Příloha č.1

TO:
IFCC National Society Presidents, IFCC Official Representatives

FROM:
John E. Sherwin, PhD, AACC President

DATE: June 28, 2006

SUBJECT: IFCC Standard on HbA1C

AACC recently voted against the proposed IFCC standard on HbA1c. Our official representative to IFCC, Mitchell Scott, PhD, copied other IFCC representatives on our letter. Because it is so unusual for AACC to vote against an IFCC standard, I wanted to write to you directly to add my comments so that the member countries of IFCC understand the reasons for our position.

We believe that the IFCC standard is scientifically sound. Our concern is about the context into which it is to be released. As noted in Dr. Scott's letter, the international diabetes community is deeply troubled by the IFCC standard. Several major groups, including the European Association for the Study of Diabetes (EASD), the American Diabetes Association (ADA), and the International Diabetes Federation (IDF), have asked IFCC to delay adoption of the standard until they have completed a major clinical trial evaluating the feasibility of reporting HbA1c as "mean blood glucose."

The major clinical groups believe that the standard poses "*a devastating blow to diabetes care world-wide.*" Their attached letter indicates that they have shared their concerns with representatives of IFCC many times over the last two years. As a long-standing member of IFCC, AACC believes that we should be working constructively and collaboratively with our clinical colleagues. We believe that it is inappropriate for IFCC to move ahead with this standard until the concerns of the clinicians have been addressed.

I urge you to become familiar with the views of the diabetes community in your own country and to advise IFCC whether the standard should be adopted and how it would affect clinicians and patients.

AACC is working with IFCC and the major diabetes groups to see if we can find a clear path forward—one that balances the scientific merits of the standard against the practical considerations of those involved in patient care. In our judgment, IFCC should take into consideration the impact of its recommendations at all levels, including scientific, clinical and patient outcome. All the members of IFCC share an interest in having it develop sound and successful standards that meet the needs of both the scientific and clinical communities.

JES: ed
cc: Jocelyn Hicks, PhD, Mauro Panteghini, MD

Professor Jocelyn M B Hicks, PhD, FACB, FRCPath
President, IFCC
4329 Van Ness St., NW
Washington, DC 20016-5625

Dear Dr. Hicks:

As you know the IFCC has developed a new reference method for the HBA1c (A1C) test. The values derived from this assay differ from those currently used in patient care. Over the last two years, there has been considerable discussion in the international diabetes community as to the best way to move forward with the new assay, yet not negatively impact the current value of the A1C test in assessing glycemic control and in setting treatment goals.

We believe it's important to be certain you appreciate the true impact of the current A1C test. First, it's only been about a decade that the world-wide clinical community has come to know (through many landmark clinical trials) the inordinate value of good glycemic control---which is to greatly reduce the incidence of diabetes complications. Second, all the trials used the A1C test to relate glycemic control to diabetes complications, and the direct relationship between these two variables has become a core principle in diabetes care. Third, all clinical guidelines promulgated by organizations and governments world-wide, use A1C values as the "goals for therapy". This facilitates everyone using the same test to establish treatment regimens and set clinical standards.

Last, it has taken a huge educational effort to get the A1C test and related goals for therapy ingrained in the minds of clinicians and patients. Most of the difficulty has been due to the fact that the name of the test has no clear relationship to diabetes (i.e. many people think it has something to do with anemia), and the values reported to physicians and patients (e.g. 6-12%) are completely unrelated to glucose values used to diagnose the disease and in patient self–management (e.g. 120-220 mg/dl). Even after years of widespread education, and many millions of dollars spent by the public sector and the medical industry promoting the concept of the A1C assay, the test and its results are still confusing—but clearly gaining acceptance.

With this background, we are now faced with the recent IFCC recommendation to change the name of the test, and create new units---both of which still have no clear relationship to blood glucose values. Such a change will simply create havoc for both clinicians and patients. At a time when the incidence and prevalence of diabetes is growing rapidly, at a time when we have finally linked the value of glucose control to this awkwardly named test with strange units—the proposed change will undermine and set-back clinical care for many years.

Our organizations are very mindful of the goals of the IFCC and the valuable work you do. To that end, knowing that some change in the assay was being discussed, representatives of our organizations met in-person and spoke with IFCC representatives many times in the last two years to work out a compromise. As a result of these discussions, it was agreed that our three organizations would do a multi-site (multi-nation) clinical study to evaluate the extent to which A1C values correlate with mean blood glucose (as determined by multiple finger-sticks and continuous blood glucose monitoring). If, as we expect, the two are linearly related, it will allow us to use the new IFCC reference method, but report out the results as "mean blood glucose" (in mg/dl or mmol/L). In that fashion, IFCC can implement the new reference method, but the clinical and patient community has a name and values that will be understood, appreciated, and finally relevant to clinical care.

With our plan in place and a multi-million dollar study recently begun, we now read that the joint IFCC Committee on Nomenclature, Properties and Units and the IUPAC Subcommittee on Nomenclature, Properties and Units, has put forth a new name and reporting units, which was adopted by your Scientific Division, and which is now out for membership vote. Passage of this recommendation will---to be very direct and clear---be a devastating blow to diabetes care world-wide. In addition, its sets an unfortunate tone of a sister specialty seeming to be unconcerned about the impact of their actions on patient care—if not patient lives.

By the signatures on this letter, please be assured that the world-wide medical community is speaking with one voice. We feel very strongly that the IFCC recommendation must be delayed until the outcome of our study is known. Even passage of the recommendation with a suggestion to "wait to implement"

will be very confusing to your constituency and manufacturers of equipment. How would implementation be controlled? If our clinical trial is successful, would it then require a vote to reverse a recent decision? Our study will almost certainly end in less than a year. If the study is successful, then we should adopt the name “mean blood glucose” and adopt its related units, while still using the new IFCC method for traceability and standardization.

This approach was viewed as a satisfactory compromise to IFCC’s original intentions; as an action consistent with the partnership we believe exists between laboratory and clinical medicine; and as an effort that fosters our mutual desire to take actions that can only improve the lives of humanity. Please help us fulfill these imperatives.

Sincerely,

Robert Rizza, MD, President, American Diabetes Association

Ele Ferrannini, MD, President, European Association for the Study of Diabetes

Pierre Lefebvre, MD, President, International Diabetes Federation

cc: IFCC Office
IFCC Executive Board
IFCC Member Organizations
Mauro Panteghini