Description of the Quality Indicators Used in Microbiology Laboratory - Methodological Approach to Quality Improvement of the clinical lab reports generated

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Abstract

Quality of clinical lab reports generated is of utmost importance because of its direct impact on the diagnosis and patient outcome. Quality indicator is an established measure used to determine how well an organization meets needs and operational and performance expectations. The quality indicators can be classified according to Operational Performance and Phase of the total testing Process. QI required to be analysed sequentially using the overall cumulative data extracted from the database on a monthly basis and year-end audit should be conducted to evaluate the individual performance and this table will help the experts to monitor trends and intervention is required if any deviation is observed. The better-quality lab results generated will assist the clinicians in better diagnosis and patient care which is the ultimate goal of the functioning of a clinical lab.

Keywords: QI, CQI, EQAS, IQC, TAT, contamination rate, repeat testing

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Introduction:

Quality of clinical lab reports generated is of utmost importance because of its direct impact on the diagnosis and patient outcome. The use of quality indicators is an integral component of Continuous Quality Improvement process (CQI). Hence documentation of structured quality indicators that would be used as internal assessment throughout the path of workflow in the Microbiology laboratory is important. These indicators will be used to perform gap analysis against internal and external benchmarks where available.

Principle:

Quality indicator is an established measure used to determine how well an organization meets needs and operational and performance expectations.

ISO 15189 [4.12.4] states that the laboratory shall implement quality indicators to systematically monitor and evaluate the laboratory's contribution to patient care. When the programme identifies opportunities for improvement, the laboratory management shall address them, regardless of where they occur. Also, it is stated that laboratory management shall ensure that the medical laboratory participates in quality improvement activities that deal with relevant areas and outcomes of patient care.

Purpose:

- give information about the performance of a process
- determine quality of services
- highlight potential quality concerns
- identify areas that need further study and investigation
- Track changes over time.

Procedure:

Ricos and colleagues have defined certain specifications for the various quality indicators that may be used for evaluating laboratory performance. Based on that, the quality indicators can be classified according to OPERATIONAL PERFORMANCE:

1. Sample collection and identification, transportation and rejection: The clinical samples need to be collected in the manner described in the SOP for sample collection

Examine the quality of the samples collected and reject the inappropriately collected samples if possible. The following are the some of the examples of Sample collection procedures that need to be followed

Eg: Urine: midstream urine to be collected under strict aseptic conditions and request a repeat sample if mixed growth (>3types) grown in culture

Sputum: Coughed out sputum from deep in the lungs should be collected after rinsing the mouth with water.

If >25 epithelial cells/ low power field is seen, request a repeat sample collection Acceptable rate of contamination and insufficient volume of specimens:

- Blood culture: 5%
- Urine culture contamination rate: 5%
- Sputum Gram stain and AFB staining: 5%
- Blood culture bottles with insufficient volume: 5%

2. Processing, analysis and reporting of results: The processing of samples and the reporting of results need to be done according to the procedures described in the respective SOPs

3. Clinical Interpretation: Organisms isolated may indicate as a pathogen or commensal or contaminant. Best microbiological judgment along with the clinical correlation should be used while reporting. 'Possible contaminant', 'possible pathogen' or 'possible commensal' may be used to indicate the role of the organism in a particular sample type to help physician to evaluate the report in light of the patient clinical condition.

Foot notes: In case of a rejected sample being processed as directed by the clinician, a disclaimer should be put on the final report, indicating that the specimen was not collected properly or transported within allowable time and that the results should be interpreted with caution.

4. Turnaround time: Time taken from collection to receipt to processing and reporting

- Culture & Sensitivity: 48-72 hours
- Serology: 8 hours
- Critical call outs and urgent samples: 1 hour
- Staining: 8 hours

5. Post-test specimen management: The SOP for archived sample testing, discard of samples and BMW management guidelines may be followed.

6. Quality control of culture media, reagents and ATCC stains: The SOP for acceptance criteria of consumables in microbiology laboratory need to be followed

7. Complaints: Review the source of complaints, maintain complaint file (containing details), investigate, inspect the complaint, assess failure, investigate failure, record failure, perform root cause analysis and take preventive action.

8. Equipment downtime:

Need to be documented and the time taken for service and the CAPA of the same may be done and documented

9. Performance in PT/EQA scheme:

Objectives of EQAS:

- To ensure credibility of the lab performing well.
- To establish accuracy by laboratory comparability.
- To influence reliability of future testing.
- In stimulating performance improvements.

Participation in the EQA scheme is 4 times a year Acceptance rate of errors: 5%

CA/PA for EQAS: Look for the source of the error, review the process, perform root cause analysis and then take PA to avoid future errors

The Quality Indicators may also be Classified according to the PHASE of the TOTAL TESTING PROCESS:

1. Pre-analytical phase: Patient identification criteria, suitable container usage, sample integrity, sample identification, collection time, collection volume, appropriate clinical history provided in the TRF

2. Intra-analytical phase: unacceptable performance in EQAs-PT, tests with inappropriate internal quality control (IQC) performance, sample storage, repeat testing

3. Post-analytical phase: a) incorrect reports issued and b) inappropriate TAT (reports delivered outside the specified time, critical values notified after a consensually agreed time, eg: CSF staining), contamination rate of urine and blood culture specimens, sample discard and BMW management

Monitoring of these indicators will be done on monthly basis to provide adequate time for

data collection and analysis

GENERAL QC/QA PROCEDURES:

ILC: Inter Lab Comparison

EQAS: External Quality Assurance Scheme

SSA: Split Sample Analysis

IQC: Internal Quality Control

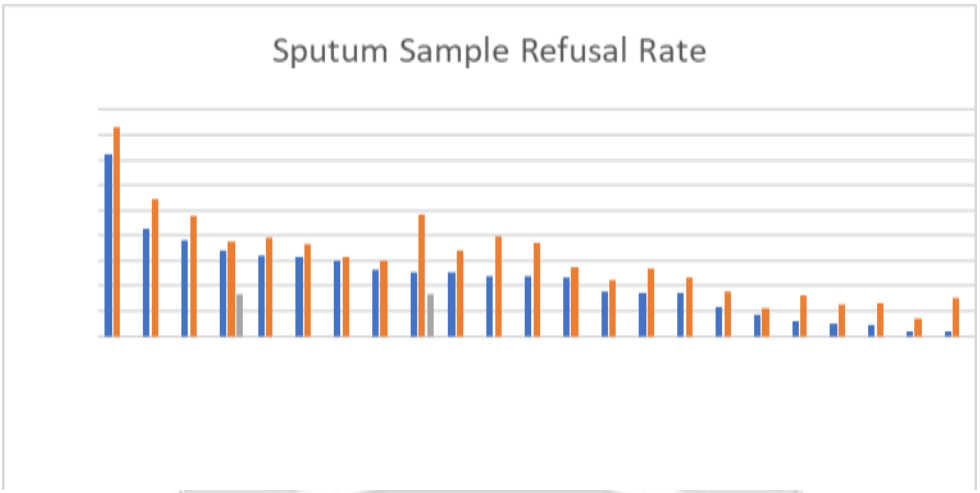
Results:

Given below is the model table of the Lab QI required to be analysed sequentially using the overall cumulative data extracted from the database on a monthly basis. A convenient date (eg.,5th of each calendar month) can be set as the cut-off date for data extraction.

Model table of Microbiology Laboratory Quality Indicators Analysed on a monthly basis using the cumulative data extraction from database (January- December)						
Quality Indicator	**Jan**	**Rates (%)**	**Feb**	**Rates (%)**	**March etc until December**	**Rates (%)**
Pre-Analytical Phase						
No: of samples received in Bacteriology, Serology, Mycology, Parasitology etc (Separate rows can be						

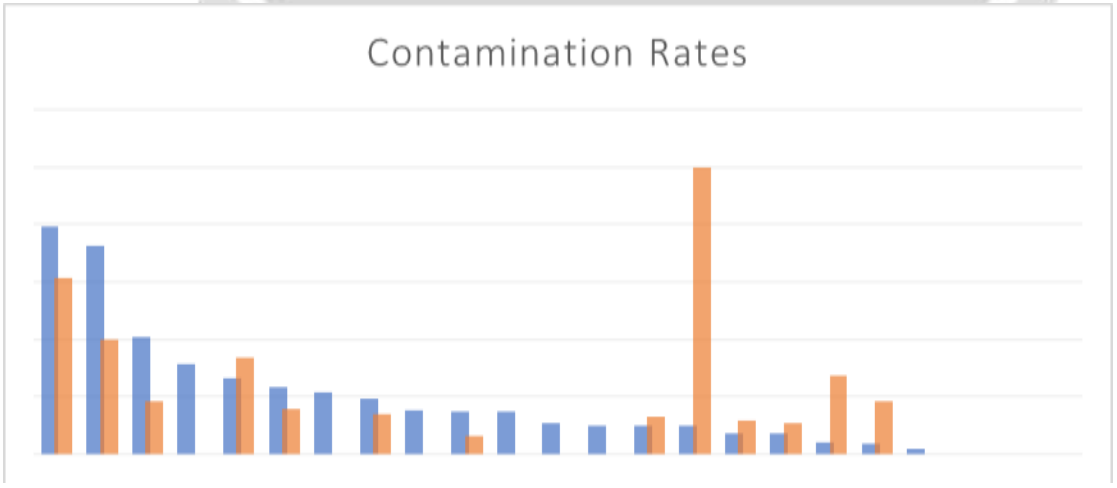
created for each section)						
No: of samples not given						
No: of samples rejected (sub sections can be made for each of the reasons like mislabelling, insufficient volume, Temperature issues, Transportation TAT issues, clotted, hemolysed or lipemic etc)						
Appropriate Clinical History Provided in TRF						
Analytical Phase						
Contamination Rates						
QC failure						
EQAS failure						
ILC failure						
Split Sample Check Failure						
Equipment Down time						
Sample Storage and archiving						
Repeat Testing						
Test not peformed						
Reagent/Stock Maintenance failure (subsections can be made for each reagent/ATCC strain)						
Post Analytical Phase						
Error Rates						
Missed Notification of Critical Alert						
Delay in Average Turnaround Time (sub sections can be made for each type of sample)						
Sample Discard						
Biomedical Waste Management						
Contamination						

Laboratory Indicators can also be classified team-wise for routine performance monitoring and evaluation of individual teams/testing labs if there are multiple labs or collection centres involved. The data can be expressed in a presentable format to the experts in the form of Charts/tables after sorting the data from the highest to lowest. This will assist the experts in viewing the large quantity of data at ease. The problems identified should also be highlighted in the charts/tables. The representative figures for each of the indicators are provided below



Turnaround Time (TAT) for Transportation

Team	Urine Sample	Blood Sample etc
Lab I		
Lab II		
Lab III		
Lab IV		
Average		



Discussion:

The cumulative data extracted on a monthly basis should be analysed during the course of the year on a monthly basis and year-end audit should be conducted to evaluate the individual performance and this table will help the experts to monitor trends and intervention is required if any deviation is observed.

Hemolysis of samples may be caused by forcefully ejecting blood through a fine needle, shaking the tubes vigorously, and centrifuging the specimens before coagulation is complete. The other preanalytical errors, such as lipemic samples, insufficient quantity, incomplete requisition slips, and inadequate dilution in cases of coagulation profiles, can arise due to ignorance regarding the requirement of a minimum volume for the various tests, patient preparation, and test principles. Chemistry and immunoassays are susceptible to interference by fibrin. Small amounts of fibrin (and other protein debris membranes) may affect the results. The presence of gross amounts of fibrin in the specimen (serum or plasma) may cause blockage of instrument sample aspiration probes resulting in erroneous assay results. Inadequate clotting time, improper mixing, and failure to place the tube in an upright position can lead to incomplete clot formation. Following centrifugation, the sample may appear satisfactory with a defined layer of cells at the base of the tube and a clear layer of serum above. Despite this appearance, the clotting process may not have been completed prior to transportation, centrifugation, and placement of the specimen on the analyzer. Further coagulation in the serum may subsequently occur, leading to the production of latent fibrin, which can interfere with the quality of a result.9 For plastic tubes, thorough mixing by gentle inversion (at least 5 times) is essential to ensure even distribution of the clot activator throughout the specimen. This will also allow completion of the clotting process. In order to minimize the occurrence of interference due to fibrin clots, special attention has been paid toward the adoption of ideal sample handling protocols. These include ensuring adequate clotting time (minimum 30 minutes) and proper centrifugation techniques, which involve centrifuging at 5000 rpm for 15 minutes. In addition, it is also essential to establish proper mixing immediately after collection.

The calculation of number of samples processed in the laboratory is required to assess the quality of history taking, reliability on the lab and it also serves as an indirect tool for quality assessment of provisional diagnosis by the clinicians. Any value above or below the benchmark means over diagnosis or under diagnosis of disease suspects. Further intervention (CA/PA) like training of staff like resident doctors and nurses in appropriate fields will be required if any deviations are observed.

Turnaround Time for the transportation of samples is important in assessing if the samples are reaching the testing laboratories on time as delayed transportation may lead to the loss of cold chain and thereby increased contamination rate, clotted samples etc. Intervention required would be tracking the TAT for transportation and temperature maintenance on real-time following which improvement if observed should also be documented.

Rejection rates will express the quality of samples collected by the collection teams and peripheral laboratories and thereby the condition of transportation. Care should be taken to maintain the Transportation TAT even from remote sites should be maintained within 24 hours and ensure repeat collection of samples which were undelivered or rejected.

Test not performed could be due to the oblivious attitude of the technicians and/or increased workload. Under ideal conditions, the figure should be near 0, but it may not be possible to attain this due to administrative and procedural constraints. Stahl and colleagues conducted a study to determine the total number of unreported tests due to preanalytical, analytical, and post-analytical variables. The frequency of errors ranged from 0.74% to 0.93%. A target range of 0.2% to 0.5% has been suggested as an achievable target. Ricos and colleagues have been more lenient with an acceptable frequency of requested tests not performed at 1.4%.

Critical value reporting is considered an important quality indicator for excellence in patient centric care. The literature quotes a frequency of critical value reporting ranging from 1 in 2000 to 1 in 100 samples. The relative abundance of critical value reporting by our laboratory is an indicator of our conscious effort to apprise the clinicians of the reports bordering the danger mark. This facilitates decision making for the institution of corrective measures that might prove to be life-saving in certain cases

Contamination rates will represent the quality of lab results generated. Hence it is always recommended to maintain contamination rates below the benchmark. This may be due to various factors such as Delay in Transportation (Temperature not maintained), Equipment breakdown, BSL III/Containment issues, Manpower attrition, delay in processing etc. The interventions required are servicing the broken-down equipment, manual backup of automated cultures, filling up of vacant posts, tracking the TAT for transportation and temperature maintenance on real-time, training and re-training of staff. Re-decontamination of positive contaminated cultures by isolating individual colonies of pathogens will increase the yield of positive cultures and reduce the contamination rates.

Conclusion: This work is in line with what is described by literature concerning laboratory quality indicators. The indicators mentioned here confirm the importance of applying them as profitable and relevant quality tools in the

context of the effective conduct of microbiology laboratories and can be used for centralized monitoring of all collection centres and labs operating remotely where there is limited access to the laboratory registers. Considering the large volume of lab data generated simultaneously from all labs and collection centres, these tools classified and monitored on a monthly basis can be implemented take necessary corrective/preventive action, of which the most considerable are continuous education and training of professionals and will as a guidance/ reference tool for future lab quality monitoring. The better-quality lab results generated will assist the clinicians in better diagnosis and patient care which is the ultimate goal of the functioning of a clinical lab.

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