

Can an Accreditation Compliant POCT Coagulation Program Be Implemented Successfully in the Cardiac Operating Room Setting?

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Background: Patients undergoing complex cardiopulmonary bypass surgery frequently require transfusions of erythrocytes, platelets and plasma due to coagulopathic bleeding. Timely assessment of a patient's coagulation status is needed intra-operatively to avoid unnecessary transfusions and associated risks. Traditional laboratory tests are often inadequate since they take a long time and typically are unable to detect coagulation defects. The objective of this work is to describe one institution's experience in the implementation of point-of-care testing (POCT) for thromboelastometry and platelet function as part of a novel transfusion algorithm during cardiac surgery.

Method: The study was undertaken by the Department of Anesthesia, Toronto General Hospital, University Health Network (UHN). Under accreditation from the Institute for Quality Management in Healthcare (IQMH) and Accreditation Canada, the implementation of the coagulation assays in the operating room are required to be compliant with ISO 22870 and Qmentum POCT standards, respectively. The instruments included ROTEM® (Tem International GmbH, Munich, Germany) and Plateletworks® (Helena Laboratories, Beaumont, Texas, USA). The POCT results would be used as part of a transfusion algorithm to guide transfusion decisions (Anesthesiology 2015;122:560-70). The continuous use of the algorithm would transition into clinical practice.

Results: The POCT department of the UHN Laboratory Medicine Program (LMP) was contacted early in the study design to consult on the quality assurance requirements for the instruments. The involvement of the LMP POCT department in the study design phase was key to the creation of procedures and processes to become compliant with accreditation standards. Instrument quality controls, consumables management, and operator training by the instrument vendor representatives were implemented from the onset of the study. For method validation, the Plateletworks instrument was compared to the main laboratory complete blood count (CBC) analyzer for total platelet count. For the functioning platelet count on the Plateletworks and the ROTEM assays (EXTEM for clot formation and FIBTEM for clot firmness), the interpretation of results followed the manufacturer's instructions and our own validation studies (Anesth Analg 2014;118:257-63; J Cardiothorac Vasc Anesth 2016;30:90-5). To transition the program to meet full POCT accreditation requirements, review of the quality assurance program for ROTEM and Plateletworks was required. Instrument operating manuals and operator training documents were obtained from the respective manufacturers. Approved procedures for monitoring thermally controlled equipment in the POCT environment were fully implemented. For External Quality Assessment, surveys from the College of American Pathologists (CAP) were chosen for the Plateletworks instrument, and the ECAT Foundation (Netherlands) for the ROTEM instrument. Standard operating procedures were written for the instruments incorporating the transfusion algorithm in conjunction with the results obtained from the thromboelastometry and platelet function testing. Training and competency of operators was formalized, and the quality control program reviewed for acceptable performance.

Conclusion: A joint collaboration among the clinical users, laboratory and product vendors led to the successful implementation of a compliant, highly-integrated POCT program aimed to optimize the transfusion practice in the cardiac operating room. The first cycle of EQA was performed in early 2016 with survey reports pending from the EQA providers.