EQALM 2024 Vienna

~ "It means nothing to me" Midge Ure, Ultravox, 1980

Measurement Uncertainty in Clinical Biochemistry and ISO/IEC 17043:2023

Birmingham Quality

We are, and always have been, part of the NHS

Dr Rachel Marrington

Birmingham Quality *UK NEQAS Birmingham*

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Measurement Uncertainty and ISO/IEC 17043

- ISO/IEC 17043:2010
  - *'specific and detailed instructions on the manner of recording and reporting test or measurement results and associated uncertainties. If the instructions include reporting of the uncertainty of the reported result or measurement, this shall include the coverage factor and, whenever practicable, the coverage possibility [4.6.1.2 (f)].'*

- ISO/IEC 17043:2023
  - One step further and allows EQA/PT providers the option *whether the measurement uncertainty of participant results shall be reported and how it will be used to evaluate the participant's performance*[7.2.2.3 (g)]

We wanted evidence as to support our approach to this clause of the standard

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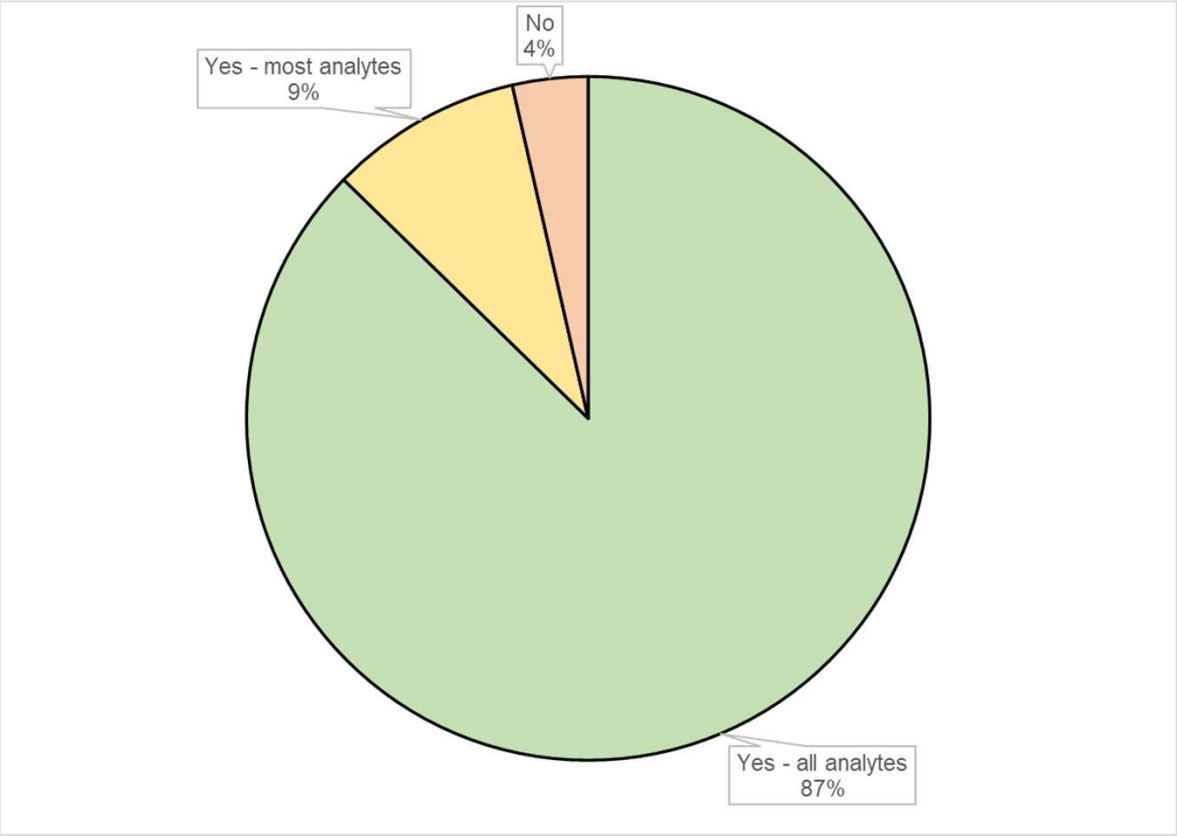
How we approached this …

- Online survey using MS Forms made available to all Birmingham Quality participants in April 2024
- 14 questions auditing current practice relating to MU within Clinical Biochemistry
- A single analyte, sodium, was chosen to assess the variation in reported MU.

Results

- 101 individual responses corresponding to 252 laboratory codes
  - 86% from UK
  - 12% from Europe
  - 2% from Rest of World

Have you calculated MU for all chemistry analytes on your main chemistry/immunoassay analyser (n=252, single choice)



100% of laboratories do not report MU on every single patient result.

Majority of laboratories record MU within their Quality Management System

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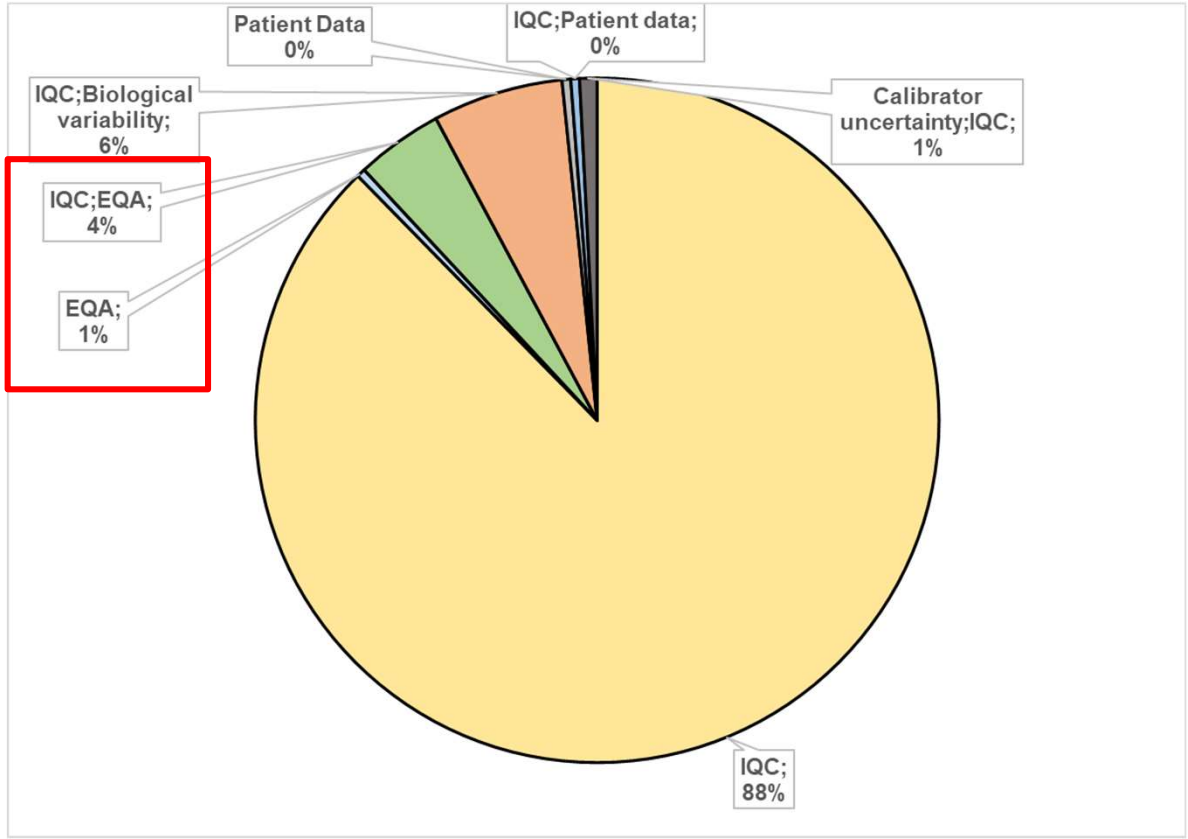
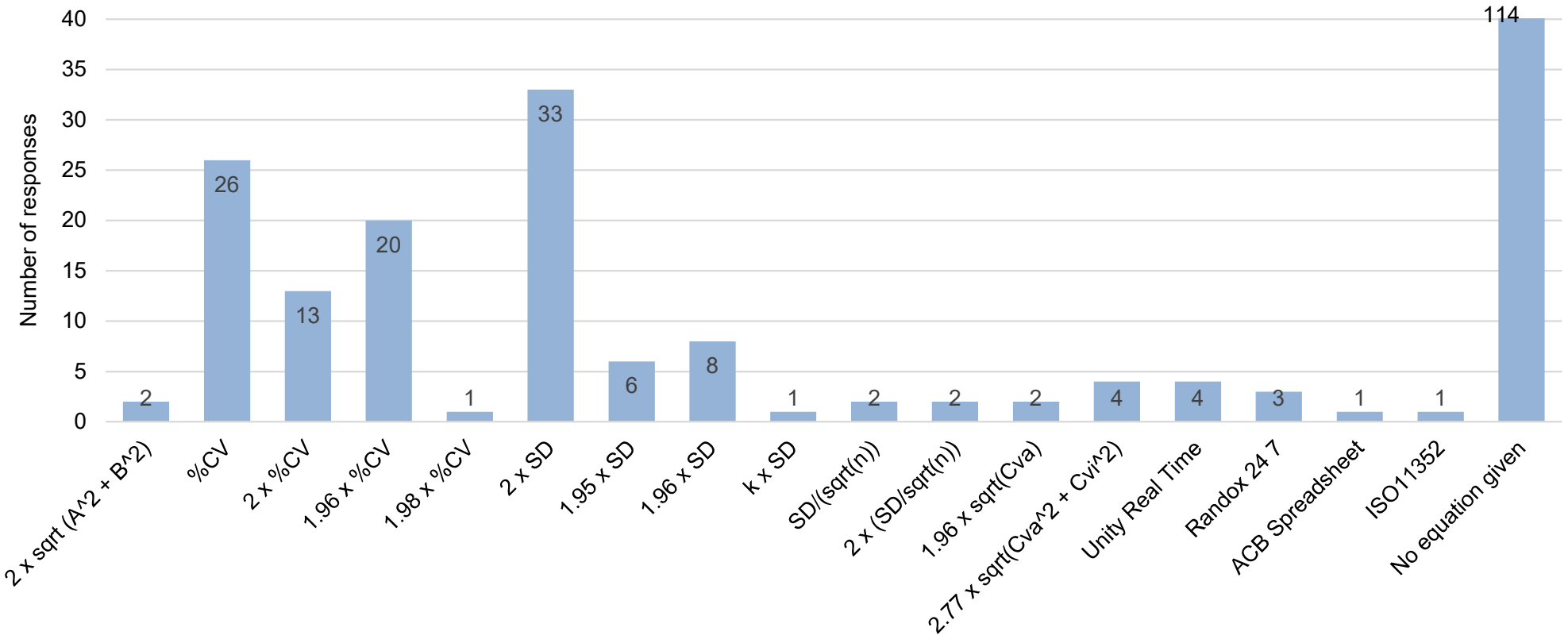
What is the source of the data that you include in your calculation of MU? (n=243, single choice)



How do you calculate MU for analytes on your main clinical chemistry/immunoassay analysers? (n=243, single choice)



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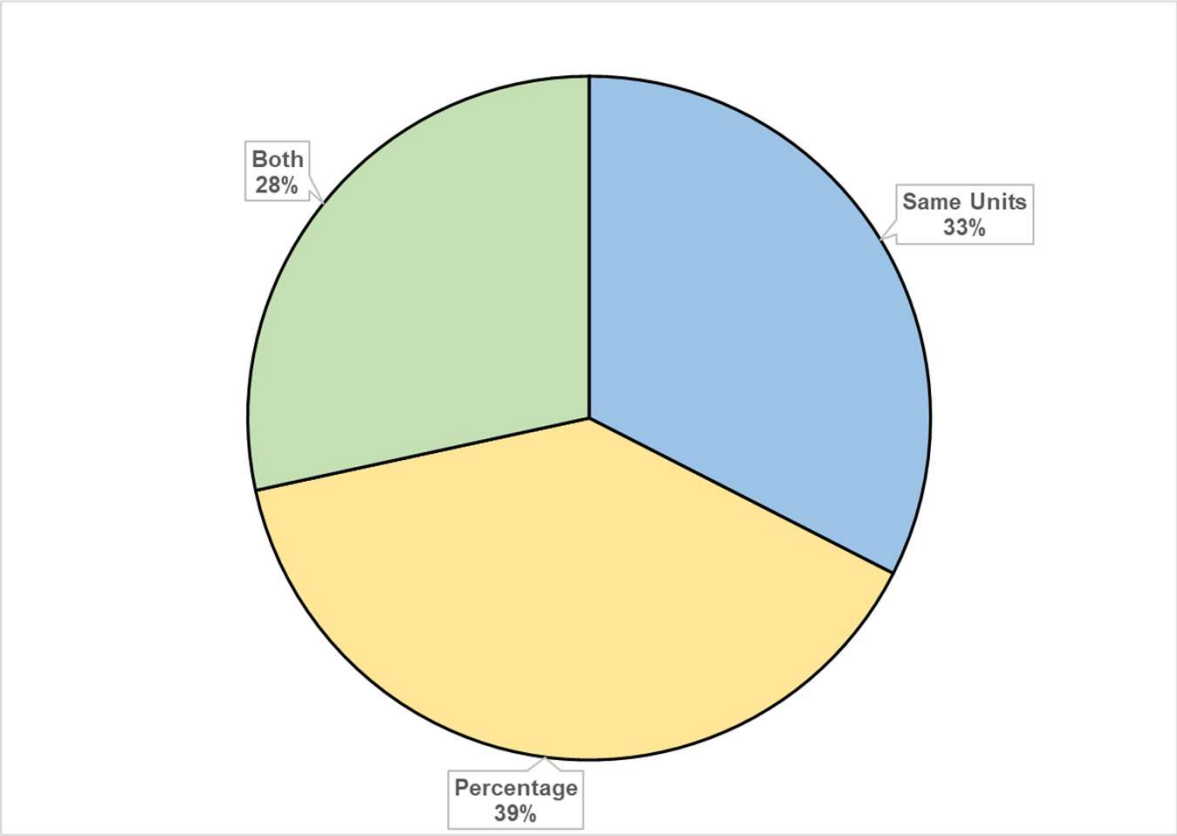
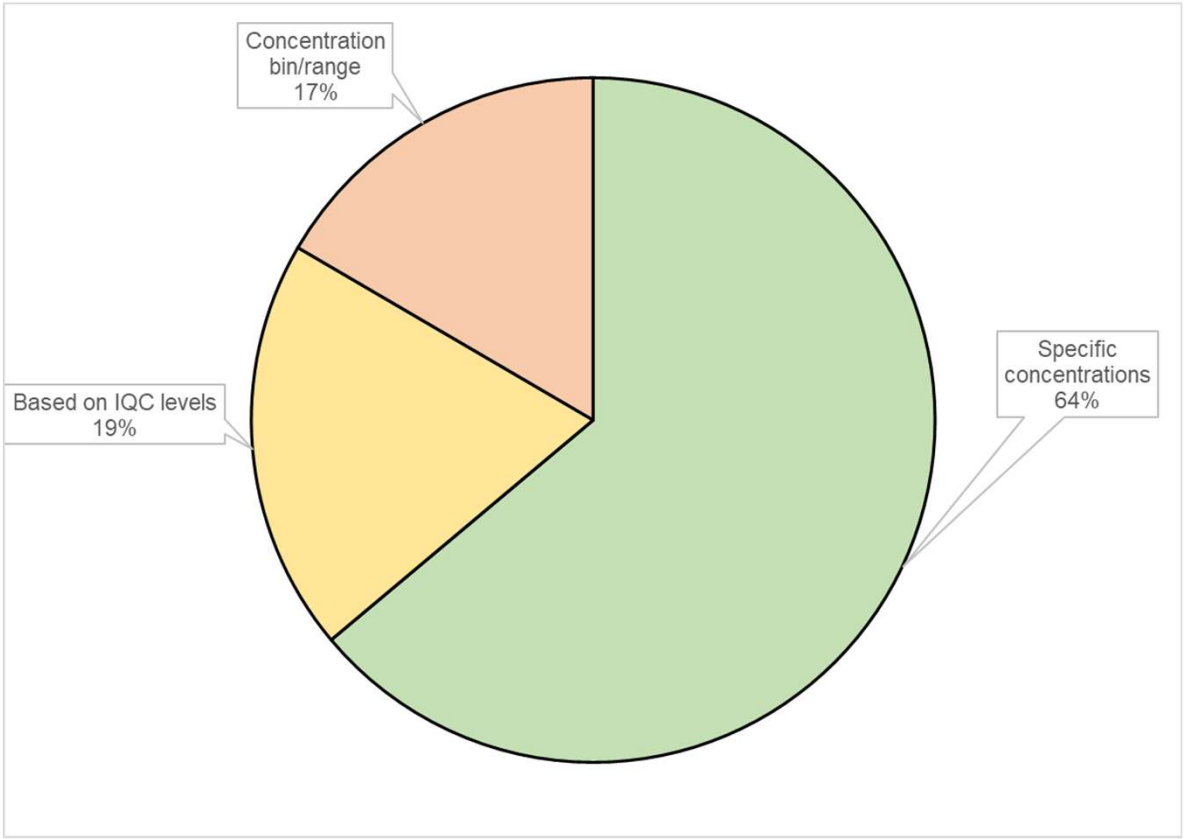
Do you report MU in the same units as the measurand or as a percentage (n=243, single choice)



Do you allocate MU at specific concentrations or across a concentration bin/range? (n=241, single choice)



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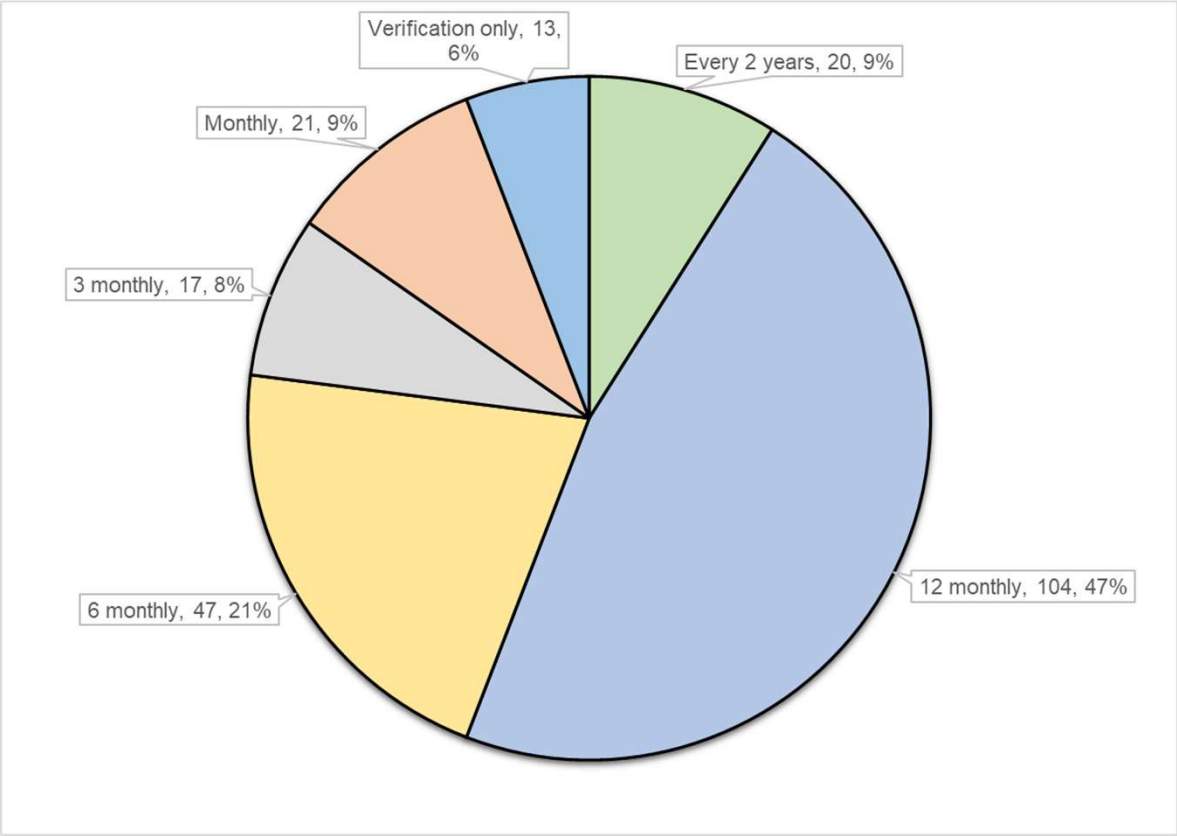
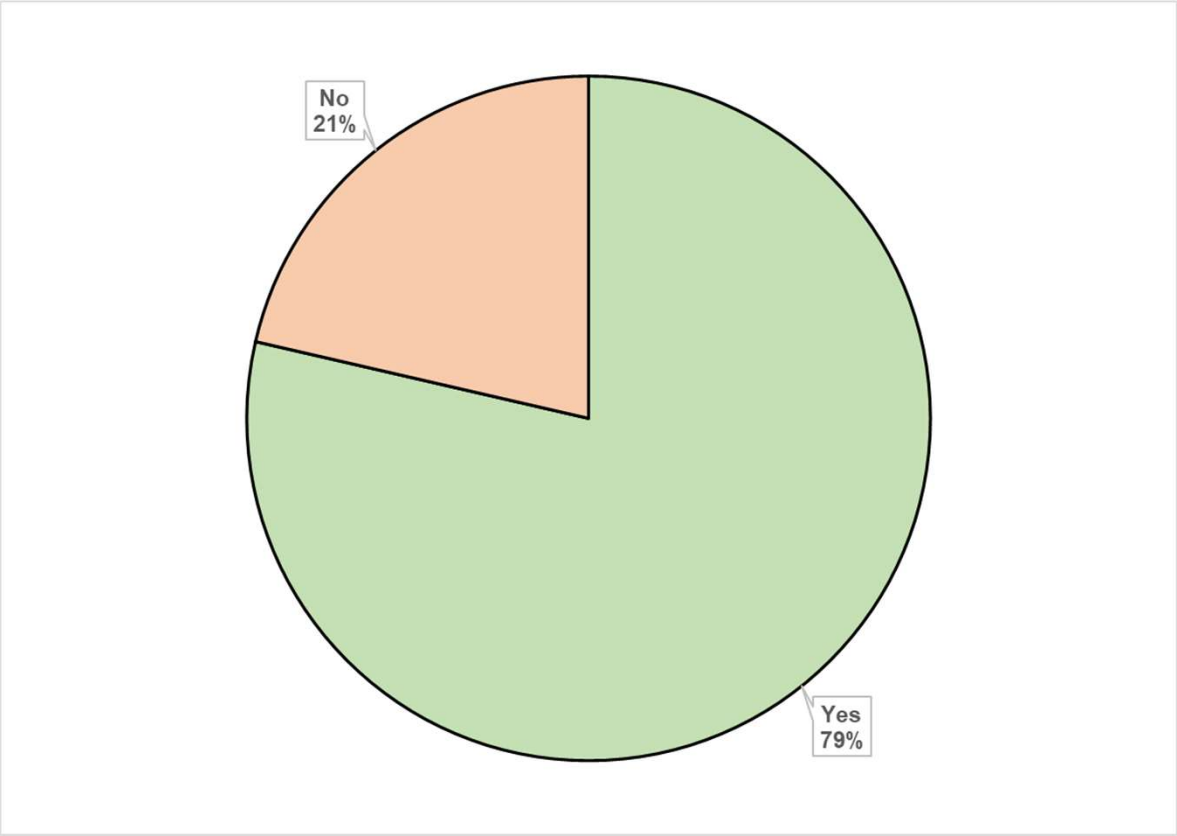
If you are not using concentration bins/ranges, how do you report uncertainty at specific concentrations where MU has not been calculated? (n=199, single choice)

- Majority of respondents would not report MU on specific patients, MU is for information only.
- Interpolate in the broadest sense between two concentrations
  - Estimate based on IQC precision profiles
  - Arithmetic mean
  - Weighted mean
  - Reported as ‘between limits’
- Select MU closest to the patient result
- Use Reference Change Values to look for statistically significant differences

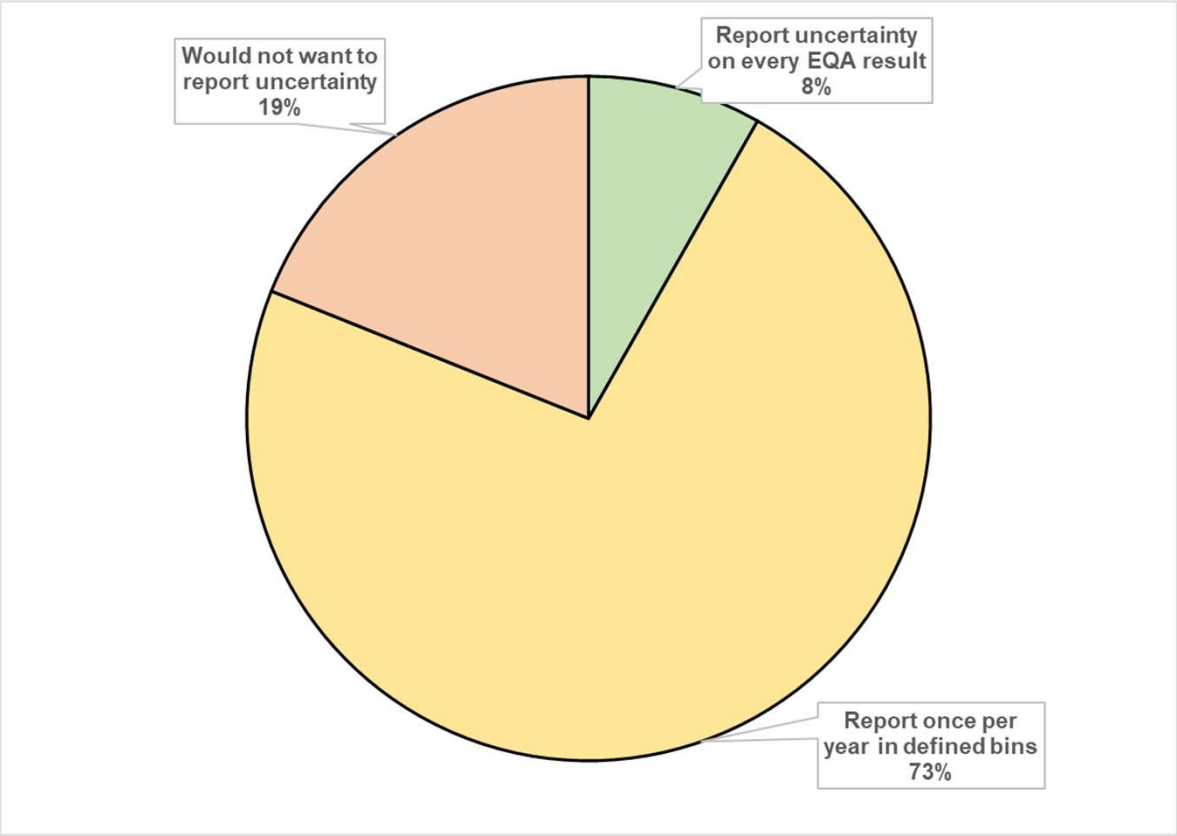
How often do you calculate your MU? (n=222, single choice)



Would you find it useful to have your MU included on your EQA report, even if only for benchmarking? (n=243, single choice)



Would you want to report MU with every EQA result, or report once per year, in defined ‘bins’? (n=243, single choice)



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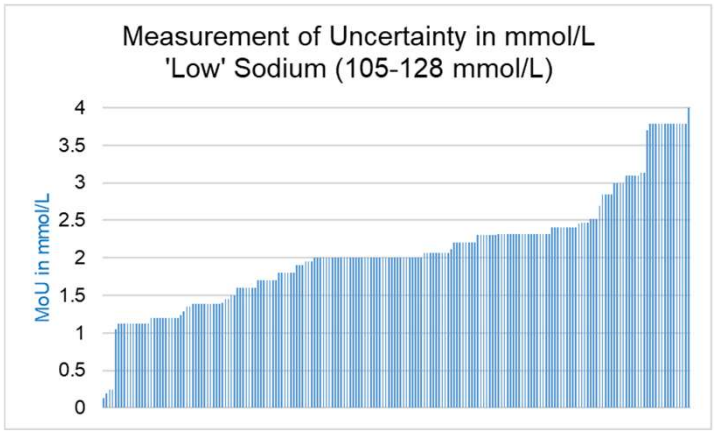
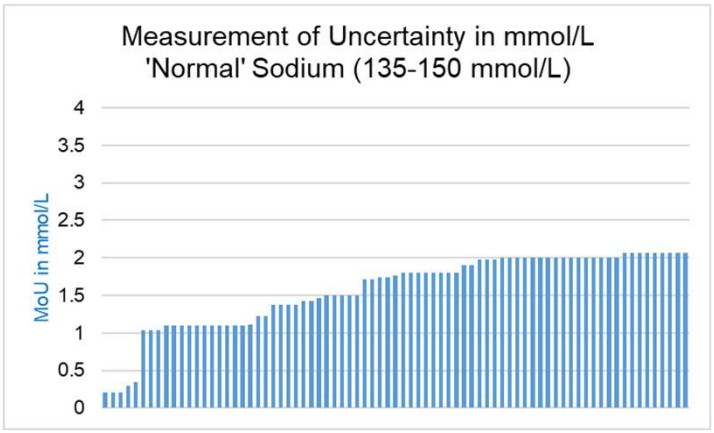
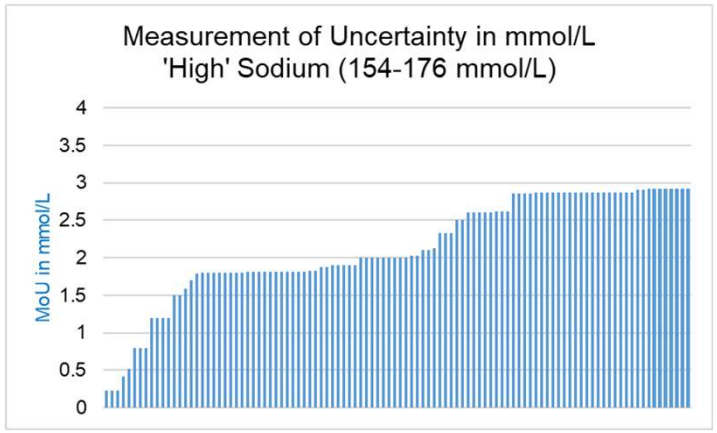
Sodium (max n=198)







What now for laboratories?

- Birmingham Quality will set up annual benchmarking exercise for MU for selected analytes across clinical chemistry
- Remind labs MU assumes a perfect assay system. MU does not take into account assay bias but it is important clinicians are aware of the bias!

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