Standardisation of HbA_{1c} Measurements: practical consequences and course of activation

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The measurement of hemoglobin A_{1c} has been the gold-standard measurement of chronic glycemia for over two decades. Since elevated HbA_{1c} values increase the likelihood of the microvascular and perhaps macrovascular complications of diabetes, clinicians have used HbA_{1c} test results to guide treatment decisions, and the assay has become the cornerstone for the assessment of diabetes care. To achieve a more uniform standardization of HbA_{1c} measurements, the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) developed a new reference method that specifically measures the concentration of only one molecular species of HbA_{1c}. Results by the new reference method have also been compared with the results obtained by current methodologies, and the relation between the assays can be expressed by simple regression equations ("master equations"). A network of IFCC Reference Laboratories is now in place, and it has been proved that the Reference system is robust and stable over time[1].

All manufacturers should implement worldwide the traceability to the IFCC reference system for HbA_{1c}. In the European Union (EU) the implementation of calibration traceability in laboratory medicine to higher-order standards is already mandatory. The EU directive 98/79/EC on in vitro diagnostic (IVD) medical devices explicitly requires manufacturers to ensure and document metrological traceability of their products. The IFCC WG-HbA_{1c} is willing to review the proposed and will be able, to provide an expert scientific opinion about the suitability of a manufacturer's proposed HbA_{1c} traceability chain and to offer some metrological advice and guidance if appropriate.

A consensus statement was published last year[2], which resulted in three main recommendations: a) the IFCC systems represents the only reference to implement the standardisation of HbA_{1c}; b) the HbA_{1c} result should be reported in both SI units (mmol/mol) and NGSP derived unit (%) using the IFCC-NGSP master equation; c) the calculation of an HbA_{1c} derived average glucose (eAG) is suggested as an aid for the interpretation of HbA_{1c} result, based on the results of a recently published international study[3].

In the presentation an overview of the above mentioned issues will be performed, focussing on the different responsibilities (IFCC, Scientific Societies, Manufacturers, Laboratory professionals, other stakeholders) along the way of the implementation of the IFCC reference system.

References

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