Minimum Analytical Performance Standards (MAPS)

Pilot

Background

Within the UK there is a well established EQA system, with surveillance of laboratory performance through National QA Advisory Panels, and ultimately the Joint Working Group of the College.

The chemistry schemes encompass by far the largest number of individual tests, predominantly assessed by quantitative assessment.

Performance has historically been assessed by comparison with peers using the same analytical system, and poor performance is defined as falling outside set criteria, usually based on statistical analysis of the comparator group.

There are a number of drivers which should tell us that this approach is now not the most appropriate. The move to having evidence-based guidelines for identification and treatment of patients requires a degree of commutability of results produced by laboratories for their application to be truly effective. The aim of MAPS is to underpin effective, safe patient care, and to enhance the EQA schemes.

Additionally. movement of patients and cross-boundary flows also indicate that to enhance the quality of patient care, wherever possible we should aim to produce comparable results.

MAPS will not result in a change as to how EQA samples are distributed, or results reported back to the Scheme Organisers. Where it will start to impact is on how performance is assessed. The current hierarchy of involvement when poor performance is demonstrated will remain. It is purely that the criteria applied will over time shift to having a more clinical basis rather than a purely statistical one.

Objectives

In order to move towards these goals, support was sought and gained from the key professional bodies; The College of Pathologists, ACB, ACP and IBMS, to pilot the production of MAPS for five key tests that can have a significant impact on patient care.

The tests are;

Total Cholesterol
HDL-Cholesterol
Glucose
HbA1c
Creatinine

All the MAPS for these tests relate to analyses performed in blood derived matrices, rather than other body fluids in analytical laboratories. They are also not an attempt at present to define MAPS for Point of Care instruments.

Together with representatives of two of the major EQA schemes (to provide supporting data), the Panel recently met to consider what MAPS might look like in this context, and this document is the product of that meeting.

Defining MAPS

Appendices accompanying this brief document give more detail on individual tests, but we have for this pilot applied certain unifying principles.

Our starting point is that Biological Variability Data (BVD), collated by Dr Carmen Ricos and her team, which is updated on a regular basis and easily accessible via http://www.westgard.com/biodatabase1.htm should form the basis for defining MAPS. This database has been revised this year [2010]

We recognise that for some tests, the desired performance is readily achievable and we have seen no need to modify the specifications for Bias, Variability or Total Error.

For other tests, the desired performance is either not possible given current available systems, or the heterogeneity of results produced, For these, MAPS are proposed which we believe will achieve a convergence of results.

For each test, we have defined a standard against which bias is assessed, a critical value at which the MAPS should be assessed, and provide values for Bias, Imprecision and Total Error.

EQA schemes will be able to assess Bias and Total Error, the imprecision value is more a guide for evaluating internal QC performance.

In brief, the proposed MAPS are;

	Concentration	Allowable Bias	Allowable variability	Allowable Total Error
Total Cholesterol	5.0 mmol/L [Desirable[1]]	4.00%	2.70%	8.50%
HDL-Cholesterol	1.0 mmol/L [Desirable[1]]	5.20%	3.60%	11.10%
	1.0 mmol/L [Achievable]	10.00%	3.60%	15.90%
Glucose	7.0 mmol/L [Desirable[1]]	2.20%	2.90%	6.90%
	2.0 mmol/L [Achievable]	+/- 10% absolute		
HbA1c	50 mmol/mol [Desirable[1]]	2.2%*	2.5%*	6.3%*
	50 mmol/mol [Achievable]	3.60%	2.50%	7.70%
Creatinine	75 umol/L [Desirable[1]]	3.80%	2.70%	8.20%
	75 umol/L [Achievable]	5.00%	2.70%	9.50%

1 - http://www.westgard.com/biodatabase1.htm

* - Values converted to reflect performance when measured as IFCC values. See attached document [Appendix 3] to explain necessity and why values not directly transferable.

In the more detailed Appendices, the MAPS have a common format, being composed of six brief sections;

Test Name - [taken from the National Laboratory Medicine Catalogue] together with other common names which might be used

Standard Options – method used to produce the defined value against which all results are evaluated

Critical Level for Performance – where one exists it is defined here

Performance Criteria – Values for Bias, Imprecision and Total Error are given. The "desirable" values are those for which BVD exists, and should be viewed as the performance that is ultimately desired as a minimum. A second set of values may also be quoted - "achievable". These values are proposed as a possible stepping stone towards the "desirable" values, and are potentially achievable.

Additional Considerations – allows comments e.g. to explain some aspects that might not be clear on first reading.

References -

Implementation of MAPS in EQA

Nothing will be changing overnight, but EQA providers will start to feedback as to performance against MAPS as soon as their reporting systems are able to reflect this. With the defined MAPS, new performance criteria will be developed, informed by experience over the next few months, following which, the normal Panel reporting mechanisms will include MAPS criteria in approximately 12 months time.

A more detailed timetable will be available in September and will be presented at the Consensus meeting.

User Involvement

The Panel is keen to receive feedback from any laboratory based professionals on the proposed MAPS. We will try to take into account all comments received before **MONDAY 6th SEPTEMBER**.

Comments should be emailed to the Chair of the Panel – Dr David James, at;

nqaapcp@tst.nhs.uk

Please keep comments as brief and as succinct as possible.

All comments will be collated for inclusion/discussion at the Consensus Meeting.

If you intend to attend the meeting on 15th September, please feedback your comments as if you were not attending.

Appendix 1 - Test specific MAPS

MAPS Cholesterol

Test Name;

Test Name – Cholesterol level	NLMC1389

Alternative Names

Total Cholesterol	
Serum Cholesterol	

Standard options

1	CDC-Validated
2	
3	

Critical level for performance

Yes/No

If Yes, define suggested concentration;

1	5.0 mmol/L
2	
3	

Performance criteria

Concentration	Allowable Bias	Allowable variability	Allowable Total Error
5.0mmol/L [Desirable[1]]	4.0%	2.7%	8.5%

Additional considerations;

CDC-Validated - The reference point that performance will be evaluated against will be the CDC calibrated value, anchored by ID-GCMS evaluation

References

1 - http://www.westgard.com/biodatabase1.htm

MAPS HDL-Cholesterol

Test Name;

Test Name - High density lipoprotein (HDL) cholesterol level	NLMC0982

Alternative Names

HDL-cholesterol level	

Standard options

1	CDC-Validated
2	
3	

Critical level for performance

Yes/No

If Yes, define suggested concentration;

1	1.0 mmol/L
2	
3	

Performance criteria

Concentration	Allowable Bias	Allowable variability	Allowable Total Error
1.0mmol/L [Desirable[1]]	5.2%	3.6%	11.1%
1.0mmol/L [Achievable]	10.0%	3.6%	15.9%

Additional considerations;

It is recognised that HDL-cholesterol is a heterogeneous analyte in terms of one step measurement. For this reason, the allowable bias has been increased. This will allow a degree of commutabilty for results between laboratories, and as techniques improve it is hoped that the MAPS can move toward the desirable parameters.

It should be noted that as with total cholesterol, the reported result may be influenced by the accompanying triglyceride concentration.

Total allowable error has been calculated [2] as TE = (1.65 * imprecision) + inaccuracy

References

1. http://www.westgard.com/biodatabase1.htm

2. Hyltoft Petersen P, Ricos C, Stockl D, Libeer JC, Baadenhuijsen H, Fraser C, Thienpont L. "Proposed guidelines for the internal quality control of analytical results in the medical laboratory." Eur J Clin Chem Clin Biochem 1996;34:983-999

MAPS Glucose

Test Name;

Test Name – Glucose level	NLMC0876

Alternative Names

Standard options

1	ID-GCMS
2	
3	

Critical level for performance

Yes/No

If Yes, define suggested concentration;

1	7.0 mmol/L
2	2.0 mmol/L
3	

Performance criteria

Concentration	Allowable Bias	Allowable variability	Allowable Total Error
7.0 mmol/L [Desirable[1]]	2.2%	2.9%	6.9%
2.0 mmol/L [Achievable]	+/- 10% absolute		

Additional considerations;

As concentration of glucose falls below 4.0 mmol/L, the ability of current systems to meet desirable specifications fails. An absolute requirement to be within +/- 10% of target value at 2.0 mmol/L is proposed.

References

1 - http://www.westgard.com/biodatabase1.htm

MAPS HbA1c

Test Name;

Test Name – HbA1c level	NLMC5563

Alternative Names

GHB	

Standard options

1	IFCC
2	
3	

Critical level for performance

Yes/No

If Yes, define suggested concentration;

1	50 mmol/mol
2	
3	

Performance criteria

Concentration	Allowable Bias	Allowable variability	Allowable Total Error
50mmol/molL [Desirable[1]]	2.2%*	2.5%*	6.3%*
50mmol/mol [Achievable]	3.6%	2.5%	7.7%

Additional considerations;

*Values converted to reflect performance when measured as IFCC values. See attached document [Appendix 3] to explain necessity and why values not directly transferable.

Total allowable error has been calculated [2] as TE = (1.65 * imprecision) + inaccuracy.

References

1. http://www.westgard.com/biodatabase1.htm

2. Hyltoft Petersen P, Ricos C, Stockl D, Libeer JC, Baadenhuijsen H, Fraser C, Thienpont L. "Proposed guidelines for the internal quality control of analytical results in the medical laboratory." Eur J Clin Chem Clin Biochem 1996;34:983-999

MAPS Creatinine

Test Name;

Test Name – Creatinine level	NLMC0874

Alternative Names

Standard options

1	ID-GCMS
2	Validated enzymatic
3	

Critical level for performance

Yes/No

If Yes, define suggested concentration;

1	75 umol/L
2	
3	

Performance criteria

Concentration	Allowable Bias	Allowable variability	Allowable Total Error
75 umol/L [Desirable[1]]	3.8%	2.7%	8.2%
75 umol/L [Achievable]	5.0%	2.7%	9.5%

Additional considerations;

Enzymatic measurements of creatinine are able to achieve the desired specification. As an interim, achievable standards are proposed which are achievable by compensated Jaffe methods

Total allowable error has been calculated [2] as TE = (1.65 * imprecision) + inaccuracy.

References

1. http://www.westgard.com/biodatabase1.htm

2. Hyltoft Petersen P, Ricos C, Stockl D, Libeer JC, Baadenhuijsen H, Fraser C, Thienpont L. "Proposed guidelines for the internal quality control of analytical results in the medical laboratory." Eur J Clin Chem Clin Biochem 1996;34:983-999

Appendix 2 - Glossary

Bias (B) - % maximum allowable deviation from defined standard

CDC-Validated - The reference point that performance will be evaluated against will be the CDC calibrated value, anchored by ID-GCMS evaluation.

Desirable MAPS – MAPS which are the same as published Biological Variability Data
Achievable MAPS – MAPS which differ in some aspect from desirable MAPS, but are intended to increase convergence of results

Imprecision (I) – Allowable Co-efficient of Variation [%CV]

Innaccuracy – Bias

Joint Working Group – see www.rcpath.org/index.asp?PageID=1609

NLMC - National Laboratory Medicine Catalogue

Panel – The National Quality Assurance Advisory Panel. The body which all EQA schemes report poor performance to. Reports to the Joint Working Group [JWG] of the College. Chairs of each Panel are members of JWG

Total Error (TE) – Defined as TE= (1.65*I)+B

Variability - Imprecision

Appendix 3 - Felix and Cyril;

A quick analogy to help explain differences in performance criteria seen between DCCT and IFCC 'numbers [Courtesy of Birmingham UK NEQAS]

Birmingham Quality

Birmingham Quality

Previously known as the *Wolfson EQA Laboratory*,
Birmingham Quality provides primarily
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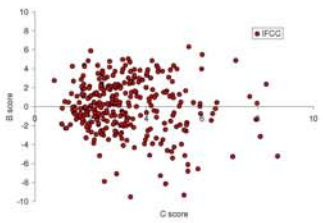
Felix and Cyril; *a quick analogy taken from a hastily mocked-up Excel sheet to help(!) any confused participant over differences in % biases seen between DCCT and IFCC 'numbers'*

The whole point of this is to show that despite the fact that results and means can be readily converted between the two measurement scales, % biases do not stay the same.

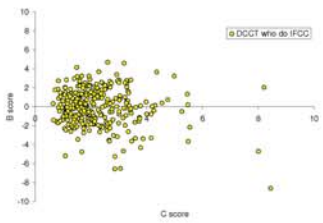
Fahrenheit and Centigrade %biases									
					F to C Eqn (F-32)*(5/9)		C to F Eqn (C*(9/5))+32		
Felix lives in Florida (and so thinks in Fahrenheit) and sits in the shade with an ice cream in a pleasant	70.0	F	locally	and	21.1	C	according to Cyril's Centigrade conversion		**agreed**
Cyril is in Cologne (and so thinks in Centigrade) and has a beer in a street Cafe where the temperature is	21.0	C	locally	and	according to Felix's Fahrenheit conversion		69.8	F	**agreed**
So both are agreed on the temperature									
A cold wind blows in from the north. In both locations the temperature drops by 33%.									
What is/are the new temperature(s)?									
Felix is now at	46.7	F	locally	which is	8.2	C	if transformed by equation into Cyril's Centigrade		Felix is colder than Cyril thinks Felix should be. Felix is at 8.2 C while Cyril is actually at 14.0 C
Cyril is now at	14.0	C	locally	which is	if transformed by equation into Felix's Fahrenheit		57.2	F	Cyril is hotter than Felix thinks Cyril should be. Cyril is at 57.2 F while Felix is only at 46.7 F
If the relationship between any two parameters is not a simple multiplicative one, ***ie*** does not pass through the (0,0) origin, then %biases are not 'equivalent' between the two scales.									
So what has this got to do with HbA1c?									
Well, though the B score limits of performance are +/- 5% for DCCT values, this might equate to approximately +/- 7.5% for IFCC values!									
Jane French and Finlay MacKenzie, Birmingham Quality, May 2010									

For completeness, here are some Penalty Box Plots showing the different performance domains.

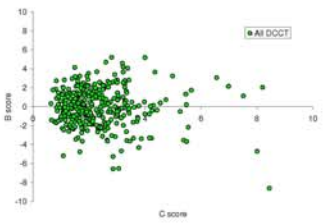
IFCC



DCCT who do IFCC



All DCCT



Jane French and Finlay MacKenzie, Birmingham Quality, May 2010