

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 SCIP 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

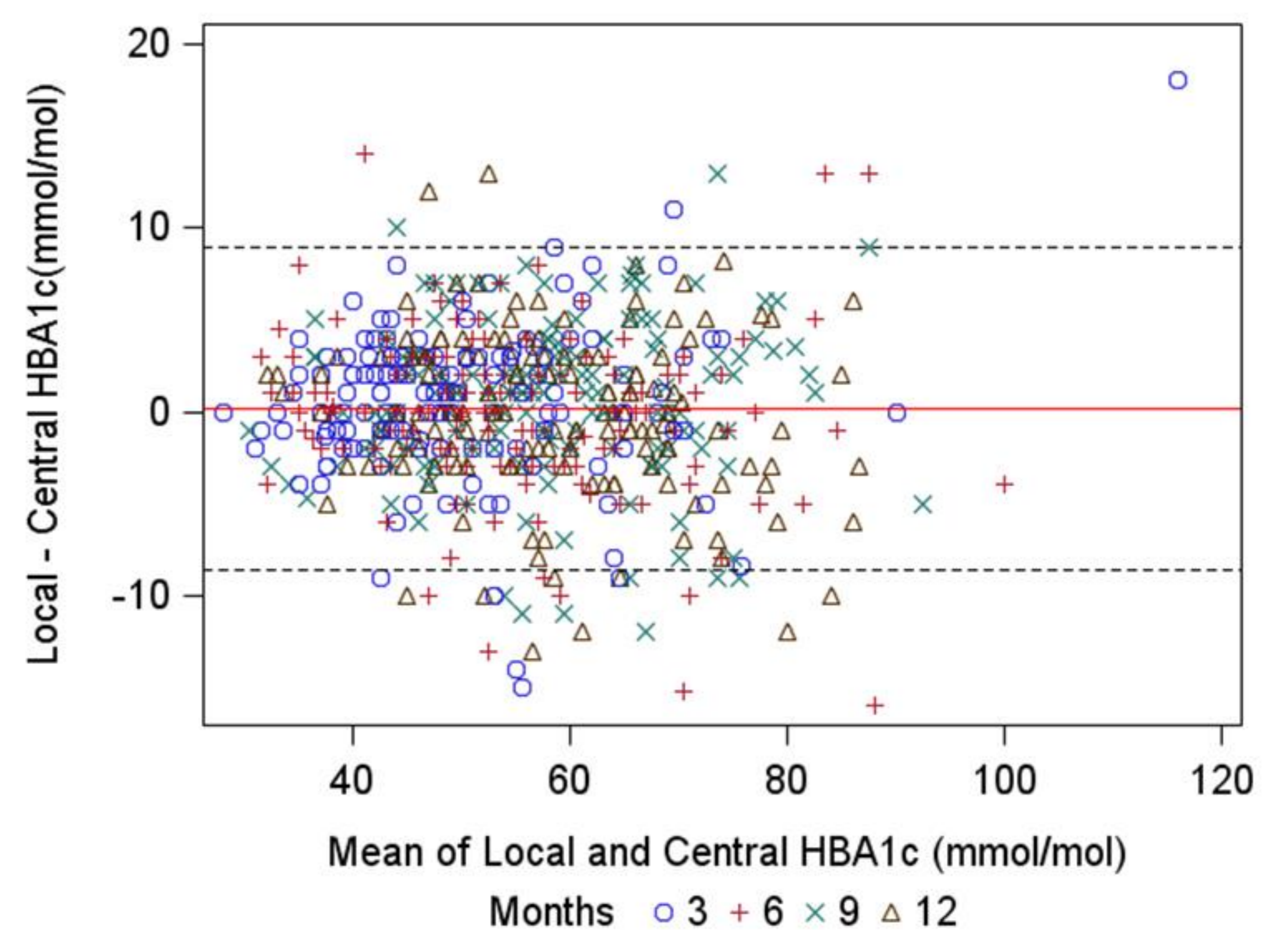
Methods

- 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

Figure 1: Limits of agreement graph (95% LOA lines: dashed, bias: red line)



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



Inspired by children

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