Long-term controversies regarding hemoglobin A1c (HbA1c) standardization seem to have finally reached global consensus. Hemoglobin A1c, an integrated measure of glycemic control, has been widely used as a ‘gold standard’ in the management of diabetes mellitus for decades (1). However, standardization of the ‘gold standard’ has been very difficult to achieve, due to so far unprecedented conflict between the analytical and clinical standardization concepts.

Ever since the results of the Diabetes Control and Complication Trial (DCCT) showed positive relationship between the degree of glycemic control (assessed as HbA1c) and risk for the development of diabetic complications, the goal for successful diabetes treatment has been anchored to the HbA1c level <7% (2). However, the ‘magic’ <7% has been set by using highly reproducible, but non-specific HPLC method for HbA1c measurement. Based on the DCCT method, the National Glycohemoglobin Standardization Program (NGSP) has been designed to harmonize the results from all methods to DCCT-traceable results. Thus, clinical harmonization has been achieved and all the results obtained by the NGSP-traceable methods could easily be compared to the globally accepted goals of the fair glycemic control (3).

In the meantime, the International Federation of Clinical Chemistry (IFCC) managed to develop the primary reference standard and reference method, which have been accepted as the only valid anchor to calibrate HbA1c methods worldwide (4). However, due to its specificity, the IFCC reference method managed to produce significantly lower HbA1c results than the DCCT-HPLC method. It was found to be unacceptable for the medical diabetology community, mostly because of the evidenced concern that lowering the HbA1c range and consequently glycemic goals could seriously compromise the degree of patient compliance and finally lead to worsening of glycemic control (5).

In order to overcome this problem, IFCC proposed to switch reporting units from conventional % to the SI units (mmol/mol), which finally resulted in the 2010 Consensus Statement on the Worldwide Standardization of the Hemoglobin A1c Measurement (6). The consensus was agreed between the American Diabetes Association (ADA), European Association for the Study of Diabetes (EASD), International Diabetes Federation (IDF), IFCC and International...
Society for Pediatric and Adolescent Diabetes (ISPAD) during the IDF World Diabetes Congress in Montreal, Canada, October 2009.

The Consensus Statement implicates global standardization of HbA1c according to the IFCC reference system and proposes dual system of HbA1c reporting by clinical laboratories worldwide: SI (mmol/mol, no decimals) and conventional (% NGSP-derived, one decimal). Conversion between units should be done by using IFCC-NGSP master-equation, and conversion tables should be available to the medical and lay parts of diabetic community. The reportable term is HbA1c. As regards publishing, there is strong recommendation to the editors of medical journals to require dual system of reporting in all manuscripts reporting HbA1c results.

The consensus should be implemented as soon as possible worldwide, with concerted efforts of laboratory and medical professionals in transferring all necessary information both horizontally and vertically in diabetes community. Further steps in global standardization of HbA1c shall be proposed on the next consensus meeting at the IDF World Diabetes Congress in Dubai, December 2011.

The implementation of the global consensus in Croatia is planned as a 4-step process:

1. Croatian Chamber of Medical Biochemists has announced on its web-pages activities regarding consensus implementation, together with translated consensus summary (October 2010).

2. Croatian Society of Medical Biochemistry as the national EQAS organizer has prepared necessary modifications in the HbA1c part of the scheme, which shall be executed with the 3rd annual EQA cycle in November 2010. Briefly, all participants shall be asked to provide results expressed in dual reporting system, and make all the necessary arrangements for the routine consensus implementation (November 2010). It should be mentioned that consensus implementation requires only a mathematical operation, which can easily be applied in LIS, and no additional expenses to HbA1c testing are to be expected. Reagent manufacturers have already prepared all the necessary NGSP conversion formula details.

3. Dual reporting of HbA1c results from all laboratories in Croatia should be operative as of January 1, 2011. Croatian Chamber of Medical Biochemists shall prepare a letter of information, addressed to all relevant partners in the diabetes community (January 2011).

4. A special report covering this issue will be published in relevant scientific journals: Biochemia Medica, Diabetologia Croatica, and a translated version in Liječnički vjesnik.

We hope that this process will ensure necessary conditions for successful implementation of the global consensus to the Croatian medical and laboratory community involved in diabetes care. Considering the rising prevalence of diabetes mellitus in Croatia (7), compliance with the global consensus not only provides harmonization of HbA1c reporting, but also ensures continuity of implementation of the highest standards of medical care for diabetic patients in Croatia.
REFERENCES


