ABSTRACT FORM ECAT SYMPOSIUM 8 – 9 NOVEMBER 2018

Name:

René Idema

Amphia Hospital, Laboratory for Hematology and Clinical Chemistry, Breda, The Netherlands

Title:

Biological variation, quality specifications and Six Sigma

Abstract:

We cannot measure without making measurement errors. To ensure that our measurement is valid for patient care, our measurement errors may not exceed a limit that makes the measurement method unsuitable for diagnosis and monitoring. This limit is known as the Total Allowable Error (TEa).
The six-sigma concept melds the TEa and the analytical errors bias and imprecision into a single metric, the sigma score. This metric enables us to select quality control rules in such a way that our measurement errors will not exceed the TEa.

The statistical basis for this method is sound and secure, and the six-sigma concept is therefore well established, e.g. in internal QC for clinical chemistry. The six sigma paradigm is less well established in the haemostasis laboratory.

We explored the route from the theoretical basis to selection of internal quality control rules for the APTT, PT, fibrinogen and antithrombin in three hospital laboratories using different analysers.

The presentation will briefly illustrate the six sigma concept and discuss the problems we encountered on our way from theory to practical application. In particular the consequences of using various sources of biological variation and analytical error will be discussed.