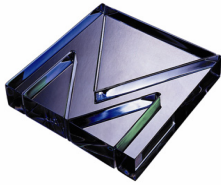


# Understanding the New IFCC HbA1c Numbers

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Ref: 3984

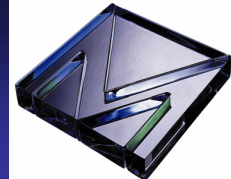




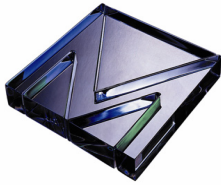
# Training outcomes

- Clear understanding of HbA1c
- Clear understanding of the new values for reporting HbA1c and what they mean
- Clear understanding of what is going to happen and what to do

# Agenda



- Introduction
- What is HbA1c?
  - What period is measured?
- Why is HbA1c important?
- Current reporting of HbA1c
- New standardisation of HbA1c
- How to read the new values and compare them with the old
- UK Consensus and plan
- Questions



# Menarini's Background in HbA1c

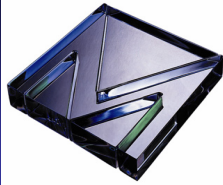


# Menarini's Background in HbA1c

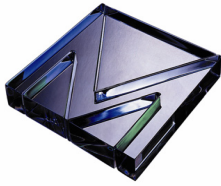


- 21 Years as market leader in the UK
- First Automated HbA1c system in the (1987)
- Most accurate and precise HbA1c systems on all external quality assurance schemes
- Nearly 60% of all HbA1cs in the UK are performed on Menarini systems
- More than **1 million people** in the UK rely on Menarini HbA1c tests **every year**

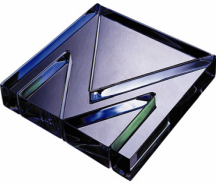
# Understanding the New IFCC HbA1c Numbers



**This presentation has been reviewed for scientific accuracy by Dr Garry John, Consultant Clinical Biochemist, Chair of the IFCC Working Group on HbA1c Standardisation.**

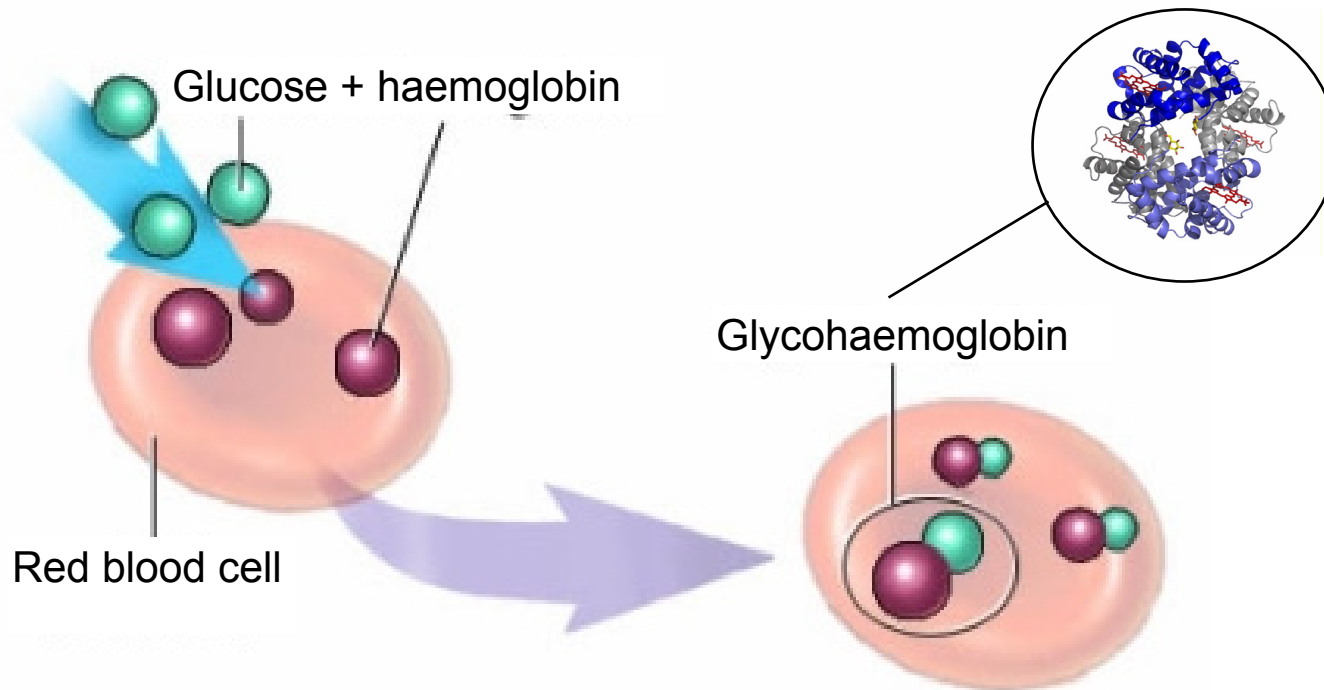


# What is HbA1c?

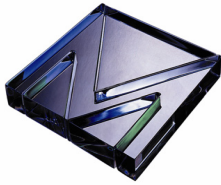


# What is HbA1c

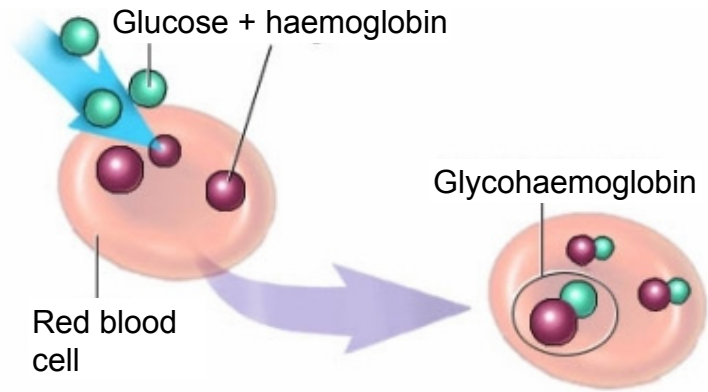
**HbA1c is simply haemoglobin to which circulating glucose has bound**



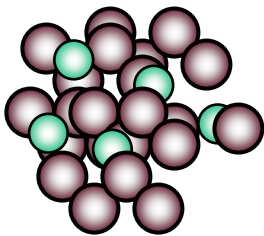




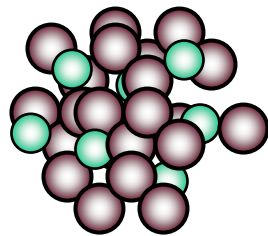
# HbA1c is Glycosylated Haemoglobin



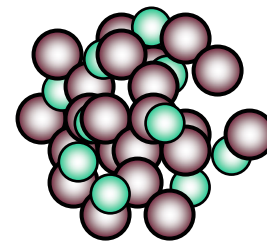
The HbA1c test reports the amount of HbA1c as a proportion of the total haemoglobin



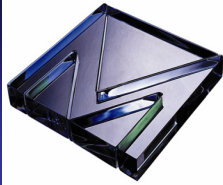
**7%**



**9%**



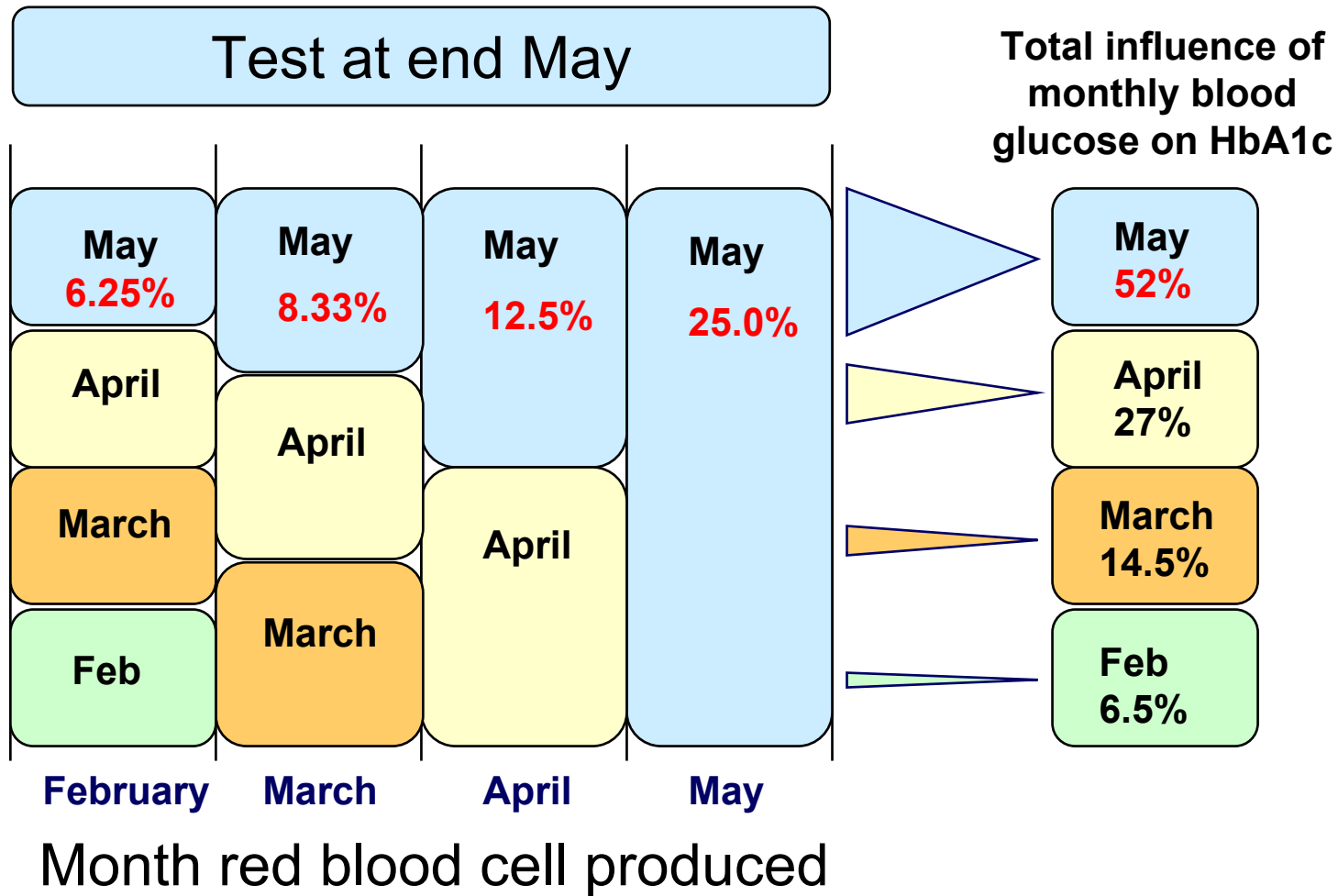
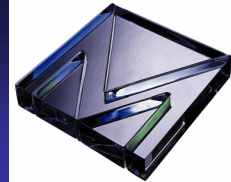
**14%**

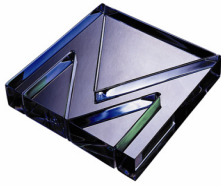


What period does HbA1c  
measure?



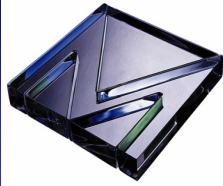
# What period is measured?





# Why is HbA1c so important?

# Why is HbA1c so important?



DCCT showed that HbA1c is the best long-term marker of diabetes control

**HbA<sub>1c</sub>**

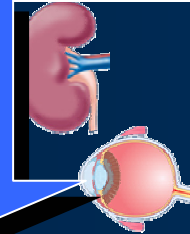
**1%**

**21%**



**Deaths related to diabetes**

**37%**



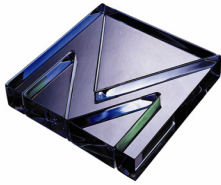
**Microvascular complications**

**14%**



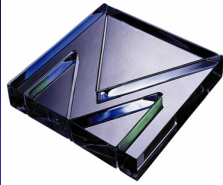
**Myocardial infarction**

Better control of HbA1c leads to better outcomes in people with diabetes



# What is DCCT Alignment of HbA1c?

# What is DCCT Alignment?



- The DCCT is the largest and most significant study into the long term control of diabetes and outcomes in type 1 diabetes
- The UKPDS is the equivalent landmark study into type 2 diabetes, and uses the same reference system for HbA1c
- All UK labs standardise their activities so that results are aligned to DCCT
- This means that data from DCCT, UKPDS and other long term studies are cross-compatible, and the patient's risk of complications can be inferred from their results.

## NICE AND DIABETES:

A summary of relevant guidelines

## CG015 – July 2004

### Diagnosis and management of Type 1 diabetes in children, young people and adults

#### Blood glucose control

Blood glucose control should be optimised towards attaining DCCT-harmonised HbA1c targets for prevention of microvascular disease (less than 7.5%) and, in those at increased risk, arterial disease (less than or equal to 6.5%) as appropriate.

## Guideline G – September 2002

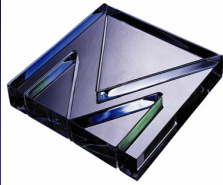
### Management of Type 2 diabetes – Managing blood glucose levels

#### Targets

For each individual a target HbA1c should be set between 6.5% and 7.5%, based on the risk of macrovascular and microvascular complications.



# DCCT Aligned Targets



Targets based on DCCT / UKPDS findings:

NICE

6.5 to 7.5%

NICE

<6.5%

Increased risk of arterial disease

IDF

< 6.5%

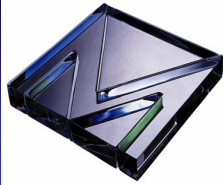
QOF

85% < 10%

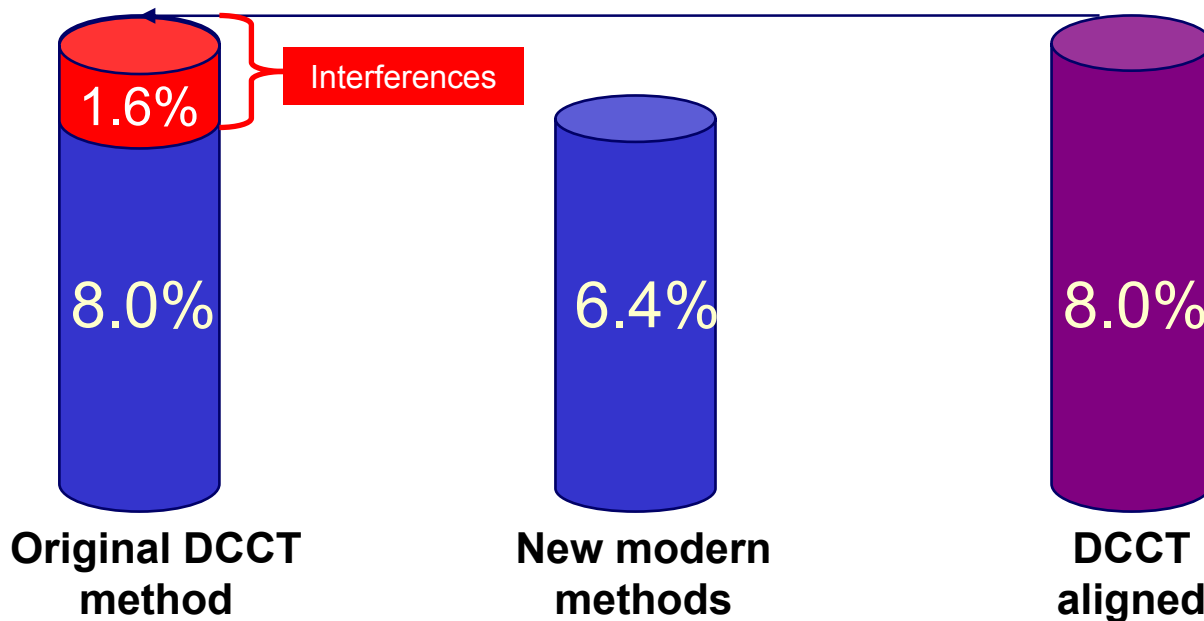
50% < 7.4%



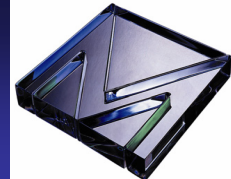
# Why change from DCCT Alignment?



- Since the DCCT, the method used then for measuring HbA1c has been found to have interferences causing a falsely high number.
- Test results from newer methods can report the accurate value without interferences but have always been adjusted to give results aligned to the old DCCT method.



- Scientists and clinicians have agreed that it is no longer tenable to report results which they know to be falsely elevated

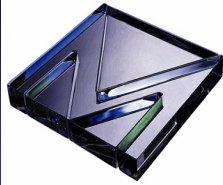


# What will replace DCCT alignment?

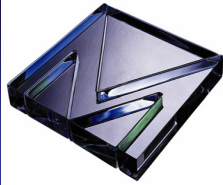


*International Federation of  
Clinical Chemistry and  
Laboratory Medicine*

# IFCC Calibration

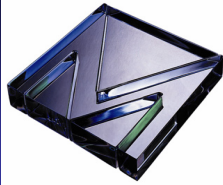


- Scientists and clinicians have been working for more than 10 years to produce a gold-standard, interference free method for HbA1c
- The new calibration method, without interferences, gives values approximately 1.5% lower than the DCCT values
- Unfortunately the two numbers are still similar enough in appearance to cause confusion, so a decision has been taken to change the units of reporting the new values in order to avoid any problems
- The new 'IFCC standardised' results will be written in units of mmol/mol



**What is the relationship  
between IFCC and DCCT?**

# What is the relationship?



- For example

DCCT HbA1c  
8.0%

=

IFCC HbA1c  
6.4%

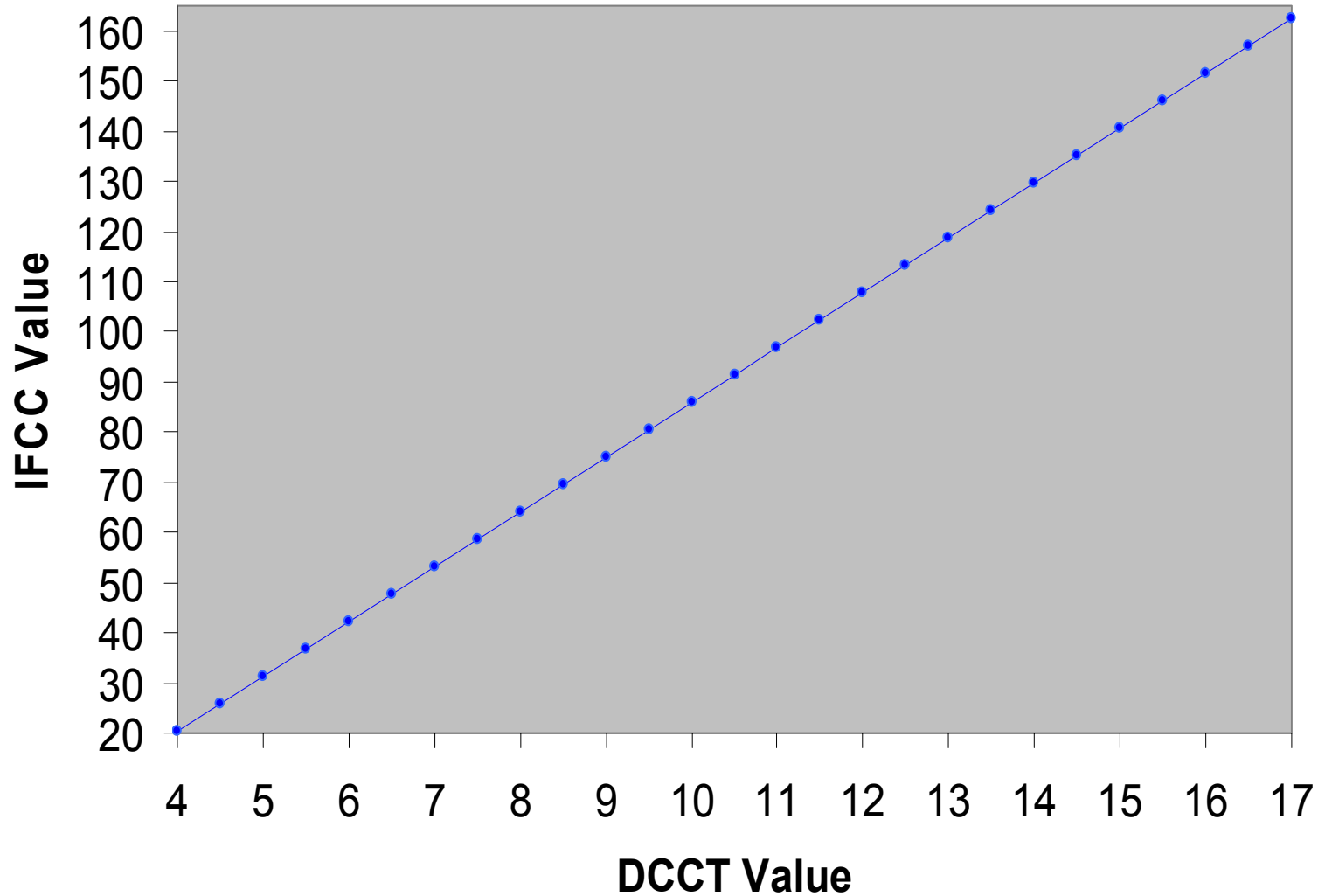
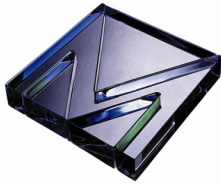
- So to help avoid confusion IFCC HbA1c will be reported as mmol/mol rather than %

DCCT HbA1c  
8.0%

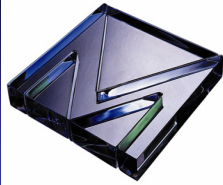
=

IFCC HbA1c  
64mmol/mol

# Conversion Graph DCCT to IFCC



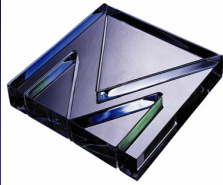
# Conversion table DCCT to IFCC



DCCT % HbA1c	IFCC mmol/mol HbA1c
4	20
4.5	26
5	31
5.5	37
6	42
6.5	48
7	53
7.5	58
8	64
8.5	69
9	75
9.5	80
10	86
10.5	91
11	97
11.5	102
12	108
12.5	113
13	119
13.5	124
14	130
14.5	135
15	140
15.5	146
16	151
16.5	157
17	162

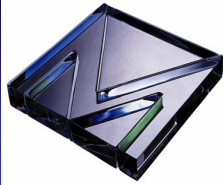


# Key treatment targets - NICE



DCCT %HbA1c	IFCC mmol/mol HbA1c
6	42
6.5	48
7	53
7.5	58
8	64
8.5	69
9	75
9.5	80
10	86

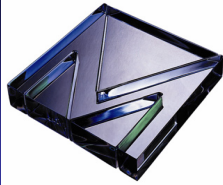
# Key treatment targets - IDF



DCCT %HbA1c	IFCC mmol/mol HbA1c
6	42
6.5	48
7	53
7.5	58
8	64
8.5	69
9	75
9.5	80
10	86

# Key treatment targets - QOF

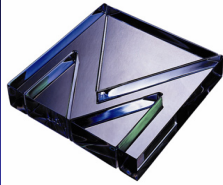
until 31st March 2009



	DCCT %HbA1c	IFCC mmol/mol HbA1c	
	6	42	
	6.5	48	
	7	53	
50%	7.4	57	17pts
	8	64	
	8.5	69	
	9	75	
	9.5	80	
85%	10	86	11pts

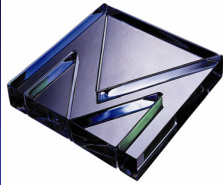
# Key treatment targets - QOF

From 1st April 2009



	DCCT %HbA1c	IFCC mmol/mol HbA1c	
	6	42	
	6.5	48	
50%	<b>7</b>	<b>53</b>	17pts
	7.4	57	
70%	<b>8</b>	<b>64</b>	8pts
	8.5	69	
90%	<b>9</b>	<b>75</b>	10pts
	9.5	80	
	10	86	

# Converting DCCT to IFCC - A quick trick



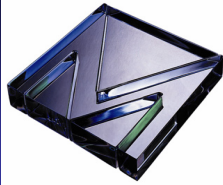
For whole numbers between 4 and 13

Minus two, minus two...

$$7\% = 53 \text{ mmol/mol}$$

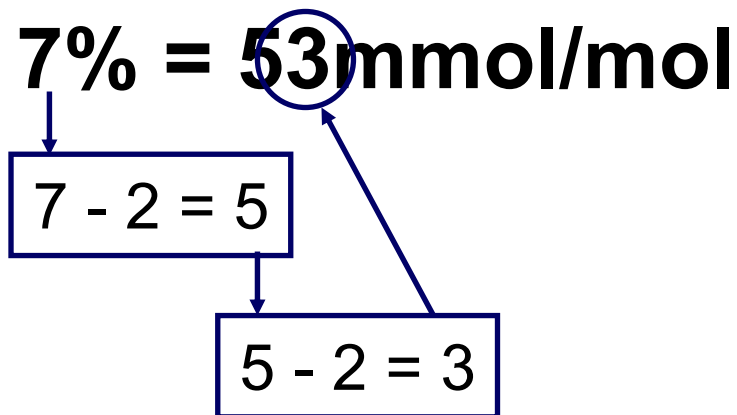
$$7 - 2 = 5$$

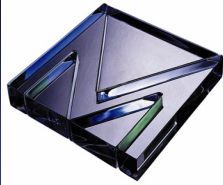
# Converting DCCT to IFCC - A quick trick



For whole numbers between 4 and 13

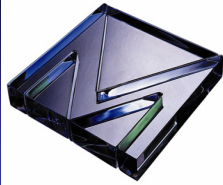
Minus two, minus two...





# What has been agreed?

# What has been agreed globally?



- Worldwide Consensus Statement published at the end of 2007

Diabetologia (2007) 50:2042–2043  
DOI 10.1007/s00125-007-0789-7

## CONSENSUS STATEMENT

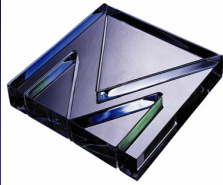
### **Consensus statement on the worldwide standardisation of the HbA<sub>1c</sub> measurement**

**The American Diabetes Association, European Association for the Study of Diabetes, International Federation of Clinical Chemistry and Laboratory Medicine, and the International Diabetes Federation**

Consensus Committee



# What has been agreed UK?



- UK Consensus Statement published July 2008

## ***Consensus Report***

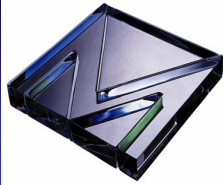
**Consensus meeting on reporting glycated haemoglobin and estimated average glucose in the UK: report to the National Director for Diabetes, Department of Health**

**Julian H Barth<sup>1</sup>, Sally M Marshall<sup>2</sup> and Ian D Watson<sup>1</sup>**

<sup>1</sup>Association for Clinical Biochemistry; <sup>2</sup>School of Clinical Medical Sciences, University of Newcastle-upon-Tyne Medical School, UK

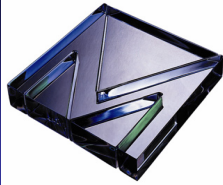
*Ann Clin Biochem* 2008; 45: 343–344. DOI: 10.1258/acb.2008.200815

# UK Consensus Statement Summary



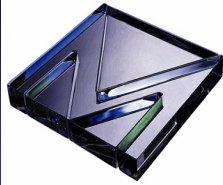
- HbA1c test results should be standardised using the IFCC reference method (already completed by manufacturers)
- Extensive education programmes should be developed for all healthcare professionals
- HbA1c results should be reported in IFCC (mmol/mol) units and DCCT (%) units
- Parallel reporting will start from June 2009 and continue for 2 years
- After this time it is envisaged that laboratories will report only IFCC units

# What happens now?



- From January of 2009 some UK labs have started producing reports with both DCCT % and IFCC mmol/mol values
- Primary Care reporting systems already have the facility to accept DCCT aligned results
- Software releases on 1st April 2009 will allow the incorporation of the new IFCC aligned results into patient records

# Reporting Formats

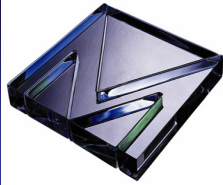


This is the format which will appear in primary care reporting systems

HbA1c level = 8.0% (DCCT aligned)

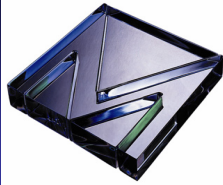
HbA1c level = 64 mmol/mol (IFCC aligned)

Internal hospital reports and results printed directly from HbA1c analysers may appear in a slightly different format

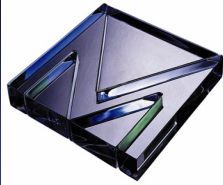


# Summary and conclusion

# Summary and Conclusion

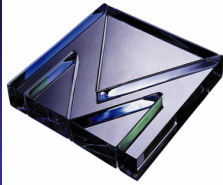


- The appearance of HbA1c results is going to change
- The new values will look very different but can easily be compared to the familiar ones
- You will see the changes in the next few months
- You have two years to get used to the new values (Dual reporting)
  - for treatment targets
  - for interpretation of results
- Questions?



# Training outcomes

- Clear understanding of HbA1c
- Clear understanding of the new values for reporting HbA1c and what they mean
- Clear understanding of what is going to happen and what to do



# Understanding the New IFCC HbA1c Numbers

RCN Accredited Training  
Ref: 3984

