Evaluating an ex-vivo point-of-care testing device for blood gas and electrolyte measurement for acceptance by the POCT committee.

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POCT committees are now commonplace in hospital trusts in the UK and they have a critical role in safeguarding and developing point-of-care testing in these settings. The roles of the committee include evaluating the quality of performance of new devices prior to implementation in the health service and for most of these the quality aspect will cover reasonably straightforward comparison data with existing laboratory-based devices. These comparisons will inform the committee approval process and there are usually shared and compatible internal and external quality assessment processes between the two analytical systems likening the process to routine evaluation of a new analyser for the laboratory. In the UK, many laboratories with responsibility for the POCT process will aim to follow guidelines from accreditation bodies such at Clinical Pathology Accreditation (CPA) which is now managed by the UK Assurance Scheme (UKAS) as well as meet British and International (ISO) Standards.

This presentation describes the more complex processes encountered when the committee is asked to evaluate for acceptability a novel ex-vivo device (Proxima; Sphere Medical, Cambridge, UK) for measuring blood gases, an electrolyte (potassium) and haematocrit that would be of value in the monitoring of patients in critical care to enable regular monitoring without the requirement for continuous blood loss as demanded by existing POC devices such as blood gas machines or cartridges. The proposed device, which may thus have many important potential advantages to the clinical service including a significant reduction if not elimination in pre-analytical errors and a reduction in blood loss and thus anemia induced by regular blood sampling, cannot by its nature be compared directly with an existing analytical process in the laboratory. Of note there is no option on this device for running external quality control samples as this would bring potential infection risk during the time the device is attached to the patient. Internal quality control monitoring is however manageable. The presentation covers description of the technical aspects of the novel analyser including its significant reduction of pre-analytical errors, its clinical utility and details the problems encountered in evaluating this for introduction to sensitive critical care situations. This includes a description of how the manufacturers manage calibration and monitoring of the device performance. Importantly there is a recalibration schedule and also the possibility to challenge the system with control solutions. There is a reflection on the RILI-BAEK quality requirements for laboratories, where the performance with respect to the manufacturers own control solutions, together with error flags and the use of percentage root mean standard deviations (%RMSD) that are graded for such parameters as blood gases and electrolytes, sets an example of a system that would be likely to satisfy the POCT committee. This is similar to that used for indwelling analysers such as continuous glucose monitoring devices. Aspects of how this device would meet the stringent ISO standards for POCT devices. The conclusion is that the device quality assessment meets an acceptable level that should provide a confident conclusion for the POCT committee. This type of issue is likely to become more commonplace in POCT committees and this presentation is aimed at presenting an acceptable solution for this.