The effect of target values on the performance of photometric glucose results in a general clinical chemistry EQA-scheme

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Introduction

Labquality, a Finnish independent EQA provider, organizes a general clinical chemistry program six times a year. In this scheme, the clients can respond up to 50 analytes and they fill in their method and device information together with their results. In this scheme, transferred values from NFKK Reference Serum X [1] are used as target value for 16 components. For the remainder of the components the assigned values are consensus values calculated according to ISO 13528 algorithm A [2]. Sometimes also samples with reference method values are used.

Objectives

The aim of this exploratory investigation was to compare the performance for glucose of the participating laboratories in the photometry group against Labquality's target limits of ± 6 % when calculating it against robust method target limit, transferred value from NFKK reference serum X and a reference method value using the same sample lot during 7 years on 15 scheme rounds.

Methods

The participants' results with method information were gathered from 2010 to 2017. The percentage of results inside the target area were calculated and the percentages compared when using robust target values, transferred values and reference method values. The reference method value was measured using isotope dilution mass spectrometry (ID-MS) at the university of Ghent. The robust value was calculated according to ISO 13528 algorithm A. The transferred values were calculated with the help of 5 Nordic laboratories analyzing the scheme round sample and NFKK reference serum X (RSX) in triplicates. The transferred values are calculated as:

T = (mean of sample) x (Certified value for RSX) / (mean of RSX)

The sample material used is a liquid, pooled human serum, fresh frozen.

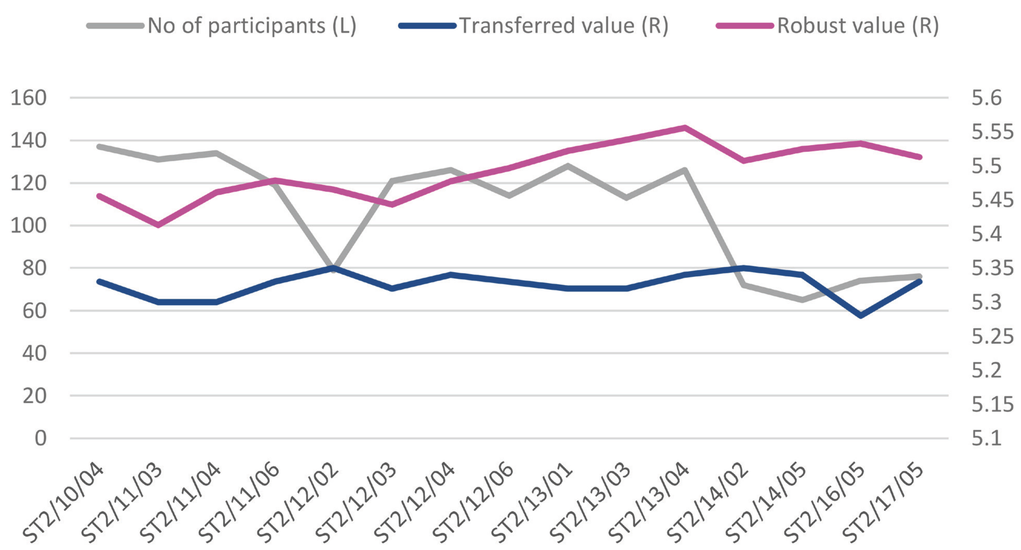
Results

There were 65 to 137 results on each scheme round during 2010 to 2017 in the photometry group. The reference value produced by isotope dilution gas chromatography mass spectrometry was 5.33 mmol/l. The robust value calculated from the results reported on each individual scheme round varied between 5.41 to 5.56 mmol/l and the transferred value varied between 5.28 to 5.35 mmol/l as can be seen from picture 1.

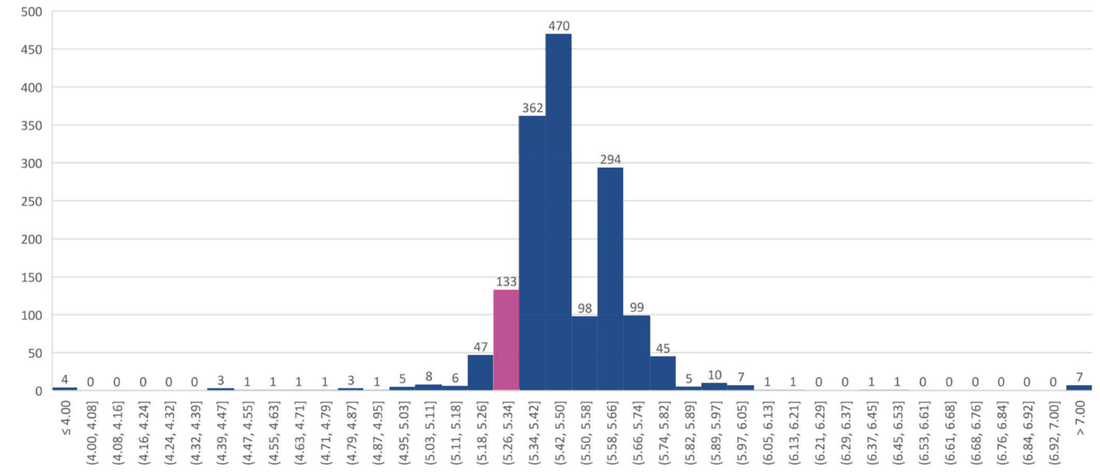
The concentration of glucose did not grow as the sample got older which means that the sample can be considered as stable during the course of 7 years. The transferred value (5.28 to 5.35 mmol/l) stayed very close to the reference method value (5.33 mmol/l) during the course of the investigation which also supports the sample being stable.

The results inside the target area of ± 6 % ranged from 79 to 95 % for the reference method value, from 95 to 97 % for the robust value and from 77 to 94 for the transferred value.

When plotting all of the 1615 results in a histogram picture seen in picture 2 it can be seen that only 133 results (8 %) of the results reported were results that could be rounded up or down as 5.3 mmol/l. The majority of the results were higher, most of which reported between 5.4 and 5.5 mmol/l, which corresponds to +2-3 % higher than the reference method value. The results were not distributed normally. The median was 5.5 mmol/l (CI 5.5 – 5.5 mmol/l) and and the inter-quartile range, IQR, was from 5.4 to 5.6 mmol/l.



Picture 1. Number of participants (left axis) and concentrations of the robust value and transferred value (right axis) in the different rounds.



Picture 2. All glucose results gathered from 2010 to 2017.

Conclusion

The target value calculated using the robust method contributes to most results being inside the target area (95 – 97 %). There were almost no differences between the reference method value and the transferred value (77 – 96 %). This means that there is a difference between the reference method value and the actual value measured by the laboratories using photometry methods. The robust mean for the photometry group was higher (ca +3 %) than the reference method during this whole time. This, however, is not diagnostically significant at this concentration.

Calculating target values using results reported only by the participants in external quality assessment schemes might hide a difference from the exact value as shown here when compared against a value obtained by a reference method.

1. NORIP home site (http://nyenga.net/norip/index.htm) – Traceability.
2. ISO 13528: 2015 Statistical methods for use in proficiency testing by interlaboratory comparisons, Annex C, Algorithm A.

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