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Implementation of Standardization of Hemoglobin A_{1c} Measurement

Condensed Summary of the Meeting with Manufacturers Held in Milan, Italy, December 12, 2007

The IFCC Working Group on Standardization of Hemoglobin (Hb) A_{1c} (WG-HbA_{1c}) has been working for several years toward global standardization of HbA_{1c} assay results. The infrastructure to achieve this objective is now in place; a reference method has been developed, and a network of reference laboratories has been established. The IFCC has also been actively discussing the issue of reporting HbA_{1c} results with the clinical diabetes associations (American Diabetes Association, European Association for the Study of Diabetes, and International Diabetes Federation). As a result of these discussions, a consensus statement has been published (*Diabetes Care* 2007;30:2399–400) that recommends reporting HbA_{1c} results in mmol/mol (SI units) and derived National Glycohemoglobin Standardization Program (NGSP) units (%), using the IFCC-NGSP master equation. There is also the option of reporting an "interpretation" of the HbA_{1c} result as "estimated average glucose" (eAG).

These proposals will not only have a significant impact on laboratory medicine and clinical diabetology, but also on industry. Thus, the IFCC sought an opportunity to discuss these changes with manufacturers of HbA_{1c} assays. A general discussion was carried out to define the requirements for implementing IFCC and NGSP numbers in central laboratory instruments and point-of-care systems and a time frame for implementation. From this discussion the following points emerged: (*a*) any manufacturer wishing to prove traceability to the IFCC reference system should contact Dr. Cas Weykamp, the IFCC network coordinator; alternatively, the Joint Committee for Traceability in Laboratory Medicine (JCTLM) is listing the reference laboratory services available to run split-sample exercises (http://www.bipm.org/en/committees/jc/jctlm/); (*b*) manufacturers wishing to directly implement the IFCC reference measurement procedure may refer to the standard operating procedure, available from the IFCC WG-HbA_{1c} Web site (www.ifcchba1c.net); (*c*) the IFCC WG-HbA_{1c} will soon define goals for imprecision, bias, and total error to be used by manufacturers and in the clinical setting of everyday laboratory measurement of HbA_{1c}.

MAIN MEETING OUTCOMES

At the end of the discussion participants agreed that:

(1) All manufacturers should implement worldwide assays for HbA_{1c}, giving results traceable to the IFCC reference system.

(2) The deadline for implementing traceability to the IFCC reference system will be December 31, 2009, for all the instruments in current use.

(3) The name (abbreviation) of the test in laboratory reports and in the clinical setting should be "HbA_{1c}" (not "A1c").

(4) All new instruments sold after January 1, 2011, will report both SI (mmol/mol, no decimals) and NGSP-derived units (percentage, 1 decimal) for results of HbA_{1c} tests, in agreement with the Consensus Statement.

(5) The implementation of HbA_{1c} results in terms of eAG will be discussed after the "A1c-derived average glucose" (ADAG) results of the ongoing clinical trial are published. Participants, however, agree that this process will not involve analytical systems, but only the computer-based systems used to calculate ADAG (e.g., laboratory information systems), a procedure analogous to that used for the implementation of the National Kidney Disease Education Program–IFCC recommendations for estimating GFR.

(6) External quality assessment programs must be introduced for HbA_{1c} testing that use commutable control materials with target values assigned using the IFCC reference measurement procedure and provide a clear definition of the allowable total error of measurements.

(7) The IFCC WG-HbA_{1c} is willing to review the proposed manufacturer's traceability chain. This does not mean that the IFCC WG will function in any regulatory role. The WG-HbA_{1c} can, however, provide an expert scientific opinion about the suitability of a manufacturer's proposed HbA_{1c} traceability chain and offer some metrological advice and guidance if appropriate.

The minutes for this meeting can be viewed and downloaded at the IFCC Web site: http://www.ifcc.org/Report%20of%20HbA1c_Meeting.pdf. A list of persons who attended this meeting is available online at www.ifcc.org.

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Increased Reporting of Estimated Glomerular Filtration Rate and Call for Improved Creatinine Traceability

Healthcare professionals have been asked to facilitate reporting of estimated glomerular filtration rate (eGFR) by all hospital and commercial laboratories in the US. A letter signed by leaders of the AACC, the