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ORIGINAL RESEARCH

Analysis of internal audit non-conformances at non-accredited public health laboratories in Gauteng province, South Africa

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Background: The International Organisation of Standardisation (ISO) 15189:2012 standard specifies requirements for the competence and quality of medical laboratories and outlines criteria for the quality management system (QMS) within these laboratories. Among the 24 public health laboratories in Gauteng, only eight (33%) achieved ISO 15189:2012 accreditation by the end of 2018, leaving a notable 16 (67%) without this status. This study aimed to identify trends in non-conformances among the non-accredited laboratories in Gauteng, as well as strategies to improve compliance with the standard.

Methods: Non-conformances were collected in three disciplines (haematology, chemical pathology, and microbiology) over five years. They were categorised as pre-analytical, analytical, and post-analytical testing phases, and quality system essentials (QSE) for those non-conformances outside the testing phases. The distribution of non-conformances across the five years was compared. Non-conformances were categorised according to severity and compared. Chi-square test evaluated differences ($p < 0.05$) between categories.

Results: The findings showed a statistically significant difference between the years for the testing phases and QSE non-conformances ($p < 0.001$). Additionally, the severity of the non-conformances between these laboratories ($p < 0.001$) showed that medium-severity non-conformances were less common than minor- or major-severity non-conformances. The majority (364, 57.6%) of non-conformances were recorded for the QSEs (i.e. requirements outside the pre-analytical, analytical, and post-analytical phases). Gaps in the QMS were identified.

Conclusion: Extensive knowledge and analysis of laboratory non-conformances are crucial for future improvement. This study showed that fulfilling the administrative requirements of the ISO standard is an area of concern. Strategies to overcome the challenges of the ISO 15189:2012 administrative requirements need to be explored, such as appointing quality assurance officers.

Keywords: ISO 15189, quality management system, accreditation, quality assessment, quality system essentials

Introduction

The International Organisation of Standardisation (ISO) 15189 is an effective measurement to demonstrate the competence of diagnostic laboratories.[1] It verifies that the data produced for making clinical decisions meets the international standard. Furthermore, laboratories use international standards to develop their quality management system (QMS) to ensure the quality and reliability of patient results.[2]

To obtain international recognition that a laboratory complies with the ISO 15189 standard, an independent, authoritative external body is utilised to assess the laboratory's QMS.[1] In South Africa, the external independent body that verifies health laboratory compliance with the international standard is the South African National Accreditation System (SANAS).[3] Upon compliance, these laboratories are issued with an accreditation certificate, which serves as recognition that it complies with the requirements of the ISO 15189 standard.[1] To check continuous compliance, laboratories are typically required to undergo surveillance assessments at regular intervals, which may not exceed 24 months, and re-accreditation at four years.[4] This standard also guarantees patients, clinicians, and all stakeholders the accuracy and reliability of laboratory testing.[5]

A study conducted by Khadambi et al.[6] indicated that most accredited laboratories are from the private sector. The study reported that up to March 2020, only 112 (25%) out of approximately 442 accredited laboratories in South Africa were in the public sector.[6] In this study it was seen that by the end of 2018, among the 24 public health laboratories in Gauteng, only eight (33%) had achieved ISO 15189:2012 accreditation, leaving a notable 16 (67%) without this status.[7] To evaluate the ongoing effectiveness of the organisation's QMS and compliance with the ISO 15189 standard, medical laboratories are expected to perform internal audits.[8] The audit non-conformances are documented according to the severity scoring system based on patient outcomes, which is important to establish the risks associated with patient outcomes. These could be classified as minor, medium, or major non-conformances.

However, limited published research exists on the statistical analysis of internal audit non-conformances recorded in public health laboratories in South Africa. This study aimed to analyse

audit non-conformances. This will allow the evaluation of relevant improvement measures that can be applied across the non-accredited public health laboratories to address the identified gaps and strengthen the implemented QMS.

Methodology

Ethical consideration

This study was approved by the Academic Affairs and Research Division of the National Health Laboratory Service (NHLS) and the Ethics Committee of the Faculty of Health Sciences at the University of Johannesburg.

Data collection and analysis

A total of 884 retrospective non-conformance data were analysed from 10 randomly selected, non-accredited laboratories from the NHLS in Gauteng. Three disciplines were included (haematology, chemical pathology, and microbiology) because most laboratories offer support in these disciplines.[9] The annual compliance internal audit non-conformances recorded from 2015 to 2019 in each of these selected 10 laboratories were obtained from the internal auditor's reports.

Data were categorised into four categories. Category one included management and technical non-conformances. Category two comprised the testing phases (pre-analytical, analytical, and post-analytical). The third category encompassed non-conformances' severity (minor, medium, and major). The fourth category was the QSEs, the term generally used to describe the essential elements of the QMS. Minor non-conformances indicate no change in patient management and no adverse clinical outcome.[10] Medium non-conformances do not cause patient harm but are repeated occurrences.[11] Major non-conformances indicate a significant adverse clinical outcome requiring the laboratory to immediately implement corrective actions to prevent adverse patient impact.[10]

The ISO 15189:2012 standard was used to classify the non-conformances according to management and technical non-conformances and the three testing phases. The non-conformances were further analysed to establish which non-conformances were recorded under specific ISO 15189:2012 standard clauses. The non-conformances that did not fall within the classification of the three testing phases per ISO 15189:2012 standard were categorised as QSEs. The QSEs include requirements outside the testing phases (i.e. the document control system, evaluation and audits to ensure compliance with the standard, storage of records, personnel requirements, purchasing and inventory, and management of non-conformances).[12]

Data were collated in a Microsoft Excel (Microsoft Corporation, Redmond, USA) spreadsheet, decoded, and stored electronically in a password-controlled folder. Data sets were analysed using the Statistical Package for the Social Sciences (SPSS) program. Chi-square test was used to establish if there was a statistically significant difference between categories. A p-value < 0.05 was considered statistically significant. Where a statistically significant difference between the compared variables occurred, Cramér's V was calculated to establish the strength of the relationship (the effect size).

Results

A total of 884 non-conformances were recorded and categorised according to the type of non-conformance (categories one, two, three, and four). After duplicates were removed, a total of 632 types of non-conformances were recorded. Of these, 45.1% (n = 285) were management non-conformances and 54.0% (n = 341) were technical non-conformances. Six non-conformances were for safety and could not be categorised as either management or technical non-conformances because there is no separate ISO 15189:2012 standard clause number for safety.

Management and technical non-conformances

There were no statistical differences between the 10 laboratories' management 45.1% (n = 285) and technical 54.0% (n = 341) non-conformances in the 2015–2019 review period (p = 0.364).

The management requirements of the ISO 15189 standard comprise clauses 4.1–4.15, and the technical requirements consist of clauses 5.1–5.10. Most (5.9%, n = 37) management non-conformances were recorded against Clause 4.3 (document control). Clause 4.1 (organisation and management responsibilities) made up 5.4% (n = 34), and Clause 4.14 (evaluation and audits) comprised 5.2% (n = 33) of the management non-conformances. Other non-conformances were reported against Clause 4.13 (control of records) (4.0%, n = 25), Clause 4.9 (identification and control of non-conformances) (3.6%, n = 23), Clause 4.2 (QMS) (3.5%, n = 22), and Clause 4.15 (management review) (3.0%, n = 19) (Figure 1).

For the technical requirements, the frequently observed non-conformances (13.8%, n = 87) were documented against Clause 5.3 on laboratory equipment, reagents, and consumables. These were followed by clauses 5.6 (ensuring the quality of examination results) (9.8%, n = 62) and 5.1 (personnel) (7.6%, n = 48). Clauses 5.4 (pre-examination processes) at 6.2% (n = 39) and 5.5 (examination processes) at 5.2% (n = 33) were also included (Figure 1).

Clause 4.3 (document control) non-conformances (n = 37, 5.9%) included out-of-review standard operating procedures (SOP), the procedure for document control not followed, unavailability of some procedures and policies, and lack of acknowledgement of reading SOPs and policies. The organisation and management responsibility Clause 4.1 non-conformances (n = 34, 5.4%) were mainly related to internal and external communication. Minutes of meetings had not assigned tasks to staff, no target dates, the procedure for staff meetings was not followed (i.e. items to be discussed in staff meetings were not discussed), and records of staff meetings were not available and approved by all staff.

Clause 4.14 non-conformances (n = 33, 5.2%) on evaluation and audits indicated that the audit findings were not addressed and closed within agreed timeframes; there was no evidence of an action plan for the clearance of findings. Non-conformances

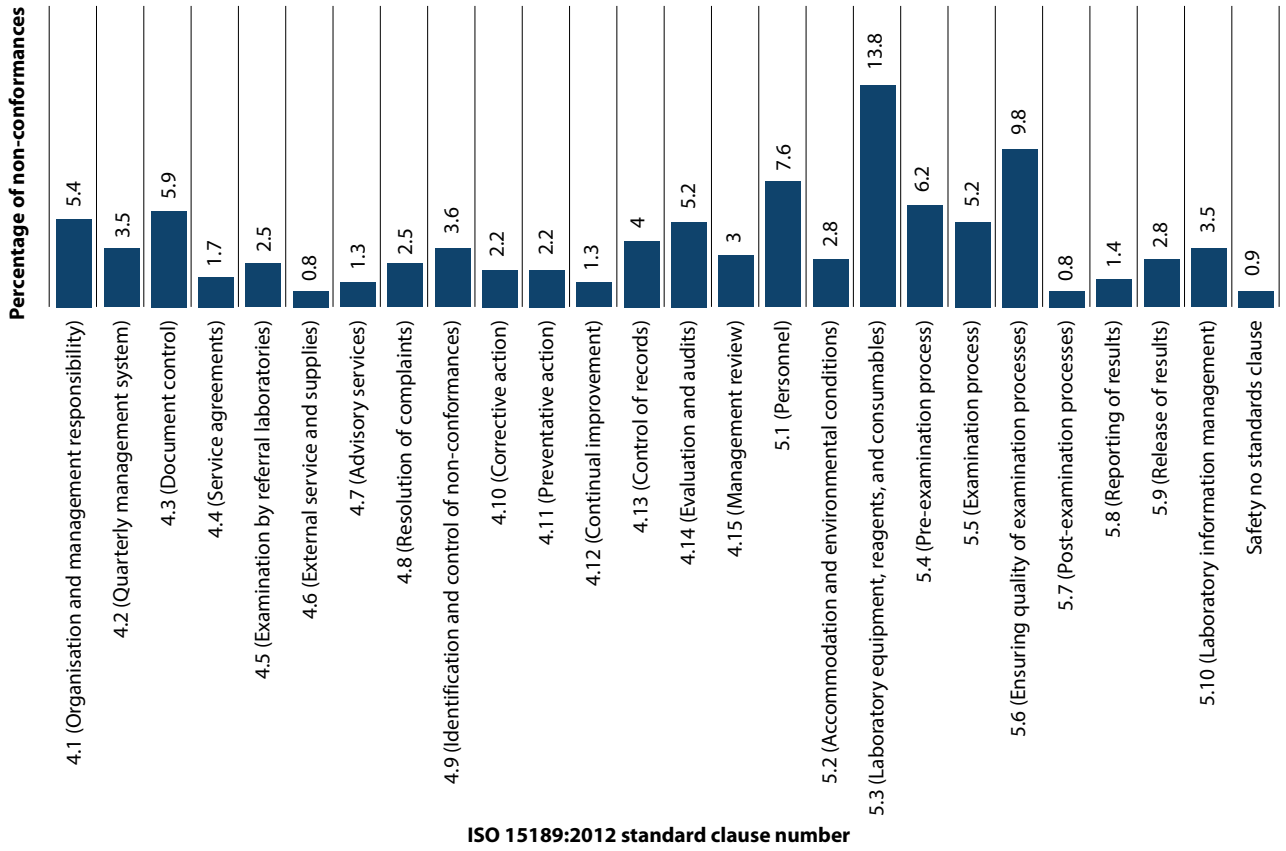

Figure 1: Percentage of management and technical non-conformances

recorded for Clause 4.13 (control of records) (*n* = 25, 4.0%) included archived records not being appropriately stored, discrepancies in retention of records between laboratory-specific procedures and the quality manual, worksheets not document controlled, old versions of forms used, hand amendments on records not done according to the procedure, storage boxes not properly labelled, and no evidence of completed forms to indicate storage of records.

Non-conformances for Clause 4.9 (*n* = 23, 3.6%) on managing non-conformances indicated that not all non-conformances were recorded within the laboratories. When recorded, corrective actions were not implemented within agreed timeframes. The root cause analysis was not performed, and non-conformances were not reviewed for trends. The effectiveness of corrective actions was not monitored.

Recorded technical non-conformances

The leading technical non-conformance (*n* = 87, 13.8%) was Clause 5.3 (laboratory equipment, consumables, and reagents). It was highlighted that records concerning equipment calibration, service, and maintenance were not kept up to date. Regarding reagents and consumables, the reagent inventory was also not kept up to date. The non-conformances (*n* = 62, 9.8%) under Clause 5.6 (ensuring quality of examination results) showed a lack of reviewing Levey–Jennings (LJ) charts to assess quality control (QC) trends and biases to enable timeous corrective actions; the frequency of QC testing was not adhered to. There was no documented evidence of patient sample rerun after the internal quality control (IQC) failure was corrected.

The personnel Clause 5.1 non-conformances (*n* = 48, 7.6%) were related to poorly kept training and competency records for laboratory personnel (i.e. unavailable or incomplete training and competency records). This could have resulted in variations in performing the laboratory tests, as staff with missing or non-updated competencies may not have been aware of the necessary changes implemented for the performance of tests.

Non-conformances compared according to the three testing phases and QSEs

The majority (364, 57.6%) of non-conformances classified into QSEs did not fall within the pre-analytical, analytical, or post-analytical phases compared to the non-conformances

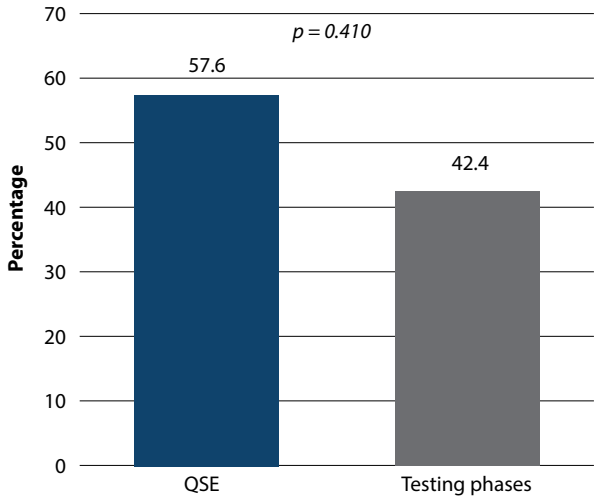

Figure 2: Differences between the QSE and testing phases (pre-analytical, analytical, and post-analytical)

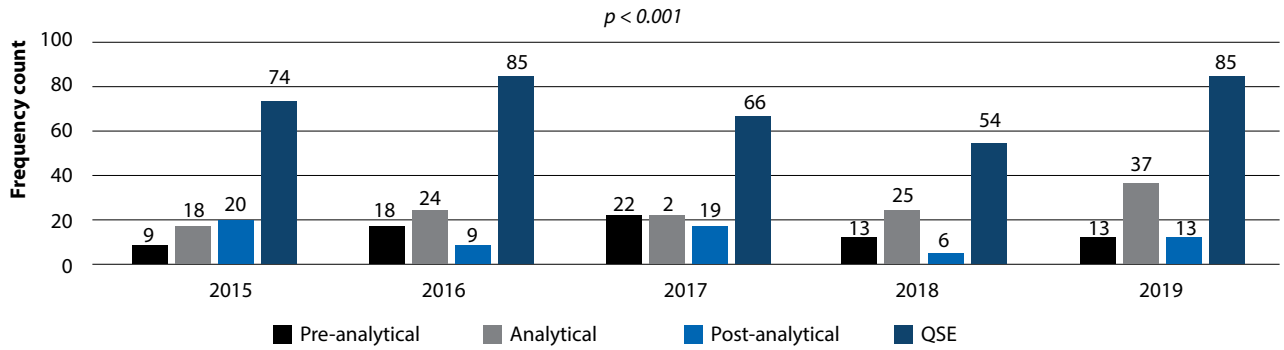

Figure 3: Frequency of non-conformances between the testing phases and QSEs in 2015–2019

(268, 42.4%) classified into these three phases. When classified according to the three testing phases, the majority (19.9%, *n* = 126) of non-conformances were documented in the analytic phase, while 11.9% (*n* = 75) were in the pre-analytical phase, and 10.6% (*n* = 67) in the post-analytical phase. The frequency of the testing phase non-conformance and QSE non-conformances were similar, as illustrated in Figure 2 ($p = 0.410$).

The frequency of the pre-analytical, analytical, post-analytical, and QSE non-conformances were compared over time. There was a statistically significant difference between the five years regarding the frequency of pre-analytical, analytical, post-analytical, and QSE non-conformances ($p < 0.001$). The Cramér's V calculated was 0.114, indicating a slight difference between the testing phases and the QSEs over the five years. Most testing phase non-conformances were recorded against the analytical phase, and these analytical non-conformances increased over the five years; however, the QSE non-conformances remained high throughout the years, as indicated by Figure 3.

In the pre-analytical phase, non-conformances included incomplete information on the request slip, using incorrect sample containers, inconsistent monitoring of sample transportation, not completing the specimen rejection log sheet, inconsistent request slip data checks for errors before results are reported, and not following the procedure for requesting additional tests.

The analytical phase non-conformances highlighted unavailable or incomplete equipment verification records, non-adherence to the equipment service schedule, and inconsistently maintained equipment. QC data were not reviewed at regular intervals to detect trends in examination performance, and there was no evidence of controls plotted on LJ charts to detect trends.

Most non-conformances in the post-analytical phase were related to increased turnaround time (from when the patient sample was collected until the results were reported to the corresponding physician). Additionally, the criteria for phoning critical results were not adhered to.

Several QSE non-conformances highlighted critical challenges with the administrative functions. These included a lack of complete documentation for the staff, incomplete inventory for equipment and reagents, lack of an action plan to clear internal audit non-conformances, and not ensuring proper control of documents and records.

Non-conformances categorised according to severity: minor, medium, and major

Most audits (*n* = 291, 46.0%) did not record the severity of non-conformances. Non-conformances with no severity recorded were not included in the analysis as they did not indicate minor, medium, or major non-conformance.

Out of the 341 (54%) non-conformances for which non-conformance severity was recorded, 20.3% (*n* = 128) were major, 21.4% minor (*n* = 135), and 12.3% (*n* = 78) medium (Figure 4). The medium severity non-conformances were less common than minor- or major-severity non-conformances.

There was a significant difference in reported minor, medium, and major non-conformances ($p < 0.001$). The Cramér's V was 0.369, indicating a moderate difference between the testing phases in these laboratories.

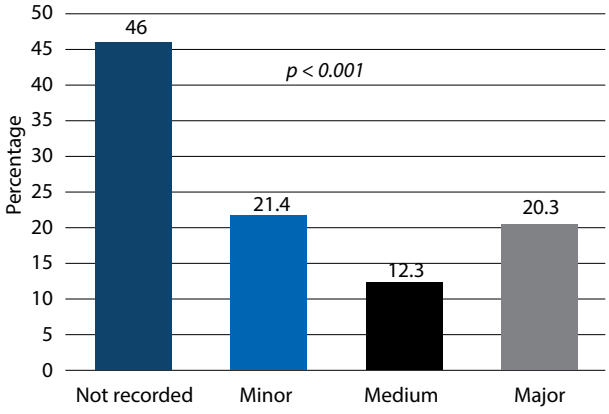

Figure 4: Comparison of the relative percentages of the non-conformance severities

Discussion

The laboratories had similar frequencies of management and technical non-conformances. The majority (57.6%) of non-conformances were recorded outside the pre-analytical, analytical, and post-analytical phases, referred to in this study as QSEs. These management ISO 15189:2012 standard requirements are linked to administrative duties, including retaining updated personnel records, managing staff meetings, ensuring a good document control system, managing non-conformances, and planning corrective actions for internal audit non-conformances.

Similar non-conformances outside the testing phases were reported by Luman et al.[13] in the analysis of the Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) audit findings from 126 laboratories in 12 countries in 2014. The study highlighted that the weakest areas were the identification and management of non-conformances, internal audits, and management reviews.[13] The common non-conformances in Gauteng, as seen in this study, were further highlighted for 27 laboratories in 10 counties in Kenya for a project of intensified mentorship approach towards accelerated medical laboratory accreditation between 2016 and 2019.[14] The common non-conformances were reported for management review meetings, evaluation, audits, and identification and control of non-conformances. Mentors with specific expertise in these deficient areas were assigned to the laboratories.[14] This led to rapid improvement in laboratory audit results and fast-tracked progress towards accreditation. The mentors in the Kenya study were assigned to the laboratories for 360 days.[14]

Assigning a quality assurance officer to assist with administrative duties may fast-track the process towards accreditation and maintain the accreditation status. The study in Kenya highlighted that each country may need to adjust the standard approach and develop a country-specific strategy towards laboratory accreditation.[14] To improve the number of accredited laboratories in Gauteng, a gap analysis indicated space for improvement in the QMS. The quality assurance coordinators from the accredited laboratories were assigned to mentor the non-accredited laboratories. By June 2023, 83% (20/24) of the laboratories in Gauteng were accredited through QMS gap analysis and addressed identified gaps.[15]

In the three testing phases (pre-analytical, analytical, and post-analytical), this study found the analytical phase to have the most non-conformances of 19.9%. Osegbe et al.[16] agreed with this finding in a study conducted at the NHLS in the accredited laboratories in the Western Cape in 2013. The study reported that the majority of non-conformances were in the analytical phase.[16] This finding contradicts several worldwide literature findings that most laboratory errors are in the pre-analytical phase followed by the post-analytical phase.[17-24] Osegbe et al.[16] indicated that the finding could result from increased non-conformance documentation in this phase and the retrospective study approach compared to other studies' prospective and observational approaches. Non-conformances in the analytical phase were related to the review of internal QC data (i.e. review of LJ charts and adherence to equipment service and maintenance schedules). This further highlights challenges with the administrative functions.

The results highlight the severity of non-conformances in the laboratory setting. The impact on patient care is most severe/crucial to address, as non-conformances directly affect patient results. This includes errors in diagnostic testing, incorrect reporting of results, or failure to detect critical conditions. Major non-conformances that pose a significant risk to quality and patient safety may lead to accreditation suspension or revocation. Osegbe et al.[16] established that 63% of non-conformances were classified as major in the analysis of non-conformances at a tertiary public health accredited laboratory in South Africa. The non-conformances had a major impact on patient care (i.e. delay in treatment, specimen recollection, and therapy). Limited literature exists on the analysis of non-conformance severity; the gaps identified in the pre-analytical, analytical, and post-analytical phases are commonly reported.

Risk management assists laboratories in prioritising corrective and preventive actions based on the risk level.[10] The major non-conformances require immediate attention and robust corrective measures to mitigate risks and prevent recurrence.[10] Medium-severity non-conformances were not as common as minor- or major-severity non-conformances. These are indicated for repeated non-conformances. The findings highlight that some non-conformances were not adequately addressed and hence repeated. Performing a proper root cause analysis will assist in properly addressing the non-conformances. By effectively managing non-conformances based on severity, laboratories can minimise the likelihood of adverse events and ensure high-quality service delivery.

The study limitations should be noted. The study focused on the laboratories of the NHLS, the largest public health laboratory in South Africa, and only included the province of Gauteng. Non-conformances of three laboratory/clinical disciplines (microbiology, chemical pathology, and haematology) were examined and did not include other disciplines (infectious diseases, histology, cytology, virology, genetic testing, and immunology). It is suggested that more provinces and private sector laboratories be included to broaden the scope of research. The lack of recorded severity, and the total frequency of minor, medium, and major non-conformances was affected. Inconsistencies in internal auditors' recording of the severity of non-conformances could have been due to unclear SOPs on recording the severity of internal audit non-conformances.

Conclusion

The findings highlighted a challenge in fulfilling QSE requirements compared to the categories involving the three testing phases. The management of administrative activities may have been overlooked as more attention is given to processing and releasing results. The mismanagement of the administrative functions is an area of concern, and strategies to overcome the QMS administrative challenges should be explored. Assigning duties to different personnel may lessen the task for the laboratory managers, and appointing quality assurance officers may relieve the laboratory managers of some administrative duties. Laboratories are expected to continuously monitor and improve their QMS, processes, and procedures to ensure ongoing compliance with ISO 15189:2012 requirements and improve patient care.

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Conflict of interest

The authors declare that they have no financial or personal relationships that may have inappropriately influenced them in writing this article.

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Ethical approval

The study was approved by the Academic Affairs and Research Division of the National Health Laboratory Service and Ethics Committee of the Faculty of Health Sciences at the University of Johannesburg.

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