

Consensus Statement Issued On Worldwide Standardization of HbA1c Measurement

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August 23, 2007 – The American Diabetes Association, European Association for the Study of Diabetes, International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), and International Diabetes Federation issued a consensus statement on the worldwide standardization of the hemoglobin A1c measurement. The consensus statement is published in *Diabetologia* and in the September issue of *Diabetes Care*.

"The hemoglobin A1C (A1C) assay has become the gold-standard measurement of chronic glycemia for over two decades," write Jocelyn Hicks, PhD, from the IFCC, and colleagues. "Anchored in the knowledge that elevated A1C values increase the likelihood of the microvascular complications of diabetes (and perhaps macrovascular complications as well), clinicians have used A1C test results to guide treatment decisions, and the assay has become the cornerstone for the assessment of diabetes care."

Contrary to popular opinion, the A1C assay may not reflect average glycemia over the preceding few months. An international study is underway to document the relationship between A1C and average blood glucose, using frequent capillary measurements and continuous glucose monitoring. When results of this study are available in September 2007, they may allow creation of a more accurate conversion algorithm.

The currently used A1C assay measures a mixture of glycated hemoglobins, but a new reference method developed by the IFCC measures only one well-defined glycated hemoglobin, which may permit more uniform standardization of A1C measurements in millimoles per mole. This new reference method cannot be used by clinical laboratories to measure A1C but is only used to standardize the A1C assay.

An A1C value of 5%, for example, would be expressed as 33 mmol/mol, and 8% would be expressed as 65 mmol/mol.

On May 4, 2007, a meeting held in Milan, Italy, gave rise to this consensus statement. All of the organizations participating in issuing this statement urged that these recommendations be implemented globally as soon as possible. Their specific recommendations are as follows:

- A1C test results, including the reference system and results reporting,

- should be standardized worldwide.
- The new IFCC reference system is the only valid basis on which to implement standardization of the A1C measurement.
 - Throughout the world, A1C results should be reported in IFCC units (mmol/mol), and derived National Glycohemoglobin Standardization Program (NGSP) units (%) should be calculated from the IFCC-NGSP master equation.
 - Provided the ongoing "average plasma glucose study" described above fulfills its a priori-specified criteria, an A1C-derived average glucose (ADAG) value calculated from the A1C result should also be reported as an interpretation of the A1C results.
 - In clinical guidelines, glycemic goals should be expressed in IFCC units, derived NGSP units, and as ADAG.

"We believe this agreement will further contribute to the worldwide comparability of A1C results, paralleling the progress of scientific knowledge related to the analytical and biochemical features of A1C testing," the authors conclude. "Expressing test results in scientifically correct units along with a clinically relevant interpretation of those results is not an uncommon practice (e.g., creatinine and estimated glomerular filtration rate). Consequently, clinicians will have the opportunity to convey the concept of chronic glycemia in terms and units most suitable to the patients under their care."

Diabetologia. 2007;00:000-000

Diabetes Care. 2007;30:2399-2400.

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