Performance Monitoring System for Low Level Leucocyte Enumeration

Outline

The use of leucocyte depleted blood products became standard practice in blood transfusion in response to the possible risk of variant Creutzfeldt-Jakob disease (v-CJD) transmission. However, leucodepletion also has many other benefits such as a reduction in febrile transfusion reactions and a reduction in the risk of cytomegalovirus (CMV) transmission. As such the majority of countries now routinely perform leucodepletion on all donated blood products to ensure a minimal number of residual leucocytes remain. Therefore, the Low Level Leucocyte Quantitation programme assesses the ability of individual participants to report the absolute values of leucocytes present (in cells per microlitre) in stabilised samples of leucodepleted blood and platelets.

Sample Frequency

Six samples (3 red blood cell and 3 platelet) are issued at each trial (send out) 6 times per annum.

Scoring System Description

The scoring system is based upon the use of z scores as described in ISO 13528. This involves the calculation of a robust mean and robust standard deviation from the returned results. Then using these values and the individual results returned a z score can be calculated for each participant. Please note that z scores are generated separately for red blood cell and platelet samples and both are used for performance monitoring as they are both used in clinical practice.

Scoring System Operation

Six samples are issued each trial. A participant's submitted result for each sample is then used in conjunction with the robust mean and robust standard deviation to calculate a z score using the following formula:

$z = (x-X)/\sigma$

where x is the result returned by the testing laboratory, X is the assigned value (robust mean) and σ is the standard deviation for proficiency assessment (robust SD).

The robust mean and robust SD are derived from participant data using Algorithm A (ISO 5725-5) that ensures that all data is included in the generation of the robust mean and robust SD but also minimizes the effect of outliers upon the final values.

Interpretation of z-scores is as follows:

- A result between 2.5 and -2.5 would be classed as satisfactory
- A result between >2.5 and 3.5 or <-2.5 and -3.5 is seen as an 'Action' result, which highlights a potential issue to the laboratory. Two 'Action' results in a period of 3 samples would result in classification as a 'Critical'

- A result above 3.5 or below -3.5 is considered to be a 'Critical' result requiring immediate investigation by the laboratory

Due to the nature of how z-scores are generated a positive z-score highlights a positive bias in a laboratory's results whereas a negative z-score shows a negative bias. As such, this adds value to the performance monitoring information provided to laboratories because the z-score immediately highlights to the participating centre if their result is above or below the expected consensus value. In addition to the z-score all methodological data featured on reports will be in the format of robust mean and robust SD. This will give participants the option to use the extra provided data to calculate additional "in-house" z-scores based on machine types, methodologies etc and allow them to monitor if there are any "in-house" technical biases. **However, it is important to stress that the z-score issued by UK NEQAS for Leucocyte Immunophenotyping based on all methods will remain the only parameter that is used for performance monitoring.**

Any laboratory who fails to return a result by the closing date will be regarded as an action for each sample. As such any laboratories that do not return results for 2 or more samples of the same type within a trial will be classified as critical.

Unsatisfactory performance in this programme is defined as any occurrence of critical performance and this will be initially communicated to participants on their trial report. Unsatisfactory performance will be initially communicated to participants on their trial report. This will be followed with an email and notification on the participant hub on each occurrence of unsatisfactory performance and offering support and guidance. The support and guidance offered will be tailored to the particular needs of the participant but may include the provision of repeat/additional samples plus telephone, email or face-to-face communications.

If a participant's status is elevated to persistent unsatisfactory performance (defined as a critical classification on 4 or more occasions within a 12 sample period) then this will be initially communicated to participants on their trial report. This will be followed with an email and notification on the participant hub on each occurrence of persistent unsatisfactory performance and offering support and guidance. The Haematology National Quality Assurance Advisory Panel informed (for UK participants only).

As with all scoring systems it is important that to note that the limits will be constantly reviewed to determine whether they are providing the information required. The management of the programme retain the right to determine if an individual trial should not be scored.