Sensitivity of Recalibrated Continuous Glucose Monitor Data

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INTRODUCTION

Continuous Glucose Monitors (CGMs) are increasingly used in research settings to examine glucose metabolism in newborn babies.

Accuracy of these devices depends on the accuracy and timeliness of calibration blood glucose (BG) measurements entered into the CGM device.

The potential impact of variations in timing and measurement accuracy of reference calibration measurements on CGM device output were assessed.

METHODS

Patient Data

Clinical CGM data from 50 neonates and blood-gas analyzer reference BG measurements were used.

Cohort and CGM data details:

No. patients	Age at birth	CGM data (days)	Avg. calibrations per day
50	>32 weeks	228	4.7

BG Measurement Error and Timing Lag

Normally distributed (SD 2%, 5% or 10%) random errors were added to reference BG concentrations, and random timing lags simulated delays in registering calibration BG with the CGM.
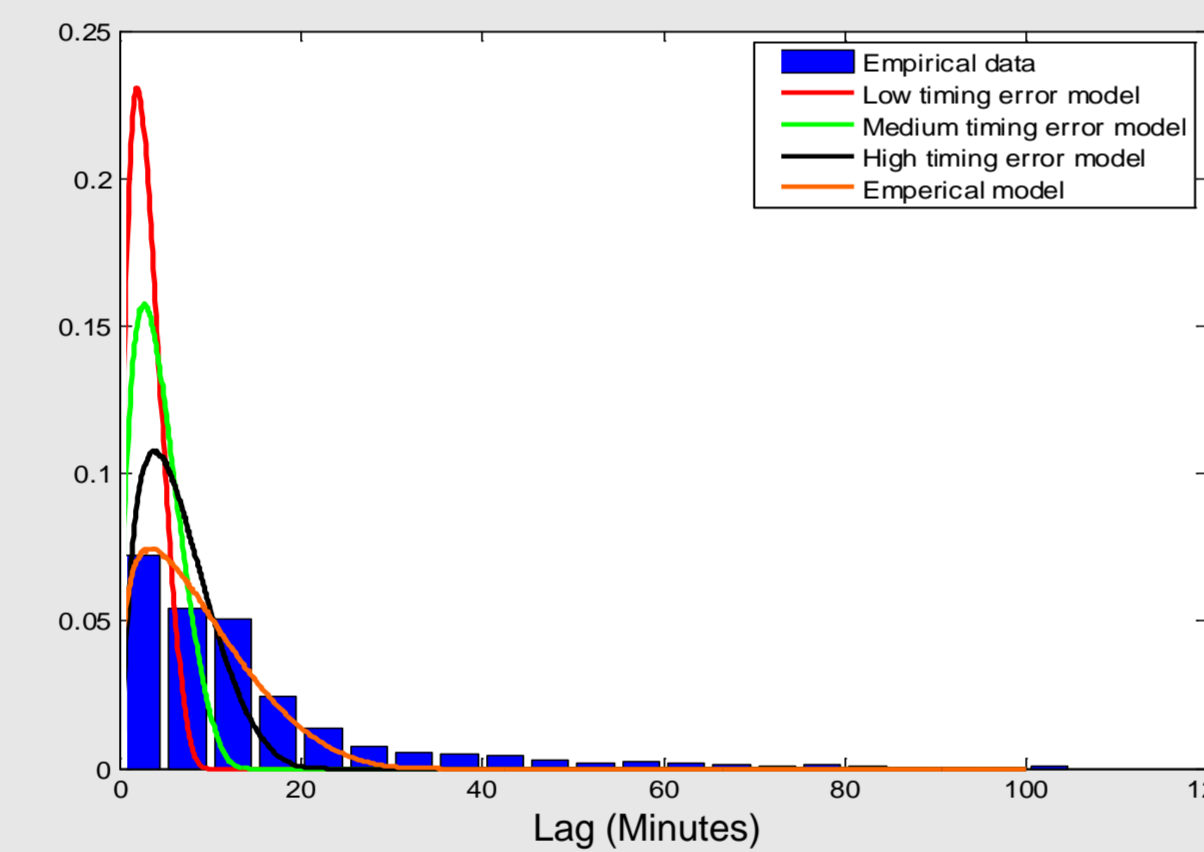
Figure 2: Distributions of the four random timing lag models tested

Recalibration

CGM data was recalibrated to make use of the accurate calibration measurements. Recalibrating forces the CGM trace through all reference BG measurements.
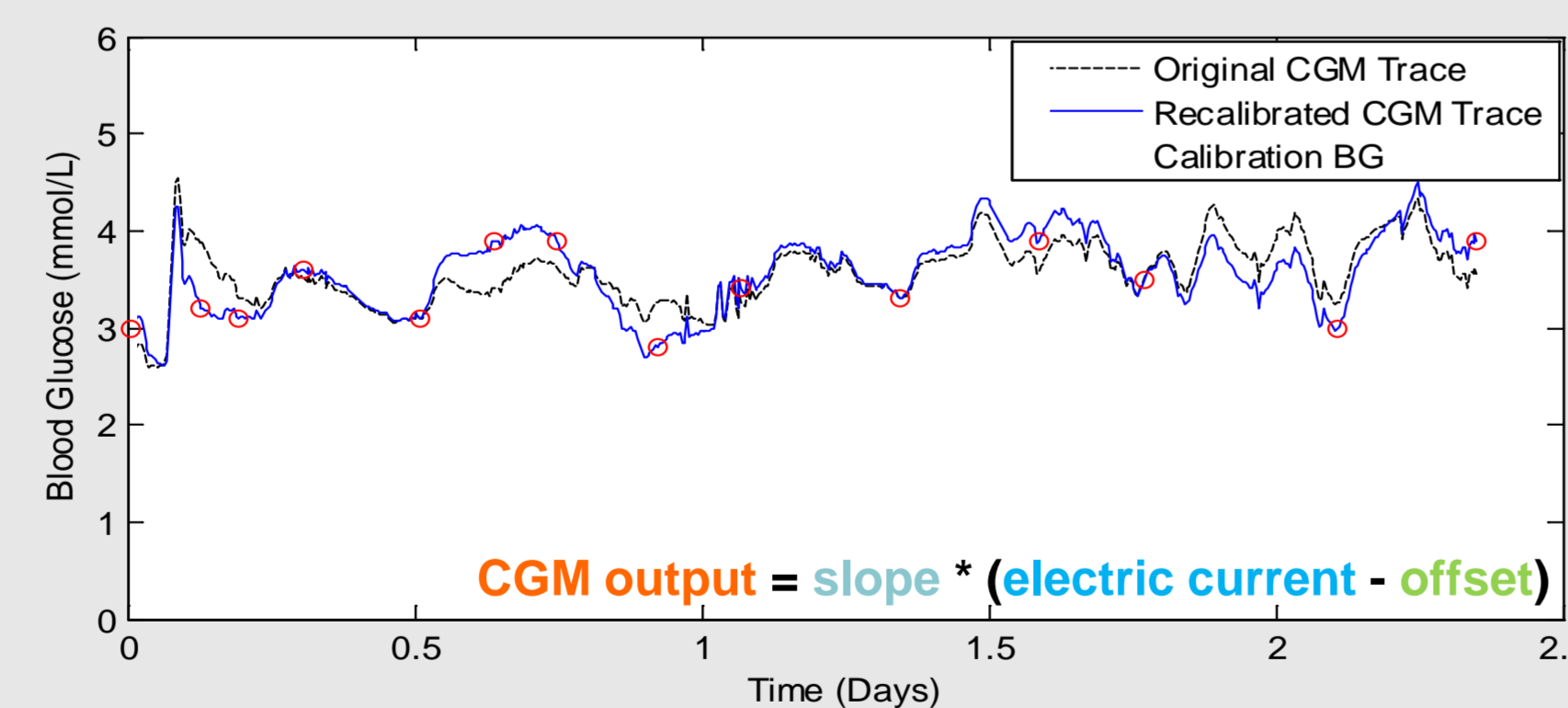
CGM output = slope * (electric current - offset)

Figure 1: Example of Original CGM output vs. Recalibrated CGM output

Monte Carlo Simulation

Each CGM trace was recalculated 1,000x in a Monte Carlo analysis using the randomly modified calibration measurements. Uncertainty in each CGM measurement was defined as the range (mmol/L) of that measurement over the 1,000 runs.
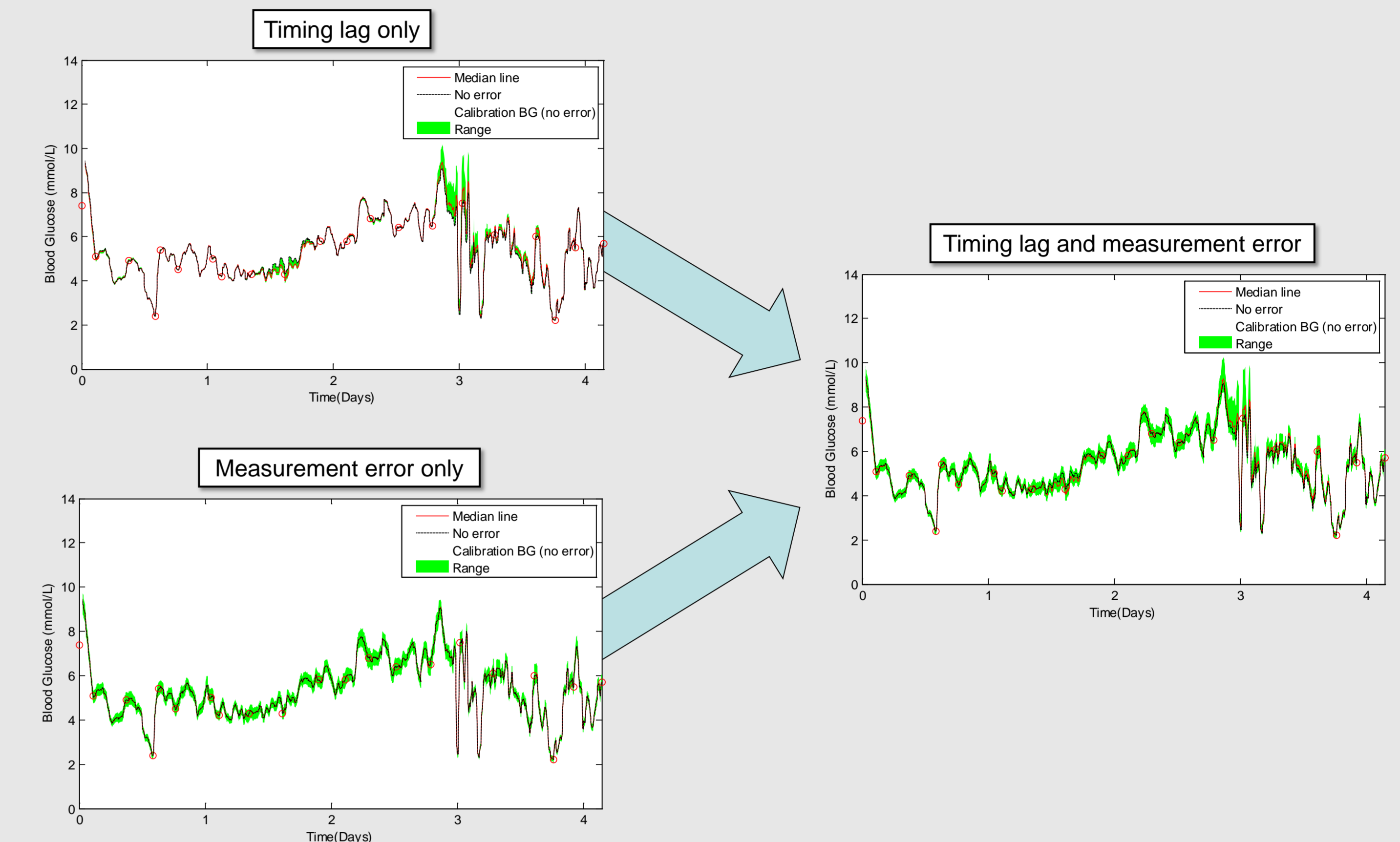
RESULTS

Timing Lag vs. Measurement Error

Results show that the timing lag causes uncertainty when calibration measurements are taken during high rates of BG change. BG measurements taken during stable glycaemia introduce little or no uncertainty, regardless of the timing lag.

The measurement error models we tested tend to cause an almost uniform band of uncertainty, independent of BG dynamics.

Simulating with timing lag and measurement error shows the uncertainties to be additive.

Overall Cohort Results

The overall cohort results show two main things:

1) The contribution from increasing timing errors depends on the level of BG measurement error. With very accurate BG measurements, timing error are the significant contributor to overall uncertainty.

2) Increasing BG measurement error increases the median uncertainty in CGM measurements linearly from 0.5mmol/L for 2% BG error to 2.5mmol/L for 10% BG error
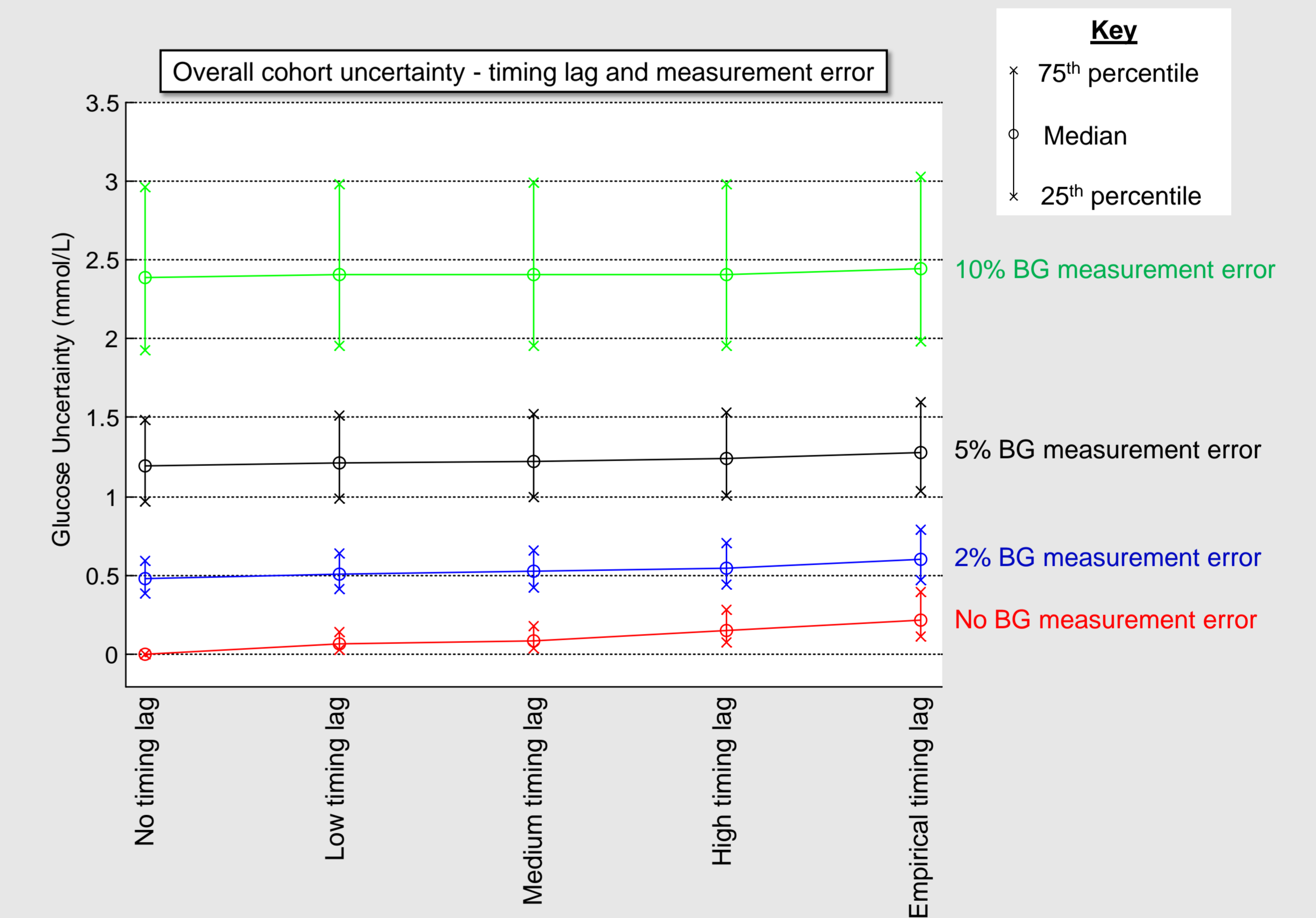
CONCLUSION

Reference BG measurement error causes an almost uniform uncertainty band around the CGM trace, with level of uncertainty depending upon reference sensor accuracy. The effect of timing lags is highly dependent on the local rate of change of glucose, with high rates of change causing very large uncertainties. Clinically, timing lags should be minimized for high variable situations (e.g. Brittle diabetics or post-prandial measurements) to reduce uncertainty.