Standardised Advice

Relating to the Implementation of the IFCC, ADA, EASD and IDF Consensus Statement of on reporting of HbA_{1c}

From: the IFCC Working Group on Standardisation of HbA_{1c}

To: Clinical Biochemists, Diabetologists, EQA-organisers, Manufacturers of Diagnostic Devices, Editors of Journals and Scientists giving lectures

General Advice

- 1. The Consensus Statement of the IFCC, ADA, EASD and IDF forms the guideline for this advice.
- 2. The Working Group on Standardisation of HbA_{1c} (WG) has been tasked by the IFCC to guide the implementation of the Consensus Statement.
- 3. From discussions with interested parties we have identified that the changes manufacturers have to make to their systems create the bottle-neck. Therefore the proposed Transition Date is "1111": 1st January 2011.
- 4. From these discussions we also learned that the implementation of the Consensus Statement might differ from country to country due to national legislation and preferences. We strongly advice countries to organise a meeting of leading Clinical Biochemists, Diabetologists, EQA-organisers and Manufacturers to decide a uniformed approach on implementation at a national level.
- 5. As a guide to making decisions the WG offers the advice outlined below.
- 6. WG members are available to help, either by mail/phone or by attending such meetings at a national level.

Advice to Clinical Biochemists

- 1. Initiate a meeting of leading Clinical Biochemists, Diabetologists, EQA organiser(s), Manufacturers in your country to decide on the implementation of the Consensus Statement.
- 2. If possible, adopt the transition date of 1st January 2011 ("1111")
- 3. Decide if you will report HbA_{1c} in both units (mmol/mol or NGSP%) or in one unit (mmol/mol or NGSP%HbA1c).
- 4. If both numbers are to be reported, decide whether this will be permanent or temporarily.
- 5. Decide if eAG will be reported in your country; if yes will this be in mmol/L or in mg/dL.
- 6. If decisions are made, inform all Clinical Biochemists in your country and advice them to educate staff, inform Diabetologists and change documents in time for the implementation date.
- 7. Publicise this issue in e.g. your national journals, during meeting of your national society.
- 8. We would appreciate if keep IFCC WG informed of decisions made for your country. These decisions will be posted on the website of the IFCC WG (www.ifcchba1c.net)

Advice to Manufacturers

- 1. Participate in national meetings organized by Clinical Biochemists, Diabetologists, EQA organisers and Manufacturers.
- 2. Make sure that all new instruments in development for launch after 1st January 2011 are able to report HbA_{1c} in mmol/mol and %NGSP and eAG in mmol/L and mg/dL. The customer should have the option to switch off the number he does not want. In this way you are prepared for any situation.
- 3. Modify existing instruments in the same way. If this can not be done, provide the facility that the calculations can be made by the laboratory, either the LIS, a stand-alone PC or other way.
- 4. The basis for numbers to be reported is your traceability to the IFCC Reference Method, the Master Equation to derive the %NGSP (Ref...) and the eAG equations to derive eAG (Ref...)
- 5. Change your documentation in time for the implementation date.

Advice to EQA Organisers

- 1. Participate in national meetings organized by Clinical Biochemists, Diabetologists, EQA organisers and Manufacturers.
- 2. Start requesting results and reporting HbA_{1c} results in the correct units, according to the decisions you made in your country.
- 3. You might consider an educational role: start parallel reporting of HbA_{1c} in mmol/mol and eAG one or two years before the transition date.

Advice to Diabetologists

- 1. Participate in national meetings organized by Clinical Biochemists, Diabetologists, EQA organisers and Manufacturers.
- 2. Educate your staff and adjust documentation in time for the transition date.
- 3. Inform your patients of the implications of the change of numbers.

Advice to Journal Editors

- You play an important role in educating readers: start publishing HbA_{1c} in mmol/mol and %NGSP as well as eAG in mmol/mol and mg/dL starting from 1 January 2009. Ask of all authors to adopt these nomenclatures in their manuscripts.
- 2. You might think of an editorial which addresses the transition issue.

Advice to Lecturers

1. To all those who give lectures on HbA_{1c} : you play an important educational role: refer to HbA_{1c} in mmol/mol and %NGSP as well as to eAG in mmol/L and mg/dL in your lectures.