The Association for Clinical Biochemistry

Diabetes UK

PRESS RELEASE

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Standardisation of the reference method for the measurement of HbA1c to improve diabetes care

Strategy agreed for the worldwide standardisation of HbA1c measurements

An important blood test that is measured at least once a year in each of the UK's 2.5 million patients with diabetes is undergoing a major change. Because glucose levels can vary throughout the day, and from day-to-day a test called glycated haemoglobin (HbA1c) has been used to give an indication of how high a patient's glucose has been over the previous 6 to 8 weeks.

Worldwide standardisation of the reference method used to measure glycated Haemoglobin (HbA1c), the test used to assess long-term blood glucose level stability in people with diabetes, has been endorsed at a meeting of 18 expert bodies including leading health charity Diabetes UK and the Association for Clinical Biochemistry (ACB).

The meeting was convened by the Department of Health's National Director for Diabetes, to discuss a consensus paper recently published by the The International Federation of Clinical Chemistry (IFCC), American Diabetes Association and European Association for the Study of Diabetes. The IFCC put forward to the meeting its Reference Measurement method, which would, for the first time, allow healthcare professionals across the world to easily report HbA1c results uniformly.

As well as offering improved accuracy, the Reference Measurement method would make primary and secondary reference material available to manufacturers worldwide, meaning results could be accurately standardised in any lab measuring HbA1c across the world. Results would be delivered to patients in units of mmol/mol.

It was agreed unanimously at the meeting that the IFCC's Reference Measurement method would become the international standard for the reporting of HbA1c results. However, concerns were raised that the global standardisation process could be confusing for people with diabetes and in the short term have a detrimental effect on blood glucose control.

To avoid this, it was agreed that a dual reporting system would be introduced whereby HbA1c results would be given both in mmol/mol, as per the IFCC's method, and as a percentage, as currently used, until an extensive education programme for both patients and healthcare professionals had been carried out.

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Dr Garry John, Chairman of the IFCC Working Group for HbA1c Standardisation and a spokesperson for the Association for Clinical Biochemistry said: "Worldwide standardisation of the measurement of HbA1c would be enormously beneficial. In today's world of huge population mobility consistent international monitoring would ensure that all patients had optimal care."

Simon O'Neill, Director of Care, Information and Advocacy at Diabetes UK, added: "Diabetes UK is working with various bodies to look at the informational needs of people with diabetes and healthcare professionals to understand what the standardisation process will mean for them."

In addition, a third way of reporting HbA1c was introduced to the meeting. But concerns were raised across the board about the evidence supporting the accuracy and value of the estimated average glucose (eAG) reporting system.

"We have grave concerns about the research that has been done to back up the introduction of eAG, as there is not enough of it and it has largely been conducted on a white population," continued Mr O'Neill. "At this stage eAG would serve only to confuse people with diabetes which could be detrimental to their diabetes management and overall health."

Dr John concluded: "It was a concern of the professionals participating in the meeting that at this stage there is insufficient experimental evidence to support the introduction of eAG. We need further research especially in different ethnic populations, children and during pregnancy".

Note to editors

Summary Recommendations for the UK

- *HbA1c test results should be standardized using the new IFCC Reference Measurement procedure*
- *An extensive education programme should be developed urgently for all health care professionals and people with diabetes to help the understanding and interpretation of the new IFCC units. Provision of this programme will require considerable resource*
- *HbA1c results should be reported in both IFCC units (mmol/mol) and derived NGSP units (%) (synonymous with DCCT), using the IFCC-NGSP master equation for the time being*
- *There is currently insufficient experimental evidence to support the introduction of eAG*
- *Further research into the individual utility of eAG and of its use in all groups of individuals with diabetes is required in order to determine what role reporting of eAG has in clinical practice*

A copy of the report of the meeting on standardisation by Julian H Barth, Sally M Marshall and Ian D Watson, Association for Clinical Biochemistry is at: www.acb.org.uk.

More information

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To find out more about Diabetes UK or to arrange an interview with Simon O'Neill contact Sarah Milsom or Maria Lam in the Diabetes UK press office on 020 7424 1165 or e-mail sarah.milsom@diabetes.org.uk. Visit Diabetes UK at www.diabetes.org.uk.