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Defining analytical performance specifications and monitoring performance over time for five biochemistry analytes

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Introduction

Laboratories and point-of-care users must ensure that the analytical quality attained for that test is appropriate for the needs of the clinical service and the clinical utility of the test. Analytical performance specifications (APS) are quality standards defining the range of values around a target which are considered acceptable for the performance of that test. APS are typically expressed as total allowable error (TEa). Various strategies to establish acceptable APS have been proposed over the last 25 years, including the consensus hierarchy from the Stockholm conference in 1999, and the simplified EFLM Milan strategy in 2014. The aim of this study was to define APS for five common biochemistry analytes by producing a TEa matrix for each analyte using recent EQA data.

Methods

To calculate the APS, performance data from the Weqas Serum Chemistry and Weqas Lipids programmes were collected over a 12-month period for samples covering a wide clinical range for sodium, creatinine, glucose, calcium and total cholesterol. The performance of each method was calculated in terms of bias to the reference method procedure and the between-laboratory imprecision and plotted on a TEa matrix. The data was evaluated against the EFLM Model 2 optimal, desirable, and minimum TEa limits to determine the most appropriate APS for each analyte. Using the formula *Total Allowable Error (TEa) = 1.65 x Imprecision + Bias*, the effect of increasing imprecision on the allowable bias is illustrated for each TEa limit. Where this was unachievable, the method with the best analytical quality was determined (EFLM Model 3). The Weqas TEa was also shown on each TEa matrix.

Results – total cholesterol, creatinine and glucose

TEa matrices for total cholesterol, creatinine and glucose are shown in Figure 1.

Total cholesterol performance was good across all enrolled assays, with most participants achieving desirable (TEa = 8.6 %) or optimal (TEa = 4.3 %) EFLM APS across the concentration range tested (3.41 – 6.84 mmol/L).

The performance for **creatinine** varied according to assay method. Participants using enzymatic creatinine assays generally achieved either desirable (TEa = 7.7 %) or optimal EFLM APS (TEa = 3.9 %), across the concentration range tested (102 – 529 µmol/L). Performance for participants using Jaffe creatinine assays was more variable. Although most achieved desirable EFLM APS, a proportion of results fell into the minimum range (TEa = 11.6 %).

Glucose performance varied between manufacturers, although most participants achieved desirable EFLM APS (TEa = 6.2 %) across the concentration range tested (4.7 – 33.8 mmol/L), with some achieving optimal (TEa = 3.1 %), and the remainder achieving minimum (TEa = 9.3 %) performance standards.

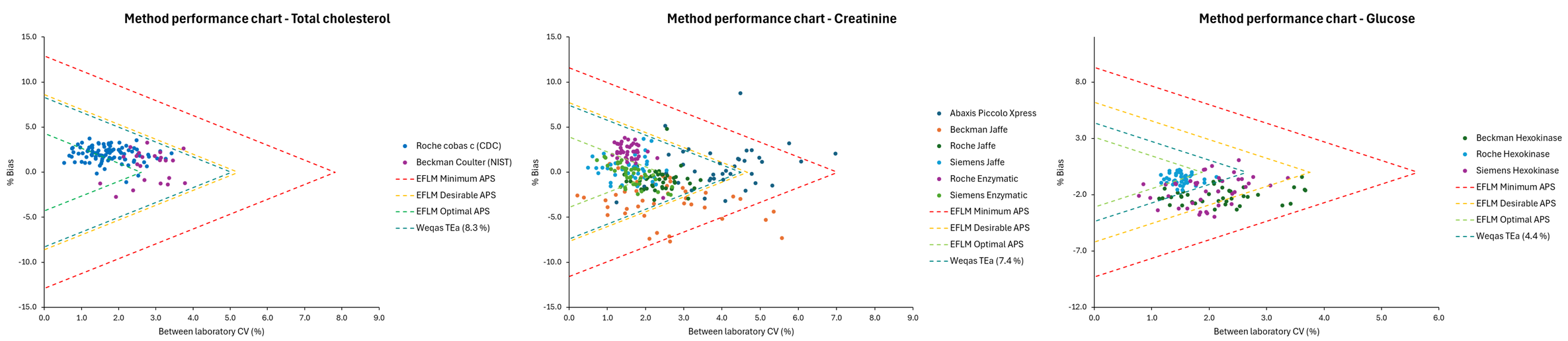

Figure 1: Method performance charts for total cholesterol (left), creatinine (centre) and glucose (right). Each point represents between-laboratory CV % and % bias of the method mean for that distribution. EFLM minimum (red), desirable (amber) and optimum (green) APS are plotted, as well as Weqas TEa for each analyte. For total cholesterol, creatinine and glucose, desirable EFLM APS are achievable for most platforms.

Results – sodium and total calcium

TEa matrices for total cholesterol, creatinine and glucose are shown in Figure 2.

Sodium performance was comparable across all platforms; however minimum EFLM APS (TEa = 1.0 %) was not achievable across the concentration range tested (121 – 163 mmol/L). Thus, for sodium, Model 3 (state-of-the-art) APS are used.

Performance for **total calcium** was more variable. Platforms using NM-BAPTA typically achieved minimum EFLM APS (TEa = 3.3 %), across the concentration range tested (1.74 – 2.94 mmol/L), whereas platforms using Arsenazo III generally did not. Similarly, for total calcium, Model 3 (state-of-the-art) APS are used.

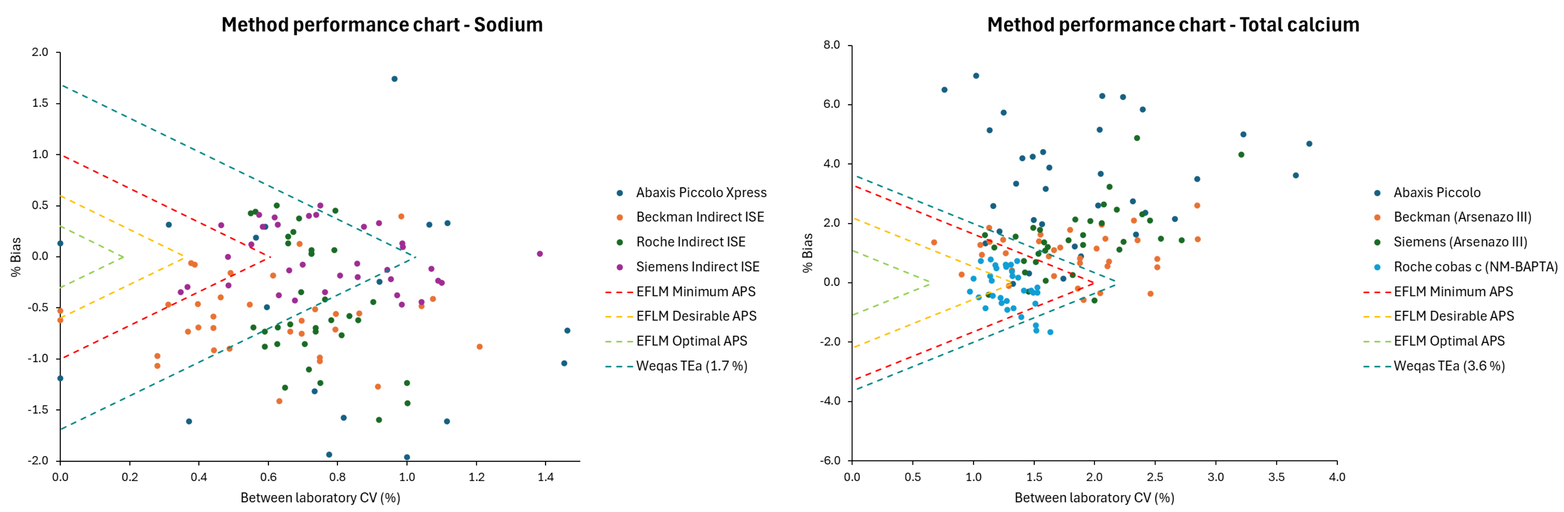

Figure 2: Method performance charts for sodium (left) and total calcium (right). Each point represents between-laboratory CV % and % bias of the method mean for that distribution. EFLM minimum (red), desirable (amber) and optimum (green) APS are plotted, as well as Weqas TEa for both analytes. Minimum EFLM Model 2 is not achievable for either sodium or glucose for all methods, thus Model 3 APS are in use.

Conclusions

TEa matrices provide a simple and effective visual representation of method performance against EFLM APS standards. APS for five common biochemistry analytes were defined by producing a TEa matrix for each analyte using recent EQA data.

For total cholesterol, creatinine and glucose, desirable EFLM APS was achievable for most platforms, with optimal performance frequently achieved.

Where minimum EFLM Model 2 TEa is not achievable (sodium and total calcium), alternative Model 3 (state-of-the-art) APS are in use.

Weykamp, C et al. *Investigation of Two Models to Set and Evaluate Quality Targets for HbA1c: Biological Variation and Sigma-metrics.* Clin Chem. 2015 Mar 3;61(5):752–759