Limits of agreement between HbA1c levels measured in different laboratories following the introduction of the International Federation of Clinical Chemistry and Laboratory Medicine standardised values

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Background
• Since 2009 HbA1c assays have been calibrated against the International Federation of Clinical Chemistry and Laboratory Medicine standardised values.
• This should remove the need for centralised measurement of HbA1c for clinical or research purposes.
• 294 children from 15 UK centres have been randomised to the SCIPI study (SubCutaneous Insulin: Pumps or Injections?), which compares insulin delivery by pump to multiple daily injections during the first year following diagnosis of diabetes
• HbA1c is measured every 3 months, locally by (1) a ‘point of care’ device or a local laboratory and (2) a central laboratory.

Aim
To determine the limits of agreement between local and central measurements of HbA1c

Methods
• Bias and 95% limits of agreement were determined using the Bland and Altman method.

Results
• 590 pairs of measurement, representing 255 children and 15 trial-centres were compared
• There was no significant or systematic bias
• Local measurements were 0.16 mmol/mol (±4.5, 95% CI: -0.2 to 0.5) higher than central.
  (Figure 1)
• 95% limits of agreement were -8.6 to 9.0 mmol/mol (local minus central).
• 5% of paired measures differed by > 9 mmol/mol
• 7% of pairs showed >10% difference between central and local measurements

Conclusion
• Despite calibration against the International Federation of Clinical Chemistry and Laboratory Medicine standardised values, differences between laboratories persist
• These may be significant when comparing outcomes of diabetes care between centres
• We recommend that centralised analysis continues in multicentre research studies

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Inspired by children