

Expert Working Group 'FIT for Screening', Vienna, 17 October 2014.

Piloting new FIT programmes

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.

Healthcare within the United Kingdom is devolved. The Scottish Bowel Screening Programme currently uses a two-tier reflex guaiac-based FOBT/qualitative Faecal Immunochemical Test for haemoglobin (gFOBT)/(FIT) algorithm to screen men and women aged 50–74 years. All eligible subjects are mailed an invitation, information on colorectal cancer (CRC) and an initial gFOBT card. Strong positives (0.4%) are referred directly for colonoscopy and weak positives (8.0%) receive a qualitative FIT, colonoscopy being offered if this is positive (overall positivity in Programme now 2.1%). Programme organisers undertook an evaluation of the feasibility of introducing FIT as the First Line Test (FFLT) within this context.

As part of the FFLT study, 70,000 consecutive screening-eligible individuals from two Health Boards were invited to take part with the FIT device over a six month period. Faecal haemoglobin (Hb) concentration was collected for 38,000 participants. These data were compared with data from the previous six months and six months after invitation with the FIT device and with contemporaneous data from two Health Boards with similar population demographics. The cut-off used was 400 ng Hb/mL buffer (80 µg Hb/g faeces) estimated to reproduce the overall positivity rate of the Programme.

The data from this study have not only been presented to healthcare providers in Scotland as a way forward from the current test modality, but have also been analysed to determine the dynamics of screening with FIT. A number of publications and collaborations, most notably with Taiwan and Italy, have arisen from this work.

Initial outcome data showed improvement in positive predictive value for total neoplasia detection when compared with the contemporaneous and 'six months after' data, but FFLT was less effective when compared with the historic data (which included some incident screening) (Steele RJC, *et al.* UEG Journal 2013; 1:198-205). Quantitative data partitioned by age and gender showed that, in all age-groups, men have a higher faecal Hb than women and that there is a striking relationship between increasing age and faecal Hb concentration in men and women (McDonald PJ, *et al.* Clin Chem Lab Med 2012;50:935-40). We reasserted our previous observation that faecal Hb increases with disease severity (Digby J, *et al.* J Clin Path 2013;66:415-419). Our research group has shown that faecal Hb concentration increases with increasing deprivation in men and women (Digby J, *et al.* J Med Screen 2014;21:95-97). Further analysis of the data showed that during the period using the FIT sample device, uptake increased more in men than in women and that it increased significantly in the groups that were most deprived (Digby J, *et al.* J Med Screening 2013;21:9577). In the period after screening, uptake fell back to pre FFLT rates.

Although we have published widely from one set of screening data, there is also value in looking at longer term outcomes in the FFLT group, such as investigating Hb concentration in participants who have cancer detected at the next screening round and those found to have interval cancers. We encourage others who undertake trials of FFLT to use the data generated for purposes other than simply assessing feasibility and clinical outcomes to gain as much knowledge as possible on the application of FIT in CRC screening programmes.