Expert Working Group 'FIT for Screening', Vienna, October 2014.

Quality in faecal immunochemical testing - what to monitor, what to control

Paula McDonald - Laboratory Team Leader, Scottish Bowel Screening Programme, Dundee, Scotland and Centre for Research into Cancer Prevention and Screening, University of Dundee, Ninewells Hospital and Medical School, Dundee, Scotland.

Before the introduction of any new method can be considered in the laboratory, detailed verification of manufacturer's specifications and validation within the proposed clinical setting must be undertaken. Variation within the total test process must be identified: this may arise from two sources, pre-analytical and analytical.

Pre-analytical sources of variation are any biological, sampling or participant issues that may affect the reported clinical outcomes. These must be identified by the laboratory, then described and related back to performance of the test modality. The Faecal Immunochemical Test (FIT) is a test for an indirect tumour marker. It does not identify all cases of colorectal cancer (CRC) and blood may not always be present in faeces in concentrations large enough to be detected by current methods. The sample device takes a measured amount of faeces into a volume of buffer with stabilisers and preservatives: this, when strictly defined, gives a semi-quantitative outcome. Taking the faeces into such buffers reduces degradation of haemoglobin by faecal microbiome but does not eliminate it entirely.

Analytical variation arises within the laboratory process, which includes the supply of reagents. Manufacturers have a responsibility to ensure metrological traceability of the purportedly measured analyte, thereby reducing inherent bias. Once in the laboratory activities are undertaken such as preparing reagents and internal quality control materials. Embedded within this are 'good laboratory practice' and quality improvement processes to record and monitor performance, allowing correction where handling of reagents is poor. Overall performance of the test process is usually assessed by an external quality assessment scheme, where the aim is to protect patient safety by improving the quality and interpretation of testing by providing feedback to laboratories: this should provide an early warning of problems with methods.

Many factors contribute to variation: unacceptable variation can lead to a poor quality laboratory service. The tools outlined here provide a way to measure and control variation in day-to-day practice and ensure consistent, meaningful results are reported within the screening programme.