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The UK Pathology Harmony initiative; The foundation of a global model

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ABSTRACT

The United Kingdom Pathology Harmony project commenced in 2007 and has been widely mirrored around the world. This initiative evolved through three separate phases of work. Fundamental to the project has been the ability to question variation in the work of the pathology laboratory that has been in place sometimes for a very long time, and yet appears to have little scientific foundation. Work has been undertaken on a methodological approach to studying variation in reference intervals and then moving forward with consensus values. On a wider level there is much else in pathology that can be harmonised from test names and units, through to the clinical guidance we offer for using our tests and work has been undertaken in several of these areas.

1. Introduction

In 2007 representatives from sixteen laboratories in the West Midlands, UK, met to consider aspects of laboratory harmonisation. This initiative was founded on the realisation that many laboratories in the Birmingham conurbation had procured the same mainframe clinical chemistry analysers but, even when using identical analytical techniques offered different reference intervals for basic tests. At the same time laboratory users were becoming more enquiring about variation from different laboratories. This was not just in relation to reference intervals but included much wider aspects of the laboratory service. The original group of laboratories looking at harmonisation issues soon expanded, to include representation from a further eleven laboratories in Wales. A further eighteen laboratories who had started to look at similar issues in the North West area of England also joined in the work.

A key driver for change comes from the desire to link up the results from different laboratories enabling tests requested in one part of the healthcare environment to be viewed in another. As those providing IT solutions worked on different aspects of electronic patient records, the variation in things such as test names, reporting units as well as in reference intervals all impact on the ability to transfer pathology results across platforms. In the UK pathology a key driver for harmonisation is certainly now the governmental initiative of "any willing provider". This puts much greater emphasis on those that commission pathology services to build into their specification the need for harmonised processes for the service being offered.

2. Harmonisation methodology

In our studies raw data were collected using a questionnaire format sent to participating laboratories. Raw data that were accumulated included details of methods, currently used reference intervals assigned to tests and test names and units. Pathology Harmony team members were assigned to different projects depending on their experience. Collated data were presented to review meetings where laboratory representatives were present. Where appropriate, returns were anonymised and also grouped by the types of analytical platform and methods used. Data was extracted in various ways as appropriate for the analytes under study. For example studying the variation in reference interval according to age, sex and ethnicity were all extracted when relevant.

A process that became known locally as "churning" was derived to consider the variation in the data for any given analyte as shown in Fig. 1. This process included consideration of difference in analytical variability as well as age and sex related variation or other variances in populations where these were seen as relevant to the analyte under consideration. Once this had been undertaken for a number of analytes proposals were produced which were more widely propagated before being adopted as Pathology Harmony recommendations. It should be noted that our process is designed to harmonise current practice and that our project did not seek new evidence from populations. The aim is to remove unnecessary variation that can be demonstrated to lack scientific validity. When this is established, then new work that more formally defines validated reference intervals can be applied.

An example of the data produced by the "churning" process for serum potassium and sodium is shown in Figs. 2 and 3, which eventually led to the recommendations of harmonised reference intervals 3.5 – 5.3 and 133 – 146 mmol/L respectively.

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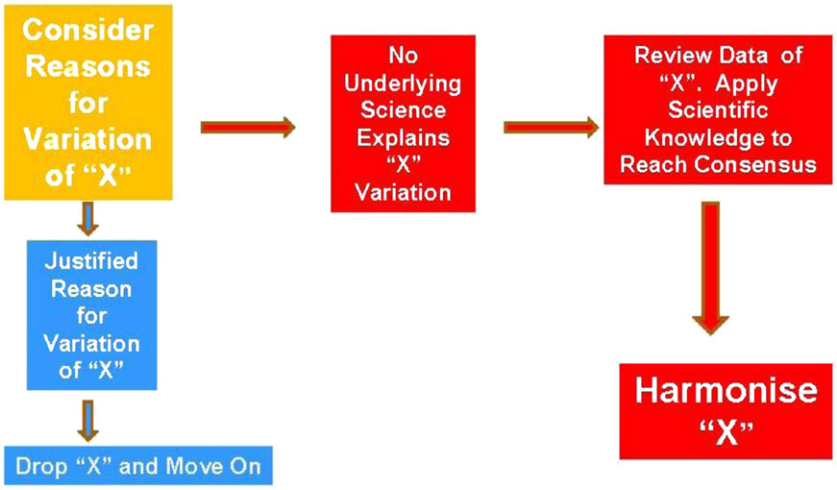

Fig. 1. The process for evaluating whether an analyte is suitable for harmonisation and then undertaking the review.

3. Phases I, II and III

A total of three phases of Pathology Harmony were undertaken between 2007 and 2013 as we learnt from our experiences and added to the process.

3.1. Endpoints from Phase I

This was very much about establishing foundations and getting everyone involved. Table 1 looks at the feedback from West Midlands laboratories on where reference intervals were thought to have been derived. A majority of laboratories either did not know where reference intervals came from or took them from manufacturers' information or the literature. Where reference intervals were produced locally this was often suggested as being based on original work done in the 1970s.

As the Pathology Harmony group met together we were quickly confronted with data suggesting that there was very little scientific validity to the variation that we were delineating [1–3]. For example the derivation of reference intervals was for the majority of laboratories not known or "historical" as shown in Table 1. The Oxford Textbook of Medicine, Tietz and manufacturer's kit inserts were given as examples of where reference intervals had been derived, though as commonly was the answer that no-one really knew. Where more detailed population studies had been undertaken to derive reference intervals then these were often historical and not necessarily relevant to today's methods.

The various areas of work undertaken in Phase I and the results and suggested outcomes were agreed at a consensus meeting attended by representatives from all the Strategic Health Authorities in England as well as people from other UK principalities and also Eire. Recommendations from Phase I are shown in Tables 2–4 and indicate the wide range of harmonisation studies that were worked on.

3.2. Endpoints from Phase II

A key difference in Phase II was that we ensured formal support and representation from the key professional groups in the UK and the Department of Health. In addition to working on haematology and immunology we undertook a major piece of work offering clinical

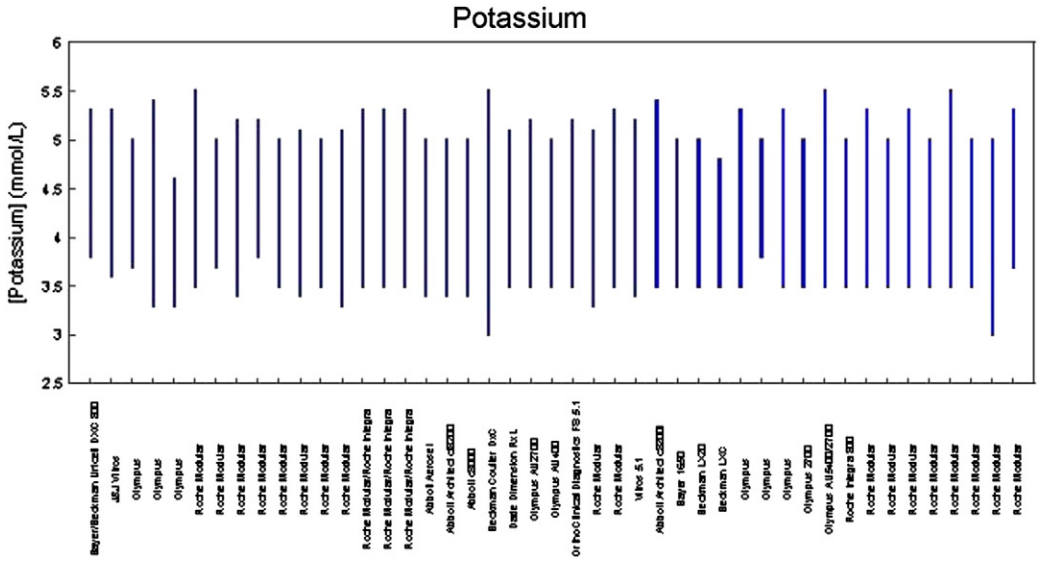

Fig. 2. Reference intervals for potassium from 46 laboratories in England and Wales.