Performance Monitoring in Newborn Screening - a Co-ordinated National Approach
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Introduction
In January 2015, the NHS newborn blood spot screening programme was expanded to include four additional disorders. Six conditions are now screened for by MSMS, PKU, MCADD, GA1, MSUD, IVA and HCU. Nationally agreed screening protocols were adopted with specified analytical and clinical cut-off values (COV) so harmonisation between labs was important. To assist with performance monitoring and provide assurance of the efficacy of the screening programme, the national co-ordinating centre commissioned a team to collect and analyse population data and results from common IQC material from 14 screening labs in England and Wales.

Population Data
Labs returned data monthly by instrument on 8 analytes. Results above the alphabetical cut off and from babies not aged between day 5 and 8 were excluded. The 10th, 50th, 90th and 99th centile of each analyte was calculated for each analyte and plotted monthly and cumulatively. The graphs below show 1 year worth of data (>600,000 babies) by laboratory except tyrosine (>410,000) as not all labs submit tyrosine data.

Results
Commercial QC would be expected to produce relatively precise results, however this is not apparent for a number of analytes. The QC was used to calculate the MU for the national programme as babies born in England and Wales are screened against a common cut off value. Horwitz ratio indicates the between lab variation (MU) is greater than the predicted CV and the performance for phenylalanine and total leucine is unacceptable.

Discussion
Possible causes for the variation seen could be due to the differences in the instruments, setup parameters, mobile phases, internal standard. There is no certified reference material to ascertain what the actual concentrations should be.

Although the programme is not unsafe, there is the potential for unnecessary referrals due to the variability across the country, which has a detrimental effect on the parents. Considering the MU there is also the potential to miss a referral.

Is enough being done to troubleshoot the differences or to harmonize the results considering we are using a national cut off?

Should we consider setting population based COV within each lab?