



Topic Exploration Report

Topic explorations are designed to provide a high-level briefing on new topics submitted for consideration by Health Technology Wales. The main objectives of this report are to:

1. Determine the quantity and quality of evidence available for a technology of interest.
2. Identify any gaps in the evidence/ongoing evidence collection.
3. Inform decisions on topics that warrant fuller assessment by Health Technology Wales.

Topic:	Faecal Calprotectin Home Testing
Topic exploration report number:	TER289

Introduction and aims

Health Technology Wales researchers searched for evidence on the use of faecal calprotectin home testing (FCHT) for people with a confirmed diagnosis of inflammatory bowel disease (IBD). The topic proposer highlighted the IB Doc test and similar tests are available.

Elevated faecal calprotectin is a marker of intestinal inflammation in people with IBD. FCHT can facilitate rapid testing of this marker by providing people with stool sample collection and testing equipment, which can be interpreted with use of a smartphone camera and be used at home. Use of FCHT could allow people to feel more in control of monitoring their condition and could reduce the need for people to travel to hospital for outpatient testing. It has been suggested that it could also reduce the need for colonoscopy due to rapid confirmation of flares and appropriate alteration of drug regimes.

Summary of evidence

Technology Assessments

A NICE medtech innovation briefing (MIB) on FCHT for monitoring in people with IBD has been published previously (NICE, 2017). It summarises four prospective observational studies, one retrospective observational study and one randomised controlled trial. The evidence summary notes that these studies mostly simulated at-home testing in experimental settings rather than evaluating use by people in their own homes. Some also appear to have limited reporting of their methodologies and details of the included population. In general, the studies reported moderate to high correlations between findings of FCHT and reference tests and moderate to high diagnostic accuracy. One retrospective observational study with 77 children with IBD reported that 86% of abnormal tests led to changes in treatment that significantly improved outcomes.

Primary studies

Several studies published since the NICE medtech innovation briefing were identified. Puolanne et al. (2019) conducted a randomised controlled trial comparing FCHT and usual

care in Finland. One hundred and eighty participants were randomised but only 123 were analysed due to drop out and only 24 participants (n=38%) in the FCHT arm and 12 participants (20%) in the usual care arm continued in the study for follow up at one year. The study reports that there were no differences in health-related quality of life between the groups at any point in the study and the disease course was similar across groups. Participants receiving FCHT were less likely to have more than two visits to outpatient clinics than those in the control group (24% vs. 40%, $p=0.05$). However, the number of laboratory visits did not differ across groups and these were planned mainly for monitoring of drug safety.

Another randomised controlled trial was conducted in Sweden (Ostlund et al. 2020) and included participants who agreed to take part in testing after being invited by letter and people identified as being eligible for inclusion. Using this approach, 48 participants were included in the FCHT arm and 74 participants in the control arm. Only 24 participants (50%) in the FCHT arm activated the testing app and used a test. Participants in the two groups did not differ on healthcare visits but those in the FCHT arm were more likely to receive an increased dose or a new drug compared to the control arm.

Weimers et al. (2018) present findings on patient satisfaction with FCHT in a poster abstract. Across two groups who were randomised to at home testing either every three months or at their own discretion, there were high levels of satisfaction with people wishing to continue with the approach (n=64, 94%). However, some reported difficulties completing the testing (n=14, 21%) and as with other studies, there was a high level of drop out within a year (n=15, 18%).

Areas of uncertainty

Studies of FCHT had high levels of drop out and it is unclear whether this was due to the research methods used in the studies or due to dissatisfaction with the approach to testing. Studies that reported satisfaction did find high levels for participants who completed follow-up. It seems possible that there are distinct groups within the patient population who are and are not satisfied with the approach. However, this is highly uncertain.

Several studies published since the NICE MIB were identified. However, they rely on small populations and limited follow-ups. Due to this, there is a large amount of uncertainty on the effectiveness of FCHT on different outcomes.

Conclusions

FCHT may allow people with IBD to take a more active role in managing their condition. A large group of people indicated satisfaction with the FCHT approach and would continue to use it in the future if available. However, studies had high levels of drop outs and the reasons for this are unclear.

Identified studies do not suggest that FCHT leads to large reductions in healthcare visits, improvements in disease course, or improvements in quality of life. However, there is some evidence that treatment changes are made in response to FCHT but this is based on small patient numbers and limited numbers of events.

Larger scale, high-quality randomised controlled trials may be able to provide clearer evidence on these issues and provide more definitive answers to the effectiveness and acceptability of FCHT.

Brief literature search results

Resource	Results
HTA organisations	
Healthcare Improvement Scotland	We did not identify any relevant information or guidance from this source.
Health Technology Assessment Group	We did not identify any relevant information or guidance from this source.
Health Information and Quality Authority	We did not identify any relevant information or guidance from this source.
EUnetHTA	We did not identify any relevant information or guidance from this source.
International HTA Database	We did not identify any relevant information or guidance from this source.
UK guidelines and guidance	
SIGN	We did not identify any relevant information or guidance from this source.
NICE	We did not identify any additional information or guidance from this source.
Secondary literature and economic evaluations	
Cochrane library	We did not identify any relevant secondary literature or economic evaluations from this source.
Medline	We did not identify any relevant secondary literature or economic evaluations from this source.
Primary studies	
Cochrane library	<p>Ostlund et al. (2020). Self-monitoring with home based fecal calprotectin is associated with increased medical treatment. A randomized controlled trial on patients with inflammatory bowel disease. <i>Scandinavian Journal of Gastroenterology</i>, 56, 38-45. https://doi.org/10.1080/00365521.2020.1854342</p> <p>Puolanne et al. (2019). Is home monitoring of inflammatory bowel disease feasible? A randomized controlled study. <i>Scandinavian Journal of Gastroenterology</i>, 54, 849-854. https://doi.org/10.1080/00365521.2019.1618910</p> <p>Weimerset al. (2018). Patient satisfaction with home monitoring of disease activity and fecal calprotectin in adult patients with inflammatory bowel disease-interim analysis of 68 patients. <i>United European Gastroenterology Journal</i>, 5, A281-282. https://doi.org/10.1177/2050640617725676</p> <p>Additional studies were identified that compared differing frequency of FCHT. These were not included in the summary as they are less useful in assessing whether FCHT has benefits compared to standard care.</p>
Medline	
Ongoing primary or secondary research	
PROSPERO database	We did not identify any ongoing systematic reviews from this source.
Other	
<i>Provided by the topic proposer</i>	NICE. (2017). Point-of-care and home faecal calprotectin tests for monitoring treatment response in inflammatory bowel disease. Medtech innovation briefing 132 (MIB132). London: UK https://www.nice.org.uk/advice/mib132

Date of search:	May 2021
Concepts used:	Faecal calprotectin home testing; inflammatory bowel disease; flare;