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Evaluation of Quality Indicators in a Laboratory Supporting Tertiary Cancer Care Facilities in India

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ABSTRACT

Objective: To collect and tabulate errors and nonconformities in the preanalytical, analytical, and postanalytical process phases in a diagnostic clinical laboratory that supports a super-specialty cancer center in India, and identify areas of potential improvement in patient services.

Methods: We collected data from our laboratory during a period of 24 months. Departments in the study included clinical biochemistry, hematology, clinical pathology, microbiology and serology, surgical pathology, and molecular pathology. We had initiated quality assessment based on international standards in our laboratory in 2010, with the aim of obtaining accreditation by national and international governing bodies. We followed the guidelines specified by International Organization for Standardization (ISO) 15189:2007 to identify noncompliant elements of our processes.

Results: Among a total of 144,030 specimens that our referral laboratory received during the 2-year period of our study, we uncovered an overall error rate for all 3 process phases of 1.23%; all of our error rates closely approximated the results from our peer institutions. Errors were most common in the preanalytical phase in both years of study; preanalytical- and postanalytical-phase errors constituted more than 90% of all errors.

Conclusion: Further improvements are warranted in laboratory services and are contingent on adequate training and interdepartmental communication and cooperation.

Keywords: quality indicators, laboratory medicine, tertiary cancer center, errors, quality control, quality management

Advances in our knowledge of the molecular basis of disease have increased the capability of laboratory professionals to investigate complex diseases such as cancer using a variety of tests that provide diagnostic, prognostic, and risk-stratification information.1-3 The clinical use of these tests makes it essential that the results are highly accurate and reproducible with a minimal occurrence of errors.4-6 Thus, objective measures must be identified that enable quantitative evaluation of the performance of a laboratory in providing critical diagnostic data domains.7,8

In a large clinical laboratory, mistakes are inevitable given the volume of specimens, the number of individuals handling these specimens, and the number of steps involved in the testing process. However, appropriate training, quality control (QC) checks, and periodic review of protocols have been shown9,10 to minimize errors. Medical laboratories have developed rigorous quality management systems (QMSs) consisting of a number of quality indicators (QIs) that are used to monitor laboratory functions. Such systems include audits by internal and external evaluators, as well as accreditation by nationally and internationally recognized organizations such as the National Accreditation Board for Testing and Calibration Laboratories (NABL) and the College of American Pathologists (CAP), all of which have been demonstrated11,12 to promote highly effective quality assurance (QA) procedures.

Preparations for such audits include documentation, implementation, and adherence to International Organization for Standardization (ISO) 15189:2007

Abbreviations
QC, quality control; QMSs, quality management systems; QIs, quality indicators; NABL, National Accreditation Board for Testing and Calibration Laboratories; CAP, College of American Pathologists; QA, quality assurance; ISO, International Organization for Standardization; SOPs, standard operative procedures; TAT, turnaround time; NCs, nonconformances; LIS, laboratory information system; ILQA, interlaboratory QA.

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Materials and Methods

Our cancer care hospital caters to the needs of more than 30,000 new patients annually. Its headquarters, located in Bangalore, India, is a 250-bed hospital that offers a wide spectrum of services, including diagnostic support for a variety of cancer-associated morbidities. The diagnostic services of the laboratory involve the disciplines of biochemistry, hematology and clinical pathology, microbiology and serology, surgical pathology, and molecular pathology. The laboratory is accredited by the NABL and CAP; it is well equipped with biosafety level–2 (BSL–2) facilities for handling a variety of clinical specimens. The staff are well trained in virtually all common laboratory techniques and in ISO 15189:2007 quality system principles.

The clinical biochemistry section is equipped with the Vitros 350 autoanalyzer (Ortho-Clinical Diagnostics, Johnson & Johnson, Raritan, NJ), the Vitros ECiQ immunoassay analyzer (Ortho-Clinical Diagnostics, Johnson & Johnson), the MINICAP electrophoresis platform (Sebia Electrophoresis, Norcross, GA), and other auxiliary equipment for specimen processing. The hematology and clinical pathology departments use the Sysmex XT-4000i and 1800i automated cell count analyzers (Sysmex Corporation, Kobe, Japan), the Stago STA Compact and Stago STart automated and semiautomated hemostasis workstations ( Diagnostic Stago Inc, Parsippany–Troy Hills, NJ), and the CLINITEK Status automated urine analyzer (Siemens AG, Munich, Germany). For blood cultures, the microbiology section uses the semiautomated mini API and the BacT/ALERT 3D automated systems (both by bioMérieux SA, Marcy l’Etoile, France) for identifying bacteria and typing their antimicrobial resistance levels. The surgical pathology section is supported by the Leica TP1020 automated tissue processor, the Leica EG1150 H automated embedding module, a Leica CM1850 cryostat (Leica Biosystems, Wetzlar, Germany), and several Xmatrix automated slide processors (BioGenex Laboratories, Inc, San Ramon, CA). Our molecular pathology section is equipped with a Dako CyAn ADP flow cytometer (Beckman Coulter, Inc, Brea, CA). All instruments are calibrated at regular intervals according to a defined schedule of maintenance; laboratory personnel document daily maintenance, instrument failures, and corrective actions for each instrument. We subject all instrumentation to required validation studies before clinical use.

Specimens received from the outpatient and inpatient departments, are labeled with the patient identifying and order information and a unique barcode generated by our laboratory information system (LIS). Specimen data captured in the LIS include the name, age, and sex of the patient; full name of the referring consultant; specimen type; date and time of collection; time of receipt of specimen; and signature of the technical staff member(s) who handled the specimen. Laboratory personnel screen specimens for preanalytical errors before processing those specimens; specimen acceptance and rejection criteria are based on ISO 15189:2007 guidelines. Data from specimens not adhering to the criteria are rectified, sometimes by requesting a repeat specimen, and the reason for rejection is documented. Laboratory staff members periodically review and perform root cause analysis of specimen-rejection trends to identify frequent preanalytical errors.

Specimens marked “urgent” are processed by laboratory personnel immediately after receipt; consultants enter the reports for such specimens as soon as possible into the LIS. Consultants will convey predefined critical
laboratory findings to the treating physicians immediately; a read-back policy is in place for the nursing staff and the consultants who receive the information. Laboratory personnel release regular reports to the physician and patient (depending on circumstance) after verification and authentication. This report includes the TAT, which is the time period from collection of the specimen through dispatching of reports. The TAT varies from test to test; the following TAT values constitute a representative range for different departments: biochemistry, 2 hours to 24 hours; hematology and clinical pathology, 2 hours to 48 hours; microbiology and serology, 24 hours to 7 days; surgical pathology, 20 minutes to 4 days; molecular pathology, 2 days to 14 days. Laboratory staff members also maintain a record of amended reports issued, to evaluate the occurrence of postanalytical errors. Laboratory managers analyze these records monthly and suggest or undertake corrective and/or preventive actions to reduce or eliminate the future occurrence of such errors.

Our laboratory subscribes to proficiency evaluations at the national and international levels, such as the external QA programs offered by CAP and interlaboratory QA (ILQA) measures. We process QA specimens in the same manner as routine specimens. If proficiency testing programs are unavailable for a particular test, we perform split-specimen analyses to ensure the accuracy of results. We document all steps in the analytical process to minimize the occurrence of errors. Staff training, in the form of a continuing education program, is mandatory at regular intervals, to ensure that staff members possess current knowledge of the techniques and technologies used in the laboratory.

We based our evaluation of laboratory performance on quality indicators in all 3 phases of specimen processing; namely, the preanalytical, analytical, and postanalytical phases. The data presented herein were collected from specimens that arrived in our laboratory between January 2010 and December 2011.

Results

Our referral laboratory received a total of 144,030 specimens during the 2-year period of our study. We observed a 30.49% increase in the specimen numbers from the first year to the second. We calculated the overall error rate for all 3 analytical phases by dividing the total number of errors by the total number of specimens; the result was 1.23%. Errors were most common in the preanalytical phase in both years of the study; preanalytical- and postanalytical-phase errors constituted more than 90% of the total errors (Figure 1).

Preanalytical components included specimen collection, quality, labeling, and delivery. Table 1 identifies the various preanalytical indicators that we used as benchmarks in this study. Hemolysis was the most common cause of specimen rejection (4.74/1000), followed by clotted specimens (0.83/1000). The other indicators included incomplete request forms (0.01/1000), labeling errors (0.08/1000), and inappropriate or wrong container (0.07/1000). We combined indicators with an extremely low frequency of errors, such as lipemic specimens (0.006/1000), and observed a total prevalence of 0.39/1000 for the low frequency indicators.

Table 2 shows the prevalence of certain quality indicators for the analytical processes we use in our laboratory. We decided to include noncompliance with quality assurance...
measures for the analytic process as an indicator of the performance of the laboratory (0.06/1000). Proficiency testing performance, which compares the analytical results in our laboratory to peer laboratories, appeared to be the major source analytical errors (0.9/1000). The postanalytical variables that we used to measure the quality of our laboratory services are listed in Table 3. Analysis exceeded the specified testing time for 666 specimens (4.62/1000), whereas we gave out a total of 82 amended reports (0.57/1000).

We followed the guidelines specified by ISO 15189:2007 for laboratory quality and competence. Accordingly, we recorded incidents of NCs with the standard management and technical requisites outlined in the ISO quality manual. The number of such NCs that occurred during the 2-year duration of our study is shown in Figures 2A and 2B. Among the management requirements, the highest number of NCs was recorded for maintenance of quality and technical records in both years. Regarding the technical specifications, we most often recorded deviations from the required standards for the preexamination procedures.

### Discussion

Quality, as a measure of excellence, is a critical feature of service-oriented professions such as healthcare from the medical and commercial standpoints. Modern medical interventions rely heavily on laboratory testing; hence, the quality of these services can have crucial repercussions on patient safety and the effectiveness of treatments. Quality assurance becomes especially critical in tertiary cancer care centers that offer advanced therapies for intractable cancers. In such patients, healthcare professionals often order and/or perform a battery of tests to assess the status of the patient and his or her disease before formulating a plan of therapy. In this environment the precision, accuracy, and speed at which these tests are performed are highly important in determining the type and timing of the clinical interventions. Our hospital is supported by a multidisciplinary laboratory that performs routine tests and advanced diagnostic tests that encompass the disciplines of molecular pathology and molecular biology. We report herein the error rates in our laboratory and compare them to recently reported averages.

The overall error rate in our laboratory during a 2-year period was 1.23%; this figure is within the range of 0.1%
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Figure 2

to 3.0% that had been published by Lippi et al15 in a summary of data from a number of studies. The rate decreased across the study period from 1.28% to 1.19%, which may be due to the increased number of specimens handled by the laboratory and also the implementation of the QA training program in the laboratory. Our reports mirrored the results of several earlier studies16-19 in that the preponderance of errors occurred in the preanalytical and postanalytical phases. The analytical phase of the laboratory process, which consists of steps directly related to specimen testing, has been shown20-23 to be amenable to improvements; this is due to technological advances, as well as adoption of universal internal QC procedures. In keeping with this trend, our analytical error rate showed the largest improvement, falling from 1.26 per 1000 to 0.72 per 1000 during the 2-year period of our study. We believe that improved instrumentation, in tandem with enhanced training of personnel, will further decrease this error rate.

The preanalytical phase, which encompasses processes that mostly occur outside the laboratory, includes test ordering, specimen transport, and specimen processing, is the phase where most errors in the total testing process occur; for instance, Hammerling4 reported a range of 46% to 68.2% (of total laboratory-related errors). Some studies have focused solely on errors occurring in this phase.24,25 All of our preanalytical variables dealt with specimen quality; we observed that hemolysis was the most frequent cause of specimen rejection. These results are consistent with those of other studies performed in India and elsewhere.26-28 We observed a slight increase in the rate of hemolyzed specimen across the study period (4.72/1000 to 4.76/1000), which may have occurred because of an increased patient load that produced greater demand on the infrastructure at the phlebotomy counter. Rates of mistakes in labeling (0.08/1000) were low in our study; we expect this low error rate is due to the barcoding system in place for specimen handling in our laboratory.

Postanalytical errors can occur in processes involving the verification, transcription (electronic or manual), and communication of test results to the health care professionals. Our postanalytical error rates were within a range reported previously,29 with increased TAT being the most commonly recorded NC issue (4.62/1000); this is within the specifications reported in another study by Kirchner et al.30 Report reissue was the other criterion that we and other researchers enumerated; the rates for this item were comparable to those reported by Kirchner et al.

Although merely reporting on the performance status of QIs does not improve the quality of services provided by the laboratory, it plays a highly important role in identifying potentially problematic areas within the total testing process.24 Further, preparations for audits hinge on the systematic, transparent, and consistent reporting of deviations from the established procedures. This process, coupled with appropriate and conscientious corrective and preventive actions, will address failures within the system and help laboratory staff to achieve the goals of a patient-centered laboratory service. LVM

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References