

# Implementation of the International Standardisation of the HbA<sub>1c</sub> assay in Ireland

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## **HbA<sub>1c</sub> plays a pivotal role**

in assessing the effectiveness of  
diabetes care

and in the identification of those at  
greater risk of developing the  
complications of diabetes.



The Health Service Executive has assigned the task of leading the implementation of the international standardisation of the HbA<sub>1c</sub> assay in Ireland to its Diabetes Expert Advisory Group (Diabetes EAG).

The EAG has appointed a sub-committee to drive the project.



# Obligations arising from the Consensus Statement agreed by the ADA, EASD, IFCC and IDF

- “We agree that the HbA<sub>1c</sub> results should be standardised worldwide, including the reference system and results reporting.
- We agree that the IFCC reference system for HbA<sub>1c</sub> represents the only valid anchor to implement standardisation of the measurement.
- We agree that the HbA<sub>1c</sub> assay results be reported worldwide in IFCC units (mmol/mol) and derived NGSP units (%), using the IFCC-NGSP master equation.”



- 1) "All manufacturers should implement worldwide the traceability to the IFCC reference system for HbA<sub>1c</sub>. In the European Union (EU) the implementation of calibration traceability in laboratory medicine to higher-order standards is already mandatory. The EU directive 98/79/EC on in vitro diagnostic (IVD) medical devices explicitly requires manufacturers to ensure and document metrological traceability of their products.
- 2) The deadline for implementing traceability to the IFCC reference system is December 31st, 2009 for all the instruments in current use.
- 3) The name (abbreviation) of the test in the laboratory reports and in the clinical setting should be "HbA<sub>1c</sub>" (not "A1c")."

- 4) "All new instruments sold after January 1st, 2011 will report (as a result of an HbA<sub>1c</sub> test) both SI (mmol/mol – no decimals) and NGSP derived units (percentage – one decimal), in agreement with the Consensus Statement.
- 5) The implementation of HbA<sub>1c</sub> results in terms of eAG will be discussed after the "A1c-derived average glucose" (ADAG) results of the ongoing clinical trial are published. Participants, however, agree that it is not an issue for analytical systems but, e.g., for laboratory information system (LIS) vendors (in analogy with the NKDEP/IFCC recommendation for implementation of the GFR estimating equation)."

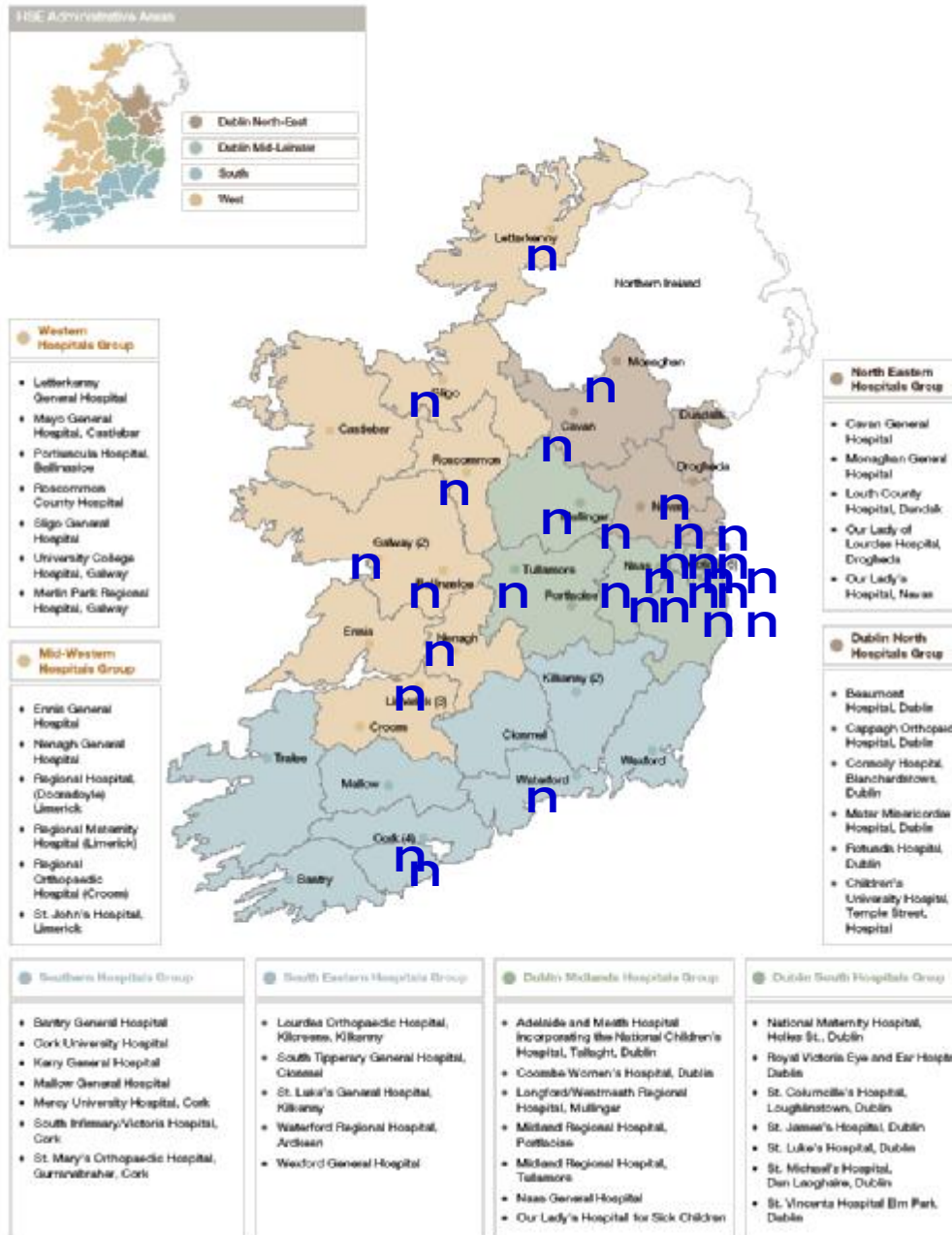
# Tasks (1)

- Identification of target groups for communication (laboratories, doctors, GPs, nurses, dietitians, people with diabetes, ICT personnel, etc);
- Selection of training modes and channels of communication (leaflets, websites, professional bodies, advertising, patient organisations, hospital diabetes clinics, primary care practices, pharmacies, etc.);
- Close liaison with the Irish External Quality Assessment Scheme for Laboratory Medicine (IEQAS; [www.ieqas.ie](http://www.ieqas.ie));

# Tasks (2)

- Liaison with Healthlink and the providers of software for primary care practices;
- Selection of a date for the commencement of dual reporting of IFCC and NGSP results nationwide;
- Identification of opportunities for promoting better diabetes control in all people with diabetes
- And other related tasks.

## Location of HSE's Four Administrative Areas and 50 Acute Care Hospitals

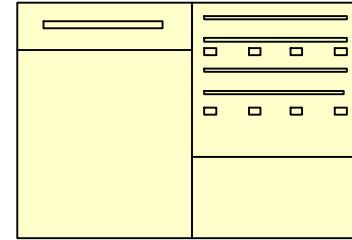


**The primary goal** is that the HbA<sub>1c</sub> assay in all Irish clinical laboratories will be fully metrologically traceable to the IFCC Standard so that the primary result (IFCC) will be reported in mmol/mol and that the DCCT-aligned secondary result, expressed as % and reported alongside it, will be derived from it using the IFCC/DCCT Master Equation.

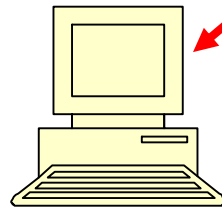
A number of **secondary goals** follow from this. These include the adoption of a national reference range for HbA<sub>1c</sub> and, perhaps later, the setting of standards of analytical performance and agreement on result turnaround times.

The means to achieve these goals will provide opportunities for the Expert Advisory Group to highlight the importance of good blood glucose control as evidenced by HbA<sub>1c</sub> results in the management of diabetes and to promote the *Standards of Care* published in its First Report.

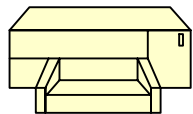
HbA<sub>1c</sub> analyser using manufacturer's calibrator and reagents: Calibrator value is fully traceable to the IFCC Primary Calibrator whose value has been assigned by the Primary Reference Measurement Procedure



The analyser reports the HbA<sub>1c</sub> (IFCC) result:  
HbA<sub>1c</sub> (IFCC) 53 mmol/mol



The LIS derives the HbA<sub>1c</sub> (NGSP/DCCT) value using the Master Equation:  
HbA<sub>1c</sub> (DCCT, derived) 7.0%



Patient Report	
HbA <sub>1c</sub> (IFCC)	53 mmol/mol (20 - 42)
HbA <sub>1c</sub> (DCCT, derived)	7.0 % (4.0 – 6.0)

# Project Schedule (1)

No.	Project deliverable	Start date	Finish date
1	Inform Directors of PCCC and NHO	April 2009	April 2009
2	Establish register of laboratories reporting HbA <sub>1c</sub> patient results	May 2009	May 2009
3	Meeting of laboratories to assess readiness	25 June 2009	25 June 2009
4	Appoint Project Manager (Loraine McGrattan) at HSE Head Office for the project	July 2009	Oct 2010
5	Inform DoH&C, IES, ICGP, DFI	July 2009	July 2009
6	Inform suppliers of HbA <sub>1c</sub> equipment and reagents	July 2009	July 2009

## Project Schedule (2)

No.	Project deliverable	Start date	Finish date
7	Inform HSE Procurement	July 2009	July 2009
8	Explanatory article for publication in <i>Diabetes Professional</i>	July 2009	July 2009
9	Decision on commencement date for dual reporting	Sept 2009	Oct 2009
10	Name to be used on reports for HbA <sub>1c</sub> (IFCC)	Sept 2009	Oct 2009
11	Format of HbA <sub>1c</sub> result number	August 2009	August 2009
12	Establish a register of HbA <sub>1c</sub> equipment in the point-of-care setting in clinics etc	Sept 2009	Nov 2009

## Project Schedule (3)

No.	Project deliverable	Start date	Finish date
13	Remind suppliers of traceability deadline	Oct 2009	Dec 2009
14	Notification of software providers to laboratories, GPs and Diabetes Centres and organisation of a meeting with them to assess their readiness	Sept 2009	Nov 2009
15	Decision on communication programme, form it will take, how it will be organised and funded	Sept 2009	Nov 2009
16	Identification of opportunities to promote better diabetes control in association with the communication programme	Sept 2009	Nov 2009
17	Adoption of national reference range for HbA <sub>1c</sub>	Aug 2009	Aug 2009

## Project Schedule (4)

No.	Project deliverable	Start date	Finish date
18	Demonstration of concordance of Irish laboratories with the IFCC Reference System in the months ahead of commencement of dual reporting	Jan 2010	Mar 2010
19	Public announcement of date for commencement of dual reporting (D-date)		
20	Go live with information and communication programme		
21	Meeting with representatives of all laboratories reporting HbA <sub>1c</sub> one month from commencement date for dual reporting		
22	Consideration of need for a free phone enquiry service for 1-2 weeks after commencement of dual reporting		

## Project Schedule (5)

No.	Project deliverable	Start date	Finish date
23	Go live with dual reporting	1st July 2010	
24	Continued surveillance		
25	Setting of assay performance criteria and expected turnaround times for HbA1c	Sept 2010	Oct 2010
26	Evaluation of clinical impact of the process undertaken		



Date for commencement of dual reporting:

**Thursday, 1<sup>st</sup> July 2010**

# HbA<sub>1c</sub> Reference Range

		HbA <sub>1c</sub>	
	Comment	NGSP (%)	IFCC mmol/mol
DCCT	Mean of non-diabetics + 2SD	<6.05	<42
Tietz (Fourth Edition)	DCCT	4.0-6.0	20-42
IFCC Reference Method paper	120 non-diabetic subjects (fasting plasma glucose <7.0 and 2 hour glucose during OGTT < 11.1, aged 35-55 years. No M/F difference noted.	4.8-5.6	29-38 (33.3±4.8; mean±2SD)


## National HbA<sub>1c</sub> Reference Range

HbA <sub>1c</sub> (IFCC)	20 – 42 mmol/mol
HbA <sub>1c</sub> (DCCT)	4.0 – 6.0 %



# Communication Plan

# Risk Management



“The medical laboratory provides the health services with results of examinations related to healthy and diseased persons, describing their physiological or pathological state. Many of these examinations are measurements of quantities expressed in terms of measurement units.”

**ISO TC 212, (2009)**

“The quantity intended to be measured (i.e. the measurand) should be defined in terms of


- relevant system, usually a part of the human body, e.g. plasma or urine;
- pertinent component (analyte), e.g. glucose; and
- kind-of-quantity, e.g. amount-of-substance concentration.”

ISO TC 212, (2009)

“Then, a measurement procedure and a measuring system should be selected and validated so as to produce quantity values that are

- metrologically traceable to a measurement unit, sometimes with the proviso that a specified measurement procedure and/or calibrator has to be used;
- reliable estimates of the measurand; and
- comparable with other quantity values of the same type measured in the same or different laboratories at different times in the same or other persons, or with chosen comparison values, such as biological reference intervals or decision limits.”

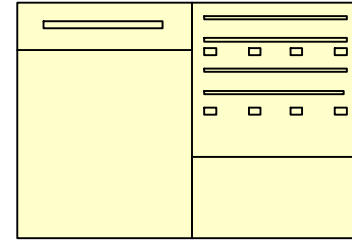
**ISO TC 212, (2009)**



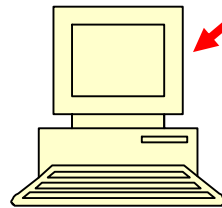
“These three requirements are interrelated and all necessitate the calculation of a measurement uncertainty characterizing the dispersion of values that are being attributed to each measurand.”

ISO TC 212, (2009)

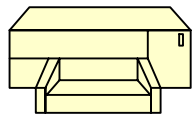
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