Correspondence

To the Editors

Concern regarding point of care laboratory testing in neonates

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Dear Editors,

Point of care (POC) laboratory testing is currently used in many clinical settings. In clinical neonatology, the use of POC for laboratory analysis is interesting. POC might be used for determination of many laboratory parameters such as potassium, haemoglobin and bilirubin levels. In laboratory medicine, there are many important points for consideration. First, it is necessary to compare the POC tool versus the standard analyser. These data are necessary for clinical judgments in neonates.

The instrument used for POC testing requires calibration and maintenance using the same standards as the main laboratory. All samples used for POC testing are “whole blood”, and not centrifuged to separate serum or plasma. Ideally, there should not be any differences that may arise as a result of using serum or plasma as opposed to whole blood.

Additionally, the quality control of any laboratory testing is important. Pre-analytical error might occur and it can affect the results. Any laboratory tool has to be approved and should be accredited according to the international clinical laboratory standards such as Clinical Laboratory Improvement Amendments (CLIA) standards proposed by the Centre for Clinical Standards and Quality (CCSQ).

Also, it is necessary to assess the precision of the test. There is a chance for ‘within run’ and ‘between run’ variability for any test. For a POC analyser, imprecision is detectable and there is also high variability due to different kinds of samples (blood, serum or plasma). Basically, both equipment used for the central laboratory and POC testing must receive approval from the referencing certified body (such as the U.S. Food and Drug Administration as In Vitro Diagnostic (IVD) Devices and the European CE IVD mark). The precision of these tests has to be revealed by multiple regulatory institutions. Based on previously described principles, the clinician should be aware of the background of POC laboratory testing in neonates. Often there may be a spurious result from a POC test. For example, there is a discordant finding between laboratory result and clinical appearance of the neonate. Before making a clinical judgement for any further clinical action, it is necessary to recheck the condition of the POC tool. All testing must be done under standards and it is necessary to seek for a non-pathological source of laboratory abnormality such as interference, analyser error and failed quality control of POC tool.

References


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