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Cross-sectional evaluation of online direct-to-public calprotectin testing

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ABSTRACT

Objective Why about a quarter of patients with inflammatory bowel disease (IBD) suffer symptoms for more than a year before their diagnosis made is unclear. Low public awareness, embarrassment and the apprehension of invasive tests are cited. The anonymity of direct-to-public calprotectin testing may overcome these barriers. We sought to characterise what calprotectin testing is available directly to the public in the UK.

Design/method We conducted a cross-sectional evaluation of the calprotectin assays available online in the UK. Collection kits were procured from eligible providers, and surplus stool tested to receive follow-up advice for known positive (>50–100 µg/g) and negative (<50 µg/g) stool samples.

Results Half (54.5% (6/11)) of the available tests were home lateral flow tests and the remainder were laboratory-based ELISAs. The lateral flow tests were considerably cheaper than the laboratory-based tests (median (range) cost £14.20 (£7.85–21.00) vs £75.85 (£59–151), p<0.0001). The median turnaround time for the laboratory tests was 14 (range: 1–23) days. All but one provider used a positivity threshold of 50 µg/g. All tests included written and pictorial instructions with the testing kit. Contact with a physician was recommended for similar proportions of positive and negative calprotectin results (54.5% (6/11) vs 54.5% (6/11), p=1).

Conclusion In the UK, the public can choose between inexpensive home-based lateral flow tests or send stool samples for gold-standard laboratory testing of calprotectin. The low cost and rapid turnaround times suggest that direct-to-public calprotectin testing could be promoted to try to reduce the time to IBD diagnosis.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ About one-quarter of patients report symptoms for more than a year before the diagnosis of inflammatory bowel disease (IBD) is made.
⇒ The longest component of the time-to-diagnosis is the interval between symptom onset and an individual seeking help.
⇒ Direct-to-public testing has improved the time-to-diagnosis of hepatitis C and sexually transmitted infections.

WHAT THIS STUDY ADDS

⇒ In the UK, online direct-to-public calprotectin testing is already readily available from multiple providers.
⇒ Consumers can choose between cheap, rapid lateral flow tests or send stool samples for gold-standard laboratory testing.
⇒ Recommendations for care in the setting in positive and negative results were variable between tests.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Increased use of direct-to-public calprotectin testing driven by consumer demand seems inevitable and there is a need for an evidence base to inform integration of these results into referral pathways.
⇒ Further work is needed to redefine the diagnostic accuracy of stool calprotectin when it is used directly by the public.
⇒ The rapid turnaround times suggest that direct-to-public calprotectin testing could be used to reduce the time to IBD diagnosis.

BACKGROUND

Direct-to-public tests are initiated, paid-for and interpreted by the consumer without the involvement of a healthcare provider. The potential benefits, pitfalls and ethical concerns of direct-to-public genetic testing such as 23andMe and Ancestry that first emerged about 15 years ago are well rehearsed.[1–3] However, the

usefulness to healthcare systems of routine laboratory tests requested in this way is poorly defined.[4]

Over the course of the last few years, the market for direct-to-public routine laboratory testing, driven in part by the need for remote disease monitoring and SARS-CoV-2 testing during the COVID-19 pandemic, has expanded 23-fold.[5 6] Suitable analytes, which are usually measured in blood, saliva, urine or stool are stable for a few days at room temperature to permit postal delivery to testing laboratories or are measured by point-of-care methods.[7]

While healthcare autonomy should in general be supported, how actionable direct-to-public results are handled by healthcare providers is less clear. Scepticism extends beyond free market involvement to concerns relating to the misuse and repeated-use of tests bought by patients and the diagnostic accuracy, reproducibility and validity of the assays used.[4] On the other hand, direct-to-public laboratory testing may provide access to diagnostic tests and reduce the time to the diagnosis of an illness for patients who are otherwise hard to reach. These include adolescents and young adults who find it difficult to take time off work to attend medical appointments and where language, cultural, religious or health-related stigma deters self-referral. By way of example, direct-to-public testing has reduced the overall time to diagnosis of sexually transmitted infections and hepatitis C.[8–10]

Delay in the diagnosis of inflammatory bowel disease (IBD) is reportedly common.[11] Pooled estimates suggest that about a quarter of patients experience symptoms for more than a year before their diagnosis is made.[12 13] Delayed diagnosis of Crohn's disease and ulcerative colitis is associated with a twofold increased risk of stricturing and/or penetrating complications and intestinal surgery and a fourfold increased risk of colectomy, respectively.[12] The longest component of the time-to-diagnosis is the interval between symptom onset and an individual seeking help .[13] Thereafter, in children and adults, faecal calprotectin reliably discriminates IBD from functional gut disorders and has been introduced to primary care referral pathways to prompt secondary care referrals straight-to-test colonoscopy.[14 15] Why people wait so long to present with gastrointestinal symptoms is unclear.[16] Low public awareness of IBD, embarrassment, stigma and mislabelling of symptoms are cited.[17]

Promoting the use of direct-to-public faecal calprotectin testing alongside disease awareness campaigns to identify people at risk of IBD could reduce patient-related delay and is worthy of further study. We sought to characterise what calprotectin testing is available directly to the public in the UK in 2023.

METHODS

Study design, clinical setting and eligibility criteria

The Royal Devon and Exeter NHS Foundation Trust is a tertiary referral centre for IBD in the Southwest of England, UK. The Redesigning A faster Pathway to IBD Diagnosis (RAPID|IBD) is our current programme of research that aims to determine if direct-to-public stool testing reduces the time-to-diagnosis of IBD.

Here we report a cross-sectional evaluation of the types of calprotectin assays available online in the UK in May 2023 and a mixed-methods analysis of the accompanying consumer information and clinical recommendations for positive and negative test results.

We undertook an online search using the Google search engine in the UK on 25 May 2023, with the terms 'buy' or 'purchase' AND 'calprotectin' AND 'inflammatory bowel disease'. We excluded providers selling calprotectin kits in bulk and those that stipulated a clinic visit alongside the direct-to-public calprotectin testing. Two collection kits were procured from eligible providers, and surplus stool tested to receive follow-up advice for positive (>100 µg/g) and negative (<50 µg/g) stool sample results.

Outcomes, derived variables and statistical analysis

We recorded data regarding the assay type (stool collection method/device, cost, laboratory turnaround time and positivity threshold used), consumer information (context for use, target consumer, readability of the written information using the Flesch-Kincaid score[18], the use of visual material and e-mail/text message updates) and screened both online advice and individual test reports for clinical recommendations in the setting of positive and negative test results.

Statistical analyses were undertaken in R V.4.0.3 (R Foundation for Statistical Computing, Vienna, Austria). All tests were two-tailed and p values <0.05 were considered significant. We included providers with missing data in analyses for which they had data and have specified the denominator for each variable. Continuous data were reported as median and IQR (unless otherwise stated), and discrete data as numbers and percentages, unless otherwise stated and used Mann-Whitney U and Fisher's exact tests to identify differences between groups, respectively.

Ethical considerations and funding statement

In accordance with UK Health Research Authority guidelines, formal ethical approval was not mandated for this service evaluation. Patients were not involved in the conception or design of this study. MB and RS are funded by the Royal Devon University Healthcare NHS Trust. RAPID|IBD is funded by Crohn's and Colitis UK.

RESULTS

Our search strategy identified 17 direct-to-public calprotectin providers. We excluded four providers who were selling calprotectin kits in bulk mainly to healthcare providers, and two providers who stipulated a private clinic assessment alongside the direct-to-public.

Assay types

About half (6/11) of available tests were home lateral flow tests, the remainder required consumers to send stool samples to testing laboratories. Of the laboratory-based tests, three were conventional ELISAs and two were OC-sensor (OCS) tests. The OCS-Pledia calprotectin test uses a latex immunoturbidity assay and the same stool collection device as the OCS-Pledia faecal immunochemical test (FIT) used in the UK Bowel cancer screening programme. In brief, rather than returning raw stool samples for the ELISAs, individuals transfer a sample of their stool with a picker to a preprepared buffered diluent, which is then returned to the laboratory for fully automated analysis. Overall, the lateral flow tests were considerably cheaper than the laboratory-based tests (median (range) cost £14.20 (£7.85–21.00) vs £75.85 (£59.00–151.00), p<0.0001). The median turnaround time for the laboratory tests was 14 (range: 1–23) days. All but one provider used a positivity threshold of 50 µg/g, while further tests were recommended by three providers using the laboratory ELISA and OCS for samples with calprotectin concentrations between 50 and up to 250 µg/g. A summary of the results is provided in table 1.

Consumer information

Most providers included advice on the context for use of their test: 36.4% (4/11) tests included marketing towards patients with an established diagnosis of IBD. Four providers recommended use in adults only and one provider promoted FIT in individuals over 40 years. Six out of the 11 platforms (three of the lateral flow tests and three of the laboratory-based tests) explicitly stipulated testing in the setting of gastrointestinal symptoms or set exclusion criteria. Only two providers made recommendations for testing based on symptom duration. All tests included written and pictorial instructions with the testing kit. The median (IQR) Flesch Kincaid readability score for the instructions and result reporting were 54.3 (46.2–63.7) and 62.9 (51.8–72): equivalent to a school reading grade of 9.2 (7–10.4) and 7.6 (6.7–11.3), respectively. Two providers supplied a link for video-based instructions. Email notification for tracking results was provided by four out of the five laboratory-based test providers and results were delivered by an online portal or email in all cases.

Clinical recommendations for positive and negative test results

Two out of six lateral flow tests and four out of five laboratory tests providers made direct clinical recommendations to consult a doctor in the setting of positive or negative results. One lateral flow and one laboratory test providers included generic recommendations on their website and three further lateral flow test providers did not include any recommendations. Overall, contact with a physician was recommended for the same proportion of positive and negative calprotectin results (54.5% (6/11) vs 54.5% (6/11), p=1). Several providers recommended links to private clinicians for both positive and negative test results

DISCUSSION

Key results and interpretation

There is considerable interest from patients, charities and healthcare providers in how to reduce the time-to-diagnosis of IBD. While streamlining primary and secondary pathways is important, arguably because the interval between symptom onset and seeking help is the longest component of the time-to-diagnosis, novel interventions should be aimed at reducing patient delay.[13]

Symptom awareness campaigns are being actively pursued, for example by Crohn's & Colitis UK with their 'cut the crap' programme,[19] but whether they change self-referral behaviour, is unknown. In this regard, the UK Government's 'Be Clear on Cancer' awareness campaign, which highlighted the importance of presenting to primary care with rectal bleeding to exclude bowel cancer, despite being well-funded, was ultimately ineffective.[20 21] An alternative, but more contentious approach, would be to use these campaigns to promote not only disease awareness but also direct-to-public stool biomarker testing.

We have shown here that in the UK, online direct-to-public calprotectin testing is readily available from multiple providers with turnaround times under 14 days. Consumers can choose between home-based lateral flow tests that return a quantitative or semi-quantitative result or send stool samples for gold-standard laboratory testing. While the laboratory tests are considerably more expensive and take longer, they are reportedly more accurate.[22 23] Across the available methods comparison studies, and allowing for false negatives in mild terminal ileal Crohn's disease,[15] the diagnostic accuracy of the lateral flow platforms seems to be adequate around the positivity threshold to distinguish IBD from the irritable bowel syndrome but not at higher calprotectin concentrations.[24 25] About half of providers included information regarding the context for use of calprotectin testing. Previous studies suggest that adding an assessment of the duration and presence of gastrointestinal alarm symptoms increases the diagnostic accuracy of calprotectin testing for IBD.[15] However, because these tests are open to allcomers from multiple competing providers, stipulating testing only in the presence of symptoms, while best-practice, seems unfeasible.

There is no gold-standard analytical method for the measurement of calprotectin nor reference material to calibrate assay reporting to. Consequently, there is marked interassay variability in calprotectin reporting. It is somewhat surprising then that most of the assays

Table 1 Lateral flow and laboratory-based test providers outcomes

Provider (assay)	Type of test	Instruction type (readability score)	Cost £ (including postage where applicable)	Turnaround time business/total days (email updates)	Positivity threshold	Clinical recommendations (positive result)	Clinical recommendations (negative result)	Result (readability score)
Nova Detox (Veda lab)	LFT	Written and pictorial (63.7/7)	17.49	10–15 min (n/a)	>50 µg/g	Consult a doctor	Consult a doctor if symptoms persist	62.9/7.6 Includes pictorial illustration
Stress no more (Veda lab)	LFT	Written and pictorial (63.7/7)	18.95	10–15 min (n/a)	>50 µg/g	Consult a doctor	Consult a doctor if symptoms persist	62.9/7.6 Includes pictorial illustration
Home Health UK (AllTest)	LFT	Written and pictorial (43.9/10.8)	8.35	5 min (n/a)	>50 µg/g	No recommendation	No recommendation	72/6.7 Includes pictorial illustration
GP diagnostics via ebay (AllTest)	LFT	Written and pictorial (43.9/10.8)	7.85	5 min (n/a)	>50 µg/g	No recommendation	No recommendation	72/6.7 Includes pictorial illustration
Test your intolerance (AllTest)	LFT	Written and pictorial (46.2, 10.4) Video on website	21	5 min (n/a)	>50 µg/g	No recommendation From website: the results can be used to seek further medical treatment. Diagnosis cannot be based on the results of the one single lateral flow test. Results do not substantiate a medical diagnosis on their own but may be used by your doctor to help form a diagnosis or to request a secondary analytical test or physical investigation	No recommendation	72/6.7 Includes pictorial illustration
Valuemed (AllTest)	LFT	Written and pictorial (46.2/10.4)	10.9	5 min (n/a)	>50 µg/g	No recommendation	No recommendation	72/6.7 Includes pictorial illustration

Continued

Table 1 Continued

Provider (assay)	Type of test	Instruction type (readability score)	Cost £ (including postage where applicable)	Turnaround time business/total days (email updates)	Positivity threshold	Clinical recommendations (positive result)	Clinical recommendations (negative result)	Result (readability score)
Verisana	ELISA	Written (62.5/7.6)	105.85	10/14 days (email update on arrival to lab 72 hours after postage)	>50 mg/kg	No direct recommendation with electronic result Quantitative results in mg/kg Also provided results of lysozyme From website: instructions on interpretation results based on coloured text. 'You can then discuss results with your doctor or health practitioner, who can give you further guidance and treatment recommendations'	No direct recommendation with electronic result Quantitative results in mg/kg Also provided results of lysozyme	64.9/7.2
Smart nutrition	ELISA	Written (55.9/8.9)	75.85	15/22–23 days	>100 µg/g	Results presented in traffic light chart Advised to discuss result with a doctor Link to consultation in IBS and SIBO clinic	Link to consultation with nutritional therapist	51.9/11.7
Selph	OC sensor	Written (54.3/9.2) Video	59	2/2 days (email update after 1 day)	>50 µg/g 50–250 µg/g repeat test in 2 weeks	Consult a doctor Doctors' report provided	Results presented in traffic light chart Consult a doctor if symptoms persist	47.2/11.3
Blue Horizon	ELISA	Written (73.7/6.2), but many illegible words due to printing quality	151	10/14 days (included 2 days for doctor's comments)	>50 µg/g 50–120 µg/g repeat test in 4–6 weeks	Consult a doctor	Consult a doctor	51.8/10.8
Online Clinic	OC sensor	54.3/9.2	68.95	1/1 day	>50 µg/g as per pathology result cut-off >100 µg/g as per website 50–250 µg/g repeat test in 2 weeks	Consult a doctor Doctor's interpretation provided Offered a private referral letter	Consult a doctor if symptoms persist	12.9/15.8

IBS, irritable bowel syndrome; LFT, lateral flow test; SIBO, small intestinal bacterial overgrowth.

reported here use a positivity threshold of 50 µg/g. This may reflect a lack of access to biological samples to define positivity thresholds. By way of example, we like others have shown that compared with conventional calprotectin ELISAs, the OCS assay has a positive bias across the calprotectin reporting range.[26 27] That said, it seems inevitable that assays employing a stool picker collection device will supersede conventional ELISAs because they are cheaper, easier to automate, do not involve laboratory staff preprocessing stool samples and laboratories already process FITs using this platform.

We observed marked heterogeneity across collection kits in the ease of reading of patient instructions and the quality and type of visual materials. Understanding how to use test kits is important because preanalytical processing of stool samples can significantly influence the results of the home and OCS assays in particular. Both rely on the consumer transferring a sample of stool into a diluent ready for testing. Their accuracy depends on not over or underfilling the sampling device, accurately measuring the diluent and complete mixing of the stool sample and diluent, which in part depends on the composition of the initial stool.[28]

Recommendations for ongoing care following both a positive and negative result were frequently linked to further contact with primary care. It is critical to consider what impact the increasing use of these tests by the public will be on primary and secondary care pathways.[29] As the incidence of IBD at least in the industrialised North and East of Europe is stable, we do not anticipate diagnosing significantly more patients with IBD.[30 31] However, because these tests are open to all, before they can be recommended by public healthcare bodies and IBD charities, further work is needed to define the positive and negative predictive values of calprotectin testing when used in this way.[4]

For the time being the risk of overwhelming secondary care colonoscopy services with false positive results should be mitigated by confirmatory laboratory tests for at least intermediate results.[32] In this regard, close attention will need to be paid to managing patient expectations of the need for further tests where there are discordant sequential results.

Increased use of direct-to-public stool testing driven by consumer demand seems inevitable. Therefore, there is an urgent need for an evidence base to inform integration of these results into referral pathways. Key to integration into conventional healthcare pathways is establishing the diagnostic accuracy of calprotectin and/or FIT used in this way and access to colonoscopy. Dedicated rapid access clinics could be designed to remove additional pressures on primary care while also safeguarding against multiple unnecessary colonoscopies.

CONCLUSION

In the UK, online direct-to-public calprotectin testing is already readily available from multiple providers. Consumers can choose between home-based lateral flow tests or conventional laboratory testing. While further work is needed to redefine its diagnostic accuracy when used in this way, the rapid turnaround times suggest that direct-to-public calprotectin testing could be used to reduce the time to IBD diagnosis.

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Competing interests NAK has consulted for Amgen, Bristol Myers Squibb, Celltrion, Falk, Galapagos, Janssen, Pfizer, Pharmacosmos, Takeda and Tillotts and received honoraria from Amgen, Celltrion, Falk, Galapagos, Janssen, Pharmacosmos, Galapagos, Takeda and Tillotts for unrelated topics and is a deputy editor of Alimentary Pharmacology & Therapeutics Journal; TA has received unrestricted research grants, advisory board fees, speaker honorariums and support to attend international meetings from AbbVie, Merck, Janssen, Takeda, Ferring, Tillotts, Ferring, Pfizer, NAPP, Celltrion, Hospira for unrelated topics, no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work. JRG, MB, RS, CR, YD, CB and RN have no conflicts of interest to declare.

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