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Quality in Clinical Laboratory-I: Total testing Processes and Measurement Practices-Two important components of Pre-analytical and analytical phases

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Abstract Quality control standards in a clinical laboratory means the reports that patients are getting were assessed, standardized, every step regarding pre-analytical, analytical and post analytical carefully executed using internationally recognized protocols. Several scientific organizations, quality assurance fora, standardization councils and institutes, including IFCC, EFLM, AACC, CLSI, CAP, ISO 15189 Clinical Lab standards (QMS) and generic ISO 9001:2015 QMS, are some of the entities that provides principles to control steps, measures, phases, processes, management, analysis and reporting of clinical lab parameters. This review article provides a general vision of what are the components of a quality assurance/control system in a clinical laboratory for pre-pre, pre-analytical and analytical phases.

Short title: Quality in Clinical Laboratories
Key words: Total testing Processes (TTP), Measurement Practices, Pre-analytical, analytical phase

Introduction

Quality control measures or simply quality standards in a clinical laboratory means the reports that patients are getting were assessed, standardized, every step regarding pre-analytical, analytical and post analytical carefully executed using internationally recognized protocols with usage of internal as well as external quality control materials and chemicals. Quality standards in clinical laboratory facilitates already existing methodologies, protocols, steps and/or provide guidance to introduce and establish newer, advance technologies and methods to improve standing patient care services [1]. . Clinical decision making is now dependent on laboratory results, which means erroneous reports can produce deleterious and disastrous outcome. Such dependency although seems laborious, exhausting and sometimes superfluous, but on the other hand provide opportunities, venues and views to keep laboratory services under check and balance and where needed, possibility of improvement and advancements. Several scientific organizations, quality assurance fora, standardization councils and institutes, including International federation of Clinical Chemistry (IFCC), American Association of Clinical Chemistry (AACC), Clinical Laboratory standards institute (CLSI), college of American pathology (CAP), ISO 15189 Clinical Lab standards (QMS) and generic ISO 9001:2015 QMS, are some of the examples that provides principles to control steps, measures, phases, processes, management, analysis and reporting of clinical lab parameters. This review article provides a general vision of what are the components of a quality assurance/control system in a clinical laboratory for pre-pre, pre-analytical and analytical phases.

What is Total Testing Process (TTP)?

TTP is the complete collage of all pre-pre, pre-analytical, analytical and post-analytical steps and processes involved from patient's preparation till availability of reports to the patients [1-4]. It was reported that 70% errors takes place in pre-pre and pre-analytical phases of TTP, causing systemic errors in the whole process [5]. International federations and societies associated with quality measures of clinical laboratories suggested several procedures to deal with pre-analytical steps such as protocols for error-free tests requests, patient's preparations, proper fasting conditions, and sample collection, type, storage and transfer of samples, avoiding needle-stick injuries, measures, procedures for evidence based quality management system for pre-analytical steps and processes [6]. All the articles published and meetings held by international bodies, emphasized regarding stern control over, collection techniques, proper patients counselling and preparation, time of blood, urine and other body fluids collections, how to properly store and transport as per requirement of room temperature, ice or sealed, error-free demography, and test requests, receiving in laboratory and retrieval. Proposal of pneumatic transport system, one-window-IT-based Laboratory information system (LRS) for tests requests and reporting are few measures that have been documented by International forum. Universal harmonization of patient's demography, collection tubes labelling, checking of sample integrity, transport and even storage before transport to labs are few suggestions that have been continuously made to reduce the risks of pre-pre and pre-analytical errors and enhance credibility of reports, patients safety, clinical decision making and sustainability [7, 8].

Measurements-One major significant entity of Analytical Phase

Analytical measurement is one of the core component of inter and intra analytical phase and depends on several factors, ranging from quantity/volume of sample and reagents, correct analytical protocol, methods, standard chemicals, quality control material, instrument/analyzer mechanism and mechanics, reference ranges and precision, variances and uncertainty of measurements. Most reported uncertainties in measurements are due to improper samples, its integrity, biological variation within the patients that reflects in samples, incorrect imprecision, ranges and analytical artifacts. Although analytical imprecision and biasness have been minimized by using several QA/QC methods, but still complete elimination of such uncertainties is not possible, but needs continual check and balance. However, clinical laboratories, in last two decades have come a long way and introduced ways and means to control, minimize biasness and improves result outcome with routine practices of validation, verifications, establishment of accuracy, precision, calibrations that ensures consistent, sustainable and reproducible reports. In last two decades, attempts have been made to ensure that characteristics of analytical operations actually matches and correlated to specifications given and required by analytical protocols that are intended for a specific analytic entity and must be useful for medical decisions and clinical outcomes. Several efforts have been made to monitor measurement uncertainty mainly focusing laboratory uncertainty, utilizing quality control (iQC) materials internally. This acts as a major factor in maintaining characteristics of analytical operations, improving customary iQC, integration of traditional programs directly correlated with patient-based-real-time quality controls [3]. Furthermore, variations in kit lot, within a lot and amongst several kits is a matter of grave concern, that some of the time induce systemic error of unprecedented outcome that was notified by end-users and not by standardized in-place-laboratory protocols and quality systems. Drift and shift in controls and ultimately in analytical results can produce deleterious consequences with expected clinical indecisions and probability of harm. To overcome such deviation, which sometimes, cannot be avoided due to work-load, inter and intra systemic mechanisms and not much external quality assessments. Suggestions have been made by several international scientific societies related to lab work that kit manufacturing industries, which are some of the time-sub vendors and not directly under the control of principal company, needs to produce wide range of lot, range of concentrations, lengthy period of expiry, commutability as well as acceptable analytical performance of each lot and how much variation from preceding and proceeding lots. Moreover, in-house transparency for processes, more elaborate definition of reagent lot, validation and verification processes and precision acceptance by manufacturers are some of the propositions that were put forward by international quality organization and systems. External quality control programs, patients based quality control materials, evidence based-clinical outcome oriented processes were few insights that European Federation of

Clinical Chemistry and Laboratory Medicine (EFLM) had put forward and provides a guideline for harmonizing lot-to-lot acceptance criteria, controlling measurement of uncertainty, and sustaining characteristics of analytical operations with acceptable utility of laboratory reports in clinical conduits and decision making [1, 3].

Conclusion

Current review provided an insight and Birdseye view of two important apparatuses of Pre-pre; Pre analytical; analytical and correlation outcome with Post-analytical phases, which are total testing process (TTP) and Measurements, with its probable components of uncertainty. This review is part of a series of articles that will encompass issues related to pre; analytical and post analytical phases of a clinical laboratory testing processes.

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