Original Article

AUDIT OF LABORATORY REQUEST FORMS IN ISO 9001:2015 CERTIFIED LABORATORY

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ABSTRACT

Objectives: To evaluate the frequency of improperly/ properly filled Laboratory Request Forms.

Material & Methods: This descriptive cross-sectional study was conducted in the Department of Pathology, Combined Military Hospital Multan Cantt from 26th Feb2018 to 24th March 2018. We have collected LRFs from Main ITC, CCU, Surgical ITC, Pediatrics, Medical, Surgical and Gynecology wards at an ISO 9001:2015 Certified Lab and evaluated for endorsement of Patient Particulars (complete/ incomplete), Clinical Notes (Yes/No), and LRFs signed by House Officer, Medical Officer, Postgraduate residents (PGR), Consultant & not signed. Data was entered in Microsoft excel for compilation.

Results: A total of 6702 LRFs were received in lab, which were advised for Haematology, Clinical Pathology, Microbiology, Chemical Pathology, Endocrinology, Histopathology & Virology. Patient Particulars were complete in 6018 cases, incomplete in 684 (10.2%) cases, Clinical Notes on request form were endorsed in 652 cases and 6050(90.3%) forms were without any clinical information and LRFs were signed by House Officer -1159, Medical Officers- 2069, PGR -2717, Consultant- 519 & not signed 270 times.

Conclusion: Laboratory request forms are not filled properly and clinical notes are missing most frequently.

Key Words: Laboratory request forms, Pre-analytical, Quality assurance.

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INTRODUCTION

The total system of procedure in Labs ranges from requesting of a test to interpretation its result. It starts and ends with patient, and is subdivided into 3 stages i.e. Pre-analytical, analytical and Post-analytical. Pre-analytic Phase involves test request, patient/ specimen identification and collection/ transporting it to lab [1]. This phase describes all actions of Lab that occur before analysis [2]. Many studies have determined significance of this phase; it is quite vulnerable stage, where most Lab errors occur [3].

Mismanagement of lab services by requesting inappropriate Lab test is being studied globally because of its impact on finances, and integral increased risk of errors. The approximations of incongruous lab tests vary from 11-70% for common chemistry & hematology tests, 5-95% for urine screens & microbiology, and 17 to 55% for cardiac markers & thyroid tests [4]. Importance of clinical information before a procedure has been studied in detail including drug intake, surgical and obstetrical history, hospitalization or blood transfusion [5] blood group [6,7] pregnancy [8] and contraceptives [9].

Magnette A *et al* have concluded that supervision of Pre-analytical errors is critical to improve health care. They were also compulsory for all clinical labs accredited by International Organization for Standardization (ISO) document 15189 [10]. The importance of proper patient identification has been studied in detail; principle of "double identifiers" should be used, matching their identification with particulars including name, and an additional identifier, like date of birth or medical record number [11,12]. Pre-analytical variables inducing error in reporting is an integral part of Lab testing has been studied by Bhushan R *et al* who reported higher occurrence of Pre-analytical errors in Government Tertiary Care setup, they stressed on need for proper training Programs for Paramedical staff [13].

Incomplete LRFs are key source of Lab error leading to incomplete information which has been found in >2/3rd of all rejected samples in Lab [14]. Several other studies confirm that improper test requests can be a source of Lab errors [15]. There is a concern that Incomplete LRFs are rarely rejected; Specific missing information involved physician's

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name, misidentification of patient and requested tests [16, 17].

Naz S *et al* have concluded that Pre-analytical errors accounted for 32-75% of total Lab errors; Lab workers need to adopt a comprehensive approach towards close harmonization with clinicians so as to provide effective diagnostic services to protect patient interests and to deliver high quality lab services [18]. Kiani RA *et al* carried out Audit of LRFs at a tertiary care hospital of Pakistan; it was highlighted that standard of filling of LRFs was poor and Lab services were utilized inadequately; physicians should be sensitized about implication of information of LRFs [19].

As Pre-analytical stage of lab offers a wide area for improvement [20], there is emphasis regarding documentation, root cause analysis and preventive strategies for such errors [21]. Advances in technology have led to transformation of lab diagnostics from manual, cumbersome testing methods to fully automated instruments. However, Labs cannot function in isolation and are dependent on clinical side for sending properly filled LRFs and samples for production of reliable data. It is therefore, imperative to ensure integrity of results springing from Labs. In this context lab forms serve as a key link between clinicians and labs. In view of above, present study was planned to evaluate the frequency of improperly/ properly filled LRFs.

MATERIAL AND METHODS

A Descriptive, Cross-sectional study was carried out at Department of Pathology, CMH Multan; an ISO 9001:2015 Certified Lab w.e.f 26th February 2018 to 24th Mar 2018. Non-probability consecutive sampling technique was used for collection of LRFs at reception of Pathology Department. Data was entered in Microsoft excel for compilation. Frequency & percentage was recoded for numerical data.

DATA COLLECTION PROCEDURE

A total of 6702 patient's LRFs reporting to Department of Pathology at CMH Multan were included in the study after obtaining approval from hospital Ethical Committee. Both outdoor & indoor patients from Main ITC, CCU, Surgical ITC, Pediatrics, Medical, Surgical and Gynecology wards at an ISO 9001:2015 Certified Lab were included in study. Variables in study were Patient Particulars (complete / incomplete), Clinical Notes on request form (yes / no), and LRFs signed by House Officers, Medical Officers, Postgraduate Residents, Consultants & not signed.

RESULTS

A total of 6702 LRFs were received in lab (detail is shown in Figure-1 & Table-1). Samples were advised for Haematology, Clinical Pathology, Endocrinology, Microbiology, Chemical Pathology, Histopathology and Virology as shown in Figure-1. Patient Particulars were complete in 6018 cases, incomplete in 684(10.2%) cases, Clinical Notes on request form were endorsed in 652 cases and 6050(90.3%) forms were without any clinical information, and lab request forms were signed by House Officer-1159, Medical Officers- 2069, PGR-2717, Consultant-519 & not signed 270 times (4%).

Table-1: Lab request forms details (n=6702).

Department	Patient Profile		Clinical Notes		LRFs signed by				
	Complete	Incomplete	Yes	No	House Offr	Med Offr	PGR	Consultant	NIL
Hematology 1845 (27.5%)	1455 79 %	390 21 %	71 4 %	1774 96 %	269 14 %	649 35 %	660 36 %	156 8 %	111 6 %
Clinical pathology 1388 (20.7%)	1277 92 %	111 8 %	54 4 %	1334 96 %	70 5 %	278 20 %	907 65 %	131 9 %	02 0.14 %
Microbiology 441(6.5%)	402 91 %	39 9 %	99 22 %	342 78 %	97 22 %	137 31 %	109 25 %	72 16 %	26 6 %
Chemical pathology 1929 (28.8%)	1918 99 %	18 1 %	148 8 %	1781 92 %	531 28 %	818 41 %	529 26 %	51 3 %	31 2 %
Histopathology 280 (4.1%)	247 88 %	33 12 %	186 66 %	94 34 %	02 0.7 %	07 2.5 %	214 76.4 %	57 20.3 %	00
Virology 819 (12.2%)	719 88 %	100 12 %	94 12 %	725 88 %	190 23 %	180 22 %	298 36 %	51 6 %	100 13 %
Grand Total 6702	6018 89.8 %	684 10.2 %	652 9.7	6050 90.3 %	1159 17.2 %	2069 30.8 %	2717 40.4 %	518 7.6 %	270 4.0 %

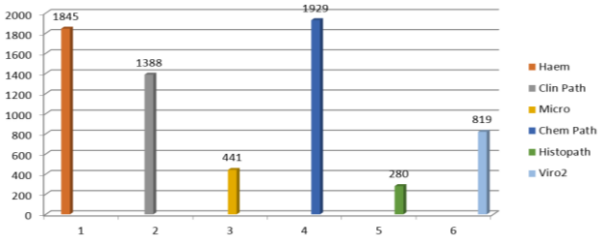

Figure-1: Distribution of Lab Request Forms in different sections of lab (n=6702).

DISCUSSION

Quality is the fundamental issue for all labs which requires total quality management in Pre-analytical, Analytical, and Post-analytical phases. At the same time reliance on accurate lab results for diagnosis makes it obligatory to ensure accountability and accuracy of results. It comprises all actions, starting with origination of a query, and includes patient preparation, sample collection, handling, transportation, processing and storage until time of analysis [22, 23]. Incomplete LRFs are commonly encountered in Labs and reception staff in Lab may not know implications of missing information. Result of present study show that Patient Particulars were complete in 6018 (89.8%) cases, incomplete in 684 (10.2%) cases which is in accordance with Oyelekan AA *et al* (n=2241) who have concluded that 99.8% LRFs were incomplete in one aspect or other. The most ample information on these forms included test required (98%), requesting physician's identity (94%) and gender (97%), however least available information was the time of collection of the specimen (0.7%) [24].

In present study Clinical Notes on LRFs were endorsed in 652 cases and 6050 (90.3%) forms were without any clinical information which is in agreement with Adegoke OA, *et al* who have highlighted that Clinical notes were meagerly endorsed on Lab forms which affected correct interpretation of result [25]. Similarly, Kiani RA *et al* (n=4122) concluded that standard of filling of LRFs was poor & reported that only 2.57% cases provided clinical information which supports present study [19, 26].

As regards advice of tests, LRFs were advised & signed by House Officer -1159, Medical Officers- 2069, PGR -2717 (40%), Consultant- 519 (7.6%) & not signed 270 times (4%) which is in accordance with Malik MF *et al* have who have studied 1000 forms, and found that none was completely filled with clinical notes being present in 2.4% and 13% of forms sent to CMH and AFIP Rawalpindi respectively. In our study about 48% forms were signed by Consultants/ Post Graduate Residents which is a reasonably good observation as lab requests are more evidence based in this situation [24, 27]. Similarly, Haroon ZH *et al* have determined that among 328418 tests, clinicians/ lab staff notified 350 undefined findings, 270 of which were definite errors; 77% were pre-analytical, 8% were analytical and 15% were post analytical errors. Among them 8% were improper samples, 21% were misidentifications, 51% were substandard sampling techniques and 20% were incomplete LRFs [28]. Similarly, in an Australian survey the transcription error rate was 39% and the most frequent types of errors was misidentification of requested test and the requesting doctors which is in agreement with present study [29]. Alavi N *et al* (n=113,817) found Pre-analytical errors in 1,688 samples, which was 1.5% of total samples studied. Management of these errors needs involvement of the clinicians for proper patient identification and test requisition/ completely filling LRFs [30]. Similarly, Jegede F *et al* have studied 2084 LRFs; piecemeal information was mostly faced on Blood bank forms for physician's name (60%). The level of completion of LRFs was not upto mark, which emphasized the need to review LRF & continuous communication between lab and clinical staff [31]. Nasir N *et al* conducted audit of 1000 transfusion requisition forms and found a compliance rate of 47%, while re-audit after educating staff improved it to 100% which is also in agreement with present study [32].

Malik MF *et al* have also emphasized to establish clinical lab interface (CLI) by establishing communication of clinicians with labs. They stressed that even Medical students and house officers must be exposed to labs to learn logical approach to advise tests which supports present study too. Processing incomplete LRFs lead to incorrect explanation of test results affecting outcome. Age & sex were missing on 48% and 55% of the forms received at CMH lab while on 72% and 71% of the forms received at AFIP Rawalpindi [27]. Carobene A *et al* have concluded that endorsement of age & gender are extremely significant, considering that reference values for a number of analytes are dependent on age & gender as was found in this study [33]. Favaloro EJ *et al* have advised Labs and clinicians to be watchful on issues as; requesting best suitable tests, incorporating maximum clinical information; following recommendations of local Labs experts/ specialists; repeating tests when not in keeping with clinical prospects; ensuring identification of samples; and promoting CLI where both parties discuss the problems within meetings as well as actively collaborating to achieve maximum outcome [34].

CONCLUSION

Laboratory Request Forms are not filled properly and clinical notes are missing most frequently creating difficulty in laboratory smooth functioning.

AUTHORS CONTRIBUTION

Muhammad Younas: Idea conception, proof reading
Hamid Iqbal: Data collection
Muhammad Rizwan Ullah & Muskan Younas: Literature review
Kainat Younas: Draft preparation
Asma Naseer Cheema: Data analysis

REFERENCES

1. Troobants AK, Goldschmidt H. Plebani MM. Error budget calculations in laboratory medicine: Linking the concepts of biological variation and allowable medical errors. Clin Chim Acta. 2003; 33: 169–76.
2. Guder WG. History of the pre-analytical phase: a personal view. Biochem Med (Zagreb). 2014; 24: 25–30.
3. Loeffen R, Kleinegris MC, Loubele ST, Pluijmen PH, Fens D, van Oerle R, ten Cate H, Spronk HM. Preanalytic variables of thrombin generation: towards a standard procedure and validation of the method. J Thromb Haemost. 2012; 10: 2544–54.
4. Silverstein MD. An approach to medical errors and patient safety in laboratory services. In: A white paper. Atlanta: The Quality Institute Meeting; 2003.
5. Stepanian A, Biron-Andreani C. Primary hemostasis exploration. Ann Biol Clin (Paris). 2001; 59: 725–35.
6. Franchini M, Capra F, Targher G, Montagnana M, Lippi G. Relationship between ABO blood group and voWillebrand factor levels: from biology to clinical implications. Thromb J. 2007; 5: 14.
7. Cattaneo M, Cerletti C, Harrison P, Hayward CP, Kenny D, Nugent D *et al*. Recomme-ndations for the standardization of light transmission aggregometry: a consensus of the working party from the platelet physiology subcommittee of SSC/ISTH. J Thromb Haemost. 2013; 11: 1183–9.
8. Lipets EN, Ataullakhanov FI. Global assays of hemostasis in the diagnostics of hypercoagulation and evaluation of thrombosis risk. Thromb J. 2015; 13:4.
9. Raps M, Helmerhorst FM, Fleischer K, Dahm AE, Rosendaal FR, Rosing J *et al*. The effect of different hormonal contraceptives on plasma levels of free protein S and free TFPI. Thromb Haemost. 2013; 109: 606–13.
10. Magnette A, Chatelain M, Chatelain B, CateHT, Mullier F. Pre-analytical issues in homeostasis: guidance for clinical laboratories. Thrombosis J. 2016; 14: 49.
11. CLSI. Collection, Transport, and Processing of Blood Specimens for Testing Plasma Based Coagulation Assays and Molecular Hemostasis Assays: Approved Guideline. 5th ed. CLSI document H21-A5. Wayne, PA: Clinical and Laboratory Standards Institute; 2008.
12. Kiechle FL, Adcock DM, Calam RR. So, You're Going to Collect a Blood Specimen. An Introduction to Phlebotomy. College of American Pathologists. 12th ed. Northfield, IL; 2007.
13. Bhushan R, Sen A. Quantitative assessment of prevalence of pre-analytical variables and their effect on coagulation assay. Can intervention improve patient safety? Med J Armed Forces India. 2017; 73(2): 152–8.
14. Adegoke OA, Idowu A, Jeje O. Incomplete laboratory request forms as a contributory factor to pre-analytical errors in a Nigerian teaching hospital. Afr J Biochem Res. 20115: 82-5.
15. Kirchner MJ, Funes VA, Adzet CB. Quality indicators and specifications for key processes in clinical laboratories: a preliminary experience. Clin Chem Lab Med. 2007; 45: 672-7.
16. Burnett L. Chesher D, Mudaliar Y. Improving the quality of information on pathology request forms. Ann Clin Biochem. 2004; 41: 53-6.
17. Wiwanitkit V. Types and frequency of pre-analytical mistakes in the first Thai ISO 9002:1994 certified clinical laboratory, a 6 - month monitoring. BMC Clin Pathol. 2001; 122: 5-8.
18. Naz S, Mumtaz A, Sadaruddin A. Preanalytical Errors and their Impact on Tests in Clinical Laboratory Practice. Pak J Med Res. 2012; 51.
19. Kiani RA, Waheed U, Khan H, Zaheer HA. Audit of Laboratory Request Forms at a Tertiary Care Hospital of Islamabad, Pakistan. J Soc Obstet & Gynaecol Pak. 2016; 6: 133-6.
20. Lima-Oliveira G, Lippi G, Salvagno GL, Picheth G and Guidi GC. Laboratory Diagnostics and Quality of Blood Collection. J Med Biochem. 2015; 34: 288–294.
21. Lima-Oliveira G, Cesare GG, Guimaraes AVP, Abol Correa J and Lippi G. Pre-analytical nonconformity management regarding primary tube mixing in Brazil. J Med Biochem. 2017; 36: 39–43.
22. Cornes M, van Dongen-Lases E, Grankvist K, Ibarz M, Kristensen G, Lippi G *et al*, Working group for pre-analytical phase EFoCC, Laboratory. Order of blood draw: opinion paper by the European federation for clinical chemistry and laboratory medicine (EFLM) Working group for the pre-analytical phase (WG-PRE). Clin Chem Lab Med. 2016; 55: 27–31.
23. Van Dongen-Lases EC, Cornes MP, Grankvist K, Ibarz M, Kristensen GB, Lippi G, Nybo M, Simundic AM. Working group for pre-analytical phase EFoCC, laboratory M. Patient identification and tube labelling - a call for harmonization. Clin Chem Lab Med. 2016; 54: 1141–5.
24. Oyelekan AA, Ojo OT, Olawale OO, Adeleye OO, Sogebi OA, Osinupebi OA, Olatunji PO. Pattern of completion of laboratory request forms in a tertiary health facility. Annals of Health Research. 2018: 4: 155-61.
25. Adegoke OA, Idowu AA, Jeje OA. Incomplete laboratory request forms as a contributory factor to pre-analytical errors in a Nigerian teaching hospital. Afr J Biochem Res. 2011, 14: 82–5.
26. Kipkulei J, Lotodo T. Evaluation of the completeness in the filling of laboratory request forms submitted to the haematology laboratory at a tertiary hospital in Kenya. Health. 2019; 11: 862-8.
27. Malik MF, Khan DA, Ansari WM, Khan FA. Injudicious use of laboratory facilities in tertiary care hospitals at Rawalpindi, Pakistan: A cross-sectional descriptive study. BMC Health Services Res. 2013; 13: 495.
28. Haroon ZH, Javaid H, Rashid H, Tahir M, Butt MQ, Afridi N. Pre-analytical errors in a peripheral hospital laboratory. Pak Armed Forces Med J. 2014; 64(2):315-8.
29. Khoury M, Burnett L, McKay MA. Error rate in Australian chemical pathology laboratories. Med J Aust. 1996; 165: 128-30.
30. Alavi N, Khan SH, Saadia A, Naeem T. Challenges in pre-analytical phase of laboratory medicine. JIFCC. 2020; 31: 21-7.
31. Jegede F, Mbah HA, Dakata A. Evaluating laboratory request forms submitted to haematology and blood transfusion departments at a hospital in Northwest Nigeria. Afr J Lab Med. 2016; 5(1): 381.
32. Nasir N, Shaikh MU, Ali N, Hussain S. Compliance of hand written transfusion requisition form and improvement after online request. J Pak Med Assoc. 2020: 70: 694-8.
33. Carobene A, Graziani MS, Cascio CL, Tretti L, Cremonese E, Yabarek T *et al*: Age dependence of within-subject biological variation of nine common clinical chemistry analytes. Clin Chem Lab Med. 2012, 50(5): 841–4.
34. Favaloro EJ, Dorothy M, Funk A, Lippi G. Pre-analytical variables in coagulation testing associated with diagnostic Errors in Hemostasis. CE update Lab Med. 2012; 43: 1-10.