Point-of-care and home faecal calprotectin tests for monitoring treatment response in inflammatory bowel disease

Summary

- The 5 **technologies** described in this briefing are point-of-care and home-use faecal calprotectin tests for monitoring treatment response in people with inflammatory bowel disease (IBD).

- The **innovative aspect** is that the test results can be acted on more quickly than waiting for standard laboratory tests. Most of the home-use tests use smartphone apps. Information from the tests can be used to guide further treatment and inform the need for colonoscopy.

- The intended **place in therapy** would be alongside clinical observations and patient-reported symptom severity in people having drug treatments for IBD, such as anti-TNF therapies.

- The **main points from the evidence** summarised in this briefing are from 4 prospective studies, 1 retrospective study and 1 randomised controlled trial including a total of 558 patients. The evidence suggests that point-of-care and home-use faecal calprotectin tests have comparable accuracy to laboratory ELISA tests, but with better patient satisfaction.

- **Key uncertainties** around the evidence or technology are the lack of a standard NHS pathway for the use of faecal calprotectin. There is limited evidence on long-term clinical outcomes of treatments guided by faecal calprotectin tests or on the clinical impact of people self-testing in a home-setting. Only 1 of the 6 studies summarised included UK patients so there is also limited evidence of their use in an NHS care pathway, and there are limited data specific to children.

- The **cost** of point-of-care and home-use faecal calprotectin tests range from £23.25 to £85.85 per unit (exclusive of VAT). The **resource impact** would be greater than standard care because of the test costs, but this could be offset if their use reduces colonoscopies and clinical appointments. Costs may also be saved if the tests can more quickly identify ineffective treatments. Implementing the technologies may need changes to the NHS care pathway.

This briefing describes technologies which fulfil a similar purpose. During development, every effort was made to identify and include relevant technologies but others may not have been identified, or excluded when important information was unavailable.

The technology

Elevated faecal calprotectin (FC) is a marker of intestinal inflammation, including that caused by inflammatory bowel disease (IBD). NICE diagnostics guidance recommends FC testing for the diagnosis of IBD; this briefing summarises the available information on the use of FC to monitor treatment response in patients with IBD.

There are 3 types of FC test available: point of care (used by healthcare professionals), home use (used by patients or carers) and laboratory (used by laboratory scientists). This briefing includes only point-of-care and home-use tests because laboratory tests are widely available in the NHS, although their usage varies.

Point-of-care tests provide rapid results on FC levels. They come as single-use, disposable kits which are usually used with a dedicated, reusable reader (connected to a computer). The tests use lateral flow immunoassays specific to FC. The patient provides a

stool sample that is collected and an extract from the sample is prepared for analysis by a healthcare professional. This typically involves placing the extracted sample into an extraction solution which is mixed together using a vortex mixer or centrifuge. Once this step is complete, the extracted sample is then added to the test plate, which is inserted into a reader. Results are displayed on the connected computer. The results can be quantitative or semi-quantitative; the latter show the results as ranges or as a traffic light rating scale. The result is shown 10 to 15 minutes after applying the sample to the test plate.

Home-use tests allow patients to monitor their own FC levels and transmit the results directly to their healthcare professional. Most home-use tests need a smartphone with camera, which is not provided with the test. Home-use tests generally consist of a stool sample collection kit, a sample extraction tube, FC extraction solution, the test plate, a smartphone camera calibrator and a smartphone app to interpret and transmit the results.

To use the tests, the user logs into an app on their smartphone. A stool sample is collected, a small sample of which is placed into an extraction tube with some extraction solution. The tube is shaken by hand for a few minutes and left to process. Once this stage is completed, 1 or 2 drops of the sample are released from the sample tube (by turning a lever or squeezing the tube) onto the test plate. The test is left to develop and the smartphone camera is used to capture an image of the completed test. The app interprets the test and provides the user with the test results and transmits them to a healthcare professional if needed. The test itself takes 10 to 15 minutes to complete; however, some tests require the sample to be left in the extraction solution for at least 2 hours before transferring to the test plate. Like point-of-care tests, home-use tests provide either quantitative or semi-quantitative data. Semi-quantitative results will not display slight variations in calprotectin levels; this can avoid unnecessary stress or anxiety, but rising calprotectin levels may precede a relapse. If the test reports an abnormal FC level, the healthcare professional is alerted either manually by the patient or automatically by the app, depending on the settings. The clinician can make an informed decision about the person's condition and whether to change their treatment regimen based on the data provided.

Table 1 below summarises the 5 FC tests included in this briefing.

Table 1: Summary of technologies

Technology	Type	Additional information	Regulatory status
IBDoc (Buhlmann)	Home use; quantitative	Results range from 30 to 1,000 mcg/g. They can be presented in a traffic light rating scale with patient-specific thresholds established by the clinician. An Android or iOS smartphone is needed. The app can be setup so that the patient does not see their own results.	IVD (March 2015)
Quantum Blue (Buhlmann)	Point of care; quantitative	Three kits are available: results range from: • LF-CAL25: 30 to 300 mcg/g • LF-CHR25: 100 to 1,800 mcg/g • LF-CALE25: 30 to 1,000 mcg/g. A separate test reader is needed.	IVD (LF-CAL25 and LF-CALE25: February 2017; LF-CHR25: May 2017)
Calprosmart Home (Calpro)	Home use; quantitative	Results range from 70 to 1,500 mcg/g. They can be presented as 1 of 3 ranges: <200, 200–500 and >500 mcg/g. An Android or iOS smartphone is needed for the home version. The app can also be setup so that the patient does not see their own results.	IVD (December 2015)
Calprosmart Office (Calpro)	Point of care; quantitative		
Calfast (Eurospital)	Point of care; semi-quantitative	Results range from less than 50 to over 300 mcg/g. Exact values are shown for results between 51 and 300 mcg/g. A separate test reader is needed.	IVD (July 2011)

Innovations

Point-of-care FC tests may enable treatment decisions to be made during a single clinic visit, without having to wait for laboratory test results, ensuring that ineffective treatments are stopped as early as possible.

In addition, home-use FC tests are designed to reduce avoidable clinic visits; in some

cases an app interprets the results based on a locally determined, predefined threshold. These can be setup so that they automatically alert healthcare professional if the results are abnormal. Establishing patient-specific thresholds needs regular testing to determine the normal range. This is not possible through traditional testing methods that require a patient to attend a clinic.

Current NHS pathway or current care pathway

NICE diagnostics guidance on faecal calprotectin diagnostic tests for inflammatory diseases of the bowel recommends using FC tests in conjunction with clinical symptoms, monitoring and blood tests (C-reactive protein [CRP] and erythrocyte sedimentation rate [ESR]) for distinguishing between inflammatory and non-inflammatory bowel diseases. It does not include recommendations on monitoring treatment response.

After diagnosis, FC testing can be used to monitor FC levels at check-ups, or in-between if symptoms reoccur. The British Society of Gastroenterology guidance on the use of faecal calprotectin testing in IBD does not recommend the routine use of FC testing for monitoring treatment response in IBD, but suggests it can be used circumstantially as an aid to treatment decisions. FC levels are measured using in vitro diagnostics, such as ELISA, completed in a laboratory by a trained HCPC-registered biomedical scientist or clinical scientist. ELISA is considered to be the gold standard in measuring FC levels. For monitoring treatment response, laboratory ELISA, clinical monitoring, CRP and ESR are all regularly used in NHS practice, although local protocols vary. Colonoscopy may be considered if the previous tests are inconclusive.

Population, setting and intended user

FC testing would be used for people with IBD to monitor remission and treatment response. Elevated FC levels are also associated with colorectal cancer and so this must be ruled out before treatment decisions are made.

Home-use tests can be used by the patient without supervision. Training is needed in the form of a demonstration by a trained healthcare professional, or using instructions for the test (either written or a video tutorial). Training is also essential because the home tests require handling of stool samples, so there is a biohazard risk. Healthcare professionals may verify that the first home test is done correctly.

Point-of-care FC tests are used by GPs, specialist nurses or gastroenterologists in primary or secondary care. The sample can be posted to the clinic if needed. Many companies offer training and support for healthcare professionals using their tests.

Costs

Table 2 shows the costs of the FC tests included in this briefing.

Table 2: Technology costs

Technology	Costs	Total cost per use	Additional information
IBDoc home-use test (Buhlmann)	£64.35 per test. One appointment with nurse (25 minutes, including patient training; first appointment only) £17.92. Checking results sent from patients' mobile (5 minutes) £3.58.	First test: £85.85 Later tests: £67.93	Expendables: £512 for 8 tests (including training). An annual £350 maintenance fee applies. No reader is needed.
Quantum Blue point-of-care test (Buhlmann)	£23.22 per test. One appointment with nurse (15 minutes) £10.75.	£33.97	Expendables: £508.93 for 25 tests (including training). Reader: £2,864.63.
Calprosmart Home home-use test (Calpro)	£50.00 per test. One appointment with nurse (25 minutes, including patient training; first appointment only) £17.92. Checking results sent from patients' mobile (5 minutes) £3.58.	First test: £71.50 Later tests: £53.38	–

Calprosmart Office point-of-care test (Calpro)	£30 per test. One appointment with nurse (15 minutes) £10.75.	£40.75	Cost of test includes training. No reader is needed.
Calfast (Eurospital)	£12.52 per test. One appointment with nurse (15 minutes): £10.75.	£23.27	Expendables: £211.17 for 20 tests (including training) Reader: £1,960.
All costs exclude VAT. Maintenance and reader costs were divided by 1,000, based on the assumption that the test will be used by 1,000 patients. Nursing costs are taken from PSSRU 2016.			

Costs of standard care

Standard care includes symptom monitoring, ESR, CRP and colonoscopy (if clinically indicated).

Table 3 shows the estimated costs of standard care.

Table 3: Cost of standard care for monitoring people diagnosed with IBD

Treatment	Cost (excluding VAT)	Additional information
ELISA in laboratory	£23.30	Including test cost and 11–12 minutes of staff time at grade 6/7. This cost was uplifted*.

Clinical monitoring	£126.51	Weighted based on these assumptions: • 20.4% of people with IBD are children (Betteridge et al. 2013) • All children with IBD are in secondary care • 24% of adults with IBD are in primary care, 76% are in secondary care (UK IBD primary care questionnaire 2012).
ESR	£3.75	This cost was uplifted*.
CRP	£1.97	This cost was uplifted*.
Colonoscopy	£458.00 (adults), £1,705.30 (children).	Colonoscopy should only be used if clinically indicated.
All monitoring (no colonoscopy)	£155.53	Costs are higher with colonoscopy: £613.53 (adults) and £1,860.83 (children).
* These costs were uplifted to 2016/17 prices using the hospital community health services index. When possible, costs are taken from NICE guidance or NHS reference costs.		

Resource consequences

Quantum Blue is currently used by 9 NHS hospitals in the UK. IBDoc is used in 1 NHS hospital. None of the other FC tests included in this briefing is routinely used in the UK.

All 5 included FC tests would represent additional acquisition costs compared with standard care. Training is needed in their use but this is generally included in the purchase price. Point-of-care tests need a healthcare professional to prepare the sample and carry out the test.

The higher acquisition costs could be offset if using the tests reduces the need for colonoscopy or for clinic attendance for check-ups involving symptom monitoring.

Compared with standard care, point-of-care and home-use FC tests may allow for faster identification of disease relapse. No published evidence on the resource consequences of adopting FC tests for monitoring people with IBD was found.

Regulatory information

A search of the Medicines and Healthcare products Regulatory Agency website revealed that 2 manufacturer field safety notices have been issued for Buhlmann faecal calprotectin tests. One of these was for an incorrect assay date with Quantum Blue; the other was for positive bias with the CALEX Cap extraction device and corrective action with CALEX Cap "N" (used with IBDoc and Quantum Blue).

No other field safety notices or medical device alerts were identified for the technologies in this MIB.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to: promote race and disability equality and equality of opportunity between men and women, eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

Inflammatory bowel disease is more likely to be diagnosed in people in their 20s, but it can occur at any age. It is more common in people of African-Caribbean family origin or European family origin, particularly those with Eastern European Jewish backgrounds. Crohn's disease is more common in women and ulcerative colitis is slightly more common in men. Age, sex and ethnicity are protected characteristics under the Equality Act 2010.

The need for a compatible smartphone for home-use technologies may exclude some people.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the interim process and methods statement. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

This briefing summarises 6 studies, including a total of 558 patients: 4 prospective studies (n=260), 1 retrospective study (n=77) and 1 randomised controlled trial (n=221). Only 1 study was done in the UK.

Overall assessment of the evidence

Most of the evidence comes from small studies that use different reference standards (ELISA or EliA) or different technologies (for example, Buhlmann ELISA or Calpro ELISA) as the comparator. The studies of home-use tests were generally done in environments replicating home use, rather than in people's actual homes.

Most of the studies on treatment monitoring were short term, and none of the studies compared multiple faecal calprotectin (FC) tests directly. Only 1 of the studies focused specifically on children.

Further research is needed to determine the long-term clinical outcomes of point-of-care and home-use FC testing on maintaining remission compared with periodic clinical check-ups.

Table 4 summarises the clinical evidence as well as its strengths and limitations.

Table 4: Summary of evidence

El-Matary et al. (2017)

Study size, design and location	77 children with IBD in a retrospective single-centre study, Canada.
Intervention and comparator(s)	Intervention: Quantum Blue (POC). Comparator: standard practice, including ESR, CPR and clinical outcomes.
Key outcomes	86% of abnormal FC tests resulted in a treatment change that significantly improved clinical outcomes. 83% of children with normal FC measurements maintained remission on follow-up 3–6 months later. 88% of treatment decisions were based solely on FC testing.
Strengths and limitations	In the sample, the children were prescribed different medications (a total of 8 different medications were prescribed in the study, some children were prescribed multiple) and the performance of FC testing across different treatment regimens was not discussed. Unlike most of the literature, in this study, FC testing did not correlate with CRP. Only 12% of the children had colonoscopies, so the prevalence of false negatives is unknown.

Ferreiro-Iglesias (2016)

Study size, design and location	53 adults with IBD in a prospective, cross-sectional, observational, single-centre study, Spain.
Intervention and comparator(s)	Intervention: Quantum Blue (POC). Comparator: clinical symptom indexes (Harvey and Bradshaw index for CD, Partial Mayo index for UC).
Key outcomes	Monitoring of treatment with infliximab over 2 months found people with low FC levels when administering infliximab had no relapses during this time. The sensitivity and specificity for predicting relapse was 91.7% and 82.9% respectively. FC testing was the only independent predictor of IBD relapse (p<0.005).

Strengths and limitations	The follow-up period was just 2 months.
	Clinical symptom questionnaires were used to define relapse, rather than colonoscopy.

Heida et al. (2017)	
Study size, design and location	101 children and adults (aged 10 years or older) in a prospective single-centre comparative study, Netherlands.
Intervention and comparator(s)	Intervention: IBDoc (home use) and Quantum Blue (POC).
	Comparator: laboratory ELISA (Buhlmann).
Key outcomes	Correlation was 0.94 for results obtained by IBDoc versus Quantum Blue and 0.85 for IBDoc versus ELISA. Discordant test result pairs (IBDoc versus ELISA or IBDoc versus Quantum Blue) that could potentially lead to different treatment outcomes occurred in 6 of 152 stool samples (4%).
	In a self-reported usability questionnaire, 87% of respondents said the test was not difficult and 97% were interested in using the home test in the future.
Strengths and limitations	The proportion of children and adults, and the results for each of those groups, were not outlined in the study. IBDoc tests were done at home using patients' own smartphones.
	There was a median delay of 2 days between IBDoc home testing and stool arriving at the hospital for Quantum Blue and laboratory ELISA testing; this delay could influence the agreement between the results
	Only 62% of the patients completed the self-reported usability questionnaire.

Parr et al. (2016)	
Study size, design and location	54 adults with IBD (23 people with CD and 31 people with UC), consecutively recruited in a prospective single-centre pilot study, UK.
Intervention and comparator(s)	Intervention: IBDoc (home use).
	Comparator: laboratory ELISA (Buhlmann).

Key outcomes	Strong positive correlation of numerical FC results was reported between the 2 methods (r=0.77, p<0.0001). 63% of respondents preferred using IBDoc for routine testing, under the caveat that they could obtain contact from their designated healthcare professional (gastroenterologist or GP) within 1–3 days of receiving an abnormal IBDoc test result. A further 22% preferred the IBDoc test and stated that they did not think further contact before their next scheduled appointment was necessary.
Strengths and limitations	These results are from a poster abstract so there is limited information to assess study methodology. The IBDoc test was conducted once a month for 4 months at home without supervision, accurately replicating the intended environment of the test.

Ungar et al. (2017)

Study size, design and location	52 adults with CD in a prospective, single-centre study, Israel.
Intervention and comparator(s)	Intervention: IBDoc (home-use) and Quantum Blue (POC). Comparator: none.
Key outcomes	There was a strong correlation between results from both assays (r=0.924, p<0.0001). Level of education and age did not significantly influence the correlation between tests results (r>0.92, p<0.0001, for both comparisons). However, in 27 out of 52 tests the difference in quantitative result of the paired tests was more than 25%.
Strengths and limitations	These results are from a poster abstract with limited details of methodology, the reference standard used or how educational status was considered. IBDoc was done under guidance by qualified personnel, which does not reflect the setting in which it is intended to be used.

Vinding et al. (2016)

Study size, design and location	221 adults with IBD (115 with UC and 106 with CD) in a prospective, single-centre randomised control trial, Denmark.

Intervention and comparator(s)	Intervention: CalproSmart (home use and POC). Comparator: standard ELISA at 2 different laboratories (Buhlmann and Calpro).
Key outcomes	CalproSmart had high sensitivity (82%) and specificity (85%). A significant difference in the correlation between results was found based on educational status; 2 populations were defined according to whether or not they held a postgraduate degree. Both populations showed moderate positive correlation, but CalproSmart completed by people with postgraduate degrees aligned more significantly with the laboratory ELISA test. No other significant differences based upon population characteristics were identified.
Strengths and limitations	The tests were done in an outpatient clinic simulating a home environment. Patients were trained in accordance with manufacturer's recommendations. Patients used a phone provided by the researchers and not their own. This may have led to technical difficulties arising because of the smartphone technology rather than any difficulties in completing the test. No timer was provided during the experiment.
Abbreviations: AUC, area under curve; CD, Crohn's disease; erythrocyte sedimentation rate, ESR; C-reactive protein, CRP; IBD, inflammatory bowel disease; POC, point of care; UC, ulcerative colitis.	

Recent and ongoing studies

- Home-based Faecal Calprotectin Measurements Predicting Adalimumab Induction Destiny (HELP-AID). ClinicalTrials.gov identifier: NCT02634060. Status: Ongoing, currently recruiting. Location: Belgium. Indication: Crohn's disease, ulcerative colitis. Devices: IBDoc.

- Home Versus Postal Testing for Faecal Calprotectin: a Feasibility Study. ClinicalTrials.gov identifier: NCT02542917. Status: Unknown. Location: UK. Indication: IBD, Crohn's disease, ulcerative colitis. Devices: IBDoc.

- Is Relapse Rate Reduced by Home Monitoring of IBD Patients Tightly or on Demand by FC and Disease Activity? ClinicalTrials.gov identifier: NCT02492555. Status: Ongoing, currently recruiting. Location: Denmark. Indication: IBD. Devices: Calprosmart.

- [Are Rates of Colectomies, Resections, Mortalities and Cancer Reduced by Home Monitoring of IBD Patients](#) ClinicalTrials.gov identifier: NCT03038984. Status: Ongoing, currently recruiting. Location: Denmark. Indication: IBD. Devices: Calprosmart.

Specialist commentator comments

Comments on these technologies were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

Two of the 6 specialist commentators were familiar with point-of-care or home-use faecal calprotectin (FC) tests and had used them before. All 6 were familiar with laboratory FC tests.

Level of innovation

Two specialists thought that the tests were innovative; 1 specifically mentioned home testing. One specialist stated that they considered IBDoc to be innovative, based on their own experiences. Conversely, 2 specialists felt that the technologies were only a minor variation on the current UK standard of care.

None of the specialists was aware of any alternative technologies available on the NHS that offer similar functionality for point-of-care or home use.

Potential patient impact

Two specialists believed that almost all people with inflammatory bowel disease (IBD) could benefit from these tests; 2 others believed that they could benefit around half the population with IBD. One commentator felt that they would benefit people with stable IBD, and another felt they would most benefit people having an acute symptomatic episode and after resection surgery for Crohn's disease. However, another specialist felt the benefits of the tests were too uncertain to provide an estimate.

Two specialists stated that people who cannot or prefer not to attend clinic appointments would benefit from home-use FC tests. One specialist commented that the tests were more appropriate for use in adults because of their low specificity in children, which may

lead to unnecessary invasive procedures such as colonoscopies. Two specialists commented that FC testing is unlikely to change gastroenterologists' decision to request a colonoscopy.

One specialist mentioned this these FC tests would be beneficial if they allowed for more immediate assessment of symptoms as they arise. They noted that laboratory FC in their trust can take up to 4 weeks to provide results.

Three specialists mentioned the benefits of promoting self-management through home tests in people with IBD, citing reassurance of treatment efficacy, convenience and patients having control over their own condition. However, one specialist noted that the need to use a smartphone may limit the tests' usage. Another specialist commented that home testing would be the responsibility of the patient, and that there is a risk of incorrect usage. They also noted that the cost of using a smartphone to transmit the results, though negligible, must be paid by the patient themselves.

Two specialists suggested that unnecessary anxiety may be an issue with home testing when FC levels rise or if there are false positives. Using a traffic light rating scale may help ease anxiety in people using the tests.

Four specialists believed that the FC tests could improve clinical outcomes with fewer outpatient appointments and hospitalisations. One specialist noted that frequency of testing will affect the outcomes.

Potential system impact

Three specialists cited cost reductions from fewer colonoscopies and referrals to secondary care as benefits. One specialist believed that the FC tests would be cost neutral because of the higher associated acquisition costs, but another felt that the tests would increase costs in monitoring of children with IBD.

Two specialists noted that point-of-care and home-use FC tests could move monitoring of IBD from secondary to primary care. They pointed out that this would mean changing follow-up pathways to include phone or online methods. Improved convenience for patients and testing for people in remote locations were cited as potential benefits. However, 1 specialist noted that heterogeneity in the results may lead to difficulties in interpreting and comparing the data.

Three specialists felt that training for both point-of-care and home-use tests would be needed; 1 felt that if training were needed, a specific resource may need to be provided. One specialist noted that patient data protection and IT capabilities must be considered. Three specialists mentioned that patients and GPs may be reluctant to handle stool samples. Another commentator raised concerns over biohazard issues from handling stool samples in primary care or at home.

General comments

One specialist noted that it was unclear how these FC tests could be implemented and what benefits there would be. They stated that adherence to MHRA guidelines on point-of-care testing could be challenging for non-laboratory sites. Another pointed out that these tests may have lower accuracy and higher variability than laboratory-based tests. Two other specialists agreed that accuracy considerations must be considered before implementing point-of-care or home-use FC tests.

Three specialists believed that these kinds of FC tests would be an addition to the current UK standard of care. One thought that they could replace laboratory FC testing.

Eurospital Calfast requires centrifugation of a stool sample before a test can be done. Three specialists confirmed this would potentially limit its application in primary care because it needs extra equipment, handling and staffing.

Three specialists mentioned the need for further research into the tests. This included investigations into their analytical performance, variability of outcomes in home testing, and resource utilisation studies from centres already using them.

Patient organisation comments

Responses were received from 2 patient organisations, 1 of which stated that some patients associated with the organisation are likely to have used point-of-care or home-use faecal calprotectin (FC) tests. They commented that a focus group of people with inflammatory bowel disease (IBD) responded positively to the ease of use and convenience offered by the tests.

The representatives from both organisations thought that the tests had the potential to improve health outcomes, but 1 stated that there is not yet enough evidence for this. Both

noted the potential negative implications of using the tests such as anxiety and false positives leading to unnecessary invasive procedures.

One representative stated that these tests offer people with IBD more convenience and fewer hospital visits. Point-of-care testing could provide quicker responses during a single clinic or GP appointment, and home-use FC tests offer people a sense of control and improved understanding of their condition.

One patient organisation noted that some people may find testing unpleasant and some may not have access to smartphones.

People who work full-time, have young families or cannot drive were identified as benefiting most from the tests. Children were also identified also benefiting through a reduced need for blood samples.

Both organisations stated that point-of-care and home-use FC tests are a major service variation to the current UK standard of care; 1 organisation observed that the NHS pathway may need to change to fully benefit from patient-specific, real-time data.

Specialist commentators

The following clinicians contributed to this briefing:

- Dr Graham Briars, consultant paediatric gastroenterologist, Norfolk and Norwich University Hospitals NHS Foundation Trust. No relevant conflicts of interest.

- Dr Daniel Gaya, consultant gastroenterologist, NHS Greater Glasgow and Clyde. No relevant conflicts of interest.

- Prof Ingvar Bjarnason, consultant gastroenterologist, King's College Hospital NHS Foundation Trust. No relevant conflicts of interest.

- Ms Zehra Arkir, consultant clinical scientist, Viapath Analytics, Guy's and St Thomas' Hospital NHS Foundation Trust. No relevant conflicts of interest.

- Ms Hannah Yarrow, clinical nurse specialist (IBD), Guy's and St Thomas' NHS Foundation Trust. No relevant conflicts of interest.

- Dr Robert Palmer, GP with a special interest in gastroenterology, NHS City and Hackney Clinical Commissioning Group. No relevant conflicts of interest.

Representatives from the following patient organisations contributed to this briefing:

- Crohn's and Colitis UK.

- Crohn's in Childhood.

Development of this briefing

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