

Expert Working Group – ‘FIT for Screening’

Short Discussion Document No. 2 – FIT Reporting Units

Prepared by:

Callum G Fraser, Centre for Research into Cancer Prevention and Screening, University of Dundee, Ninewells hospital and Medical School, Dundee DD1 9SY, Scotland (e-mail: callum.fraser@nhs.net)

1. Case for change

Faecal immunochemical tests (FIT) for haemoglobin are replacing traditional guaiac faecal occult blood tests (gFOBT) in population screening programmes. However, the many available FIT differ with regard to a number of key factors. In particular, the methods for sampling, the mass of faeces collected, and the volume and characteristics of the buffer used in the sampling device differ among FIT. This makes comparisons of analytical and clinical test performance characteristics difficult. FIT results may be expressed as the haemoglobin concentration in the sampling device buffer and, sometimes, albeit rarely, as the mass of haemoglobin per mass of faeces. The current lack of consistency in units for reporting haemoglobin concentration is particularly problematic because apparently similar haemoglobin concentrations obtained with different FIT devices can lead to very different clinical interpretations. This also makes selection of the best test for a programme difficult. These considerations apply to both qualitative and quantitative FIT.

2. Proposed solution

Consistent adoption of an internationally accepted method for reporting results would facilitate comparisons of analytical performance characteristics and clinical outcomes. A simple strategy for reporting faecal haemoglobin concentration has been proposed (1,2) that will facilitate the comparison of results between FIT and across clinical studies, namely, by defining the mass of faeces sampled and the volume of sample buffer (with confidence intervals) and expressing results as μg haemoglobin/g faeces. Manufacturers of FIT should provide this information on the mass collected and volume of buffer. All users of FIT, including authors of research articles, guidelines, and policy articles, as well as FIT analysts and regulatory bodies, should adopt these units when reporting FIT results. For existing data, calculation in these recommended units can be achieved simply since:
$$\mu\text{g haemoglobin/g faeces} = (\text{ng haemoglobin/mL}) \times (\text{volume of buffer in the device in mL}) / (\text{mass of faeces collected in mg}).$$

3. Issues for consideration

A. Is it now the time to remove one major unnecessary variable in assessing the analytical and clinical performance characteristics of FIT, that of reporting units, and adopt μg haemoglobin/g faeces ubiquitously: **will all agree to adopt this recommendation?**

B. To facilitate this rational approach, manufacturers and suppliers of FIT that report results as ng haemoglobin/mL buffer will need to supply detailed validated information on the mass of faeces and the volume used in the FIT specimen collection device: **will manufacturers make these data available?**

4. Relevant publications documenting the problems and proposed solutions

1. Allison JE, Fraser CG, Halloran SP, Young GP. Comparing fecal immunochemical tests: improved standardization is needed. *Gastroenterology* 2012;142:422-4.

2. Fraser CG, Allison JE, Halloran SP, Young GP. A proposal to standardize reporting units for fecal immunochemical tests for hemoglobin. *J Natl Cancer Inst* 2012, doi 10.1093/jnci/djs190.