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Evaluation of Pre- and Post-Analytical Variables in Clinical Microbiology Services in Multidisciplinary ICU of A Medical College and Tertiary Care Hospital

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Abstract

Optimal outcome of clinical microbiology services is dependent on vertical, horizontal and internal integration involving various specialties, patient care wards and out-patient services. The pre- and post-analytical variables are difficult to assess and address due to variable structure of wards, laboratories and processes in hospital setups and often fall beyond the purview of accreditation processes. The pre- and post-analytical variables of clinical microbiology services of a developing country medical college and tertiary care hospital located in Western India were evaluated under a cross-sectional study. Pre-analytical evaluation revealed antimicrobial exposure, incomplete requisition forms, improper labelling of containers, delay in dispatch and transport of samples to the laboratory, inadequacy of samples in varying proportions. Post-analytical evaluation revealed delay from report generation to receipt in Intensive Care Unit.

A strength, weaknesses, opportunities and challenges analysis revealed the strengths of a robust Intensive Care Unit and laboratory infrastructure, competent and disciplined clinicians, nurses, microbiologists and lab technicians, well laid down policies and procedures and supportive top management. The weaknesses included numerical deficiency of trained nurses and lab technicians, lack of knowledge about quality, lack of sustained enthusiasm and motivation, inadequate supervision at all levels and inertia to behavioral change. Opportunities exist at ensuring knowledge, high motivation levels and efficiency of human resource as well as successful implementation of change. Challenges of delay at various levels, improving turnaround time, wastage of resources and improving knowledge in patients need to be addressed.

Keywords: Pre-analytical variables, post-analytical variables, SWOC analysis, structure-process-outcome

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Introduction

Advanced treatment and diagnostic modalities in modern healthcare have brought forth increasing technical and administrative complexities at ensuring quality in service delivery. With the resurgence of infectious diseases in the past three decades owing to emergence of multiresistant mutant microorganisms, environment change and immunocompromised population, clinical microbiology services have gained prominence for ensuring optimum patient care. Outbreaks of both community and healthcare associated infections by multiresistant organisms in the backdrop of limited antimicrobials, threaten the outcome of diagnostic and surgical interventions (1).

The concept of quality in clinical microbiology services has been largely addressed through laboratory accreditation of structure and processes. While accreditation is meant to ensure a desired and measurable outcome, there exists a felt need towards optimal outcome. Optimal outcome of clinical microbiology services is dependent on vertical, horizontal and internal integration involving various specialties, patient care wards and out-patient services (2). Pre- and post-analytical variables are known to interfere in the overall outcome of microbiology services, however they are often not considered during the accreditation processes. The pre- and post-analytical variables are difficult to assess and address due to variable structure of wards, laboratories and processes. In addition, systematic studies on pre- and post-analytical variables are rare in research literature.

This cross-sectional study intended to evaluate the pre- and post-analytical variables of clinical microbiology services of a developing country medical college and tertiary care hospital located in Western India.

Methods

A cross-sectional study to evaluate the pre- and post-analytical variables in the process component of clinical microbiology services rendered through the microbiology lab of a medical college and tertiary care hospital was undertaken after approval from the hospital ethical committee. A hundred consecutive common microbiology investigations generated from the multidisciplinary Intensive Care Unit (ICU) including blood, urine and pus cultures were randomly studied through pre-analytical and post-analytical phases.

A brief screen of existing structure along with analytical process for availing clinical microbiology services was evaluated

in ICU and microbiology laboratory. Structure evaluation included screening of existing infrastructure, Mission Statement(s), Standard Operating Procedures (SOPs), staff and equipment. Analytical evaluation of microbiology laboratory included discrepancy in processing from SOPs, if any, quality control procedures, equipment reliability, calibration, validation; and proficiency of personnel.

Pre- and post-analytical processes with respect to microbiology samples were evaluated in ICU in comparison with available SOPs. Pre-analytical evaluation included prior exposure of patients to antimicrobial drugs, correctness of investigation ordered, completeness of requisition forms, sterility of containers, labelling of containers, barcoding system for sample identification, aseptic collection of samples, procedure of sample collection, delay in dispatch, storage of samples, time taken during transport to the lab, adequacy of samples before processing and waiting time of sample in the lab prior to processing.

Post-analytical evaluation included transcription of results, completeness of reports, dispatch procedure, time taken from report generation to receipt in ICU, data backup in the laboratory, internal audit, critical reporting and endorsement of investigation reports in case sheets. Outcome was evaluated by turnaround time (TAT) from sample receipt to delivery of reports, proportion of sample mismatch and requirement of repeat testing.

Results

The sample distribution included 55 blood cultures, 28 urine cultures and 17 pus cultures. The multidisciplinary ICU is located approximately 800 meters from the microbiology laboratory. Structure evaluation of both ICU and laboratory revealed adequacy of infrastructure, availability of mission statements, accessibility and adherence to SOPs, and adequate and proficient staff for sample collection and dispatch. No separate area for collection of samples existed in the ICU and samples were collected bedside. The laboratory infrastructure included availability of separate space for sample collection and sorting, storage of reagents, chemicals, records, washing, media preparation, autoclaving, staff room and wash rooms. SOPs on sample collection, laboratory safety and sample processing were being renewed annually in both ICU and laboratory. There was no discrepancy in sample processing as per SOPs. Adequate quality control procedures existed. All equipment was calibrated, validated and under Annual Maintenance Contract with the original manufacturer.

Pre-analytical evaluation revealed 100% exposure of patients to antimicrobials prior to admission in ICU. 100% investigations ordered were appropriate for patient's condition. However, only 90% requisition forms were complete in all respects as signatures/stamps of clinicians were missing on 10% requisition forms. 100% containers for sample collection were pre-packed under sterile conditions. Proper labelling of containers was observed only in 90% sample containers while incomplete information was seen in 10% containers. No barcoding system existed for sample identification except for blood cultures. There was 80% compliance in aseptic collection and 80% correctness in procedure of sample collection as per existing SOP in ICU. The average delay was 30 min in dispatching of samples from the ICU through established procedure while it was reduced to 10 min when delivered by patient's representative or nursing staff or resident doctors. All samples were kept at room temperature before being dispatched. The transport time of samples to reach the lab was 30 min owing to distance of ICU from laboratory. All blood and urine samples were found adequate for processing whereas 40% of pus swabs dried prior to being processed. There was an average of 30 min delay prior to processing.

Post-analytical evaluation revealed adequate transcription of results and adequate dispatch procedures. The reports from the laboratory were delivered to ICU directly. Signatures of microbiologist was present on all results, however, signature of technician were absent. There was an average delay of 3 hours from report generation to receipt in ICU. Complete manual and/or electronic data backup in the laboratory existed for all tests. Internal audits were carried out yearly and documented. Critical reporting was being practiced and documented. However, only 50% reports were being endorsed in case sheets. The TAT was appropriate in 90% cases as referenced from SOPs. There was no sample mismatch and no requirement of repeat testing amongst the samples studied.

Discussion

The observations revealed a sturdy structural integrity, process compliance and expectant outcome of microbiology services in the medical college and hospital ICU and microbiology laboratory. The heterogeneity of a multidisciplinary ICU, laboratory tests and patient requirements form a dynamic and complex triad thereby influencing the outcome of microbiology services.

The exposure of patients to multiple antimicrobials prior to admission in ICU is directly related to negative culture reports. The phenomenon of rising empiricism in antimicrobial therapy at primary and secondary care levels is increasing being encountered in clinical situations, which in turn tends to reduce the sensitivity of culture reports and increases selection pressure for emergence of multidrug resistant microorganisms. While there is great emphasis on completeness of investigation forms and labelling of containers, incomplete forms and improperly labelled containers are received in microbiology laboratories of most developing nations due to overwhelming patient load, paucity of staff, time and training as well as indifferent attitude of staff. The advent of pre-sterilized equipment has reduced reliance on manual sterilization and improved standardization. Proper sample collection utilizing aseptic precautions and correct procedure can be reinforced by frequent training, sensitization, behavioral modification and vigilance. Delay at every level from sample collection to final processing in the laboratory is expected due to lack of adequate staff, lack of pneumatic tubes for sample transportation and need of batch processing of samples. Pneumatic tubes are not feasible to use in a horizontally spread out structure of hospitals and laboratories. Batch processing also leads to wastage of reagents. The delay in receipt of samples in the laboratory after collection affects the quality of results as pus swabs may dry, fastidious organisms may die or contaminants may overgrow in the sample. In addition, it increases the TAT. The storage of urine samples at room temperature is likely to promote growth of contaminants. Signatures of the technician carrying out the test should also be present on the results in order to track the variability due to human error. Endorsing of reports in case sheet is important as it improves the assessment by multiple clinicians and forms a record in case the investigation form is lost or handed over to the patient on discharge. However, as the TAT of microbiology culture reports is 3-5 days, endorsing is missed due to change in diagnosis, treatment or transfer/discharge/demise of the patient.

A strength, weaknesses, opportunities and challenges (SWOC) analysis revealed the strengths of a robust ICU and laboratory infrastructure, competent and disciplined clinicians, nurses, microbiologists and lab technicians, well laid down policies

and procedures and supportive top management. The weaknesses included numerical deficiency of trained nurses and lab technicians, lack of knowledge about quality, lack of sustained enthusiasm and motivation, inadequate supervision at all levels and inertia to behavioral change. Opportunities exist at ensuring knowledge, high motivation levels and efficiency of human resource as well as successful implementation of change. Challenges of delay at various levels, improving TAT, wastage of resources and improving knowledge in patients need to be addressed.

Within the purview of limitations in the study such as cross-sectional design, temporal brevity, lack of correlation of human factors involving knowledge, attitude, practices and behavior of nurses, lab technicians and patients, the study brings forth a pertinent assessment on the overall concept of quality at pre- and post-analytical levels in clinical microbiology services. The study is unique as no studies on similar parameters have been published in available literature. There are no suitable comparisons available. It is difficult to compare the results in terms of process as structural variables may exist in other laboratory setups. As a pilot study in the subject, this study can form a baseline for large scale studies on the subject, which in turn can help formulate better guidelines on total quality management (TQM) in microbiology services.

As structure standards are non-negotiable while process standards are modifiable, the pre- and post-analytical procedures can have an impact on the quality deliverance in microbiology services (3, 4). The overall impact of pre- and post-analytical variables are by and large neglected from the ambit of accreditation of laboratories. This forms a gray area especially in developing country set up where resources may be limited, mandating attention by healthcare service planners and process auditors. An intact structure, process and outcome is likely to improve TQM initiatives in clinical microbiology services which in turn can boost patient care, early clinical decisions, work environment, comparative competitor analysis and clientele satisfaction (5-7).

A successful TQM is based on a continuum of concept development and capacity building. A multitude of improvements require a collective impetus from clinicians, microbiologists and hospital administrators for which an incremental approach is advocated. Interventions at various levels can augment initiatives towards TQM. Structural improvement initiatives can be targeted at installation of pneumatic tubes for sample transport, camera-based networks in areas of patient care to improve procedural compliance, web based networks and smartphone applications for sample requisitions, retrieval of reports and data availability. Policy initiatives should reinforce prudence on standard precautions, infection control procedures and hand hygiene, dissemination of sample rejection criteria to clinical specialties, patient education about sample collection and incorporation of feedback system by staff and patients. Human resource initiatives should be targeted at enhancing knowledge of nursing staff, behavioral modification in staff, evaluation of nursing staff through knowledge, attitude, practices and behavior studies on sample collection and supervision of samples by nurse administrators. Procedural interventions can include using microbiology lab software for sending requisitions and reports, online availability of reports on hospital intranet or local area network and availability of reports to patients on internet or short messaging service.

Conclusion

The pre-and post-analytical variables of clinical microbiology services of a developing country medical college and tertiary care hospital revealed a sturdy structural integrity, process compliance and expectant outcome in the in the current scenario of resource limitations compared to patient load. However, there exists is a scope for improvement in sync with the progressive continuum of quality. Targeted efforts at improving pre- and post-analytical variables can improve TQM in clinical microbiology services which in turn can boost patient care, work environment, clientele satisfaction and community confidence.

Conflicts of Interest: None

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