

Discontinued Availability of the Guaiac Fecal Occult Blood Test (gFOBT)

To all Physicians and Health Providers

- Effective January 2014, the guaiac Fecal Occult Blood Test (gFOBT) will no longer be available for use in community health care settings. It will continue to be available in acute care facilities but may be discontinued at a later date.
- The Fecal Immunochemical Test (FIT) has replaced the gFOBT for colorectal cancer (CRC) screening of average risk asymptomatic individuals (50 to 74 year olds) and is available province-wide.
- There is little evidence for use of the gFOBT in the diagnostic work-up of symptomatic patients. Use of the gFOBT in the work-up of symptomatic patients may delay appropriate and timely referral for endoscopic investigation.
- Patients with signs or symptoms indicating possible gastrointestinal pathology should be investigated and referred for consultation.

Background

The gFOBT has been commercially available for decades and was designed to detect the heme component in hemoglobin in the feces through peroxidase activity. The gFOBT has been consistently shown to reduce CRC specific mortality in randomized controlled trials of screening.

Alberta Health Services, with support from Alberta Health, has introduced a new CRC screening test in Alberta, the FIT. The FIT is an easy-to-use and highly sensitive test that uses human-specific anti-globin antibodies to detect trace amounts of blood in stool. The FIT will be considered the primary screening modality for average risk individuals, replacing the gFOBT as well as average-risk screening colonoscopy.

Use of gFOBT for non-screening purposes

There is little evidence to support the use of the gFOBT beyond CRC screening. Despite this, gFOBT has been frequently and commonly used as an adjunct for the investigation of patients with lower gastrointestinal symptoms.

In Alberta there has been inconsistent messaging and/or a lack of a standardized approach for the required investigations to obtain a gastrointestinal (GI) consultation. Depending on local practitioners and their understanding of required investigations for referral, use of the gFOBT is “*thought*” to be necessary in patients with GI symptoms, especially when anemia is present. However, the gFOBT result does not provide critical information and can be misleading. In general, baseline investigations of patients with possible GI blood loss must include a complete blood count and serum ferritin. Patients with iron deficiency anemia and suspicion of GI blood loss should be referred to GI care for endoscopic follow up investigations. Although the gFOBT can detect upper GI bleeding, current evidence reveals that the gFOBT does not reliably screen for upper GI cancer or other, benign pathology. Long-term follow-up studies of subjects who had gFOBT-positive screening with normal colonic investigations had a low incidence of upper GI cancer^{1,2}.

To further demonstrate the ineffectiveness of the gFOBT as a diagnostic test, gFOBTs were ordered because of anemia (41%), suspicion of rectal bleeding (17%), abdominal pain (14%), changed bowel habits (10%) or others (18%) in one recent report³. A positive test result was found in 66 (33%) patients and a negative in 133 (66%). Thirty eight percent (25/66) of the patients with a positive and 41% (55/133) of the patients with a negative gFOBT result, respectively,

eventually received a GI follow-up investigation. This study clearly demonstrates the lack of diagnostic value of the gFOBT in patients with symptoms.

Elderly patients (>75 years) are likely to have a higher incidence of comorbidity, which might create a barrier for referral for invasive diagnostic tests. Therefore, the gFOBT as a diagnostic test may be perceived by physicians as a more appropriate diagnostic test compared to the endoscopic test. However, persons in this age group have the highest pretest likelihood of gastrointestinal pathology (e.g. cancer). As symptoms are common, it is important to refer these patients for further endoscopic examination. Furthermore, the use of the gFOBT with its relatively low predictive value, could lead to further delay in these patients' diagnostic evaluation. If the gFOBT result is negative it may discourage physicians from referring to GI care, despite the presence of symptoms.

At this time national and international guidelines recommend that "symptomatic patients" (i.e. suspicion of rectal blood loss or melena, anemia, changes in bowel habits or abdominal pain) be referred directly for endoscopic evaluation, especially for individuals who are 50 years of age or older^{4,5}. Because of the low sensitivity of the gFOBT, a diagnosis of cancer may be delayed in symptomatic individuals based on a negative gFOBT, resulting in a worse outcome.

Conclusion and Recommendations

The gFOBT is often used as a diagnostic tool for a variety of reasons in symptomatic patients, i.e. for non-screening purposes. This practice is not evidence based and can lead to unnecessary and consequential delays in the diagnostic work-up. Based on this evidence, the use of the gFOBT for indications other than colorectal cancer screening in the asymptomatic average risk population (aged 50 to 74) is not warranted and will no longer be available. At this time, the Fecal Immunochemical Test (FIT) is to be used for asymptomatic colorectal cancer screening only.

This communication was prepared by the Primary Care Engagement Working Group.

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