

Pathology Harmony drives forward

From 2007, the Pathology Harmony initiative started to look at the harmonisation of several aspects of work within the clinical laboratory.

This work began as part of the Department of Health's Pathology Action Learning Programme. It was initiated in West Midlands Clinical Biochemistry departments, but soon gained considerable momentum, growing to incorporate other work being done by colleagues in the North West Strategic Health Authority and in Wales.

Several areas were identified where it was felt there was potential for harmonisation. Working groups were then formed to consider each area. The following were examined:

- ◆ Units of measurement
- ◆ Reference intervals
- ◆ Test name harmonisation
- ◆ Standardising procedure for phoning abnormal results to primary care
- ◆ Standardising advice on protocols for simple tests

The final meeting for this first phase of the project took place in November 2007 in central Birmingham. The outcomes of the studies were presented to clinical biochemistry colleagues representing Strategic Health Authorities within England, together with representatives from Wales, Scotland and Northern Ireland. Harmonisation proposals from the working groups were tabled and voted on at the meeting.

The results of this meeting are now published here as the first set of Pathology Harmony recommendations.

Delegates from across the UK met to consider the first Pathology Harmony recommendations.

Phase 2

The success of the Pathology Harmony initiative has been clearly recognised. It is obvious that there is now a desire to ensure that where we can drive out variation which has no scientific or clinical foundation we should do so. Phase 2 of the project aims to widen the work to include other pathology disciplines and will also link in to other key strategic developments being driven forward with the support of the Department of Health.

For more details see page 4.

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Why harmonise?

There are many reasons why appropriate harmonisation of pathology output is important at the present time in the NHS. Some key factors to consider are:

Electronic patient records

Where we have differences in reference intervals it can be very difficult to link databases between various laboratories and our users. Of course, where there are differences that have a scientific foundation we have to circumnavigate these problems somehow. However, when there is no scientific foundation for variation, pragmatic harmonisation of reference intervals is absolutely essential. Interestingly, as networks are evolving at a local level, the harmonisation of reference intervals has been a key area for consideration. The Pathology Harmony project simply aims to ensure that we do this sensibly at a UK wide level.

Clinical Governance Issues

There are many situations where differences in the output from pathology laboratories are, at the very least, confusing for our end users. For example, we commonly find different reference intervals for common analytes in laboratories in major cities in the UK. This can be the case even though the analytical platforms producing these results and the reagents on board the analysers are identical. Our busy medical and nursing colleagues are frequently required to 'think on their feet': failure to standardise reference ranges, test names and units increases the risk of errors and mismanagement, especially with junior doctors moving so frequently from site to site.

Confusion among our users and the public

The single biggest enquiry to the website www.labtestsonline.org.uk is 'why is there no reference interval associated with the tests on the site?' By the application of pragmatic science and appropriate harmonisation of tests we can quickly overcome this criticism for many tests.

Phase 1 Results

The table below shows the recommendations that resulted from the work of the first phase of Pathology Harmony. Only those proposals which met with overwhelming acceptance at the final meeting in November 2007 have been included in the recommendations.

Reference intervals and units – in adults, non-pregnant

Code No.	Analyte	Lower/upper limit	Units
PH 07 001	Serum Sodium	133 – 146	mmol/L
PH 07 002	Serum Potassium	3.5 – 5.3	mmol/L
PH 07 003	Serum Urea	2.5 – 7.8	mmol/L
PH 07 004	Serum Chloride	95 – 108	mmol/L
PH 07 005	Serum Bicarbonate	22 – 29	mmol/L
PH 07 006	Serum Phosphate	0.8 – 1.5	mmol/L
PH 07 007	Serum Magnesium	0.7 – 1.0	mmol/L
PH 07 008	Serum Albumin	35 – 50	g/L
PH 07 009	Serum Total Protein	60 – 80	g/L
PH 07 013	Serum Osmolality	275 – 295	mmol/kg

Implement drugs units recommendations

Code No.	Analyte	Units
PH 07 014	Carbamazepine	mg/L
PH 07 015	Phenobarbitone	mg/L
PH 07 016	Phenytoin	mg/L
PH 07 017	Theophylline	mg/L
PH 07 018	Valproate	mg/L
PH 07 019	Paracetamol	mg/L
PH 07 020	Salicylate	mg/L
PH 07 021	Methotrexate	µmol/L
PH 07 022	Digoxin	µg/L
PH 07 023	Tacrolimus	µg/L

Note: The work also incorporated the implementation of the consensus recommendations on units for reporting drug concentrations, published in October 2006 (ACB News No. 552)

Calcium

Code No.	Analyte	Report
PH 07 025	Total & Adjusted Calcium	Adjusted Calcium alongside total unadjusted

Out of hours telephoning

Code No.	
PH 07 026	Laboratory, PCT and out of hours service should agree procedures. Agreed limits for phoning should be written down in protocol

Endocrine protocols

Code No.	
PH 07 027	Under medical supervision with written protocol available
PH 07 028	Under medical supervision
PH 07 029	3FSH as first line test

Test names

Code No.	Analyte
PH 07 030	Glucose
PH 07 031	Bicarbonate
PH 07 032	Cortisol
PH 07 033	CK
PH 07 034	Adjusted calcium
PH 07 035	Total bile acids

Example of analyte harmonisation: Serum sodium

Aim

To consider if serum sodium reference intervals can be harmonised.

Method - phase 1

Questionnaire to all laboratories asking for current reference intervals for serum sodium, including any sex, age or other variations.

Method - phase 2

Meet to review questionnaire results. Request further information and consider if variation has any basis either due to difference in equipment and reagents, population served or other technical, scientific or clinical reasons for observed variation.

Method - phase 3

Consideration of where variation has come from between laboratories, including assessment of original work undertaken on patient samples.

Results

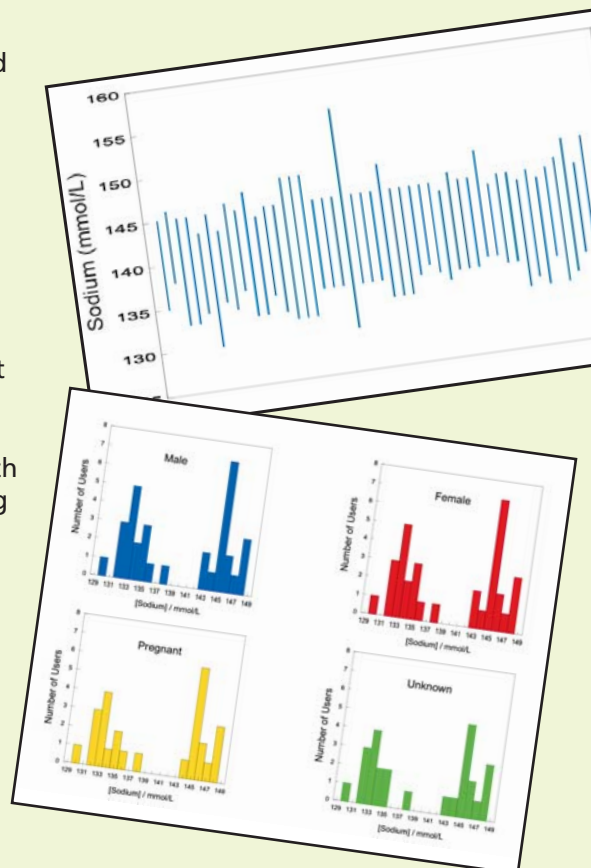
Variation in serum sodium in West Midland laboratories is shown in the figures. When the analytical platforms were reviewed it was found that the variation in reference intervals was not related to analytical platforms. Indeed, many laboratories used identical equipment and reagents but had small variations in the reference intervals they quoted for serum sodium. Population studies in no way explained variation.

Further work looking at variation between laboratories was brought back to the meeting and it was clear that the major reason for variation was simply historical, with no scientific foundation. Following this conclusion 'pragmatic science' was applied whereby the group considered the variations at the bottom and top end of the reference intervals and came to a consensus view on a sensible reference interval to propose.

Suggested reference interval: 133-146 mmol/L

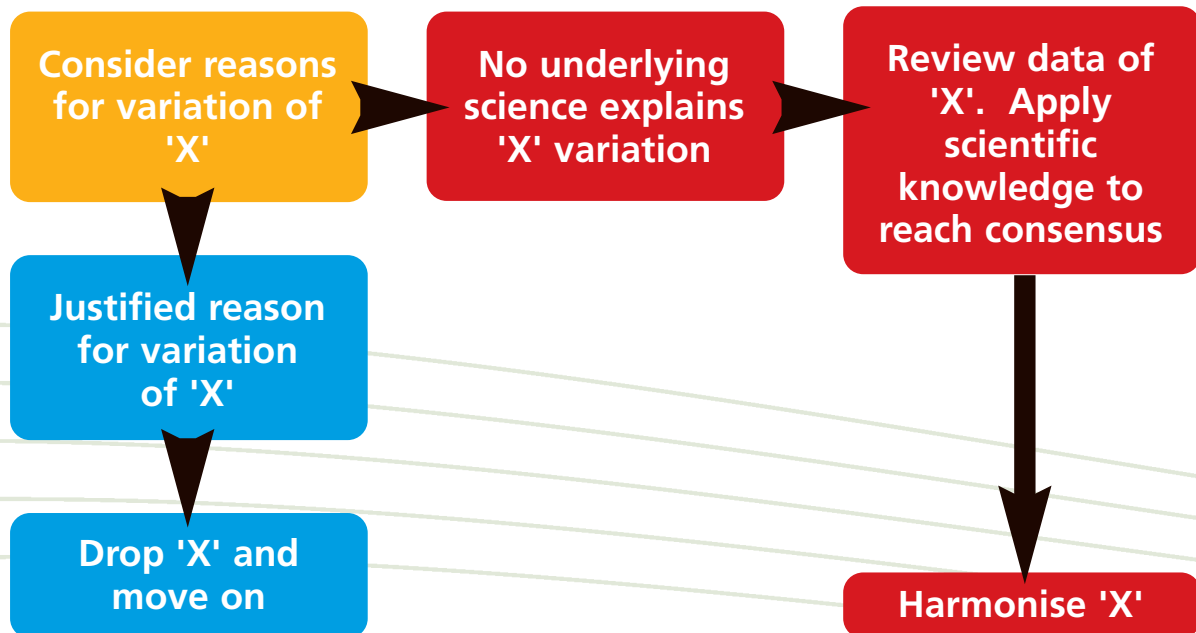
Conclusion

The evidence was presented at the final action learning set and was unanimously approved.



Pathology Harmony - a method

In 2007, during the Birmingham meetings a methodological approach to harmonisation gradually evolved. This is best shown by the following diagram.



Pathology Harmony Phase 2

Key Targets for 2008-09

- ◆ Take forward the 2007 proposals to completion with national consultation on a timetable for adoption of the recommendations.
- ◆ Address new areas for harmonisation both in clinical biochemistry and other pathology disciplines.
- ◆ Give a firmer foundation to the evolving methods for harmonisation.

The next phase of the Pathology Harmony project will start in earnest in autumn 2008.

The major professional bodies in United Kingdom pathology – including the Royal College of Pathologists, the Association for Clinical Biochemistry, the Institute of Biomedical Science, the Association of Clinical Pathology and the British Society of Haematology Groups – will be invited to be represented on a new Steering Group.

The Steering Group will push forward harmonisation in areas where they consider that it will lead to improvements in pathology services in the United Kingdom.

Sponsorship from the Department of Health

We are very pleased to announce that the Department of Health are supporting Phase 2 of Pathology Harmony with a grant.

Dr Ian Barnes, National Clinical Lead for Pathology at the Department of Health, sees Pathology Harmony as one of a number of key initiatives to take forward in the post-Carter era. The Pathology Harmony Steering Group will be reporting to the Department of Health on a regular basis on the progress that is being made.

Formation of Steering Group

Pathology Harmony was a concept conceived by Dr Jonathan Berg at City Hospital, Birmingham. He has been asked to take this initiative forward into Phase 2 and is working together with Mr Jeff Seneviratne representing the North West SHA and Mr Gethin Roberts from Wales.

The Steering Group will be inviting representatives from key professional bodies, as well as clinical and scientific staff, to help take Phase 2 forward.

The proposed time scale is as follows:

September 2008

Initiation of projects

December 2008

First feedback

March 2009

Final working meeting

Summer 2009

Presentation of Phase 2 recommendations

Contacting Pathology Harmony

You can contact Pathology Harmony in the following ways:

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Pathology Harmony Website

Further details of the work of Pathology Harmony are available on the Pathology Harmony website: www.pathologyharmony.org.uk

