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LETTER TO THE EDITOR

Quality Management System in Coagulation Laboratory of a Public Sector Hospital- An experience from a Developing Country

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The National Institute of Cardiovascular Diseases (NICVD) Karachi is a public sector hospital which is part of the biggest cardiac network in the region that offers comprehensive care at absolutely no cost. NICVD Karachi houses a dedicated anticoagulation clinic which caters to approximately 200 patients daily. Prothrombin time (PT) and activated partial thromboplastin time (aPTT) are the most frequently requested primary hemostatic tests in our setup. INR is often reported with PT which is adopted to attune the discordance between different laboratory results.

Clinical laboratories in developing countries continue to face multiple challenges when it comes to providing improved overall quality assurance. In this letter to the editor, we wanted to highlight the actions taken to improve quality of collection, processing, and reporting of basic hemostasis tests in our laboratory at NICVD Karachi. All actions were taken to secure over expenditure with minimal investment. We focused on utilizing available resources, simultaneously educating all people involved in the process of requesting and processing.

Preanalytical phase

It has been documented that most errors occur in the preanalytical phase of testing [1]. All the personnel involved in sample collection including phlebotomists and nursing staff were informed and retrained about “order of draw” to reduce contamination of coagulation samples with tissue factor. An illustration of the “order of

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draw" was distributed across all the areas where clinical samples are collected. Training was provided to phlebotomists about appropriate labelling and to draw blood samples up to a specified mark, ensuring the correct ratio of sample to anticoagulant. This significantly reduced the consumption of tubes and repeat testing by reducing recollection of inappropriate and QNS (quantity not sufficient) samples. In settings like ours, where we treat pediatric cardiovascular diseases, high hematocrit samples due to underlying cyanotic heart disease are commonly encountered. To address this problem, in cases where the hematocrit (Hct) values exceed 0.55 L/L in the samples, it was made imperative to make adjustments to the final citrate concentration in the tube to maintain the pertinent blood to anticoagulant ratio at 9:1. One of the important factors in the preanalytical factor is duration and temperature under which the coagulation samples are transported. In the absence of a cybernated sample receiving system, it was made sure that the manual entry system was in place, making sure the samples are received and processed in due time of 4 hours. Quality Control of centrifuge to obtain platelet free plasma was implemented and documented in each shift.

The subsequent step involves the formalization and recording of Standard Operating Procedures (SOPs). Barriers to appropriate application of SOPs not only include misunderstanding of manuscript but also lack of adherence and conviction towards it. We have formed a set of SOPs utilizing simple language, pictures, and flowcharts to clearly outline the procedures. Moreover, policies for sample handling, processing, retention, and rejection were composed in a language and format which is easily readable and reasonable to all laboratory staff bringing consistency and uniformity in output.

Analytic phase

For the analytic phase, it is recommended that IQC must be run with each assay with pertinent time intervals [2]. QC (Quality Control) samples are meant to be indistinguishable from patient samples and undergo identical testing procedures. Stringent evaluation of QC outcomes serves as a valuable practice for upholding quality control standards for patient samples. However, in an environment where the focus is to utilize available resources with cost effectiveness, we run commercial controls in morning batches which handle the highest workload of the coagulation clinic. For evening and night shifts, handling the limited number of samples, frozen aliquots of plasma of known samples are run and results are verified against the recorded values.

Hemolysis, hyperbilirubinemia, and lipemia of samples can affect the results of coagulation tests if processed via optical method [3]. However, rejecting these samples may delay the treatment of patients [4]. In the absence of an automatic check, we have implemented a rigorous visual inspection process to identify samples exhibiting such features. We ensure that such samples are subjected to alternative testing methods, such as mechanical techniques, to obtain accurate results. This reduced the recollection of such samples and simultaneously enhanced patient containment.

Despite the equipment's age, a leverage we had was its leasing agreement with the manufacturer. This arrangement afforded the management a substantial degree of flexibility with added benefit of the vendor being responsible for regular maintenance and calibration. Additionally, we worked with the IT division to create a connection between the equipment and the laboratory information management system. This integration made it possible for results to be transferred automatically, which decreased the likelihood of typing mistakes.

Post analytic

Providing timely and comprehensive reports of investigations conducted is essential from the customer's perspective [5]. To reduce variation in reporting during each shift, we have developed a simplified format for laboratory results. This format is designed to be user-friendly and easier to understand and comprehend. By implementing this standardized format, we aim to streamline the interpretation process.

Most regulatory authorities advocate that all clinical laboratories should develop and implement critical value policies which may vary in specific details depending on the institution's requirements, but they generally share the same fundamental concept [6]. We also established our protocol for notifying the primary care team about critical values, making sure that these values are promptly communicated to enable timely interventions.

Appropriate documentation is another imperative segment of medical care [7]. The majority of public sector setups are unable to use a Management Information System and rely on manual documentation processes which sometimes lead to loss of information and data. This issue was addressed by implementing record retention policies. The staff was trained accordingly and by keeping retrospective check on documentation record.

In conclusion, we recommend that quality improvement should be seen as an ongoing process. It is crucial not only to establish checks and measures but also to prioritize continuous training and education for all individuals involved. By utilizing the tools and resources available, we can effectively enhance the quality of care.

Declaration of Interest:
None.

References:

1. Dukic L, Jokic A, Kules J, Pasalic D. The knowledge and understanding of preanalytical phase among biomedicine students at the University of Zagreb. Biochem Med (Zagreb) 2016 Feb 15; 26(1):90-7. (PMID: 26981023)

2. Bonar R, Favaloro EJ, Adcock DM. Quality in coagulation and haemostasis testing. Biochemia Medica 2010 Jun 4;20(2):184-99. https://mail.biochemia-medica.com/en/journal/20/2/10.11613/BM.2010.023

3. Bronic A, Coen Herak D, Margetic S, Milic M. Croatian Society of Medical Biochemistry and Laboratory Medicine: National recommendations for blood collection, processing, performance and reporting of results for coagulation screening assays prothrombin time, activated partial thromboplastin time, thrombin time, fibrinogen and D-dimer. Biochem Med (Zagreb) 2019 Jun 15;29(2):020503. (PMID: 31223257)

4. Arora S, Kolte S, Dhupia JS. Hemolyzed samples should be processed for coagulation studies: the study of hemolysis effects on coagulation parameters. Ann Med Health Sci Res 2014;4(2):233-7. (PMID: 24761244)

5. Alvarez L, Soler A, Guinon L, Mira A. A balanced scorecard for assessing a strategic plan in a clinical laboratory. Biochem Med (Zagreb) 2019 Jun 15;29(2):020601. (PMID: 31015782)

6. Genzen JR, Tormey CA; Education Committee of the Academy of Clinical Laboratory Physicians and Scientists. Pathology consultation on reporting of critical values. Am J Clin Pathol 2011 Apr 1;135(4):505-13. (PMID: 21411773)

7. Narayanan J, Dobrin S, Choi J, et al. Structured clinical documentation in the electronic medical record to improve quality and to support practice-based research in epilepsy. Epilepsia 2017 Jan;58(1):68-76. (PMID: 27864833)