If we acknowledge our interpretations are critically important, how can we agree which interpretive comments are correct and which aren't? For quantitative results we can use statistics to test agreement, however for qualitative results we need some sort of gold standard. While the ultimate health standard is clinical outcome, it is difficult to ascertain if our interpretations have been truly beneficial, therefore we use the professional judgement of a group of experts to define the interpretations that are most appropriate. Ideally that reference expertise is both clinical and laboratory based, and we should aim to agree with the experts or at the very least be largely in agreement with them. Disagreement with the experts may similarly be an opportunity for quality improvement. Interpretations that cannot be supported by clinical outcome or expert opinion may undermine the quality and value of pathology testing.

OUTCOME-BASED ANALYTICAL PERFORMANCE SPECIFICATIONS – MISSION IMPOSSIBLE?

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The 1999 Stockholm hierarchy for setting analytical performance specifications (APS) has recently been revised.¹ The top of the new hierarchy is based on a model that focuses on the link between testing and clinical outcomes.² This is based on the recognition that high quality analytical performance does not guarantee positive patient outcomes and poor analytical performance of a test that plays a very small part in a complex clinical pathway may not lead to unfavourable outcomes.

This talk reviews the need for outcome-based specifications, the most relevant types of outcomes to be considered, and the challenges and limitations of setting outcome-based APS. It will be highlighted how outcome-based APS should reflect the clinical needs of patients; be tailored to the purpose, role and significance of the test in a clinical pathway; and be defined at a level that achieves net benefit for patients at reasonable costs. The evidence-based methodology of direct (Model 1a) and indirect (Model 1b) outcome studies will be illustrated with examples on how outcome data can be translated to APS using the linked evidence and simulation or decision analytic techniques. Whilst it is acknowledged that direct evaluations of testing-related outcomes are difficult and may not be possible for all measurands, all other forms of setting APS are inferior to that standard, and can be regarded as approximations. Better definition of the relationship between the analytical performance of tests and health outcomes may contribute to the development of tests with improved clinical and cost-effectiveness.

References

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LIMIT OF DETECTION – A CONTRARIAN'S VIEW

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Measurement of analytes close to zero poses unique challenges. This includes two important functions: to accurately detect the presence or absence of a substance, and to report minute amounts with appropriate accuracy. The approach to deal with this is based on statistical theory that has a long and murky history leading unfortunately to misconceptions, mystery and complexity. The inappropriate application of statistical parameters results in unexpected problems. In this presentation, I will highlight some of the tricky areas and will demonstrate how they may have far reaching implications. A fit-for-purpose approach will be presented that will provide a practical and logical solution.

WHY IS THERE CONCERN ABOUT ADOPTION OF THE NEW GDM CRITERIA?

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In 2010, the International Association of Diabetes in Pregnancy Study Groups (IADPSG) recommended the adoption of new criteria for the diagnosis of gestational diabetes. Using thresholds derived from the Hyperglycaemia Outcomes in Pregnancy (HAPO) Study, these criteria are based on more evidence than previous diagnostic criteria, and held the promise of international standardisation.

In the subsequent 5 years, the IADPSG criteria have generated considerable controversy. They been accepted by a number of organisations including the WHO, but do not have universal support in Australia, the USA, and the UK. Concerns about the criteria include the fact that the thresholds were determined by consensus, lack of evidence that treatment at these thresholds improves outcomes without causing harm, the increased number of women with GDM, questionable cost-effectiveness, the implications of lower treatment targets, and the extrapolation of these criteria for the diagnosis of early GDM.

Until these concerns are addressed, clinicians are faced with the dilemma of whether to adopt the IADPSG criteria for the sake of standardisation, without clear benefit.

URINE FREE CORTISOL MEASUREMENT: CLINICAL PERSPECTIVE

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Amongst even esteemed endocrinologists, making the diagnosis of Cushing's syndrome and determining the source of excess