On September 2007 a consensus document was published, by the American Diabetes Association (ADA), the International Diabetes Federation (IDF), the European Association for the Study of Diabetes (EASD) and the International Federation of Clinical Chemistry (IFCC) where the different points of accordance are gathered about the global standardization and the issuance of analytic results of the HbA₁c. Among other measures, it was agreed to use the method proposed by the IFCC to calibrate the different techniques of determination of HbA₁c, as well as to issue the results of the HbA₁c in traceable units of the DCCT study (NGSP [%] and in IFCC units (mmol/mol).

With this background, the Spanish Diabetes Society (SED), and the Spanish Society for Clinical Biochemistry and Molecular Pathology (SEQC), took the initiative of organizing a symposium that allowed, together with the companies of in vitro diagnostic, to recommend a series of actions which where presented at a later time to the “Commission of Strategies in Diabetes of the National Health System of the Department of Health and Consumption”, to the Health Local Ministry of the Autonomous Communities and to the board of Directors of the Scientific Associations’, specialized magazines, etc., with the purpose of reaching the best diffusion possible for the consensus. The afore mentioned symposium was celebrated in Seville the 6th and 7th, of November of the year 2008, and it counted with representatives of the main institutions and national scientific associations for the study of diabetes (table 1). It is the second strategy in a European level for the harmonization of the HbA₁c results, only preceded by the one that took place in the United Kingdom in January 2008, in which similar proposals to those presented here were made. Other European countries will hold meetings with the same objective in the following months.

List of acronyms quoted in the text:

ADA: American Diabetes Association; ADAG: A₁c – Derived Average Glucose; EASD: European Association for the Study of Diabetes; HbA_{1c}: harmonization of HbA_{1c}; estimated average glucose; IDE: International Diabetes Federation; IFCC: International Federation of Clinical Chemistry and Laboratory Medicine; JDS/JSCC: Japanese Diabetes Society/ Japanese Society for Clinical Chemistry; NGSP: National Glycohemoglobin Standardization Program; SED: Spanish Diabetes Society; SESC: Spanish Society for Clinical Biochemistry and Molecular Pathology; UKPDS: United Kingdom Diabetes Prospective Study
In the year 2002, 70% of the results of HbA1c published in our country were expressed in JDS/JSCC (Japan) units and 30% in DCCT/NGSP (United States) units. The number of systems which give the results in NGSP units has increased progressively, with a value somewhat superior to 50% at present, in detriment to the number of reports using JDS/ JSCC units.

The main clinical guidelines for the control of the diabetic patient are based in the recommendations of the results obtained through the DCCT and UKPDS studies, due to that reason it is important to use units which are equivalent to these studies and, therefore, to these clinical guidelines. Furthermore, experiences like the one of the United States show us that it is possible to reach a global harmonization of results in a term inferior to three years, in a way that most of the laboratories could give the results in DCCT/NGSP units with an error lower than 4%.

Due to the fact that all the harmonization results systems (JDS/JSCC, Mono-Sweden, NGSP) have proven their traceability and stability in respect to the method of reference of the IFCC, the conversion of DCCT/ NGSP units (%) it will be achieved through the equations which relate the different systems among themselves. Besides, following the international consensus, it is agreed to give the results in DCCT/NGSP (%) units and IFCC (mmol/mol) units.

Regarding to the inclusion of the estimated average glucose (eAG) in the control reports of the diabetic patient, it is estimated in spite of its possible potential to help the patients to improve the understanding of their disease, it is necessary to fulfill the results of the ADAG study with those of other studies that include pediatric population, elderly people, pregnant patients and other ethnics as well as the Caucasian, to be able to determine the utility in the clinical practice.

The first draft of the document was made by the organizing committee of the symposium and send to all institutions and scientific Associations, as well as companies of in vitro diagnostic. Observations with regard to this matter where received during the months of September and October, until a consensual text was presented in Seville on November 7th of 2008. The consensual points where the following:

The laboratories shall use traceable methods of reference of the IFCC.

1. Following the international advices, it is agreed to give the HbA1c results, in two types of units in a simultaneous way in all the laboratory reports:

2. The publications and clinical guidelines done from the date of the agreement will include both units in their texts.
3. The conversion of the units DCCT/NGSP (%) will be done through different conversion equations, using the informatic systems of each laboratory (annex).
4. The methods used shall have an error (coefficient of variation) lower than 4%; although the final objective shall be of obtaining an error lower than 2%.
5. In transitory situations, as is the case of the actual use of JDS/JSCC (%), it is recommended to inform, if it is considered necessary, during a transitory period of (12-24 months) as much as in JDS/JSCC (%) units as in NGSP/DCCT (%) units.
6. The associations that sign this document oblige themselves to carry out formation programs and the diffusion to its members.
7. The inclusion of the estimated average glucose (eAG) together with the glycemia and HbA1c in the reports about the glycemic condition does not have enough scientific evidence to allow its use in the clinic. More research is required in all groups of diabetic patients, including pediatric patients, elderly people, pregnant patients, as well as other Ethnical groups, to determine the real role that could be carried out in the clinical practice.

References

Annex
a. If one works with calibration JDS/JSCC (Japan): \( \text{NGSP} \% = 0.985 \times \text{JDS/JSCC} \% + 0.46 \)
b. If one works with calibration Mono-Sweden (Sweden): \( \text{NGSP} \% = 0.923 \times \text{Mono-Sweden} \% + 1.34 \)
c. If one works with calibration IFCC (%): \( \text{NGSP} \% = 0.915 \times \text{IFCC} \% + 2.15 \)
d. To calculate the equivalence of units IFCC (mmol/mol), on the basis of Units NGSP/DCCT (%): \( 11 \text{ IFCC} (\text{mmol/mol}) = (\text{NGSP} \% - 2.15/0.915) \times 10 \)