Original Article

Evaluation of Phlebotomy Quality Metrics: An Effective Tool for Quality Patient Care

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Abstract

Introduction: Contrary to popular belief, phlebotomy is not just about venipuncture. Still, it is much more than that as phlebotomy is considered a natural face of any laboratory that provides vital support for complete diagnostic services. Quality in laboratory results significantly impacts the diagnosis and management of patients since about 80% of all medical decisions are based on laboratory results. Quality indicators (QIs) are known to analyse the performance of laboratories and monitoring of QIs leads to finding areas that need improvement. QIs are qualitative or quantitative information associated with an event, process or result put under observation, which can evaluate the changes over time. It is also able to verify achievement by comparing it with set criteria. **Materials and Methods:** A laboratory-based cross-sectional study was conducted to evaluate QIs from January 2017 to date undertaken to evaluate the following quality parameters: (a) incompletely filled requisition forms (RFs), (b) wrongly labeled samples, (c) haemolysed samples, (d) clotted samples, (e) turnaround time estimation and (f) topographical errors. These indicators were captured daily and analysed monthly, and appropriate remedial steps were taken. **Results:** A total of 315,250 samples were received during the study period. In the pre-analytical phase, incomplete RFs 3783 (1.2%) was the poorest QI, followed by haemolysis 2522 (0.8%) samples. **Conclusion:** Continuous monitoring of QIs not only helps provide error-free services but also helps qualitative improvement of diagnosis services along with better patient care.

Keywords: Phlebotomy, quality indicators, quality patient care

Introduction

Laboratory error ranges from ordering tests to reporting results. The incidence of laboratory is around 0.012%–0.6% of all test results, which greatly impacts diagnosis and management as 90% of diagnoses are made by laboratory tests.[1] A systematic approach is needed to eradicate the errors. Quality indicators (QIs) are utilised to assess the quality of all the processes. The implementation of quality management system (QMS) is the initial step towards this direction. Contrary to popular belief, phlebotomy is not just about venipuncture. Still, it is much more than that as phlebotomy is considered a real face of any laboratory which provides vital support towards the entire diagnostic services.[2] QMS results impacted the diagnosis and management of patients since about 80% of clinical decisions are based on laboratory results. QIs are known to analyse the performance of laboratories. In accordance with the last version of the International Standard for clinical laboratory accreditation (ISO15189:2012) clause 3.19, QI can evaluate how well an organisation meets the needs and also the overall quality of operational procedures.[2] ISO also states that the laboratory should establish QIs to assess performance in all aspects, including pre-examination, examination and post-examination.[3] For laboratory testing, common term utilised is a total testing process (TTP), divided into three (pre, intra and post) analytical phases. The frequency of errors in TTP is more profound in the pre-analytical phase attributed to person/system design defects. QI depicts the quantification of certain selected aspects of care.[4] A lack of training guidelines, standard operating procedures and biosafety mechanisms may affect the compliance of laboratory results derived from blood collection and needs to

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be addressed.[5] The following standards were kept in mind for training the staff according to the WHO recommendation guidelines for phlebotomy training:

- In-service training supervision was provided
- Training programme provided theoretical and practical knowledge in blood sampling and blood drawing
- Information was given regarding infection prevention and control procedures
- A competence certificate was awarded to every candidate after completing this training programme.

Aim and objectives

1. To recognise the most vital indicators for recognising laboratory errors
2. To Evaluate the role of medical, nursing and laboratory personnel training in preparing patients and collecting and transporting samples
3. To assess quality assurance and reporting of results and noting the errors during TTP, over 12 months, i.e. from January to December 2010, helping improve laboratory performance.[5] QI's were assessed for 5 years to ascertain certain aims;
    a. Areas of strength and weakness
    b. Possible remedial measures
    c. Scope for further improvement of blood specimens received for routine biochemistry, haematology and serological testing was included in the present study. Histopathology and microbiology (other than serology) samples were excluded from the study.[6] All the tests were evaluated utilising fully automated auto analysers-XL-300 from Transasia Pvt. Ltd. Along with Ion Selective Electrolyte Analyser from CL Micromed (for clinical chemistry) and SYSMEX (for haematology).

Materials and Methods

This study was a hospital-based, cross-sectional observational study. The questionnaire was utilised to evaluate the phlebotomy service practice. The questionnaire layout was intended to be simple and relevant to ensure that it could be completed within the shortest time. Prior IEC (ICE/ER/234) was taken, and confidentiality was maintained. The data collection was qualitative and quantitative, and data were particularly used for research purposes. In the current study, indicators assessed the performance of each section of the laboratory as follows: biochemistry, haematology including identification and rejection of specimen, TATs (Turn Around Time), reporting of critical value and outliers in proficiency testing. This list is in accordance with the requirement of laboratory improvement amendments of clinical laboratory improvement amendments.[7] After receiving the samples in the laboratories, QIs are noted in the lab after a careful screening of the sample and requisition form (RF) by the laboratory technician to assess the pre-analytical phase. Parameters checked for this phase were completeness of RF (name, age, sex, hospital no., ward/emergency outpatient department, requesting doctor's name with signature, clinical information, date and time of sample collection), quality of the sample (haemolysed/clotted/lipaemia/quantity not sufficient/inappropriate vials).[8]

The performance during the analytical phase is assessed as repeat testing along with proficiency testings and performance indicators monitored in the post-analytical phase are critical ample reporting and TATs for biochemistry, haematology and serology. Repeat testing was done in situations such as to confirm the test value by the laboratory personnel and at the treating doctor's request.

As a part of total quality management and towards the improvement of patient care, our institute has started a 3-month long 'Phlebotomy Certificate Course' under the National Skills Qualifications Framework Ministry of Skill Development and Entrepreneurship, Government of India to exclusive deals with phlebotomy issues.[9] The course is managed by qualified staff and is done in the skill lab of our institute. After completion of the course, theory and practical examinations are conducted with the 2 external examiners.

The course contents are highlighted in Table 1. A total of 150 students, with 65 qualified nurses and 85 qualified technicians, enrolled in the course and voluntarily participated in the research. Phlebotomy performance was assessed in patients who received the service after Oral consent was taken from phlebotomist volunteers participating in the current study. According to clinical and laboratory standards institute (CLSI) recommendations, phlebotomists were monitored for 5 different blood sample collection practices. The remarks were reviewed by independent expert evaluators and scored against a criterion-based CLSI checklist to identify pre-analytical technical errors made by the phlebotomists.[10]

Table 1a: Details of phlebotomy course showing various lecture classes organised according to the syllabus (*n*=150)

Criteria	Percentage of candidates who gave correct answer (pre-test before training)	Percentage of candidates who gave correct answer (post-test after training)
Phlebotomy techniques	60 (40)	147 (98)
Vacutainers (types and uses)	30 (20)	144 (96)
Order of draw	27 (18)	135 (90)
Sample transportation	23 (15)	144 (96)
Patient preparation	30 (20)	134 (89)
Basic anatomy and physiology	27 (18)	135 (90)

Table 1b: Percentage of correctly answered questions before and after completion of phlebotomy certificate course

Criteria's	Total number candidates appeared	Mean score (total score 150)	SD	*P*
Pre-test	150	14.6	1.3	<0.001
Post-test	150	47.5	2.9	

SD: Standard deviation

Table 1c: Comparison and statistical analysis of pre-test and post-test scores of the candidate enrolled in the phlebotomy course

Quality parameters of phlebotomy	Yes	No
Q1. Was the patient identified according to CLSI?		
Q2. Did the phlebotomist ask for permission before blood collection?		
Q3. Was the tourniquet placed correctly?		
Q4. Did the phlebotomist select a suitable venipuncture site?		
Q5. Did the phlebotomist know how to apply the tourniquet?		
Q6. Was the phlebotomist wearing gloves for each patient?		
Q7. Was the venepuncture site disinfected according to guidelines?		
Q8. Was alcohol allowed to evaporate before venepuncture?		
Q9. Did the venepuncture site remain untouched after disinfection?		
Q10. Did the phlebotomist ask the patient to clench their fists during collection?		
Q11. Was the tourniquet time within CLSI recommendations?		
Q12. Was the tourniquet released immediately after blood flow began?		
Q13. Were the tubes used labelled in front of the patient?		
Q14. Did the phlebotomist use a syringe to transfer blood to a vacutainer?		
Q15. Did the phlebotomist use vacutainer tubes with multisampling needles?		
Q16. Did the phlebotomist use a syringe to transfer blood to a vacuum tube by opening the cover?		
Q17. Did the phlebotomist mix the blood gently to avoid haemolysis?		
Q18. Did the phlebotomist have knowledge about sample kinds?		
Q19. Were the blood coagulation samples collected according to guidelines?		
Q20. Was a cotton or adhesive bandage placed over the venepuncture site after sampling?		
Q21. Did the phlebotomist recap the needles and syringes?		
Q22. Was the anticoagulated blood tube mixing time accepted or not?		
Q23. Was there any needle stick injury?		
Q24. Were syringes and needles disposed correctly after sampling?		

CLSI: Clinical and Laboratory Standards Institute

Being a National Accreditation Board for Testing and Calibration Laboratories accredited laboratory, the various non-conformities observed during the phlebotomy exercise were noted and accordingly corrective and preventing action initiated Current study evaluated the total duration of QIs monitoring and was divided into two phases as; 'Phase I' in which QIs were monitored before sensitisation of the medical, nursing and laboratory personnel before the starting of the certificate course and 'Phase II' in which QI was assessed after the completion of the course period. Statistical analysis was done utilising (SPSS software 23.0)-Statistical Package for the Social Sciences 23.0 (IBM, Chicago IL, USA). The pre-test and post-test scores of the nursing staff and the number of complaints recorded before and after the commencement of the course were compared using a *t*-test.[11]

This study aimed to compare the performance of nursing staff in the test taken in both scenarios, that is, before the training programme and after the training programme to monitor the impact of the training course on the phlebotomy staff regarding improvement in their knowledge and practice of phlebotomy.

Results

This study was a hospital-based, cross-sectional observational study. A laboratory-based cross-sectional study was conducted to evaluate QIs from January 2017 to date undertaken to evaluate the following quality parameters. A total of 315,250 samples were received during the study. The topic contents are mentioned in Table 1a. Twenty percent gave the correct answers regarding the phlebotomy techniques, 15% regarding sample transportation, 20% about patient preparation and 18% about basic anatomy after the lectures [Table 1b]. Comparing pre-test and post-test scores of candidates enrolled in phlebotomy courses showed statistically significant results [Table 1c]. Table 2 consists of the questionnaire showing the phlebotomy parameters. Pre-analytical observations recorded by phlebotomists are enlisted in Table 3. Pre-analytical errors noted by the phlebotomist before and after course completion are mentioned in Table 4. The corrective and preventive actions initiated to ensure quality service are mentioned in Table 4.

Discussion

Each step in the phlebotomy process affects the specimen quality and is vital for preventing laboratory errors. Phlebotomy also poses a risk for health workers. Nowadays, it is commonly observed that phlebotomists applying dangerous practices lead to an increased risk of needle stick injury and transmission of disease.[12] Dangerous practices include the following, (a) recapping of used needles utilising hands, (b) recapping and disassemblement of vacuum-containing tubes and holders, (c) reusing the tourniquets and vacuum tube holders may be associated with bacterial contamination or contaminated by blood and (d) working solely with confused/disoriented patients who might move unexpectedly, leading to needle stick injuries. Factors that affect the final outcome of laboratory results while collection and transportation of samples include: Knowledge level of staff deployed in the blood collection centre along with the selection of proper anatomic sites and use of appropriate

size needles. The use of correct number gauge for hypodermic needles to prevent haemolysis/abnormal results Knowledge of correct and anatomical insertion site for venepuncture usage of recommended lab collection tubes patient sample matching (i.e. labeling) transportation conditions Assessment of results for clinical management [Tables 1 and 2].

Table 2: Questionnaire showing the phlebotomy quality parameters

Steps	Yes (n=150), n (%)	No (n=150), n (%)
Phlebotomist easily identified patients	130 (86.66)	20 (13.33)
Phlebotomist asked permission before collecting blood	135 (90)	15 (10)
Wearing gloves	128 (85.33)	22 (14.66)
Wearing a new glove for each patient	132 (88)	18 (12)
Cleaning the puncture site with 70% alcohol	127 (84.6)	23 (15.33)
Collecting blood after alcohol drying	133 (88.66)	17 (11.33)
Retouching of the cleaned site	137 (91.33)	13 (8.66)
Request to clenching fist during collection	122 (81.33)	28 (18.66)
Labelling of test tube before collection	138 (92)	12 (8)
Using a syringe to transfer blood to test tube	100 (66.66)	50 (33.33)
Using multisampling needle with holder	129 (86)	21 (14)
Release the tourniquet when the blood starts flowing	90 (60)	60 (40)
Duration of tourniquet based on CLSI	111 (74)	39 (26)
Adding blood by opening the vacuum tube	140 (93.33)	10 (6.66)
Gentle mixing to avoid haemolysis	136 (90.66)	14 (9.33)
Mixing time of the specimen	127 (84.66)	23 (15.33)
Apply cotton or adhesive bandage	132 (88)	18 (12)
Collect the coagulation sample properly	141 (94)	9 (6)
Needle stick injury	20 (13.33)	130 (86.66)

CLSI: Clinical and laboratory standards institute

A QI is an objective measure assessing healthcare aspects as defined by the Institute of Medicine (IOM). A QI is a tool that helps us quantify laboratory performance by choosing certain comparable criteria. Any potential QI should fulfill two inclusion criteria (1) tt must be an indicator of routine laboratory functioning. (2) it caters to at least one of the IOM health-care aspects, such as the safety of the patient, efficacy of the equipment and centeredness for the patient Joint Commission has stressed this fact by stating that laboratories should systematically assess and improve crucial functions, work processes and their outcomes, and certain benchmarks to be created for the functions of the laboratory[13] [Table 2]. In the current study, the training programme designed for the staff in phlebotomy had a very positive impact on overall knowledge and skills regarding phlebotomy. The involved staff also applied this knowledge later in their daily practice, leading to a considerable reduction in pre-analytical errors reported in pathology laboratories[14] [Tables 3 and 4]. Phlebotomists should create a trusting atmosphere and instill confidence in patients when drawing blood specimens with proper skills, and it must be safe for patients. It is vital that phlebotomists of both sexes must be diligent and polite with good communication skills[15] and should be welcomed by other health-care professionals, inclusive nurses and laboratory professionals.

Conclusion

The role of phlebotomy in healthcare settings is not undervalued. It presents numerous opportunities for the patient and errors by phlebotomists as it is an invasive procedure. For 'policy-makers', it is crucial to plan strategies to resolve the risks involved in the availability of a trained workforce,

Table 3: Pre-analytical observations recorded by phlebotomist before taking the course and after finishing the certificate course

	Total errors	Before course, n (%)	After course, n (%)	χ^2	P
Billing error	113	78 (69.02)	35 (30.97)	53.31	<0.001
LIS error	58	33 (56.89)	5 (43.10)	10.92	<0.001
Haemolysed samples	50	30 (60)	20 (40)	12.49	<0.001
Lipomic samples	37	20 (54.05)	17 (45.94)	5.198	0.022
Insufficient quantity	27	14 (58.33)	10 (45.45)	2.92	0.087
Proportion not correct	22	12 (54.54)	18 (42.85)	3.26	0.070
Clotted samples	42	24 (57.14)	6 (23.07)	6.52	0.010
Illegible handwriting	26	20 (76.92)	6 (27.27)	2.755	0.096
inappropriate container	22	16 (72.72)	10 (31.25)	3.25	0.071
Incomplete patient information	32	22 (68.75)	8 (34.78)	6.22	0.012
Missing requisition slips/samples	23	15 (65.21)	8 (34.78)	3.087	0.07
Empty tubes	27	19 (70.37)	8 (29.62)	5.79	0.016
Double prick	26	20 (76.92)	6 (23.07)	172.0	<0.001
Mislabelling	22	17 (77.27)	5 (22.72)	2.58	0.0108

LIS: Longest increasing subsequence

Table 4: Pre-analytical errors noted by the phlebotomist before and after course completion

Sl. No	Cause	Route cause analysis	Corrective action	Preventive action
1	Billing error	Inappropriate patient identification, TRF not entered relevantly	Discussed with billing staff to go through TRF before raising the bills	Train the billing staff
2	LIS error	Server down	Discussed with IT manager to rectify issues	IT dept should be kept informed
3	Haemolysed samples	Inappropriate sample, delay in transport from wards after collection	Discussed with nursing staff regarding timely sample collection	Educate the nursing staff
4	Double prick	Thin veins, obese patients	Repeat the procedure	Train technicians in drawing blood samples in special conditions
5	Clotted samples	Delay in the transportation of samples from wards to collection	Discussed with nursing staff regarding sample collection	Educate the nursing staff
6	legible handwriting	Heavy workload of the staff, emergency sample collection	Discussed with the technicians to carefully handle the RFs	Train the technicians for legible handwriting
7	Sample collection In inappropriate container	Inappropriate technique in sample collection	Informed ward nursing staff to give the proper instructions	Train the nursing staff about the use of suitable containers for sample collection
8	Proportion not correct	Inappropriate training of the staff	Discussions with technicians regarding the accuracy of proportion of samples	Training course for technicians

RFs: Requisition forms, TRF: Test report form

creating hygienic environments, monitoring and system that can document adverse events.

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Conflicts of interest

There are no conflicts of interest.

References

1. Goswami HM, Soni ST, Patel SM, Patel MK. A study on knowledge, attitude and practice of laboratory safety measures among paramedical staff of laboratory services. Indian J Community Med 2011;2:470-3.
2. Fidler JR. The role of the phlebotomy technician. Skills and knowledge required for successful clinical performance. Eval Health Prof 1997;20:286-301.
3. World Health Organization. Guidelines on Drawing Blood: Best Practices in Phlebotomy. Geneva: World Health Organization; 2010.
4. Taniguchi J, Matsui K, Araki T, Kikawa K. Clinical training: A simulation program for phlebotomy. BMC Med Educ 2008;8:7.
5. Bölenius K, Brulin C, Graneheim UH. Personnel's experiences of phlebotomy practices after participating in an educational intervention programme. Nurs Res Pract 2014;2014:538704.
6. Bölenius K, Brulin C, Grankvist K, Lindkvist M, Söderberg J. A content validated questionnaire for assessment of self reported venous blood sampling practices. BMC Res Notes 2012;5:39.
7. Lippi G, Becan-McBride K, Behúlová D, Bowen RA, Church S, Delanghe J, *et al.* Preanalytical quality improvement: In quality we trust. Clin Chem Lab Med 2013;51:229-41.
8. Mekonon WL, Abebe AT, Haile EL, Misganaw AS. Evaluation of phlebotomy service in clinical laboratory setting in Addis Ababa Public Hospitals, Addis Ababa, Ethiopia. Am J Lab Med 2017;2:24-33.
9. World Health Organization. Guidelines on Drawing Blood: Best Practices in Phlebotomy. Geneva: World Health Organization; 2010. Available from: https://www.who.int/infectionprevention/publications/drawing_blood_best/en/. [Last accessed on 2022 Nov 01].
10. Remmen R, Derese A, Scherpbier A, Denekens J, Hermann I, van der Vleuten C, *et al.* Can medical schools rely on clerkships to train students in basic clinical skills? Med Educ 1999;33:600-5.
11. Kneebone RL, Kidd J, Nestel D, Barnet A, Lo B, King R, *et al.* Blurring the boundaries: Scenario-based simulation in a clinical setting. Med Educ 2005;39:580-7.
12. Santen SA, Hemphill RR, Spanier CM, Fletcher ND. 'Sorry, it's my first time!' Will patients consent to medical students learning procedures? Med Educ 2005;39:365-9.
13. Agarwal R, Chaturvedi S, Chhillar N, Goyal R, Pant I, Tripathi CB. Role of intervention on laboratory performance: Evaluation of quality indicators in a tertiary care hospital. Indian J Clin Biochem 2012;27:61-8.
14. Mijailovic AS, Tanasijevic MJ, Goonan EM, Le RD, Baum JM, Melanson SE, *et al*. Optimizing outpatient phlebotomy staffing: tools to assess staffing needs and monitor effectiveness. Arch Pathol Lab Med. 2014;138:929-35.
15. Koh YR, Kim SY, Kim IN, Chang CL, Lee EY, Son HC, *et al.* Customer satisfaction survey with clinical laboratory and phlebotomy services at a tertiary care unit level. Ann Lab Med. 2014;34:380-85.