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Quality Assurance in Medical Laboratories in Developing Countries: Assessment of Pre-Analytical Errors in a Chemical Pathology Laboratory in a Tertiary Hospital in Nigeria

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Abstract

BACKGROUND: The total testing process is made up of the pre-analytical, analytical and post analytical phases. Most of the non-conformities to laid down laboratory procedures are known to be at the pre-analytical phase, amounting to about 70% of errors in the total testing phase. Most laboratories, in instituting total quality assurance, concentrate mainly on the analytical phase and the post analytical phase. The ISO, in a bid to correcting this oversight introduced a modifiable quality indicator system which monitors laid down processes and procedures of the laboratories. **AIM-** This study was therefore designed to assess the pre-analytical phase of the testing process in a Chemical Pathology laboratory of a teaching hospital in southern Nigeria. **METHODS-** The ISO quality indicators were modified to suit the standard operations of the Preanalytical phase of the said laboratory. With the help of a questionnaire, non-conformities to these laid- down procedures were assessed. Defects per million (DPM) of each indicator were calculated and a sigma value assigned as the performance level. A sigma value below 3 was seen as unacceptable performance and that between 3 and 4 was seen as acceptable performance. Lastly a sigma value above 4 indicated good performance. **RESULT-** A total of 17 quality indicators were used to assess the pre-analytical phase and 12 (70.6%) had unacceptable performance levels while 2 (11.8%) had acceptable performance levels. Only 3(17.6%) of these indicators had good performance levels. **CONCLUSION-** A holistic look at the performance of the quality indicators of the pre-analytical phase in this study showed that about 71% of the pre-analytical quality indicators assessed had unacceptable performance levels; 12% had acceptable performance level and only 18% had good performance level. This grossly indicates very poor quality pre-analytical sample acquisition and processing procedures. Steps therefore need to be taken to rectify these errors.

Keywords: Pre-Analytical Phase, Quality Assurance, Quality Indicators (QIs), Total Testing Process, International Organization for Standardization (ISO), Defect Per Million (DPM)

INTRODUCTION

Laboratory results play an important role in diagnosis and treatment of patients (Kalra & Kopargaonkar, 2016). A quality result depends on a lot of factors which includes all the processes and procedures from the time of test ordering by the physician to the time the sample is analyzed and the results forwarded to the end users. Each of these processes is subject to nonconformities/errors and reducing these nonconformities/errors at every stage of the testing process will cumulatively produce or guarantee a trustworthy result.

Studies have shown that 70% of errors in the total laboratory testing processes occur at the pre-analytical phase (Salinas et al, 2011) which includes test ordering, completing/filling the order form, patient preparation, selection of site and site preparation. Others include method of tourniquet application/ venipuncture technique, correct order of draw, collection of adequate volume of blood into the right anticoagulant container or collection of adequate volume of blood into the wrong anticoagulant tubes, proper technique of mixing blood with anticoagulant and so on. Lastly, the transportation, centrifugation and handling of specimens, if correctly carried out, will guarantee high quality results (Singh, Meyer, & Thomas, 2014).

Laboratory errors are divided into pre-analytical, analytical and post analytical errors (Lima-Oliveira, et al. 2017). Most times the analytical and post analytical phases are what pathologists, scientists and accreditation bodies concentrate on. This has led to laboratories overlooking the pre-analytical errors and processes when preparing for accreditation. The introduction of pre analytical quality indicators by the international organization for standardization (ISO) has helped laboratories to identify and assess the nonconformities to the processes in relation to specifications described in the standard operation procedures/ literatures (Lima-Oliveira, et al. 2017). The ISO quality indicators which are generally accepted as the basis for the assessment of the pre analytical phase of the total testing process has the capacity for modification, based on individual laboratory practice (Da Rin. 2009 & Plebani, et al. 2014). To this effect, any laboratory can modify the ISO pre-analytical quality indicators to monitor the nonconformities to the pre-analytical processes of that laboratory. A laboratory form should contain information that identify the patient (biodata), the doctor requesting the test, the type of specimen, the storage time of specimen (time specimen was collected to time it was analyzed), brief details of patient illness and the type of treatment carried out (Simundic, et al. 2014). This information, apart from helping in identifying the doctor requesting test, the patient and patient sample, will also help with the right interpretation of results (Fraser & Fogarty.1989) his study was therefore designed to assess the pre-analytical testing processes of all requests sent to the Chemical Pathology laboratory of a tertiary hospital in Nigeria for a period of one month.

METHODS

The selection of the pre-analytical quality indicators is to a reasonable extent based on the pre-analytical variables and the processes that drive them. These processes are all subject to Nonconformities (NC) in the physician's requisitions, patient's preparation, sample collection and tests registrations and these were then evaluated during the quality checking process.

The ISO 15189: 2012 standards for laboratory accreditation recognize the need to evaluate and improve the processes in the pre analytical phase of the Total Testing Process (Barth, 2011). To this effect, the processes of the Preanalytical phase of the total testing processes were assessed as quality indicators by critically evaluating non-conformities to each process. This was done using the standard ISO pre analytical quality indicators, which were modified to suit the modus operandi of the said laboratory for this study. A questionnaire was designed to assess the nonconformities in the Preanalytical processes using the right process as an indicator of such process. Another questionnaire was also designed to get information from patient or patient relatives as well as from managing physicians.

The modified ISO pre analytical quality indicators used for this study were as follows:

Number of requests without clinical questions

Clinical questions for this study meant request with properly filled provisional diagnosis and clinical details. Studies have shown that failure to order appropriate diagnostic tests accounted for 55% of observed breakdowns in missed and delayed diagnosis in the ambulatory setting (Barth, 2011)

Errors concerning input (selection) of test (Added)

For this, requests with more than one investigation or panel of investigations were cross checked against the clinical details and provisional diagnosis to see how appropriate the request were.

Number of inappropriate tests

To assess this, the provisional diagnosis, clinical details and investigations requested were evaluated to see if they helped to make diagnosis or evaluate treatment.

Number of requests without physician identification

Physician's identification: the names and signature of the consultant in charge and the doctor that filled the form must be provided. All forms without the names and signature of both the consultant and the doctor will be regarded as without physician's identification.

Number of unintelligible requests

For the number of unintelligible requests, all vital information given on the request form will be assessed for clarity. That is, filled forms that cannot be read or understood due to lack of clarity of hand writing was regarded as unintelligible.

Requests with errors concerning patient identification

Errors of patient identification for this study will include: Patient surname, other names, age, sex, hospital number, nationality and race, eligibly and correctly written. Any of the above not properly stated or missed meant patient not properly identified.

Samples lost or not received

This was difficult to assess in this study since the hospital is yet to be computerized and so samples are brought in together with patient's request form, meaning that samples received are assumed as samples requested. So this part was not evaluated in this study.

Samples collected into inappropriate containers

Samples not collected into appropriate containers for this study will mean checking the type of test and the container into which sample was kept. Specimen bottles contain specific anticoagulants with different mechanisms of actions which may affect or interfere significantly with the result/ value. The sample is expected to be collected into the right container based on type of test. The right container in this study means container with anticoagulant which has not expired or cannot affect the accuracy of the result.

Samples haemolysed /clotted.

A visual analysis of sample for haemolysis and clotting or samples rejected due to haemolysis or clotting before analysis was used for this category.

Sample with insufficient volume

All of the containers with anticoagulant have a line indicating the minimum volume of sample needed. Any volume below the minimum sample line was deemed insufficient for this study.

Samples damaged in transport

For this study, since all samples are transported to the laboratory by hand, those that were spilled or were allowed to stay for over 24 hours unseparated, judging from the time of collection to the time it got to the laboratory, or samples brought in a lysed state, were all seen as damaged.

Samples improperly labeled

Most specimen containers have provision for patients name, hospital number, date/time sample was collected and type of test requested. This was evaluated and compared with the information on the forms. Any specimen container not properly filled or had any discrepancy with the information on the request form was assessed as not properly labeled.

Samples not transported and stored under special conditions

For this category, samples that needed special handling for both transportation and storage were assessed. Samples for blood gas analysis are expected to be transported in ice, while bilirubin and certain vitamins are to be transported protected from light. Any samples for these assays not transported and stored correctly as above where noted under this category.

Sample not transported to the laboratory on time

In assessing this, the time sample was collected to the time it arrived the laboratory should not have been more than six hours, judging from our expected turnaround time. This is because most samples are kept and transported at room temperature in our setting. These samples are mainly blood (whole blood, serum and plasma). Others include urine, cerebrospinal fluid, ascites fluid, plural fluid, sweat and stones. Since blood make up about 80% of all samples brought to our laboratory, its shelf life was a determining factor for this indicator. Whole blood is believed to be stable at room temperature for about 24 hours (Eijsden, et al. 2004) This fact and the expected laboratory turnaround time informed our decision. Therefore for this study samples were expected to arrive at the laboratory at most 6 hours from time of collection.

Samples not analyzed on time.

Most samples received in the laboratory go through a process before they are analyzed: given a laboratory number, centrifuged to separate plasma which is aliquoted and sent to various benches for analysis. Considering our expected turnaround time, samples are expected to be analyzed at most six hours after it gets to the laboratory. Any sample found to exceed this time was noted as a non-conformity, using this indicator.

Samples with inappropriate request from

Frequently, our laboratory runs short of request forms, so requests are made on plain papers with scanty information about the patient, such as patient's name and test required. This makes proper patient identification and result interpretation very difficult as vital information that will aid interpretation may be absent. Samples brought to the laboratory without the proper forms were therefore noted as non-conformity.

Samples without physician's phone number

Results with critical values need urgent attention or intervention of the managing clinician and this is made easy through phone calls. Our laboratory forms have provision for the phone numbers of the requesting clinician, which expectedly should be filled. This makes communication between the laboratory physician and the clinician a lot easier, such as seeking clarification or more information on the request form. Request forms without the physicians' phone number are noted as non-conformity.

Data Analysis

The percentage error for each pre-analytical quality indicator was calculated. Defect per million (DPM) was calculated for each indicator using the formula below¹¹.

$$\text{DPM} = \frac{\text{No of Errors} \times 1 \text{ Million}}{\text{Total number of request}}$$

The performance of each indicator was evaluated by locating the DPM value on the sigma scale for the performance level:^{11, 12}

| | |
|--------------|-------------|
| Good | > 4.0 sigma |
| Acceptable | 3.0 – 4.0 |
| Unacceptable | <3.0 |

RESULT

The data collected was analyzed using the Epi info version 7 at a 95% confidence limits and a p-value of less than 0.05 was considered significant.

A total of 1450 request forms were analyzed using a questionnaire that assesses the processes. Out of these, about 1214 (83.72%) had no clinical details. The request forms with inappropriate test requisitions with respect to clinical questions were 508(35.03%), with majority coming from the outpatient clinics. About 1089(75.10%) requests were without time of sample collection and 119(8.21%) requests were unintelligible. Requests that were not truly urgent were 363 out of 465 marked urgent and 1163(80.21%) requests had errors concerning patient's identity. The number of requests with errors concerning physician's identity was 499 (34.4%), and those without physician's phone numbers were 1019 (70.3%). A total of 18(1.3%) samples were collected into inappropriate containers while 5(0.4%) and 12(0.86%) samples were haemolysed and clotted, respectively. Samples transported to the laboratory with blood stains on containers due to leakage or method of blood collection were 346(23.86%) and those damaged in transit were 51(3.52%). A total of 1188(81.93%) samples were brought in containers not properly labeled. Special samples that were not transported or stored under special conditions when they should were 282(19.45%) but represented about 100% of such samples. Samples that were not transported to the laboratory on time were 51(3.52%) while 625 samples were brought to the laboratory with inappropriate request forms. Samples containers with inadequate sample volume (this alters the blood anticoagulant ratio) were 324(22.34%). Samples not transported in time were 331(22.83%).

The differences in the inpatient and outpatient data were statistically significant for the following indicators: Appropriate test with respect to clinical question, requests that were truly urgent, requests with errors concerning patient identity, physician's identity and phone number. The remaining indicators were all also statistically significant except for samples with inappropriate request forms, improperly labeled, without time of collection and inadequate volume.

Defect per million (DPM) was calculated for every indicator and the sigma value determined was used to assess the level of performance of each indicators.(Table 3) Sigma values above 4 were taken as good performance levels while those between 3 and 4 were regarded as average performance. A sigma value below 3 was interpreted as unacceptable performance level (Martins, Rateke & Martinello. 2018 & Giménez-Marín, 2014) All the indicators had unacceptable performance levels, except for samples in inappropriate containers and those damaged in transport, which had an average performance level and samples haemolysed and those clotted which had good performance.

Indicators that had unacceptable performance level for the overall data but average performance for the outpatients were 'appropriate test with respect to clinical questions' and 'unintelligible request forms'. All others had unacceptable performance except for samples haemolysed and samples clotted, which had good performance levels, while samples collected into inappropriate containers and those damaged in transit had average performance.

Indicators that had acceptable performance level for inpatient, out-patient and the overall data include: age, laboratory number, provisional diagnosis, and sample damaged during transportation. Sample haemolysed had a good performance value for the overall data, in-patient and out-patient data while 'samples clotted' had good performance for only the in-patients and the overall data while the out-patients had a minimal performance level.

Table 1: Quality indicators and Percentage of Nonconformities

| Variable | Yes | | No |
|--|---------------|-------------|----|
| | Frequency (n) | Percent (%) | |
| Inappropriate test (with respect to clinical question) | 508 | 35.03 | |
| Requests without time sample was collected | 1089 | 75.10 | |
| | 119 | 8.21 | |

| | | |
|---|------|-------|
| Unintelligible requests | | |
| Request that are not truly urgent | 394 | 98.5 |
| Requests with errors concerning patient identification | 1163 | 80.21 |
| Requests with errors concerning physician identification | 499 | 34.41 |
| Request without physician's number | 1019 | 70.28 |
| Samples collected into inappropriate containers | 18 | 1.24 |
| Samples haemolyzed | 5 | 0.34 |
| Sample clotted | 12 | 0.83 |
| Sample with blood stain on container (leakages) | 346 | 23.86 |
| Samples damaged in transport | 51 | 3.52 |
| Samples improperly labeled | 1188 | 81.93 |
| Samples not transported and stored under special conditions | 282 | 19.45 |
| Sample not transported in time | 331 | 22.82 |
| Sample with inappropriate request form | 625 | 43.10 |
| Sample with inadequate volume | 324 | 22.34 |

Table 2: Sigma scores of performance of quality Indicators

| | <u>IN-PATIENT</u> <u>sigma value</u> <u>interpretation</u> | <u>OUT-PATIENT</u> <u>sigma value</u> <u>interpretation</u> | <u>ALL PATIENT</u> <u>sigma value</u> <u>interpretation</u> |
|--|---|--|--|
| Appropriate test (with respect to clinical question) | 2 σ Unacceptable | 3 σ Minimal | 2 σ Unacceptable |
| Requests without time sample was collected | 2 σ Unacceptable | 2 σ Unacceptable | 2 σ Unacceptable |
| Unintelligible requests | 4 σ Good | 4 σ Good | 4 σ Good |
| Request that are truly urgent | 2 σ Unacceptable | 2 σ Unacceptable | 2 σ Unacceptable |
| Requests with errors concerning patient identification | 2 σ Unacceptable | 2 σ Unacceptable | 2 σ Unacceptable |
| Requests with errors concerning physician identification | 2 σ Unacceptable | 2 σ Unacceptable | 2 σ Unacceptable |
| Request without physician's number | 2 σ Unacceptable | 2 σ Unacceptable | 2 σ Unacceptable |
| Samples collected into inappropriate containers | 4 σ Good | 3 σ Acceptable | 3 σ Acceptable |
| Samples haemolyzed | 4 σ Good | 4 σ Good | 4 σ Good |
| Sample clotted | 4 σ Good | 3 σ Acceptable | 4 σ Good |

| | | | | | | |
|---|------------|--------------|------------|--------------|------------|--------------|
| Sample with blood stain on container (leakages) | 3 σ | acceptable | 3 σ | acceptable | 3 σ | Acceptable |
| Samples damaged in transits | 3 σ | acceptable | 3 σ | acceptable | 3 σ | Acceptable |
| Samples improperly labeled | 2 σ | Unacceptable | 2 σ | Unacceptable | 2 σ | Unacceptable |
| Samples not transported and stored under special conditions | 2 σ | Unacceptable | 2 σ | Unacceptable | 2 σ | Unacceptable |
| Sample not transported in time | 2 σ | Unacceptable | 2 σ | Unacceptable | 2 σ | Unacceptable |
| Sample with inappropriate request form | 2 σ | Unacceptable | 2 σ | Unacceptable | 2 σ | Unacceptable |
| Sample with inadequate volume | 3 σ | acceptable | 3 σ | acceptable | 3 σ | Acceptable |

Table 3: RANKING OF NON CONFORMITIES (first ten)

| | |
|--|--------|
| 1-Samples not transported under special condition | 100% |
| 2-Request that are not truly urgent | 98.5% |
| 3-Samples improperly labelled | 81.93% |
| 4-Requests with errors concerning patient identification | 80.21% |
| 5-Requests without time sample was collected | 75.10% |
| 6-Requests without physicians' phone number | 70.28% |
| 7-Samples with inappropriate request forms | 43.10% |
| 8- Inappropriate tests with respect to clinical question | 35.03% |
| 9- Errors concerning physicians' identification | 34.41% |
| 10- Samples with blood stain on containers | 23.86% |
| 11- Sample not transported in time | 22.82% |
| 12- Sample with inadequate volume | 22.34% |
| 13- Unintelligible requests | 08.21% |
| 14- Sample damaged in transport. | 03.52% |
| 15- Samples collected into in appropriate containers | 01.24% |
| 16- Samples clotted | 00.83% |
| 17- Samples hemolysed | 00.34% |

DISCUSSION

The ISO pre-analytical quality indicators as modified and used in this study, has afforded us the opportunity to assess the pre-analytical phase of the total testing process in this tertiary institution for the first time. For this study, the indicators assessed proper patient, sample and physician's identification and the quality of samples. Samples and samples that put all that have contact with them at risk were also assessed. Lastly the indicators that assess the inter phase between the laboratory and the clinicians were also evaluated.

Patient's identification

This indicator had unacceptable performance level as all the requests had patients name on them but had various degree of incomplete information on hospital number, sex, age and clinical details of patients. Most had no hospital number; 'adult' was filled in place of the real age and no clinical information on the patient's illness. These factors put together usually give more detailed and clearer information about the patients and aids the interpretation of generated results. A properly interpreted result comes with detailed information on patient identity and illness which cannot be over looked. The lack of this information on the request forms could be due to lack of understanding of the importance of these information for the proper interpretation of the results by laboratory physicians or the lack of will to do just that by the clinicians who filled the forms, judging from how easy this information could be sought and recorded.

Physicians' identification.

This indicator also had an unacceptable performance level as most of the request forms were not properly filled. Some of those that were filled had only the Physician's first or last name. This omission makes it difficult to communicate with the managing physician. This was made worse by the fact that requests without physician's phone number also had an unacceptable performance level. Most doctors didn't write their phone numbers on the request forms. The increase in kidnapping of doctors in this region of late may have contributed to this. The poor performance of this indicator was worrisome as easy communication between clinicians and laboratory physicians is very necessary, especially when dealing with some critical values of analytes.

Sample identification

Sample not properly labeled also had an unacceptable performance level. Many samples were sent with only the patient's first or last name on the container as the means of identification. Very few samples had patient's full name, date, time of sample collection and type of test requested on their containers. Most samples were brought to the laboratory with plain papers as request forms, due to unavailability of proper request forms. Others were brought in with request forms other than the appropriate one (chemical pathology) with only patient's first or last names. This can make identification of samples with same first name, last name or even the same full names difficult to identify especially if they come with ordinary plain papers. The poor performance level of these indicators mean that much needs to be done in training and retraining of staff/clinicians on the importance of properly filling request forms as well as the need to improve laboratory management to reduce or eliminate the 'out of stock syndrome', as was noticed to be the case within the period of this study.

Appropriate tests with respect to the clinical questions had a performance level that was unacceptable. Requests devoid of necessary information and those with information that could not be read made sample, patient and physician's identification, as well as result interpretation, difficult. The need for detailed information on laboratory request forms is important but more important is information that can be read. To this effect, though unintelligible requests performed well, the number of request that were unintelligible raises questions about patient, physicians and sample identification, as well as having enough information for proper interpretation of generated results.

Sample quality

Indicators assessing sample quality were seven (7) and their performance ranged from unacceptable, to acceptable and to good performance. Indicators like 'samples collected into inappropriate containers' 'number of samples that haemolyzed or clotted' and those that were 'damaged on transit' had good performance levels. Those indicators like 'samples transported in time' were difficult to assess as time of sample collection was most of the time not given. For the purpose of this study, these indicators were ticked in the negative to avoid assumptions on unavailable information. The mean estimated interval between sample collection time and time sample gets to the laboratory (according to the standard operating procedure of the laboratory) was six (6) hours. Therefore this indicator had an unacceptable performance level as exact time could not be ascertained.

Indicators like 'sample brought in haemolyzed or clotted' had good performance but action need to be taken to further reduce the number of such samples. Most of such samples were brought in by the patients or patients' relative, who most times brought these samples to the laboratory on their way home or whenever the finance was made available for payment. These samples, most times, are kept at room temperature and sent later same day or even next day. The good but worrisome performance of these indicators may also be due to lack of understanding of the need for early transportation of such samples to the laboratory.

'Samples not transported and stored under special conditions' had unacceptable performance as all bilirubin samples were brought in exposed to light. Only 282 samples fell under this category but this represented a hundred percent (100%) of such samples. These samples were separated and left standing even in the laboratory and uncovered for various lengths of time before they were assayed. This may have affected the quality of results, as the ratio of conjugated to non- conjugated bilirubin may have been significantly altered.

Some samples were brought with 'inadequate volume' and this may also affect the quality of the sample as the alteration of blood anticoagulant ratio may result to lysing of blood cells, thereby falsely increasing intracellular analytes in plasma. Most of such samples were observed to come from the Pediatrics' unit. Though most of these indicators assessing sample quality had good and acceptable performance levels, a holistic look at the entire indicators assessing the quality of samples was not too encouraging. This is because samples don't necessarily have to be clotted, haemolysed or be transported to the laboratory in inappropriate anticoagulant tubes to be deemed unfit for analysis. Quality of a sample can also be compromised when the volume in an anticoagulant tube is inadequate or the sample is left standing without separation for too long at room temperature or when not properly stored.

Safety

Some samples were sent to the laboratory with blood stains on containers due to either leaks or poor methods of sample collection and some even had blood stains on the request forms as well. It was observed that those from the wards and clinics were mainly due to leaks from improperly covered blood container caps. Those from the Pediatric unit may have been mainly due to the method of sample collection, as capillary blood may have been preferably collected by scooping oozing blood from skin due to difficulty in getting venous blood. This poses danger to all staff that come in contact with such stained blood containers and request forms. Though this had a good performance level, the health risk it poses calls for urgent need for training and re-training of all staff concerned in order to further minimize its occurrence.

Others

A total of 201 requests were marked 'urgent' but only 98 of these were found to be truly urgent. In evaluating the level of performance of this indicator, it was found to give an unacceptable performance.

Due to the frequent out-of-stock syndrome, some samples were transported to the laboratory with inappropriate request forms such as plain papers, with only patient's name, sometimes hospital number and occasionally type of test. This means that other necessary information was not given, making identification of patients, physicians and samples more difficult. Information needed to help in the interpretation of results was, in these cases, absent.

In this study it was noted that most of the indicators that had overall unacceptable performance levels, also had acceptable performance levels for the outpatient data. This could have been due to the fact that most of the request forms from the wards were filled by House Officers, while most of those from the clinics were filled by the senior doctors such as Registrars, senior registrars and Consultants.

Many of the pre-analytical indicators in this study had poor performance levels and judging by the saying 'garbage in garbage out' the results indicated that much needs to be done to ensure that samples taken from a rightly identified and prepared patient is rightly analyzed to produce the right result that will be rightly interpreted, based on rightly given information.

From the results of this study it is noted from the performance of these indicators that the pre-analytical stage of the total testing process in this hospital is currently encumbered with many errors. This calls for training and retraining of staff concerned and the need for regular communication between clinicians and laboratory staff in order to reduce these errors. Other studies have also affirmed these findings as more than half of the pre-analytical quality indicators in these studies were also noted to have unacceptable performance levels as was seen in this study (Plebani, Chiozza & Sciacovelli. 2013 & Englezopoulou, et al. 2016)

When the non-conformities to the laid down process were ranked in this study (Table 3) 'samples not transported under special conditions' was the leading non-conformity. Samples not transported under special condition was 100%. This was worrisome as results produced from this category of samples may not be reliable. This emphasizes the need for urgent intervention measures. This was followed by 'requests that are not truly urgent' which was second on the list with 98.5% frequency. Though this may not necessarily affect the outcome of the results, it is an indication of abuse of the process as the processing of such samples are usually prioritized over other samples. Most of these requests marked urgent were however left for days uncollected. A follow up of

such results by laboratory staff only showed that patients for which such results were meant for were stable in the ward. Sometimes such requests were sent on the day of patients discharge. Some of these urgent requests were made for even stable and mobile out-patients.

The Third most frequent non-conformity was, 'samples improperly labeled' which had 81.93%. This was a large percentage which meant that proper identification of samples was a major challenge. Similarly 'requests with errors concerning patient identity' was next with 80.21% followed by 'requests without time sample was collected'. Requests without Physician telephone number was 70.28%.

The performance of indicators that help in the identification of patients, samples and physicians all performed badly as most of them had more than 50% frequency. This made these indicators, and especially the others in the top five, the indicators of urgent attention. Though the other indicators on the non-conformity list had a frequency below 50%, the frequency alone may not necessarily be the only index for urgency of intervention. The effect of the indicator on the quality of samples and interpretation of the results also make them vital for urgent intervention, irrespective of their frequency. 'Samples with blood stains on container' (23.86%), 'samples not transported in time' (22.34%), 'sample with unintelligible requests' (8.21%) and those 'damaged in transport' (3.52%). They all affect the quality of samples. 'Samples collected into inappropriate container' had a frequency of 1.24%. Though this may appear low in frequency but it may have serious impact on the quality of the results.

Least on the list of non-conformities were 'sample clotted' (0.83%) and 'sample hemolysed'(0.34%). These were indicators worthy of note, as they affect the quality of samples and by extension, the quality of results/laboratory quality assurance. The poor performance of sample, physician and patient identification quality indicators are red flags for any laboratory and should be taken seriously.

From the result of this study, it could be advocated that similar studies be conducted in all major hospitals and where the pre-analytical quality indicators are found to have such poor performance levels, the Management of such hospitals and laboratories should be encouraged to introduce policies that will ensure that all House Officers and other involved staff undergo the needed training on the importance of proper filling of request forms, patient preparation and sample collection during their pre-engagement orientation exercise and periodically thereafter. The introduction of some form of a reward and penalty system may further encourage compliance with the right processes.

Conclusion

The results obtained from this study have shown that much needs to be done to improve the quality of samples sent for laboratory analysis. Results obtained from poor quality samples would be misleading as it would invalidate all the quality assurance processes put in place at both the analytical and post analytical phases (Garbage in garbage out). The use of quality control samples/measures, the regular calibration and recalibration of machines and proper interpretation of results will all be fruitless when poor quality samples are processed (garbage in garbage out). Most laboratories and accreditation bodies focus on the analytical and post analytical phase of the error control processes even though 70% of laboratory errors occur in the pre-analytical phase³. The pre analytical quality indicators holistically performed poorly in this study and this further affirmed the above fact. The poor performance of most of the pre-analytical indicators in this study is worrisome. Much therefore needs to be done to improve the quality of samples sent to clinical laboratories and this should be the first step and a very significant step in laboratory quality assurance.

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