

# Assessing the impact of test measurement uncertainty on clinical and health-economic outcomes: a case study

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## Background

Many factors can introduce bias and imprecision (i.e. measurement uncertainty) into in-vitro test measurements. If, as a result, test values are incorrectly observed as lying outside of key decision thresholds, then this uncertainty can affect clinical and health-economic outcomes. Currently, however, this impact is rarely considered within laboratory or test evaluation studies.

## Aim

To illustrate methods for assessing the impact of test measurement uncertainty on outcomes.

## Methods

In a recent review, we identified methods for assessing the impact of measurement uncertainty on test outcomes. In this study, we applied the *error model simulation approach* (based on iterative application of bias and imprecision) to a case study test: faecal calprotectin (FC) for the diagnosis of Inflammatory Bowel Disease (IBD). Two primary care FC pathways were evaluated: the 'NICE FC pathway' (single FC test; 50 µg/g diagnostic cut-off threshold) and the 'York FC Care Pathway (YFCCP)' (a repeat-FC strategy; 100 µg/g threshold). The error model simulation was embedded within an existing decision analytic model, to evaluate the impact of measurement uncertainty on diagnostic accuracy, clinical-utility and cost-effectiveness outcomes.

## Results

The NICE FC pathway was found to be highly volatile to positive bias. The YFCCP meanwhile was largely robust to increased measurement uncertainty, suggesting that this pathway is suitable for wide-scale adoption. Using the simulated results, acceptable regions of analytical performance (i.e. maximum bounds for bias and imprecision) were identified, based on the impact of measurement uncertainty on clinical and health-economic outcomes.

## Conclusions

The error model approach provides a useful method for assessing the impact of measurement uncertainty on outcomes. This information is important both for clinical decision makers (to inform whether or not to adopt a new test) and laboratory professionals (to inform evidence-based implementation and monitoring practices for tests within the laboratory).

## Keywords

Measurement uncertainty, simulation, test evaluation