Home-use faecal immunochemical testing: primary care diagnostic technology update

BACKGROUND AND ADVANTAGES OVER EXISTING TECHNOLOGY
A variety of home-use faecal occult blood testing (FOBT) kits remain commercially available to UK patients despite caution regarding their safety and accuracy.

FOBT is a relatively non-invasive and inexpensive test. The NHS Bowel Cancer Screening Programme (BCSP) and the majority of European screening programmes uses guaiac FOBT (gFOB). A Cochrane Review has shown that biennial population screening with card-based postal laboratory-analysed gFOB can reduce colorectal mortality by 15% (relative risk [RR] 0.85, confidence interval [CI] = 0.78 to 0.92) in people aged 45–74 years.1 Those who attend screening have a 25% reduction (RR 0.75, CI = 0.66 to 0.84) in their risk of death, but only 40% return all three BCSP gFOB kits, although involving gFOB. Patients may present to primary care having used home bowel-testing kits, and so this report outlines the existing evidence detailing the potential accuracy and utility of the home FIT available to the adult consumer.

Faecal immunochemical testing (FIT) measures the globin component of human haemoglobin. Unlike gFOB, FIT does not require dietary restriction, is specific to lower gastrointestinal (GI) cancers as upper GI enzymes degrade human globin, and is less affected by concomitant medication use. FIT has started to replace gFOB in some regions (for example, the Czech Republic and Italy) and guidelines (for example, the US) give these gains in diagnostic accuracy.

Home FIT kits are designed to obtain samples from multiple parts of a single stool and use immunochromatography to provide an immediate (qualitative) positive or negative result, avoiding the delay and costs associated with laboratory (quantitative) FIT and gFOB. Patients may present to primary care having used home bowel-testing kits, and so this report outlines the existing evidence detaling the potential accuracy and utility of the home FIT available to the adult consumer.

DETAILS OF TECHNOLOGY
Based on a search conducted in December 2013, Box 1 shows the CE approved FIT kits retailing to the UK consumer for between £5.59 and £15.95, marketed as stand-alone home-test kits for use on a single stool sample with rapid results. The PRIMA home test is included as a stand-alone test that is repeated on three samples. None of these kits currently has FDA approval.

PATIENT GROUP AND USE
Home-based testing of adult patients.

IMPORTANCE
Colorectal cancer is the third most common cancer worldwide after lung and breast; incidence patterns are associated with family history and genetics, and variations in diet, deprivation, body weight, and physical activity. In the UK in 2010, colorectal cancer was the fourth most common cancer, accounting for 40,695 new cases and 10% of cancer-related deaths. Early detection of low-grade colorectal cancer increases the likelihood of curative surgical resection and survival, but systematic review repeatedly shows the predictive value of individual (or combined) symptoms or signs is limited in primary care.1,4

PREVIOUS RESEARCH
Accuracy compared with existing technology
No studies evaluating the diagnostic accuracy of any of the home bowel testing kits available to the UK consumer were found.

A systematic review of the value of symptoms and additional diagnostic tests for colorectal cancer detection in primary care reported that qualitative FIT was easy to perform and well tolerated for the investigation of colorectal cancer in symptomatic patients in primary care (sensitivity 50–100%, specificity 71–93%) if compared to gFOB (sensitivity 33–100%, specificity 72–94%).2 However, five FIT kits the HomeSelect™ test, Hemoblot, iFOBT strip device, Immunohemostick, InSure® FIT™ test were compared in studies involving symptomatic patients referred to...
secondary care for investigation, and so no direct evidence was found from primary care populations. The studies included were highly heterogeneous, and validation of the findings using larger studies is needed in primary care, but subgroup analyses suggested that FIT was more sensitive for cancer at all sites and for detecting earlier-stage disease than gFOB.3

One subsequent study was found evaluating an additional FIT (OC-Light ‘Eiken’, Nagase, Japan) in 112 symptomatic patients referred to a rapid-access colorectal service without overt rectal bleeding who underwent lower GI endoscopy or barium enema. For colorectal cancer the sensitivity was 100% and specificity 95.2%, positive predictive value 77.9%, and negative predictive value 100% (confidence intervals not reported).5 It remains unclear whether this accuracy would remain if the test was used in primary care or at home.

Overall, no studies were found that evaluated the accuracy of qualitative FIT kits in asymptomatic patients at home. However, data available from laboratory (quantitative) FIT suggest that home testing may have a potential role in diagnosis, although confirmatory studies in primary care populations are required.

Accuracy of laboratory FIT versus gFOB
A Dutch randomised controlled trial detected advanced neoplasia in a screening population at significantly higher rates using laboratory-based quantitative FIT (OR 2.4, 95% CI = 1.3 to 4.1) compared with laboratory-analysed gFOB.6 and a large study of 85 149 average-risk individuals from the French colorectal cancer screening programme showed superior accuracy of automated quantitative FIT over manual laboratory-analysed gFOB.7 Numerous diagnostic accuracy studies support that laboratory-based quantitative FIT has higher sensitivity and specificity when screening colorectal cancer than gFOB, especially for detecting high-risk adenomas.8

Laboratory FIT versus qualitative FIT
A large German study combined data from asymptomatic patients undergoing screening (n = 1492) and symptomatic patients prior to colonoscopy (n = 62) to compare accuracy between six point-of-care qualitative FITs (ImmunoCARE-C®, FOB advanced, PreventID® CC, bioNexia® FOBplus, QuickVue® iFOB, bioNexia Hb/Hp Complex®) and three laboratory-based quantitative FITs (RIDASCREEN® Hb, RIDASCREEN® Hb/Hp Complex, OC-SENSOR).9 The FITs showed good inter-test agreement using similar thresholds. However, trained investigators in the laboratory setting performed the tests, and no similar evidence was found for FITs performed by primary care practitioners or by patients at home.

Single versus repeat sampling
Whereas single sampling detects large heavily bleeding lesions, repeat sampling is more suited to the intermittent bleeding

| Box 1. CE marked point of care faecal immunochemical test kits marketed for home use in the UK |
|-----------------|-----------------|
| **Kit/Manufacturer/Distributor** | **Method** | **Haemoglobin threshold** |
| **SELF-SURE®** Epitope Diagnostics Inc., San Diego, US | Plastic stool collection device stabs stool at ‘two or more sites’, is then twisted into sealed sampling tube containing developing suspension and shaken. Test strip is screwed into other end of sealed sampling tube and result given. | Not specified |
| Distributed by Personal Diagnostics, UK | Plastic stool collection device stabs stool at ‘various locations’, is then twisted into sealed sampling tube containing developing suspension and mixed. Top is unscrewed and three drops are dropped into the sample well of the test device and result given. | 40 μg/l |
| **FOBCHECK®** NanoRepro, Marburg, Germany | Sampling device incorporated into the lid of the developing solution bottle is used to stab stool at ‘three different locations’, then is fastened and shaken. Tip of top is snapped off and three to four drops are dropped into the dropping hole of the test device and result given. | 30 μg/l |
| Distributed through Amazon.co.uk | Sampling device incorporated into the lid of the developing solution bottle is used to stab stool, taking ‘3–6 samples at different locations’ then is fastened and shaken. Top of tip is snapped off and two drops are dropped into the dropping hole of the test device and result given. | Not specified |
| **Certain Bowl Health Test** Koroglu Medical Devices Ltd, Turkey | Sampling device incorporated into the lid of the developing solution bottle is used to stab stool, taking ‘3–6 samples at different locations’ then is fastened and shaken. Tip of top is snapped off and two drops are dropped into the dropping hole of the test device and result given. | Not specified |
| Distributed through Amazon.co.uk | Unscrew the syringe cap and dip the stick about 2 cm into the faeces at three separate locations, replace the collection stick to the collection device and shake well repeating this procedure three times on separate stools keeping the device in the fridge in between. Snap off the tip and drop six drops to the sample well and read the result after 10 minutes | Not specified |
| **SELFCheck: Bowel Health Kit** CARE Diagnostics, Austria | Plastic stool collection device stabs stool at ‘three different locations’, then is fastened and shaken. Tip of top is snapped off and two drops are dropped into the dropping hole of the test device and result given. | Not specified |
| Distributed by 1st Health Products Ltd, UK through Amazon.co.uk | Plastic stool collection device stabs stool at ‘two or more sites’, is then twisted into sealed sampling tube containing developing suspension and shaken. Test strip is screwed into other end of sealed sampling tube and result given. | 40 μg/l |
| **BOWEL HOME TEST Kit** The Boots Company PLC, Nottingham, England Boots Pharmaceuticals. | Plastic stool collection device stabs stool at ‘two or more sites’, is then twisted into sealed sampling tube containing developing suspension and mixed. Top is unscrewed and three drops are dropped into the sample well of the test device and result given. | Not specified |
| **PRIMA®Home Test: Bowel Test — FOB** Healthy Europe s.r.l., Milan, Italy Distributed through Amazon.co.uk | Sampling device incorporated into the lid of the developing solution bottle is used to stab stool, taking ‘3–6 samples at different locations’ then is fastened and shaken. Tip of top is snapped off and two drops are dropped into the dropping hole of the test device and result given. | Not specified |
REFERENCES


What this technology adds
FIT is more accurate than gFOB for screening, and comparable diagnostic accuracy can be achieved between laboratory based and qualitative FITs (if attention is given to the thresholds used). FIT offers advantages of one-step, single stool, home sampling. GP recommended home FIT could improve screening yield and uptake (as this has worked for gFOB), and home testing could potentially be used as part of diagnostic evaluation in symptomatic patients, but studies in primary care are needed to confirm this. The lack of robust evidence on the comparative accuracy of home bowel testing kits and laboratory methods needs urgent attention in both the asymptomatic and symptomatic patients. For example, a diagnostic accuracy study comparing laboratory [quantitative] FIT with the available home [qualitative] FITs when used at home by patients and in primary care by a GP. At present there is not enough information to confidently say whether a patient who presents to primary care having performed a home test and received a negative (or positive) result should be reassured (or investigated).

Methodology
Standardised methodology was applied in writing this report, using prioritisation criteria and a comprehensive, standardised search strategy, and critical appraisal (full details at www.madox.org). The search for this article was conducted in December 2013.

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