31st Annual Scientific Meeting 2020 *Webinar*

Singapore Association for Medical Laboratory Sciences

Evaluation Methods of Uncertainty of Measurement in Medical Testing

Join us at the comfort of your office or home
Saturday 21 November 2020 @ 0900 hrs – 1200 hrs

Programme

0900 Introduction: Ms Siti Thuraiya Binte Abdul Latiff, Khoo Teck Puat Hospital
0910 Welcome Address: Dr Eddie Ang, Singapore Association for Medical Laboratory Sciences
0915 Opening Remarks: Prof Aw Tar Choon, Changi General Hospital
> Reflections on Measurement Uncertainty and Standardization
0945 Speaker: Mr Yeoh Guan Huah, GLP Consulting, Singapore
> Part 1: A top-down approaching using routine quality control data for analytical uncertainty
> Part 2: Biological variation as an uncertainty component
1145 Questions and Answers
1200 Webinar Ends

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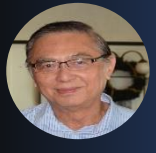
Prof Aw Tar Choon

Abstract

Clinical chemistry has a long and active history in standardization efforts. Yet this effort is not done. We hope that organizations such as the International Federation of Clinical Chemistry, and the World Health Organization (WHO) will spearhead efforts on analytical standardization. It was the European Commission's In-Vitro Diagnostics Directive to promote good manufacturing practice in the diagnostic industry that provided the impetus for the 1999 Stockholm congress on 'Global Quality Specifications in Laboratory Medicine'. Out of this, ISO Technical Committee 212 (ISO/TC 212) was formed and assigned a working group to prepare the ISO 15189 standard based on *ISO 17025 for testing and calibration laboratories).*

In the first 2 versions of ISO15189 measurement uncertainty (MU) of results was to be determined where 'relevant and possible'; unfortunately this verse has been dropped in version 3 to become mandatory. The language of the ISO documents on MU is stiff and overly mathematical reflecting the interests of the authors. It was agreed that a simpler more easily understood version would be helpful but has yet to surface. At the simplest level all of us have precision data (SD & CV) from internal QC efforts; 1 SD = 1 MU and 2 MU is where the result is 95% of the time. We also have bias data from EQA programs that reflect comparisons with our instrument and method peers.

Clinical biochemists are pragmatists seeking practical, cost-effective solutions to complex analytical problems. We take what is desirable and what is practicable given the present limited knowledge while preventing justifiable pragmatism from sliding into unsatisfactory practice. We should also not the perfect be the enemy of the good.



Mr Yeoh Guan Huah

Synopsis

Part 1: A top-down approaching using routine quality control data for analytical uncertainty
There has been a saying that a measurement result is not complete if it is not accompanied by a quantitative knowledge of its uncertainty. Although uncertainty of measurement is just an estimate, it is an important element of ISO 15189:2012 accreditation standard for medical testing as it provides a quantitative estimate of the data quality in deciding if the result is adequate for its intended purpose.

Apart from the tedious and time consuming approach by the ISO GUM method, there are few alternative holistic top-down approaches by studying the overall performance of the test method in terms of its repeatability (precision), reproducibility through inter-laboratory comparison studies, and result trueness which are popularly adopted by many US and European laboratory communities.

The ASTM D6299 using the Shewhart control chart method is of particular interest due to its simplicity and dynamic in nature because of the continual collection of QC data in routine testing. This presentation is aimed to demonstrate how this method is applicable in biochemical testing for medical laboratories.

Part 2: Biological variation as an uncertainty component
Biological variation has been identified as one of the many potential uncertainty components in medical testing. It is not part of the analytical uncertainty estimated in a test laboratory. If clinically relevant, the estimation of uncertainty of measurement on clinical use of test results needs to consider biological variation, where appropriate. Hence, the intra-individual biological variation of the measurand is normally required in the uncertainty estimation. A widely used and internationally recommended concept is to define the upper acceptable limit for *imprecision* as a proportion of the intra-individual biological variation of the test parameter. This presentation will discuss how the intra-individual biological variation can be incorporated in the overall evaluation of uncertainty of measurement and what the relationships between the analytical uncertainty and its corresponding biological variation are. The Westgard's list of desirable specifications for total error, imprecision and bias, derived from biologic variation will be referred to

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