Identification of Pre-examination Errors in the Chemical Pathology Laboratory at the University Hospital of the West Indies

Lowell L. Dilworth · Donovan A. McGrowder ·
Rory K. Thompson

Received: 25 February 2013 / Accepted: 16 May 2013 / Published online: 29 May 2013
© Association of Clinical Biochemists of India 2013

Abstract This study evaluated the types and frequencies of pre-examination errors recorded in the chemical pathology laboratory at the University Hospital of the West Indies, Jamaica. This was a retrospective analysis of errors recorded over a three year period. Data analysis was done on an average of 519,084 samples collected and tested per year. Samples included blood, urine, stool and other fluids. Pre-examination errors were identified and recorded following visual inspection of the samples and corresponding request forms by laboratory staff, then subsequently by the Senior Medical Technologist. Errors were generally classified as inappropriate sample (58 %), inappropriate form (23.4 %), inappropriate sample volume (9.3 %) and inappropriate sample tube (9.3 %). Over 90 % of recorded pre-examination errors were related to blood samples while urine samples accounted for 6.8 % error. Pre-examination errors were lower at this study location than elsewhere. Measures aimed at reducing instances of these errors are recommended for improved laboratory quality output.

Keywords Pre-examination · Error · Hospital · Chemical pathology · Laboratory · West Indies

Introduction

Concerns about errors in medicine have grown over recent years as a result of publications highlighting the problem, as well as the role played by the media [1]. In the 1980s, The United States of America Congress became involved

in the discussion by introducing the Clinical Laboratory Improvement Amendments of 1988 [2]. As a result of this act, the public's awareness was raised regarding the impact of laboratory errors while manufacturers and laboratories were forced to implement stringent measures aimed at improving accuracy of laboratory operations, thereby reducing errors. While other countries have put similar measures in place, the issue of laboratory error still remains. In line with ISO 15189:2012 guidelines, throughout this paper, the commonly used term 'pre-analytical error' is replaced by 'pre-examination error'.

Errors associated with the total testing process may occur at the pre-examination (46–68 %), examination (7–13 %), and post-examination phase (19–47 %) [3]. Further classifications of these errors are reported in literature wherein the pre-pre-examination phase accounts for 46–68 % of error, the pre-examination phase accounts for 3–5 %, the examination phase accounting for 7–13 %, the post examination accounting for 13–20 %, while the post-post-examination phase accounts for 25–46 % or errors [4]. The pre and post examination phases account for upwards of 95 % of total errors. Pre-pre-examination errors include: inappropriate test request, order entry, patient/specimen mis-identification or haemolysis; pre-examination include sorting, aliquoting, pipetting; examination errors include equipment failure, sample mix-ups, interference; post-examination include erroneous data validation, excessive turn-around-time, data entry problems; while post-post-examination errors include incorrect interpretation, inadequate follow-up plan and, failure to order appropriate consultation [4, 5].

In addition to affecting patient outcome, laboratory errors can have major impacts on the accreditation process. This is because accreditation agencies are now requiring that laboratories broaden their focus by taking responsibility for pre

L. L. Dilworth (✉) · D. A. McGrowder · R. K. Thompson
Department of Pathology, University of the West Indies, Mona
Campus, Kingston, Jamaica
e-mail: lowell.dilworth@gmail.com

and post-examination errors in addition to examination errors [5]. Since this involves undertaking activities that are out of the immediate control of the laboratory, there may be some amount of resistance on the part of laboratory staff, which laboratory managers should be aware of.

Accreditation is important to University Hospital of the West Indies, which is a type A hospital, providing secondary and tertiary health care services aimed at satisfying local needs, as well as those of the wider Caribbean region. In order to improve quality of care delivered to patients, it is important to assess the types of pre-examination errors that occur, followed by implementation of measures geared at reducing the instances of such errors. This current study is aimed at enumerating and analysing the prevalence of various pre-examination errors recorded during sample processing in the chemical pathology laboratory over a three-year period. Arising from this study, a report will be generated with recommended/implementable measures geared at reducing the occurrences of such errors. Importantly, data from this study will also be important as laboratory personnel seek to attain and maintain laboratory accreditations.

Methods

This study encompassed a retrospective assessment of pre-examination laboratory errors with the chemical pathology laboratory over a three-year period. The University Hospital of the West Indies has bed capacity of about five hundred and thirty-four (534) with current bed complement of about four hundred and fifty-three (453). The hospital is serviced by a large chemical pathology laboratory with the main analyzer being the c8000 Architect (Abbott Diagnostic Ltd, USA) on which most of the tests were done. Other equipment in the laboratory include a D-10 Haemoglobin testing system (BioRad, USA), BT3000 plus analyser (Biotechnica Instruments, USA), EasyLyte Na/K/Li analyser (Medica, USA), an Axsym autoanalyser (Abbott Diagnostic Ltd, USA), an Immulite immunoassay analyser and other ancillaries for sample processing. The lab provides routine and special tests and it is part of the United Kingdom National External Quality Assessment Schemes (UK NEQAS) for clinical chemistry.

An average of five hundred and fifty thousand (550,000) were carried out over the past six years with 539,177 tests done between August 2009–July 2010; 495,670 done between August 2010 and July 2011 and 495,602 done between 2011 and 2012. Blood Samples are collected in evacuated tubes (vacutainers evacuated tubes from BD (Franklin Lakes, NJ), while urine and stool are collected in sterilized containers.

Blood specimens from outpatients are collected on site at a centralized collection area while inpatient phlebotomies are performed by clinical department staff. Samples are then delivered to the chemical pathology laboratory for analysis. After receipt, the Medical Technologist visually inspects samples and suspected pre-examination errors are confirmed by the Chief Medical Technologist. When a problem occurs, it is recorded in the error notification log book and the requesting medical doctor or ward subsequently notified. The criteria for rejection fall under the following categories; inappropriate sample volume, inappropriate specimen container and inappropriate specimen. In addition, incomplete or incorrect information on the request form, inclusive of patients' data or lack of requisite doctors' signature, are also grounds for rejection.

Results

Table 1 shows that a total of 539,177 tests were carried out between 2009 and 2010 with 53 records of pre-examination errors, representing an error rate of 0.00983 %. Between 2010 and 2011, pre-examination errors were noted in 32 out of a total of 495,670 samples assessed, representing 0.00645 % error. Out of 459,602 samples analyzed between 2011 and 2012, pre-examination errors were observed in 132 samples representing 0.0266 % of all samples tested. Four main categories of errors were identified as depicted in Table 2 follows: inappropriate sample (IS); inappropriate request form (IF); inappropriate volume (IV) and inappropriate sample tube (IT). The frequency of each type of error was also calculated as depicted in Fig. 1. There was a 9.3 % frequency recorded for samples with inappropriate volume as well as those collected in inappropriate tubes. A frequency of 23.4 % was recorded for samples accompanied by an incomplete form while the majority of pre-examination errors (58 %) were denoted 'inappropriate samples'. On one occasion, no request form accompanied the sample. Figure 2 demonstrates that more than 90 % of errors were associated with blood samples

Table 1 Pre-examination errors expressed as a percentage of the total number of test requested over a 3-year study period

Years	Tests	Error	Percentage error
2009–2010	539,177	53	0.00983
2010–2011	495,670	32	0.00645
2011–2012	495,602	132	0.0266

Data shows a reduction in the percentage of total tests requests in which pre-examination errors are identified in year 1 compared to year 2. Notable increases in errors were recorded in year 3 compared to year 2

Table 2 Specific classification of pre-examination laboratory errors recorded by chemical pathology laboratory staff

Error	Patients
Inappropriate sample (IS)	
Unlabelled specimen	98
Grossly haemolyzed	3
Inappropriately labelled specimen	15
No test requested	1
Inappropriate form (IF)	
Incomplete form	32
Blood stained form	1
Unlabelled form	14
Inappropriate volume (IV) ^a	
Broken sample	15
Spilled sample	5
Insufficient volume	1
Inappropriate tube (IT)	21
No request form received	1

^a For all samples labelled as inadequate volume, the state of the form was not taken into consideration for this study

while the remaining errors were associated with urine, stool and other samples.

Discussion

Pre-analytical errors at the University Hospital of the West Indies are classified under the following groups: inappropriate tube, inappropriate volume, inappropriate form, inappropriate sample and no form received. Errors denoted as ‘inappropriate tube’ indicated instances where the incorrect tube was used to collect samples. There were recorded instances wherein samples for HbA_{1c} assay were collected in grey top tubes (containing potassium oxalate and sodium fluoride/Na₂EDTA) while those samples should ideally be collected in tubes containing liquid K₃EDTA only. We suggest that this specific error can be rectified by addressing ignorance of some sample collectors with respect to usage of appropriate sample collection tubes. Improved knowledge and increased vigilance will also have positive economic implications owing to reduced number of sample tubes that will be discarded.

Samples delivered to the laboratory recorded as ‘inappropriate volume’ can be broken down into three categories: broken samples, spilled samples and samples with insufficient volume. In cases of spilled samples, the tube stopper may have become loose during transport, resulting in loss. Staff members engaged in sample handling should be sensitized to the implications of this error since it accounted for 24 % of pre-analytical errors under this

Fig. 1 Frequency of occurrence of different pre-examination errors over a 3 year period at the University Hospital of the West Indies. *IS* inappropriate sample, *IF* incomplete request form, *IV* inappropriate sample volume, *IT* inappropriate collection tube. Data shows that most errors were associated with samples classified as inappropriate sample, mainly due to incorrect labeling of sample collection tubes. Low sample volume (*IV*) and samples collected in inappropriate tubes (*IT*) collectively accounted for 9.3 % of total errors

Fig. 2 Types of samples received and frequency of pre-examination errors associated with each sample. Over 90 % of all pre-examination errors were associated with blood samples while pre-examination errors were recorded in fewer than 7 % of all urine samples

category. There was only a single recorded instance of an error relating to insufficient sample volume taken from patients over the study period. The low incident occurrence may be attributed to the closed system of collection used in the outpatient department. This vacuum system ensures that the correct volume fills the tube resulting in lower incidences of under-filling, as opposed to the open system wherein higher incidences of this error are normally observed [6]. Other errors related to inappropriate sample volume (71 %) were as a result of total loss due to breakage of the sample tube during transit; glass tubes, rather than other materials, are used for collection. Since all samples are potential biohazards, breakage is a cause for

concern as it exposes the courier to infectious agents including viruses, bacteria and fungi [7].

Pre-analytical errors associated with inappropriate request form can be further categorized as incomplete form, blood stained form or unlabelled form. Sample spillage may result in a blood stained request form prior to or during transit. It is suggested that samples should therefore not be transported with request forms affixed.

Unlabelled forms accounted for thirty percent (30 %) of errors associated with the request form. In such instances, the sample was rejected and the attending physician promptly notified. The practice of manually completing request forms, as carried out in the hospital assessed in this study, may be a contributing factor to this type of error. This was corroborated by a previous study which highlighted that manual completion of forms can lead to insufficient, incorrect or illegible data on such request forms [8].

It is important to address incidences of insufficient data on laboratory request forms since it may result in difficulties in making interpretative comments as well as delaying communications with the requesting physician, especially in patients with life threatening medical conditions [9]. Of all the pre-examination errors identified within the 'inappropriate form' category, 68 % were as a result of request forms being incomplete due to omission of important data related to the patient, requesting physician, tests to be done, or a combination of factors. In line with laboratory protocol for unlabelled forms, samples that come to the laboratory with such forms are normally discarded. Physicians and attending staff responsible for completing request forms should therefore ensure that all relevant data, including appropriate signature/s, are included in order to avoid delays which can prove critical to patient care.

Samples denoted as 'inappropriate sample' accounted for almost 60 % of all pre-analytical errors over the three-year study timeframe. A detailed breakdown revealed incidences of improperly labeled specimen; grossly haemolyzed samples (3 cases); as well as an instance where no test was requested. This research shows that serious effort should be made in order to lessen such incidences as they may result in inappropriate treatment and mislabeling of blood specimens which can cause inapt patient management. Unlabelled samples accounted for eighty-four (84 %) percent of samples classified as 'inappropriate samples'. The high rates of rejection for such samples results in decreased productivity of the laboratory and additional stress to patients. In order to avoid this, it is suggested that staff adhere to international regulations regarding sample labelling. In this regard, there is a general checklist which refers to the monitoring of extra-

analytical quality and the College of American Pathologists (CAP) laboratory patient safety goals. The regulation (GEN.40490) requires that the person collecting a specimen should use at least two identifiers to positively identify the patient prior to specimen collection while GEN.40491 requires primary specimen containers to be labelled with at least two identifiers [5].

A survey of the data shows that in the first year of the study, pre-analytical errors were detected in 0.00983 % of all samples. The figure recorded for year 2 was 0.00645 % while there was a four-fold increase in year 3 (0.0266 %). It is theorized that this increase may not be due to actual increase in number of pre-analytical errors identified but to increased vigilance leading to increased emphasis placed on recording all instances of error. A literature survey shows that frequency of pre-analytical errors in this study is lower than recorded elsewhere [10, 11]. Readers should however not be misled by the seemingly low prevalence of pre-analytical errors, since the high volume of tests performed annually will result in these low numbers translating to high absolute numbers of occurrences and opportunities for adverse patient outcome as alluded to by Hawkins [5]. Of the total number of samples assessed, over 90 % of pre-analytical errors were recorded in blood samples while 6.8 % were recorded in urine samples. Only 2.0 % of pre-analytical errors were attributed to stool samples. This pattern was expected since the majority of samples received for analysis are blood samples. The main limitation identified in this study is that there is no system in place ensuring that all instances of pre-analytical errors are recorded. Vigilance in this area needs to be improved on the part of laboratory management.

Conclusion

This study shows that increased incidences of pre-examination errors may negatively impact the delivery of healthcare in the hospital setting. Error identification and implementation of measures geared at reducing their recurrence will reduce these overall negative effects. Based on this study, in-house rejection policy should be more rigorous while identifying the specific reason for rejection. Samples should also be sent to the laboratory in tube racks thereby reducing possibility of breakage and spillage. Authors conclude that improved quality management training in the laboratory and incorporation of information technology in hospital operations can improve the delivery of quality healthcare to patients in this region. Further research will be geared at identifying the risks associated with pre-examination errors before they result in harm to patients.

References

1. Bonini P, Ceriotti F, Mirandola G, Signori C. Misidentification and other preanalytical errors. *JMB*. 2008;27:339–42.
2. Public Law 100–578. Clinical Laboratory Improvement Amendments of 1988. Stat 42 USC 201. HR. 5471. 1988.
3. Wallin O. Preanalytical errors in hospitals implications for quality improvement of blood sample collection. Umeå University Medical Dissertations, Department of Medical Biosciences, Clinical Chemistry Department of Nursing, 2008. p 24.
4. Plebani M. The detection and prevention of errors in laboratory medicine. *Ann Clin Biochem*. 2010;47:101–10.
5. Hawkins R. Managing the pre- and post-analytical phases of the total testing process. *Ann Lab Med*. 2012;32(1):5–16. doi: [10.3343/alm.2012.32.1.5](https://doi.org/10.3343/alm.2012.32.1.5).
6. Ashavaid TF, Dandekar SP, Keny B, Bhambhwani VR. Influence of blood specimen collection method on various pre-analytical sample quality indicators. *Indian J Clin Biochem*. 2008;23(2):144–9.
7. Scarselli A, Vonesch N, Melis P, Massari S, Tomao P, Marinaccio A, Iavicoli S. Biological risk at work in Italy: results from the National Register of Occupational Exposures. *Ind Health*. 2010;48:365–9.
8. Burnett L, Chesher D, Mudaliar Y. Improving the quality of information on pathology request forms. *Ann Clin Biochem*. 2004;41:53–6.
9. 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;5(3):82–5.
10. Chawla R, Goswami B, Tayal D, Mallika V. Identification of the types of preanalytical errors in the clinical chemistry laboratory: 1-year study at G.B. Pant Hospital. *Labmed*. 2010;41:89–92.
11. Ottomano C. Errors in medicine and errors in laboratory medicine: what is the difference? *Blood Transfus*. 2010;8:79–81. doi: [10.2450/2010.0159-09](https://doi.org/10.2450/2010.0159-09).