary re-testing requests exceed the fair direct costs of lab tests [6]. All of these determinations assign us, laboratory professionals, the duty of providing cost-ef-



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Correspondence: Pinar EKER, MD. Maltepe Universitesi Tip Fakultesi, Biyokimya Anabilim Dali, Istanbul, Turkiye. Tel: +90 444 06 20 - 1526 e-mail: pinar.eker@maltepe.edu.tr © Copyright 2022 by Istanbul Provincial Directorate of Health - Available online at www.northclinist.com fective laboratory services in addition to offering accurate and reliable laboratory services. The cost-effectiveness calculation is essential in improving error costs and optimizing the total cost. Considering the high amplitude of preanalytical phase (PA) errors within the laboratory process, cost becomes significant, and we decided to start.

Despite the predominant emphasis in recent years on the risks and importance of the PA process in the medical laboratory, it is stated that it is rather challenging to bring PA errors under control, standardize the process, and succeed [7].

Although studies are detecting the PA causes of unqualified samples [7-10], only few studies examine the economic effect of erroneous samples on the laboratory [11, 12]. PA errors cause additional costs such as those arising from re-sampling, re-testing, additional time allocation by the personnel for testing, and making the rootcause analyses of the errors and the disposal of the generated medical waste [12]. Studies have shown that the PA phase is the riskiest period within the overall medical laboratory process [13]. According to the data analysis, there is no national or international study evaluating all together with the elements such as materials, workforce, repeated tests, and waste concerning the direct costs of the PA process errors. Therefore, the main starting point of our study is to draw the attention of system founders in this direction through specific cost amounts that will create awareness of this subject.

The consolidated medical laboratory model commenced as part of the Istanbul Anatolian North Public Hospitals Association Central Laboratory, which was introduced in 2014 in our country, has been becoming widespread gradually. The prerequisite for consolidated laboratories is collecting samples to be delivered to a center, thereby processing many samples. Managing risky processes in such massive laboratory systems can be even more challenging [14].

Istanbul Anatolian North Public Hospitals Association Central Laboratory was the first and the most extensive consolidated laboratory in Turkey, providing the highest testing volume. Therefore, we can foresee that errors in the PA process are difficult to monitor and correct in laboratories where samples are collected for testing. Laboratory systems require a budget to correct these errors, and we want to draw attention to the amount. Therefore, we chose the Health Sciences University Umraniye Training and Research Hospital (UTRH). This hospital had the highest number of tests in 2019, and we aimed to calculate the direct cost elements related

#### **Highlight key points**

- The study aims to calculate the direct cost elements of 32,783 patient samples with PA errors in 2019 in an 836bed hospital, including material, logistics, transfer, personnel workforce, and medical waste.
- This PA cost study is the first to associate the total annual PA errors with all direct costs as part of a consolidated laboratory system.
- The total direct cost for PA errors was TRY 438,284.51 (68,918.07 euros) for 32,783 patient samples and 147,893 tests.
- The 2019 direct PA error cost we calculated based on our hospital's data was 0.153% of the 2019 hospital operating cost. We calculated the direct cost per rejected sample as TRY 13.37 (2.1 Euro).

to PA errors based on public tender prices based on the hospital's data. Therefore, in this study, we will calculate the amount of the direct financial aspects of 147,893 tests and 32,783 PA period errors conducted in 2019 for Health Sciences University Umraniye Training and Research Hospital.

# MATERIALS AND METHODS

The 2019 data of the 836-bed Health Sciences University Umraniye Training and Research Hospital (UTRH) were analyzed in this study through the Laboratory Information Management System (LIMS).

For statistical methods, we used descriptive statistical analysis. All analyses were made with Microsoft 365 Excel Version 2201.

Our agency is included in the Istanbul Anatolian North Public Hospitals Association, where a total of 13 hospitals on North Anatolian side are also affiliated to. According to 2019 data, Health Sciences University Umraniye is an 836-bed hospital providing services with its general multi-purpose unit while also operating as a maternity and children's hospital. Based on 2019 capacity indicator data, the hospital incorporates 23 operating rooms and a 63-bed newborn, 46-bed adult, and 15-bed children's intensive care units. An average of 6500 patients was examined daily in 2019. In addition, an average of 4000 operations was performed monthly, including robotic surgeries. Health Sciences University Umraniye provides services to a population of 2.9 million. The hospital's fixed costs for 2019 total Turkish Liras (TRY) 286,670,545.05, corresponding to 45,077,528.90 euros based on a yearly official euro average of TRY 6.3595.



FIGURE 1. Total expenditure and hospital-based ratio distributions for Istanbul Provincial Presidency-2 central laboratory practice for 2019. HSU: Health Sciences University; TRH: Training and Research Hospital.



FIGURE 2. Distribution of the elements where direct costs of preanalytical (PA) period errors originate according to the processes they take part in the laboratory work flow.

Within the scope of the laboratory tender for this region, 22% of the patient samples collected at UTRH were transferred to and analyzed at the central laboratory located within the campus of the Health Sciences University Fatih Sultan Mehmet Training and Research Hospital, which provides laboratory services corresponding to a total of 6400 hospital beds and where samples from 13 hospitals included in the Presidency-2 are also studied. Furthermore, urgent tests comprising a rate of 78% were analyzed at the laboratory located in the hospital's local building. As of

The reason of rejection	Rejection specifications in detail	Loca	Total	
		Hospital	Central laboratory	
All factors	Worked test amount	32,512,507	14,022,025	46,534,532
	Rejected test amount	135,332	12,561	147,893
	Worked tube amount	1,516,923	422,727	1,939,650
	Rejected tube amount	26,270	6,513	32,783
	The ratio of rejected test	0.42	0.09	0.32
	The ratio of rejected tube	1.73	1.54	1.69
Hemolysis	The tube count rejected because of hemolysis	7,820	1,441	9,261
	The test count rejected because of hemolysis	17,402	2,575	19,977
	The ratio of hemolyzed tests/ rejected tests	13	20.50	13.51
	The ratio of hemolyzed tests /total worked tests	0.05	0.02	0.04
	The ratio of hemolyzed tubes/rejected tubes	30	22	28.25
	The ratio of hemolyzed tubes/total worked tubes	0.52	0.34	0.48
Fibrin	The tube count rejected because of fibrin	8,642	1,624	10,266
	The test count rejected because of fibrin	87,547	2,404	89,951
	The ratio of rejected tests because of fibrin/rejected tests	65	19.14	60.82
	The ratio of rejected tests because of fibrin/total worked tests	0.2693	0.0171	0.19
	The ratio of rejected tubes because of fibrin/rejected tubes	33	25	31.32
	The ratio of rejected tubes because of fibrin/total worked tubes	0.57	0.38	0.53
Insufficient	The tube count rejected because of insufficient volume	7,126	949	8,075
volume	The test count rejected because of insufficient volume	21,482	4,083	25,565
	The ratio of rejected tests because of insufficient volume /rejected tests	16	32.51	17.29
	The ratio of rejected tests because of insufficient volume /total worked tests	0.07	0.03	0.05
	The ratio of rejected tubes because of insufficient volume /rejected tubes	27	15	24.63
	The ratio of rejected tubes because of insufficient volume /total worked tubes	0.47	0.22	0.42
Other	Rejected tube amount because of other reasons	2,672	2,499	5,171
reasons	Rejected test amount because of other reasons	8,901	3,499	12,400
	The ratio of rejected tests because of other reasons/rejected tests	7	27.86	8.38
	The ratio of rejected tests because of other reasons/total worked tests	0.03	0.02	0.03
	The water of weighted to be a base of other water and weighted to be	10	20	15 77
	The ratio of rejected tubes because of other reasons/rejected tubes	10	20	15.//

2013, laboratory services were provided for all tests delivered to hospitals and centers (ten training and research and three state hospitals) listed in Figure 1 with a single general price tendered per Republic of Turkey Healthcare Practices Communication (SUT) point to the service procurement tender. However, in 2019, a different practice was started, in which the laboratory services tender was divided into parts and implemented. Considering the volume of samples received by the central laboratory, UTRH ranks 1<sup>st</sup> with a rate of 17% in terms of services produced for all hospitals (Fig. 1). We decided to investigate the PA period error costs with the direct cost elements due to the emerging opportunity of obtaining more accurate net prices in terms of the distributions of PA errors by their sources, thanks to the availability of the prices sub-processes for the 1st time. As the direct cost elements, the calculations were based on sample tube/container and test evaluations for all error elements rejected due to PA errors in 2019 and not reimbursed by TABLE 2. The cause distributions of tests rejected due to Preanalytical (PA) errors in 2019 at the hospital and the central laboratory and retesting costs

Reason of rejection	Total amount (test)		The ratio of rejected tests total amount of rejected tests %		The ratio of rejected tests/ total worked tests %		The cost of retesting (TRY)	
	HL	CL	HL	CL	HL	CL	HL	CL
Hemolysed sample	17,402	2,575	12.86	20.50	0.0535	0.0184	10,940.27	4,328.73
Clotted sample (with fibrin)	87,547	2,404	64.69	19.14	0.2693	0.0171	228,038.84	3,611.62
Insufficient volume	21,482	4,083	15.87	32.50	0.0661	0.0291	59,068.75	15,335.67
Wrong sample container*	2,255	1,153	1.67	9.18	0.0069	0.0082	-	_
Unsuitable sample (macroscopic hematuria)	1,058	833	0.78	6.62	0.0033	0.0059	1,649.42	2,281.02
Overfilled tube*	1,063	-	0.79	_	0.0033	_	_	_
Wrong test request*	510	296	0.38	2.36	0.0033	0.0021	_	-
Unsuitable transfer conditions	566	310	0.42	2.47	0.0016	0.0022	2,558.28	1,604.61
Empty sample cup*	515	752	0.38	5.99	0.0017	0.0054	_	_
Incorrect identification/sample collection								
from the wrong patient	734	21	0.54	0.17	0.0016	0.0001	2,411.96	215.69
Spilling in the pneumatic system*	602	_	0.44	-	0.0023	-	-	-
Sample evacuated from the hemogram tube	408	-	0.31	_	0.0019	_	989.29	_
Taking sample from the serum line	244	_	0,18	-	0.0013	-	947.67	-
Erroneous recording*	56	11	0.04	0.09	0.0008	0.0001	_	-
Not recorded sample collection time	19	16	0.01	0.13	0.0002	0.0001	79.96	267.31
Insufficient data on request/ wrong data on								
request*	15	5	0.01	0.04	0.0001	0.0000	_	_
Unsuitable stored sample	_	37	_	0.29	-	0.0003	_	206.24
Other	856	65	0.63	0.52	0.0026	0.0005	4,032.59	1,222.95
Total	135,332	12,561	100	100	0.0042	0.0009	310,717.03	29,073.84

HL: Hospital laboratory; CL: Central laboratory; TRY: Turkish Liras; \*: Error types causing sample container cost but not retesting cost.



FIGURE 3. Preanalytical (PA) error direct cost elements without reimbursement.

the Social Security Institution (urine culture rejected due to contamination is reimbursed in our country as part of the health system and therefore not included in this study to be assessed in a different study) considering the below:

- Amount of rejected but studied tests,
- Materials used as part of the PA process,
- + Costs of all expenditures, including transfers and logistics,

Blood tube/cup type	Total number		PA process cost (TRY)		Unit weight (tube/container filled at the vacuum rate in grams)		Waste cost (TRY) [Number of container/tube × weight] × [waste cost/kg (TRY 5)] (medical waste price TRY 5 per kg)	
	HL	CL	HL	CL	HL	CL	HL	CL
Yellow/red-top serum tube	10,071	3,636	15,700.69	5,668.52	13.35	13.35	134.45×5=672	48.5×5=242.5
Lavender-top EDTA tube (3 mL)	5,987	2236	9,333.73	3,485.92	9.43	9.43	56.4×5= 282	21×5=105
Lavender-top EDTA tube (9 mL)	-	40	-	62.36	_	20.04	-	0.8×5=4.0
Coagulation tube (3 mL)	8,530	84	13,298.27	130.96	9.43	9.43	80.4×5=402	0.8×5=4.0
Urine tube and container								
(2/3 full 100 mL cup)	1,513	19	2,358.77	29.62	80.0	80.0	121×5=605	1.5×5=7.5
Stool container and other								
microbiologic culture containers	133	400	207.35	632.6	6.82	6.82	0.9×5=4.5	2.7×5=13.5
Grey-top tube 3 m	36	3	56.12	4.68	9.43	9.43	0.3×5=1.5	0.02×5=0.1
24-h urine container (2/3 full)	-	10	-	15.59	-	2133	-	21.3×5=106.5
Green-top heparin tube 5 mL	-	34	-	53.0	-	8.11	-	0.27×5=1.35
Other sample container types								
(CSF tube, hirudin tube etc.)	-	51	-	79.51	-	9.34	-	0.5×5=2.5
Total sum	26,270	6,513	40,954.93	10,162.76	-	-	1,965	486.45

TABLE 3. The type distribution of the tubes rejected in the hospital and the central laboratory in 2019 due to preanalytical (PA) errors and their evaluation in terms of cost elements

HL: Hospital laboratory; CL: Central laboratory; TRY: Turkish Liras; kg: Kilogram; CSF: Cerebro spinal fluid; EDTA: Ethylenediamine tetra-acetic acid; PA: Preanalytical.

- Personnel work-time cost for repeated phlebotomy procedures,
- Work-time cost for specialist and non-specialist personnel who work for the processing of the rejected samples,
- Waste disposal costs for rejected samples.

Figure 2 shows the distribution of the main elements where direct costs of PA period errors originate according to the processes they take part in the laboratory workflow.

For calculating personnel work-time costs, the corresponding fees for the time spent per each rejected tube were detected by the projection of the rates of rejected samples and total studied samples. Salary data for non-specialist public employees were calculated based on the minimum value for employees of equivalent positions considering the payrolls of the UTRH employees. Specialist doctors are publicly funded, and the salary data for grades 1 level 4 were used for calculations. Official payments reflected on the tender were considered for the employees of the non-public contractor company. The ethics committee approval of the study was obtained from the University of Health Sciences Umraniye Training and Research Hospital Clinical Research Ethics Committee with the number 73.

While calculating the material costs, prices listed in the 2019 central laboratory tender were used, in which UTRH (Umraniye Training and Research Hospital) also participated. 2019 official average of exchange for Euro was used for all euro-based trades. The unit price for PA materials was TRY 1.5590 (0.245 euros) for each sample. Comprising all expenditure elements that may take part in the PA process, such as tubes, needles, holders, tourniquets, gloves, transfer, medical waste bags, cotton, sharp object waste containers, sorter, centrifuge, and staff were included in the study. The tender's SUT point unit price for the most extensive laboratory section (biochemistry, microbiology, culture, molecular testing, serology, immunology, electrophoresis, metabolism, and esoteric tests) was TRY 0.3393 (0.053 euros). SUT point unit price for blood count (hemogram) and Sedimentation rate tests were TRY 0.2489

TABLE 4. Distributions of specialist and non-specialist personnel working at the central and hospital laboratories and the worktime costs corresponding to the rejected tests

Type of personnel	Central laboratory		Hospital laboratory		
	Tender firm	Public	Tender firm	Public	
	employee	employee	employee	employee	
Specialist	_	27	_	7	
2019 salary amount (TRY)*	-	7,300×12=	-	7,300×12=	
		87,600		87,600	
Total amount (TRY)	-	2,365,200	-	613.2	
Non-specialist	48	32	3	17	
2019 total salary amount per person (TRY)	3,005.65×12=	4,500×12=	3,005.65×12=	4,500×12=	
	36,067.8	54,000	36,067.8	54,000	
Total amount (TRY)	1,731,254.40	1,728,000	108,203.40	918	
Total number of worked samples	6,032,	,472	1,516,923		
Number of samples rejected for UTRH	6,51	13	26,27		
Workforce cost per sample (TRY)	0.965	517	1,080.742		
Workforce corresponding to rejected samples (TRY)	6,28	8.4	28,391.1		
Total work-time cost spent for UTRH rejections (TRY)				34,679.5	

HL: Hospital laboratory; CL: Central laboratory; TRY: Turkish Liras; UTRH: Umraniye Training and Research Hospital; \*: Salary and fixed payments were considered for the specialist salary while payments from the revolving capital were excluded due to varying amounts.

(0.039 euros). SUT point unit price for coagulation tests was TRY 0.2730 (0.043 euros). Each unit price also included all reagents, analyzers, auxiliary laboratory devices (vortex, centrifuge, incubator, etc.), kits, control and calibrator materials, other consumables, and technical personnel per device.

Elements not included in the SUT unit price are work-time costs for specialists and public employees, time spent repairing extra breakdowns such as PA error-based probe blockages that are not included in the devices' routine care costs, and material and personnel expenditure costs for part replacement. PA error-caused extra device care and probe replacement were not considered. These parts were not reflected in the calculations in the study because of the difficulty in separating them from other reasons.

# RESULTS

PA phase error codes required for our study were examined over the LIMS, separated as hospital and central laboratory data, and presented in Table 1. Afterward, detailed analyses were performed regarding these error codes, and cost items were created one by one in line with the below-mentioned steps: The cause distributions of tests rejected due to PA errors in 2019 at the hospital and the Central laboratory and test study costs are shown in Table 2. The numbers and types of restudied tests of which their causes of rejection were indicated on a test basis in our LIMS records were multiplied by tender unit prices to obtain the costs.

The distribution of rejected tubes and the causes are shown in Table 3. PA errors that occur both in the hospital and central laboratory in 2019 and cost elements are shown in Table 3. Calculations were based on tube types and sample containers that we should reuse. Table 3 also includes medical waste costs over the kg price amount after detecting the unit weight (tube/container filled at the vacuum rate in grams) of each tube and container.

Distributions of specialist and non-specialist personnel working at the central laboratory and the hospital and the work-time costs corresponding to the rejected tests were calculated and shown in Table 4. Costs were calculated separately for the company and public employees working at the hospital and the central laboratory based on official salary data. The total salary was considered for the studied samples, and the amount corresponding to the number of rejected samples was calculated proportionally.

IAB	LE 5.	Personnel	work-time	cost for	repeated	phlebotomy
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	Hospital-based	Central-based	Total
Total number of resampling tubes	26,270	6,513	32,783
Time to repeat phlebotomy average 45 seconds/tube	328.4 h	81.4 h	409.8 h
Phlebotomy work-time cost TRY 25 per hour personnel expenditure	8,210	2,035	10,245
TRY: Turkish Liras			

TABLE 6. Association of the direct cost of rejected unreimbursed preanalytical (PA) erroneous samples to total costs

UTRH 2019 operating cost (TRY)	286,670,545.05
Euro for 2019 /1 TRY	6.3595
UTRH 2019 operating cost (Euro)	45,077,528.90
UTRH cost of rejected tests for PA error (TRY)	438,284.51
UTRH cost of rejected tests (EURO)	68,918.07
Ratio of cost of rejected tests/total operating cost	0.153
UTRH 2019 laboratory expenditures (TRY)	11,936,596.07
UTRH 2019 laboratory expenditures (EURO)	1,876,970.84
Proportion of the cost of rejected tests to UTRH annual laboratory expenditures	3.67
Cost per PA erroneous tube (TRY)	13.37
Cost per PA erroneous tube (Euro)	2.1
Presidency 2 predicted (calculated based on UTRH) PA error cost sum (TRY)	2,554,361.96
Presidency 2 predicted (calculated based on UTRH) PA error cost sum (Euro)	401,660.82
PA: Preanalytical; TRY: Turkish Liras; UTRH: Umraniye Training and Research Hospital.	

Personnel work-time cost for to-be-repeated phlebotomy is shown in Table 5 UTRH has high daily numbers for outpatients and hospitalized patients. According to the observational study data performed within the scope of quality system improvement efforts, the average duration of phlebotomy per patient was (average time of the procedure was considered by monitoring the 3-h morning shift) 45 s. Therefore, we calculated the fee corresponding to the duration.

The total amount of PA error direct cost elements without reimbursement are being shown on Figure 3. The total cost for hospital-related PA test errors was calculated as TRY 390,238.06, while the total cost for central laboratory-related PA test errors was calculated as TRY 48,046.45. A total of 1,939,650 patient samples and 46,534,532 tests were studied for UTRH in 2019, and the total direct cost for PA errors was calculated as TRY 438,284.51 (68,918.07 euros) for 32,783 samples

and 147,893 tests rejected because of a PA error. As a result, 89% of the total cost originated from the hospital, and 11% originated from the central laboratory. The rates for rejected tests and rejected samples (tubes) for UTRH were noted as 0.32% and 1.69%, respectively. In the Central laboratory, the most frequent causes of rejection were "other" causes (38%), clotted sample (25%), hemolysis (22%), and insufficient sample (15%). At the hospital laboratory, we had found clotted sample (33%), hemolysis (30%), insufficient sample (27%), and other causes (10%); the cost per rejected sample was TRY 13.37 (2.1 euros). In proportion to UTRH's 2019 operating cost, 0.153% of TRY 286,670,545.05 (45,077,528.90 euros) consist of the direct cost for PA errors. This proportion corresponds to 3.67% of the annual laboratory expenditures of TRY 11,936,596.07 (1,876,970.84 euros) (Table 6).

For all hospitals taking service from Istanbul Anatolian North Public Hospitals Association central laboratory predicted (calculated based on UTRH) PA error cost sum (TRY) was 2,554,361.96 and 401,660.82 in euros.

### DISCUSSION

This PA cost study is the first to associate the total annual PA errors with all direct costs as part of a consolidated laboratory system. Indirect elements, their impact on clinical outcomes, and indirect cost calculations were excluded in this study. It was reported that this impact may be 10-fold more compared to the direct elements [11].

Evaluating all approaches related to managing many diseases reveal that clinical laboratory medicine plays a central role [1]. We are not fully aware of this significant role and effect of laboratory medicine on patient care since the impact of medical treatment is more observable on the patient. When the diagnosis is incorrect, the treatment will not be appropriate either. With proper treatment as a result of an accurate diagnosis established utilizing biomarkers and other medical laboratory tests, the clinical benefit can be provided for the patient in addition to economic benefits for the entire health system [15].

Overall Europe, access to *in vitro* diagnosis opportunities varies between countries due to different usage of resources for these tests [1].

According to the 2018 European IVD market report, annual IVD expenditure varies between 4.6 euros (Bulgaria) and 54.5 euros (Switzerland) for each person [16]. The same report indicates a value of 7.99 for 2018 for Turkey [16]. In the 2019 report, no data could be calculated for Turkey, shown as "N/A" [17]. We can make such a rough comparison of the IVD expenditure per person for 2018: The direct cost of 4 rejected samples with PA errors can cover one person's annual IVD expenditure.

In 2019, Kulkarni et al. [12] published that 13.1% of a total of 557,411 INR tests were performed between September 2009 and 2013 with a total annual cost of USD 379,222.50 had a PA error code, and the cost of errors comprised 10.5% (USD 39,939.00) of annual INR test budgets. In this study, the cost was calculated based on work-time cost and materials for each INR test. The waste cost was not considered. Since being a PA error cost study focusing on a single test can explain the difference from the error cost rate obtained in our study, corresponding to 3.67% of the total laboratory expenditure. It can be foreseen that the rate based only on INR would be higher compared to that in our study due to the diversity of the number of tests evaluated in our study and their differing manners and rates of impact from PA errors.

In a study by Green published in 2013 in Clinical Biochemistry, cost effects were analyzed in a total of 7 hospitals in four countries, including the USA, Canada, Germany, and Ireland, based on error scenarios originating from erroneous samples within the preanalytical process [11]. In this study, each PA period error cost was calculated as an average of 208 US dollars/error for North America and Canada and an average of 157 euros/error for European hospitals.

PA erroneous sample cost was calculated an average of 0.23-1.2% of total hospital operating expenditures, while this value was reported as USD 1,199,122/year for a 650-bed hospital in the USA. The 2019 PA error cost we calculated based on our hospital's data was 0.153% of the 2019 hospital operating cost. On the other hand, while comparing the rate indicated in the mentioned study, it should be noticed that indirect cost elements based on patient scenarios were also considered in that study in addition to direct costs. Indirect cost elements such as prolonged duration of hospitalization, treatment delays, and the related additional further testing costs were not regarded in our study. However, considering that this rate can increase tenfold with the contribution of indirect cost elements [11] a rate of 1.53% (0.153  $\times$ 10) can be regarded as consistent with the study of Green et al. in terms of closeness to the upper limit.

According to the Turkish Statistical Institute (TUIK) data, the total health expenditure for 2019 is 201,031 million Turkish Liras [18]. A total of 96,883 million Turkish Liras (48.2%) of this amount is related to hospitals. Based on a rough projection, we can estimate that 0.153% of the UTRH's operating cost can be proportional to the amount lost due to PA error direct cost elements within overall Turkey's hospital health expenditures, which correspond to TRY 148,230,990. The TUIK data state TRY 2,434 for health expenditures per person for 2019. This number can be estimated to reach the annual health expenditure of 60,900 people. As a striking example, it can be stated that the 2019 health expenditure of the entire population of "Safranbolu" district, where 68,440 people were living 2019 [19], which is one of Turkey's touristic attractions, was spent due to PA errors. A more striking analysis is that this amount corresponds to an average 3.7-month part of the entire 2019 laboratory services budget of Istanbul's all state hospitals and family health center.

The elimination or reduction of errors within the entire laboratory process which is a sub-process of the leading health system and in the riskiest part of the whole laboratory process PA phase requires coherent efforts from health organizations, material/device producers, and policymakers as well as laboratory professionals. The affecting parameters should be identified and analyzed correctly. We have a single goal that drives us toward the need for a cure, producing a more reliable patient outcome.

#### Conclusion

The goal is to realize reliable laboratory testing services by generating the most negligible fiscal output possible. Preventing PA error costs is of priority in achieving this goal. Direct cost elements were studied as the first step since they could be detected easily, thereby attracting the attention of the decision-makers and area professionals.

In recent years, laboratory services have been undergoing significant changes in operating models and cost solutions, among other healthcare services. In this change process, having a good understanding of financial data elements, especially PA phase laboratory errors, will enhance the strength of laboratory specialists and managers in operating hospitals and related units where cost has become an essential parameter. In addition, the PA error cost analysis result will have a threshold cost regarding interventions and practices required to prevent PA phase errors.

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## REFERENCES

- 1. Jordan B, Mitchell C, Anderson A, Farkas N, Batrla R. The clinical and health economic value of clinical laboratory diagnostics. EJIFCC 2015;26:47–62.
- Bogavac-Stanojevic N, Jelic-Ivanovic Z. The Cost-effective laboratory: implementation of economic evaluation of laboratory testing. J Med Biochem 2017;36:238–42. [CrossRef]

- PLOS ONE Staff. Correction: The value of *in vitro* diagnostic testing in medical practice: a status report. PLoS One 2016;11:e0154008.
- The Lewin Group, Inc. The value of diagnostics innovation, adoption and diffusion into health care; 2005. Available at: https://www. lewin.com/content/dam/Lewin/Resources/Site\_Sections/Publications/3993.pdf. Accessed Date 06.02.2022.
- 5. Wilke MH, Schenker M, Hoffmann G. Detection and documentation of DRG-relevant comorbidities using laboratory tests. Aust Health Rev 2002;25:152–60. [CrossRef]
- 6. Plebani M, Panteghini M. Promoting clinical and laboratory interaction by harmonization. Clin Chim Acta 2014;432:15–21. [CrossRef]
- Lippi G, Simundic AM; European Federation for Clinical Chemistry and Laboratory Medicine (EFLM) Working Group for Preanalytical Phase (WG-PRE). The EFLM strategy for harmonization of the preanalytical phase. Clin Chem Lab Med 2018;56:1660–6. [CrossRef]
- 8. Plebani M. Quality indicators to detect pre-analytical errors in laboratory testing. Clin Biochem Rev 2012;33:85–8.
- 9. Plebani M. The detection and prevention of errors in laboratory medicine. Ann Clin Biochem 2010;47:101–10. [CrossRef]
- Lima-Oliveira G, Volanski W, Lippi G, Picheth G, Guidi GC. Preanalytical phase management: a review of the procedures from patient preparation to laboratory analysis. Scand J Clin Lab Invest 2017;77:153–63. [CrossRef]
- 11. Green SF. The cost of poor blood specimen quality and errors in preanalytical processes. Clin Biochem 2013;46:1175–9. [CrossRef]
- Kulkarni S, Piraino D, Strauss R, Proctor E, Waldman S, King J, et al. The cost of pre-analytical errors in INR testing at a tertiary-care hospital laboratory: potential for significant cost savings. Lab Med 2020;51:320–4. [CrossRef]
- 13. Simundic AM, Bölenius K, Cadamuro J, Church S, Cornes MP, van Dongen-Lases EC, et al; Working Group for Preanalytical Phase (WG-PRE), of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) and Latin American Working Group for Preanalytical Phase (WG-PRE-LATAM) of the Latin America Confederation of Clinical Biochemistry (COLABIOCLI). Joint EFLM-COLABIOCLI recommendation for venous blood sampling. Clin Chem Lab Med 2018;56:2015–38. [CrossRef]
- Plebani M. Clinical laboratory: bigger is not always better. Diagnosis (Berl) 2018;5:41–6. [CrossRef]
- 15. Green SM, Martinez-Rumayor A, Gregory SA, Baggish AL, O'Donoghue ML, Green JA, et al. Clinical uncertainty, diagnostic accuracy, and outcomes in emergency department patients presenting with dyspnea. Arch Intern Med 2008;168:741–8. [CrossRef]
- European IVD Market Statistics Report 2019. Available at: https:// www.medtecheurope.org/wp-content/uploads/2019/12/2019\_ MTE\_European-IVD-Market-Statistics.pdf. Accessed Feb 07, 2022.
- European IVD Market Statistics Report 2020. Available at: https:// www.medtecheurope.org/wp-content/uploads/2020/12/2020\_mte\_ european-ivd-market-statistics-2020.pdf. Accessed Feb 07, 2022.
- Türkiye İstatistik Kurumu. Sağlık Harcamaları İstatistikleri, 2019. Available at: https://data.tuik.gov.tr/Bulten/Index?p=Saglik-Harcamalari-Istatistikleri-2019-33659. Accessed Feb 07, 2022.
- 19. https://www.nufusu.com/ilce/safranbolu\_karabuk-nufusu. Accessed Feb 07, 2022.