BIG CHANGES COMING SOON TO A CLINIC NEAR YOU
CALPROTECTIN TESTING GOES MOBILE

Written by Amanda Appleton, Product Manager, Alpha Laboratories Ltd.

With the advances in technology and specifically the ubiquitous use of mobile devices developed during the last decade, a huge opportunity has arisen to change the way some healthcare services are provided. This is especially applicable to the management of chronic conditions. With most people owning a mobile device or tablet this becomes a convenient way for patients to communicate with their consultants for support and treatment advice.

In a speech to NHS bosses in 2016, Simon Stevens (NHS England's CEO) urged doctors, nurses and NHS managers to *"grab with both hands" the growing opportunities technology offers both to help promote health and tackle the service's chronic financial problems by saving on treatment and rehabilitation costs.*[1]

Since publication of NICE guidance DG11 in 2013, supporting the use of calprotectin as a cost effective method to differentiate between IBD and IBS, the rates of calprotectin testing in the UK have increased dramatically. Assays to detect calprotectin have also advanced since then to assist with changing hospital requirements. These give scalable and flexible solutions that allow hospitals to evolve their calprotectin service in line with increasing demands.

The possibility to use calprotectin for applications other than an IBS/IBD screen have also been investigated, with many publications suggesting its usefulness in monitoring IBD positive patients for:

- Indicating mucosal healing
- Predicting flares
- Predicting post-operative relapse
- Predicting response to biologic therapy:
  - Allows quicker response for optimisation when starting treatment if you monitor the calprotectin
  - Giving patient reassurance when switching to bio-similars to ensure the calprotectin levels don't start to rise
  - Withdrawal of biologics but ensuring the calprotectin levels remain low
- Keeping healthy patients out of the clinic

It is in this monitoring environment that the advance of mobile App technology has come to Gastroenterology; and so in 2015 the first CE marked calprotectin self-test was launched by BÜHLMANN in the form of their IB*Doc*® assay system. The IB*Doc* allows patients to fundamentally use the same calprotectin testing system that many laboratories employ (CALEX® extraction and Quantum Blue® lateral flow technology). Adaptions remove the requirement for technical equipment so the patient can perform the test themselves in the comfort of their own home. Using the CalApp®, the patient's Smartphone becomes the test reading device giving a quantitative result that is automatically transmitted to the clinic.

NICE published a review in December 2017 (Medtech innovation briefing 132), of technologies for 'POC and home test for calprotectin in monitoring IBD patients receiving treatment'. This states that *'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'*[2].

App technology has the potential to offer a number of advantages over standard laboratory testing:

- Individually customisable
- Reduced turn-around-time for results
- Reduced resource required
- Allows access to testing in remote locations or whilst travelling
- Improved compliance through privacy
- Better monitoring for active patients
- Keeping well patients out of hospital

One solution rarely suits all; and so the IB*Doc* is customisable by individual patients to help deliver a personalised approach to monitoring:

- The clinicians choose one of three options for patients to see when a test is completed:
  - Actual quantitative result (with a value between 30 - 1000*µ*g/g)
  - A red, amber, green traffic light system with individually defined cut-off values
  - A 'Test completed' message with no indication of the result which is useful for blinding studies or when patients need more support with the results
- The threshold levels for the traffic lights are customisable to individual patients – low when in remission or higher when severe and active
- The frequency of testing can also be adjusted depending on the severity of the condition. A message is sent to patients reminding them that a test is due

With individual customisation available, the IB*Doc* allows ultimate flexibility. Testing can be tailored to provide results to support clinical decision making in a range of different scenarios through remote and more frequent patient monitoring, enhancing management without requiring additional resource. In fact, resource could be saved, as was demonstrated in a recent poster at UEGW in Barcelona - Patients starting biologics normally had a clinic appointment at 3 months and a colonoscopy at 6 months. However, during a study of 131 patients starting biologics these did not take place if the calprotectin level determined using the IB*Doc* home test was below certain limits. This avoided 53 clinic visits and 62 colonoscopies with obvious cost and healthcare resource savings[3].

Although the number of laboratories offering calprotectin testing has increased significantly in recent years, many laboratories still perform the test in batches once a week, in order to ensure cost effective use of reagents. In smaller institutions testing is often not performed in-house, but is sent to a reference service which can then mean results take upwards of two weeks to be returned.

This delay can mean that treatment decisions have to be made without the support of the calprotectin result, or more invasive tests are performed to ultimately get the same indication.

Patient self-testing in these situations provides same day results which can improve disease management and treatment plans, without the need for additional pathology resource. It also relieves patient anxiety, which otherwise can often have a negative effect on their condition.

"Previously I had to wait more than three weeks for a result, this is a very long time to worry. Now I can just check myself at home if I am worried……."

The explosion of the mobile technology market means that healthcare based App's are highly accessible as most people these days have a mobile device or tablet. This also reflects changes in lifestyle with significantly more travel undertaken for business and foreign holiday destinations becoming ever more popular. The Apps are able to transmit results back to a local portal enabling patients to stay in touch with their healthcare providers wherever they are. This helps ensure continuity of care/treatment should things deteriorate and gives reassurance for patients to travel and 'get on with their lives' due to the support the Apps provide. These same benefits can also be used for people living in remote locations e.g. the Scottish Highland and Islands where a routine clinic visit or even a laboratory test to help determine acute symptoms is logistically difficult and expensive to achieve.

One of the big advantages of patient self-testing especially in the gastroenterology arena is privacy. Generally people are embarrassed to take stool samples to the laboratory for testing and non-compliance is often high. This is a shame, as calprotectin is well documented to give a better indication regarding the health of the mucosa, having a higher correlation to endoscopic and histological findings than patient scores. The calprotectin result helps to make sense of symptoms and guide treatment decisions. Being able to perform the calprotectin assay in the privacy of their own home seems to be well accepted by patients with studies quoting between 85 – 100% satisfaction/preference[4,5] in testing, compared to routine laboratory tests.

Although it obviously won't be for everyone, App technology is generally perceived as fairly progressive by patients and so they have the potential to enhance engagement in their disease management.

"IBDoc is amazing and allows me to feel more in control of my Crohn's disease. I can use it anytime to check if I'm having a flare up. It is very reassuring……."

Engaged patients are more likely to adhere to treatment plans which hopefully prevents illnesses from deteriorating, which often then results in more costly or invasive care. Unfortunately deterioration can still occur even when treatment plans are followed, but remote monitoring can assist through prompt detection, enabling intervention at an earlier point than standard testing might otherwise permit.

Although many of the studies with the IB*Doc* calprotectin home-test have been performed to predict flares or response to treatment in patients with moderate to severe symptoms, there is also the potential to use the technology with the patients who are experiencing mild disease or who are in remission. Using App technology to keep well patients out of hospital if they are showing low calprotectin levels, will free up limited resources and reduce waiting times for the more active patients.

As more clinics are adopting the use of patient self-testing for calprotectin this may start to become the norm for managing/monitoring IBD positive patients. Traditional laboratory tests may be reserved for the IBD verses IBS screen, which still accounts for approximately 80% of the workload.

App technology has the ability not only to improve the health of patients, but to save money through rapid optimisation of treatment, enable early interventions through monitoring before conditions get too serious and reduce routine check-up appointments/procedures, freeing up limited resource in both pathology and the clinic.

References

1. NHS to offer free devices and apps to help people manage illnesses. The Guardian 17th June 2016
2. NICE Dec 2017 Point-of-care and home faecal calprotectin tests for monitoring treatment response in inflammatory bowel disease
3. Elsafi et al 2017 UEGW. Cost effectiveness of IBDoc as a surrogate marker of mucosal healing in IBD patients post induction of biologic agents
4. Raker et al 2017 ECCO Home testing for faecal calprotectin follow-up results from the first UK trial
5. Fitzgerald et al 2017 ECCO An evaluation of patient satisfaction with IBDoc calprotectin home test system.

For further information about IB*Doc* please visit **www.alphalabs.co.uk/ibdoc** or contact **digestivedx@alphalabs.co.uk** to discuss setting up a trial for your clinic.