Peer reviewed ORIGINAL ARTICLE

THE IMPACT OF NON-CONFORMANCES ON PATIENT CARE AT A PATHOLOGY TERTIARY CARE LABORATORY IN SOUTH AFRICA

ID Osegbe (MBBS)
AE Zemlin (MBChB, FCPaTh(SA)(Chem), MMed (Chem Path))
KK Kimengech (BSc), HND (Clinical Chemistry), DMLS
RT Erasmus (MBBS, FMCPath (Nig), FWACP (WA), DABCC, DASM (Natal), FCPaTh(SA))

Division of Chemical Pathology, National Health Laboratory Service (NHLS) and University of Stellenbosch, Tygerberg Hospital, Stellenbosch University, Parow, South Africa.
Corresponding author: Annalise Zemlin | tel: +27 (21) 938 4254 | fax: +27 (21) 938 4640 | email: azemlin@sun.ac.za

ABSTRACT

Introduction Although several studies have reported that laboratory errors may have some effect on patient care, few have studied non-conformance reports specifically. Clinical governance is a framework through which laboratories can improve the quality of their service and boost high standards of patient care. One of the measures of achieving this is by the identification and control of errors. For the purpose of this publication, non-conformances will refer to the recognition and documentation of laboratory errors. They are activities that fail to conform to specified standards.

Methods This was a retrospective study of the non-conformance reports for five accredited pathology divisions (Chemical Pathology, Haematology, Medical Microbiology, Immunology, and Virology) at an academic tertiary laboratory of the National Health Laboratory Service, Tygerberg Hospital over a three year period. The medical records of patients that were directly implicated by the non-conformances were reviewed to determine the impact to their healthcare.

Results Five hundred and eighty-three non-conformance reports were recorded across the divisions with chemistry having 140 (24%), haematology 65 (11%), medical microbiology 122 (21%), virology 211 (36%) and immunology 45 (8%). Three hundred and sixty-eight (63%) non-conformances had a major impact on patient care such as: delay in treatment in 52 (20%) cases, specimen recollection in 27 (11%) cases, inappropriate or unnecessary therapy in 44 (17%) cases, and inadequate patient care in 56 (22%) cases.

Conclusion Although the data was limited by poor adherence to documentation, this could serve as a pilot study where laboratories can be encouraged to document non-conformance reports better so that the appropriate impact of non-conformances on patient care can be ascertained subsequently. With continuous quality improvement measures in the laboratory, more favorable patient outcomes are expected.

KEYWORDS:
Non-conformances; patient care; laboratory errors.

NONSTANDARD ABBREVIATIONS:
South African National Accreditation System (SANAS); National Health Laboratory Service (NHLS); Tygerberg Hospital (TBH).

INTRODUCTION

Quality patient care is the ultimate goal of clinical governance, as it dictates that laboratories should be responsible for the provision of a service that positively impacts on patient care.[1] The Institute of Medicine encourages an error reporting system which can hold providers accountable for performance, or alternatively, provide information that leads to improved safety.[2] It notes that errors resulting in serious harm are the ‘tip of the iceberg’, which represent the small subset of errors that signal major system breakdown.[2] For the purpose of this publication, non-conformances will refer to the recognition and documentation of laboratory errors.

One of the measures of continuous quality improvement in the laboratory total quality management (TQM) is the identification and control of errors. An error refers to a deviation from a specified characteristic. This results in product or service insufficiency in terms of meeting stipulated requirements. In the laboratory, such errors occur in different areas of the testing process and can be identified in various ways, including: clinician complaints, quality control indications, instrument calibrations, checking of consumable materials, staff comments, reporting and certificate checking, laboratory management reviews, and internal and external audits.[3] A non-conformance is the recognition and documentation of an error which is advised as part of accreditation. A laboratory accredited to the International standard ISO 15189:2007 for quality and competence in medical laboratories is expected to have a policy and procedure that will be implemented when it detects that any aspect of its examinations does not conform to its own procedures, or agreed upon requirements of the quality management system, or the requesting clinician.[4]

Several synonyms have been used to describe deviations from good laboratory practice, such as errors[5], mistakes[6], blunders[7], incidents[8], but non-conformances refer to the formal recognition and reporting of these deviations. Previous studies have obtained information on laboratory errors from logbooks[9], quality control charts[10], incident reports[11], information systems[12,13], complaints’ forms[14] and questionnaires[15]; but it has not been widely described from non-conformance reports. Carraro et al. recently described errors from non-conformances documented during their observational study.[16]
The possible impact of errors on patient care include: no effect, repeated testing, extra clinician appointments, unnecessary medical procedures and therapy, increased duration of hospitalization, disability, and death. Several studies have reported up to 25-30% of laboratory errors may have some effect on patient care, with about 6-10% resulting in specific adverse events, or the risk of adverse events. The latter finding could be prevented by the various check points and filtering mechanisms in Lundberg’s brain-to-brain cycle, revolving from test ordering to result interpretation and action.

Few studies on errors or non-conformances have been reported from developing countries and in particular from Africa. In this study we analysed the non-conformances detected in the pathology laboratory, with a view to determining their impact on patient care. The results of this study will lead to the practical implementation of non-conformance reporting in continuous quality improvement, as its monitoring should lead to more favourable outcomes.

METHODS AND MATERIALS

Setting

This study was conducted at the Chemistry, Haematology, Medical Microbiology, Immunology, and Virology divisions of the National Health Laboratory Service (NHLS) at Tygerberg Hospital (TBH). TBH is a 1400 bed multidisciplinary academic tertiary hospital in the northern suburbs of Western Cape Province, South Africa. These divisions provide pathology services mainly to TBH, but also service a number of regional clinics, with about 90,000 test requests monthly. Each of the laboratories was accredited to ISO 15189:2007 by the South Africa National Accreditation System (SANAS) in January 2009, except Virology which was accredited in 2002.

Ethics approval was obtained from the University of Stellenbosch, and patient confidentiality was maintained. This study was performed in accordance with the Declaration of Helsinki. The NHLS quality assurance division was consulted and involved in this study.

Non-conformance reporting

Non-conformances refer to the actual recognition and documentation of laboratory errors. They form part of laboratory governance and are issued to the person responsible for the area in the laboratory where the error occurred. Corrective action must be documented. Non-conformances are typically reported following: internal audits performed monthly by the quality assurance coordinator; annual audits carried out by SANAS assessors; and spontaneously by laboratory supervisors, who have been trained on non-conformance reporting with the help of the quality assurance coordinator. A template form is used to record the date and details of the non-conformance (figure 1) including: the severity, area of the testing process involved, the volume of tests performed during the period were 0.0047%, 0.006%, 0.042%, 0.0097% and 0.0145% respectively.

The data was analysed using Microsoft Excel 2010.

RESULTS

A total of 583 non-conformances were reported during the study period. Chemical Pathology recorded 140 (24%), Haematology 65 (11.1%), Medical Microbiology 122 (20.9%), Virology 211 (36.2%), Immunology 45 (7.7%). The relative frequencies that were determined by the ratio of the total non-conformance to the volume of tests performed during the period were 0.0047%, 0.006%, 0.042%, 0.0097% and 0.0145% respectively.

Of the 583 non-conformances, 368 (63%) were major and 215 (37%) were minor. One hundred and sixty (27.4%) non-conformances involved the preanalytical phase, 370 (63.5%) the analytical phase, and 53 (9.1%) the post analytical phase.

A total of 255 identifiable patients were affected by the non-conformances. Of the 255, Chemical Pathology was involved in 49 (19%), Haematology in 61 (24%), Medical Microbiology in 60 (24%), Virology in 66 (26%), and Immunology in 19 (7%) patients. These patients experienced the following kinds of impact on their care: delay in treatment in 52 (20%) cases, specimen recollection in 27 (11%) cases, inappropriate or unnecessary therapy in 44 (17%) cases, inadequate/ incomplete patient care (determined by tests not done, and no repeat sample sent), no significant impact (determined by potential incorrect results that were detected and corrected before the release of the results), and others in 26 (10%) cases (Table 1).

DISCUSSION

Recent publications have emphasized the importance of laboratory errors and their impact on patient care. However, few articles have studied the documentation of these errors, namely non-conformance reports. We observed a remarkably low number of non-conformances, with only 583 (0.0099%) across five laboratory divisions in three years. Laboratory error rates of 0.151%, 0.3%, 0.34% and 1.46% have been reported elsewhere. This may indicate that there is under-reporting of errors in our institution despite their occurrence.

The analytical phase had the greatest number of non-conformances, namely 370 (63.5%). This was probably because there is
more documentation in this phase. It has been widely reported that the preanalytical phase has the predominant frequency of laboratory errors ranging from 53% to 85%.[10, 21-24] The preanalytical specimen reception area has a high throughput and is labour intensive. Therefore it can be challenging to document all the errors, especially in poorly resourced laboratories. Most preanalytical errors result from system flaws and insufficient audit of operators involved in that phase.[25] For these reasons other studies[14, 21-24] used a prospective, observational approach, compared to our retrospective approach. A frequency of 9% of non-conformances in the post-analytical phase has also been reported.[6]

The majority of the non-conformances (63%) were categorized as ‘major’. Goldschmidt and Lent[12] showed up to 12.5% of laboratory errors may have an impact on patient health. Studies revealed that laboratory service problems affected 49 of 180 patients[21], and 48 of 205[26], with significant impact occurring in 10 and 13 patients respectively.[21, 26]

The major clinical impact observed in the 255 identifiable patients was incomplete/ inadequate patient care. This was as a result of tests not done due to: wrong specimen tube used lost specimens, specimen misidentification, among others; and no repeat specimen was sent to the laboratory despite contact with the clinician to resend it. This leads to substandard healthcare practice, as it has been shown that laboratory results influence 60-70% of clinical decisions on admission, discharge and medication.[27] It is for reasons such as this that evidence-based medicine is encouraged and subjective, empirical treatment discouraged.

Delay in treatment due to delay in delivery of a quality result to the clinician was seen in 52 (20.4%) cases, while studies by Astion et al. recorded 110 (85%) cases (9), and Goldschmidt reported 23%.[12]

In 27 (10.6%) cases in this study specimen collection was repeated. Although this appears not to be serious, it can affect patient safety. Witte et al.[9] reported that 51 (40%) of 129 blood specimens had to be redrawn, seven (5%) of the patients developed phlebotomy-related injuries including haematoma (two cases), haematoma possibly complicated by cellulitis (one case), pain at the phlebotomy site (two cases), excessive blood drawn from an infant (one case), and fainting and sustaining a laceration to the forehead a few minutes after phlebotomy (one case). Repeated sampling not only causes discomfort, causes patient dissatisfaction, but compounds the problem of delay in treatment. For inpatients, this may lead to prolonged hospital admissions, exceeding the ideal average length of hospital stay of seven days[28], resulting in cost implications.

Inappropriate or unnecessary therapy was given in 44 (17.3%) cases, mainly involving antibiotics based on incorrect microbiology culture and sensitivity results. Plebani et al.[7] recorded 6.4% of cases that received inappropriate care or modification of therapy and 19% of cases that required further inappropriate investigations e.g. echography, magnetic resonance imaging in their study of mistakes in a stat laboratory. Astion et al.[26] recorded seven of 205 cases that received unnecessary intervention, which included treatment and invasive testing.

No significant impact was seen in 50 (19.6%) cases, as the various laboratory-filtering mechanisms prevented potential errors from resulting in clinical effect. Plebani et al.[7], and Ross et al.[29] revealed that most laboratory mistakes (74%) and (70%) respectively, had no significant clinical effect on patient care. However, frequencies of morbidity (four transient cases, and

Table 1: Frequency of the impact of the non-conformances on patient care according to the various pathology divisions.

<table>
<thead>
<tr>
<th>Impacta</th>
<th>Chem</th>
<th>Haem</th>
<th>Micro</th>
<th>Virol</th>
<th>Immu</th>
<th>Total No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delay in treatment</td>
<td>13</td>
<td>20</td>
<td>11</td>
<td>8</td>
<td>-</td>
<td>52 (20.4)</td>
</tr>
<tr>
<td>Specimen recollected from patient</td>
<td>8</td>
<td>7</td>
<td>2</td>
<td>9</td>
<td>1</td>
<td>27 (10.6)</td>
</tr>
<tr>
<td>Inappropriate/unnecessary therapy</td>
<td>4</td>
<td>4</td>
<td>24</td>
<td>7</td>
<td>5</td>
<td>44 (17.3)</td>
</tr>
<tr>
<td>Inadequate/incomplete patient care</td>
<td>5</td>
<td>12</td>
<td>8</td>
<td>22</td>
<td>9</td>
<td>56 (22.0)</td>
</tr>
<tr>
<td>No significant impact</td>
<td>9</td>
<td>8</td>
<td>9</td>
<td>20</td>
<td>4</td>
<td>50 (19.6)</td>
</tr>
<tr>
<td>Others</td>
<td>10</td>
<td>10</td>
<td>6</td>
<td>-</td>
<td>-</td>
<td>26 (10.1)</td>
</tr>
<tr>
<td>Total No. (%)</td>
<td>49 (19)</td>
<td>61 (24)</td>
<td>60 (24)</td>
<td>66 (26)</td>
<td>19 (7)</td>
<td>255 (100)</td>
</tr>
</tbody>
</table>

a refer to the ‘Methods’ section for definitions
four cases over the period of one week) and death (one case) have been recorded.\textsuperscript{29} Despite these reports, the impact on patient care is greatly underestimated, as the level of discomfort and dissatisfaction cannot be fully evaluated.

The greatest limitation in the present study was poor adherence to documentation. This influenced the quality of data received and analysed. This is most probably due to staff reluctance to write-up non-conformances for fear of disciplinary action. Divisions with better reporting practices, including patient identification, seemed to have more non-conformances, creating a false distribution.

Despite the fact that the non-conformance reporters had been trained with a standard operating procedure, lack of standardisation of reporting was illustrated by the fact that one non-conformance was recorded per report, in some sections, while others recorded multiple similar non-conformances on a form, apart from inappropriate classification of non-conformances.

The eventual patient outcome was difficult to determine because their medical records did not document this. A change to documentation of such errors, the impact of those errors on patient care is greatly underestimated, as the level of discomfort and dissatisfaction cannot be fully evaluated.

In order to ensure a good non-conformance reporting system for continuous quality improvement, it must be standardised. Lippi \textit{et al.}\textsuperscript{29} recommended that standardisation and monitoring of preanalytical variables is very important. The same template should be applied in each laboratory division. The template should require patient identification, as well as attached documentation e.g. request forms. A checklist for root cause analysis should be developed for the easy analysis of trends. Regular training of supervisors and quality managers, on how to document and monitor non-conformances, must be implemented.

Most importantly, awareness must be created by means of regular training workshops on the reporting of non-conformances, who would only embrace it once it is not used for disciplinary measures or performance assessment. An observational study would be useful in monitoring the changes in order to appreciate the patient impact with outcome in real time.

CONCLUSION

This is one of the first studies to quantify the impact of laboratory errors on patient care by using written documentation of laboratory errors, namely non-conformances. With proper documentation of such errors, the impact of those errors on patient care can be determined. Continuous monitoring will allow for continuous improvement, decrease laboratory errors, and improve the quality of patient care.

REFERENCES