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Quality in Clinical Laboratory-II: Association of Total Testing Processes (TTP) with good Clinical Decision and Diagnostic Excellence

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Abstract
Total testing processes (TTP) involved pre-pre, pre-analytical, analytical and post-analytical phases. However, extra-analytical phases are mostly out of the jurisdiction of clinical laboratories and thus prone to errors and might cause delays in reporting and effecting good clinical decisions. Pre-analytical and post analytical errors are inherently part of both laboratory and clinical settings of OPD, wards and related and always a thorny issue amongst Lab and clinical personnel since last three decades. Current review assessed the correlation of TTP with timely and good clinical decisions with feedback generated diagnostic excellence.

Keywords: Pre-analytical, total testing process (TTP), quality indicators

1. Introduction

In last on decade, laboratory medicine improved tremendously regarding technology, integration of artificial intelligence within lab analytics, ever increasing test menu, introduction of more advanced and sophisticated tests such as rare tumor markers and genetic mapping, total lab automation, point of care testing and analytical minimization. Our earlier article covers the total testing process and measurements of analytical phase [1], whereas this review and evaluation article revolves around association of total testing process (TTP) with good clinical diagnosis or decisions and several examples of innovative measures to control errors in TTP.

2. Association of Good Clinical Decisions and Total Testing Processes:

Generally established correlation between a good clinical decision and TTP involves all phases of it which means each and every component of pre-pre, pre-analytical, analytical and post analytical phases [2, 3]. As stated earlier, lab usually have a very strong system placed, implemented and executed for analytical phase but not much for pre-pre, pre-analytical and post analytical phases which are more prone to errors [1]. Pre-pre, pre analytical and post analytical errors are inherently part of both laboratory and clinical settings of OPD, wards and related and always a thorny issue amongst Lab and clinical personnel since last three decades [3-5]. Above mentioned errors are basically errors in ordering, collection, tagging, storage, incorrect result data logging and reporting. Such errors, which compromised clinical decisions are known as testing-related diagnostic errors and earlier reviewed by Epner et al [5]. Although in western world with more sophisticated and established insurance system, these error-laden clinical decisions were covered via malpractice claims, insurance companies bearing the major burden, in addition to the clinical setup, labs that were responsible for deviated reports. It was reported such claimed-incorrect clinical

decisions was due to variable phased errors such as 74% in pre-analytical phase, 4% in analytical phase and 22% in post analytical phase of TTP [6-8]. The data presented reports that TTP associated errors were mostly manifested in missed, wrong or delayed diagnoses and related to none or incomplete specimen data, poor quality of specimen, test requested not performed, missing result data, delayed or incorrect data logging and reports [5-9]. A report published by ECRI for the period 2017-2018 including 4000 patient safety data showed errors in imaging pathology, general laboratory analyses and variable diagnostic procedures, manifesting into 1408 errors contributing 69% of all diagnostic deviations [6-9]. These reported conclusions advocated for looking into newer opportunities for clinical laboratories to participate in enhanced quality improvement schemes, involving clinicians to reduce and minimize errors for better, enhanced, good clinical decisions.

3. Identifying Errors to Minimize Deviations in TTP and Facilitating Good Clinical Decisions:

It is well documented that errors in laboratories depends on TTP for the respective phases of pre-pre, pre analytical, analytical and post-analytical, in addition to type of test, method algorithm, clinical and diagnostic setup [7-11]. It has been obvious from all the documented articles, policy papers and dossier that most errors occurs in pre-analytical and post analytical rather than analytical phase, out of which pre-analytical phase which is 50% shared by factors outside the domains of labs, has the highest percent of errors representing around 70% of all errors [9-13]. However, introduction of several modalities, procedures, and information technology related component, smart computer system, HIMS, one window services via digital technology, cause decrease in the risk of developing pre-analytical errors. Nonetheless, multiple ownership of pre-analytical phase, overlapping steps, mutually responsible tasks at the crucial interface of procedures, advocates for proper processes based on reproducible and trustworthy actions to control risk of errors. Pre-pre and pre-analytical phase not only involves the steps when sample received within the lab for analysis but also all steps done for collection, processing (various steps such as test requests, requisition, labelling etc), transport, storage and receiving within the lab system. Furthermore, introduction of integrated lab information system (LIS), hospital information management system (HIMS), and pre-analytical robotics workstations greatly reduced the chances of errors that might occur within the lab system. Additionally, robotics in pre-analytical system does all centrifugation, aliquot making, dilutions, sorting the samples into batches as per test requests before going for analysis, which effected the overall pre-analytical more technically error-less and reproducible [14,15]. It has been already well conceived that pre-analytical phase for clinical lab TTP involves phases/steps both inside the control and premises of laboratory and outside the lab, such as steps starts from patient's bedside or lab collection area. True pre-analytical phase is a term introduced by experts of quality in labs, that encompasses all steps within the lab system and/or under the administrative and technical control of lab, whereas pre-analytical steps involves most of those steps which are usually not under the control of lab such as selecting and ordering the tests, requisitions, collection, labelling, processing, handling, storage and proper transport. And off course, all mentioned steps neither performed nor under the control of lab management. Evidently, literature survey manifested that staff outside lab system that controls the processes and system related to TTP, pre-analytical phase are prone to demonstrate more errors than the staff of laboratory services [2, 15]. During pre-analytical phase activity-these staff, who are basically nurses, nurse aid, medical officers or residents, allocate tests, requests, collection, storage, labelling, transport and thus categorized as non-lab health care personnel. In post-analytical phase, most errors occurs in final data logging, reporting, STAT test time lines, abnormal results, fresh sample requirements and interpretation. Incoherent communication leads to repetitive testing, delays in clinical decisions, hindrance in timely patient care and bad reputation. Most clinicians requires quality services with better timeline, variety of services, affordable, without error and prompt turnaround time (TAT). One of the advancement that took place few years ago is the critical care/abnormal results alerting system within the analytical instrument integrated with total lab automation and also with wards, OPDs, ICUs and services centers. Timeline control from sample receiving within lab (or when collected from patients) up to the reporting is the key for better clinical diagnosis, saves times and induce sense of credibility, responsibility and fulfillment with the customer. Although promptness within analytical phase or STAT reporting of critical results sometimes doesn't affect the outcome or existing health status of patients but it does enhances patient and clinicians satisfaction. Simultaneously, mistakes in completion of

analytical or post-analytical processes, misinterpretation, misinformation to treating physician, can affect the timeliness of treatment of a critical clinical condition of can alter the outcomes.

4. Conclusions

It is suggested by experts of Quality in Clinical lab services that if one need sustainability of quality lab services or improvement in overall lab services, evaluation, assessment, audit, quality checks of all steps of TTP must be looked into, periodically as well as random. Most significantly, extra-analytical phases, means pre-pre, pre-analytical and post-analytical phases, needs to have proactive (as well as reactive) interventions, to verify and to evaluate the system errors within the methods, processes, protocols and risk related to patients safety. Quality indicators must be evaluated on periodic basis, SWOT analysis (strength, Weakness, Opportunities, threats) should be appraised, in addition to events, steps regarding overall TTP. Particularly, data of quality indicators, performances obtained in external quality programs [1], audit reports of external quality management systems, or accreditation, and protocols for management of untoward events (errors, nonconformance, and adverse events) must be reviewed and documented. Patients and end-user (clinicians) feedback is a necessity and must be viewed as information regarding gaps, opportunities and good points regarding our own clinical laboratory services.

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