EARLY DETECTION OF COELIAC DISEASE USING COMMUNITY PHARMACY

October 2015
Foreword

The need to provide new models of care at first contact in the community has never been more acute. The NHS is currently encouraging community pharmacy to support more out of hospital care with medicines optimisation, minor illness services and support for long term conditions. Community pharmacy has a wealth of untapped knowledge about the health needs of a local community, but the clinical pharmacist has, for too long, had to focus most of their contractual efforts on dispensing medicines.

Therefore, the National Association of Primary Care has been supporting programmes through its Primary Care Innovation Network (PIN) to explore new opportunities to demonstrate new provider services delivered from a community pharmacy.

One such programme is this report where Coeliac UK, in partnership with the NAPC and NAPCs community pharmacy members carried out a national clinical audit to assess an early detection programme for people suffering with undiagnosed coeliac disease.

This innovative programme enabled a community pharmacy to screen patients who may have been suffering the effects of coeliac disease and being treated for these, but the underlying cause had not been as yet detected.

I commend the following report for its truly innovative outlook and its integration of primary care provision with third sector providers to really demonstrate new ways of working.

Dr James Kingsland OBE
President
National Association of Primary Care
Facts and figures

Around 1% of the UK population have coeliac disease

But only 24% of those are diagnosed

So around 500,000 people in the UK are undiagnosed but suffering the effects of coeliac disease.

There are around 11,000 community pharmacies in England, highly accessible to the communities they serve.

On average, adults in England visit their local pharmacy 16 times a year.
Executive summary

The project

This project was designed to tackle the issue of under-diagnosis of coeliac disease in the UK population, by making use of the accessibility and capacity of community pharmacies to provide point-of-care tests for people buying prescription or over-the-counter medications that indicate the potential for coeliac disease.

The project was commissioned by Coeliac UK, and supported by the National Association for Primary Care and the Practice Innovation Network.

Over 500 people were tested in sixteen community pharmacies across England.

This report

This report summarises the background to the project, its methodology and implementation, and its results.

The findings

98% of those identified as eligible accepted the point-of-care test. Of those, 9.4% were given a positive test result for coeliac disease and 7.2% tested positive for IgA deficiency.

All pharmacy teams responding to the end-of-study questionnaire supported the concept of using community pharmacy to deliver such tests, felt confident in doing so and would recommend the tests to other pharmacies.

There are clearly benefits to using the network of community pharmacies in this way. The response from customers demonstrates that the service increases awareness of coeliac disease, that there is unanimous confidence in the ability of community pharmacies to deliver the service, and that customers would be willing to pay something for the provision of the service.
The Project

What is the problem?

This project was initiated in response to concerns over the high level of undiagnosed coeliac disease in the UK population, combined with the opportunity to use the accessibility, capacity and relevance of the network of community pharmacies across the country.

Coeliac disease is an autoimmune condition triggered by intolerance to gluten, the protein found in wheat, barley and rye, and is characterised by damage to the lining of the small intestine.

From screening studies it is estimated that around 1% of the UK population have coeliac disease \(^1\),\(^2\), however only 24% of those are diagnosed \(^3\). This means that approximately 500,000 people in the UK remain undiagnosed.

The reason for under diagnosis in coeliac disease may be due to a range of challenges including lack of awareness of the condition and misdiagnosis - one in four people diagnosed with coeliac disease have previously been treated for irritable bowel syndrome \(^4\). In addition, the symptoms of coeliac disease are similar to the symptoms of many minor gastro problems which people may prefer to discuss with their local pharmacist rather than their GPs \(^5\).

The spectrum of symptoms for coeliac disease is broad and symptoms vary widely from person to person. The National Institute for Health and Care Excellence has produced guidance for the recognition and assessment of coeliac disease in children and adults \(^6\). The NICE guideline lists the symptoms and associated conditions which should trigger testing for coeliac disease.

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5 Pharmacy Research UK, Community Pharmacy Management of Minor Illness; The MINA study. 2014
6 NICE, Clinical guidance CG86; Recognition and assessment of coeliac disease. 2009
The diagnosis process currently involves consultation with a GP in primary care to obtain a serological test (tissue transglutaminase antibody (IgA tTGA) or endomysial antibody (IgA EMA) with referral to secondary care for endoscopy and biopsy following a positive result.

A point of care test (POCT) in the form of a rapid finger prick blood test has the potential to increase recognition of coeliac disease, if used as part of an active case finding approach in community pharmacies. There are currently four POCTs available for detection of coeliac disease, with limited research around their use, however Simtomax® (IgA and IgG antibodies against a combination of Deamidated Gliadin Peptides (DGP)) is supported by an emerging evidence base. This was the test used for this study.

**Why use community pharmacies?**

The opportunity to provide additional capacity and improved patient experience by using community pharmacy is identified in the NHS England report ‘Community Pharmacy - helping provide better quality and resilient urgent care’. Community pharmacies have considerable benefits in terms of improving patient access and experience.

- There are over 11,000 community pharmacies in England providing NHS services.
- Community pharmacies are highly accessible, located in the heart of the community where people live, work and shop.
- In the areas of highest deprivation almost 100% of households live within walking or using public transport.
- Adults in England visit a pharmacy on average 16 times a year.
- Many pharmacies are open for extended hours in the evenings and weekends and nearly 900 of them are open for 100 hours a week.
- People may seek advice from the local pharmacist on 'gut problems' that they prefer not go to their GP with.

Researchers at the University of East Anglia in collaboration with Community Pharmacy Futures have already identified potential cost savings and improvement in quality of life through community pharmacy case finding of chronic obstructive pulmonary disorder (COPD).

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Wright, D., M. Twigg, and T. Thornley, *Chronic obstructive pulmonary disease case finding*
Project Objectives and Methodology

The hypothesis to be tested was that the use of community pharmacies for active case finding in coeliac disease, using a simple questionnaire and POCTs, will increase recognition of coeliac disease and will act as an adjunct pathway in helping to find the half a million people with undiagnosed coeliac disease; and that pharmacies are a good use of NHS resources, providing a cost effective, accessible and acceptable approach to early recognition of coeliac disease.

Objectives

The audit was designed to:

- demonstrate the potential value of a community pharmacy in the early detection of disease;
- evaluate patient experience of using community pharmacy as the first point of contact for health screening and the acceptability of a pharmacy setting for this;
- evaluate the use of a POCT for coeliac disease in a community pharmacy setting with regard to feasibility, acceptability and willingness of patients to pay for a screening test;
- evaluate the impact of these approaches to increase the recognition rate of patients with coeliac disease; and
- describe the educational impact on participating health professionals and patients with coeliac disease.

Methodology

People coming to a community pharmacy with a prescription or purchasing over the counter medicines, where the medication has been identified as a treatment for conditions which may be indicators of having coeliac disease, were entered into the audit process.

Inclusion criteria:

- All men and women aged 18 years and over on prescribed treatments, or requesting OTC treatments for index conditions.
- Index conditions were irritable bowel syndrome and all anaemias (iron deficient and folate)
- No previous diagnosis or investigation for coeliac disease
- Registered with a GP

Exclusion criteria:

- Patients under the age of 18 years
- Adults on a gluten-free diet or people excluding gluten from their diets
- Adults with learning disabilities
- Adults who have a terminal illness
- Adults unable to give verbal consent
- Women receiving folate due to pregnancy
- Adults previously tested for coeliac disease with a negative result

Those people meeting the inclusion criteria were asked to complete, in association with a trained member of the Pharmacy team, a short questionnaire. If any of the exclusion criteria were identified, their participation in the study ended. It was also ascertained if any first-degree relatives had been diagnosed with coeliac disease.

**Process**

Following consultation and with the verbal consent of those agreeing to participate, a trained member of the Pharmacy team carried out a POCT which gave a positive or negative result for coeliac disease. In a pilot study the specificity and sensitivity of the POCT were consistent with current NHS laboratory tests for this disease (Mooney P. et al. unpublished).

The test result was given to the patient, becoming their property; it was then the patient’s choice whether to pass it on to their GP or not.

If negative they were informed that the POCT indicated that they were highly unlikely to have coeliac disease, offered the opportunity to ask any further questions and given a letter for their own record.

If positive they were provided with a description of the POCT, confirmation they have tested positive for coeliac disease and advised to see their GP. All those with a positive outcome
were also given an information leaflet on coeliac disease and given the opportunity to ask any further questions.

Customers visiting the community pharmacy with prescriptions for medications or asking for OTCs for the index conditions were identified and asked to complete a brief questionnaire. Customers collecting prescriptions on behalf of someone else were given a study information leaflet.

**Evaluation**

All customers who had a POCT were asked to complete a short questionnaire on customer satisfaction, whether they would have been prepared to pay for the service, and how much, had it not been offered for free.

Patients declining the test were asked to fill in a short questionnaire to capture their reasons for declining, provided with an information leaflet on coeliac disease, and signposted to their GP should any symptoms persist or appear.

The Pharmacy team also filled in a baseline and end of study questionnaire to determine Pharmacy experience of providing service.

**Implementation**

Sixteen community pharmacies were identified across England, and each one expected to test a minimum of forty patients. Each pharmacy involved had to meet certain criteria, including arrangements for waste disposal, an appropriate consultation room and connection to the internet.

Efforts were made to contact the local GP practice to inform them of the study taking place. No patient identifiable data was used for the purpose of the audit.

**Training and support**

Online modules on recognizing and understanding coeliac disease along with further information provided by Coeliac UK, manufacturers’ training on the use of the POCTs and additional training on the audit processes and procedures were provided to the pharmacies involved.
Project Outcomes

Demographics

565 people were identified as eligible for the POCT test, of which the majority – 98% - agreed to participate in the study so totaling 554 people undergoing testing.

Of the very few that did not, lack of time was the primary reason, with a small proportion preferring to discuss the issue with their GP.

Most (62%) of the people accepting the test were women; the majority of those tested were in the age ranges 25 – 39 and 45 – 54, although all ages between 18 and 75+ were represented.

In keeping with the project’s eligibility criteria, all those tested were registered with their GP and none had excluded gluten from their diet or been tested for coeliac disease previously.

Clinical profile and trigger factors

The majority of those invited to join the study were identified through requesting over-the-counter (OTC) medicines; 43% presented to collect prescription medicines.

The commonest triggers were loperamide 2mg tablets and mebeverine 135mg tablets, accounting for around 33% of requests, but a very wide range of medicines in differing formulations were recorded – nearly 90 variations in all.

The symptoms most frequently recorded were bouts of diarrhoea (36%), gut problems (44%) and regular abdominal problems (52%). Prolonged fatigue was reported by 25% and a small number of people reported other symptoms. 10% reported that they had none of the symptoms they were asked about.

The vast majority, 67.5%, did not know whether or not a family member had a diagnosis of coeliac disease, with only 5% confirming that a family member did.

When asked about other diagnoses, 17.5% had an existing diagnosis of Irritable Bowel Syndrome, with only very small proportions of the sample population reporting any of the other diagnoses listed; 75% had none of them.
POCT results

Of the 554 people tested, 9.4% (52 people) were given a positive result for coeliac disease, and 7.2% (40 people) tested positive for IgA deficiency.

Administration of the POCT by community pharmacies

The pharmacy teams involved in the study were invited to complete an end of study questionnaire.

All respondents felt that community pharmacy was a suitable location to carry out POCT to identify coeliac disease, with 80% strongly agreeing that it was.

All respondents felt confident or very confident in carrying out the tests.

And all respondents were willing to continue with the service, and would recommend it to other pharmacies.

Very nearly all POCTs were carried out on weekdays – under 3% of those accepting the test attended the pharmacy at a weekend.

Customer satisfaction

Forty responses were received to the customer experience questionnaire. The responses were spread across all age ranges from 18 years to 85+ years, with the majority in the 46 years to 65 years bracket. 75% of the respondents were women.

70% of the respondents said that before being introduced to the service that day they had not heard of coeliac disease, and 87% of all respondents said that the service had increased their knowledge of coeliac disease.

All respondents felt that the pharmacy provided a safe and confidential environment for the service, that the pharmacy team were able to answer all questions, and that the service provided was valuable or very valuable to them. All respondents felt that community pharmacy was the ideal place for this type of service, and would recommend the service to others.
Comments made by respondents were uniformly positive:

“The pharmacist was very professional”
“Was very happy to know I could have this done here”
“Very pleased to know one way or another”
“Very quick and professional”
“Excellent advice”
“Good service, informative”
“Service at the right time for it and much appreciated”
“It is good to know”

When asked about willingness to pay for a service of this type, 80% said they would pay and only 20% said they would not pay for such a service. Of those willing to pay, the majority (65% of the total number of respondents) would pay £10. No-one was willing to pay more than £30.
Conclusion

The use of community pharmacy to improve detection of coeliac disease clearly has potential benefits.

The accessibility of community pharmacies, the confidence with which pharmacy teams feel able to administer the tests, and the willingness of people attending the pharmacy to accept the tests all point to a valuable opportunity to identify undiagnosed cases of coeliac disease.

Provision of the service demonstrates a clear impact on awareness and understanding of coeliac disease, and there is unanimous support from customers for the service to be provided through community pharmacies.

The majority of customers would be prepared to pay something for the service.
Appendices

Appendix 1: Study Project Details

**Title of project**
Early detection of coeliac disease using community pharmacy to case find people with the condition.

**Project Managed by**
The National Association Primary Care (NAPC)

**Funder of project**
Coeliac UK

**Duration of the study**
April – October 2015

**Project Delivery Group**
National Association of Primary Care (NAPC):
James Kingsland (Project SRO)
Sally Kitt (Logistics and Contracts)
Min Grout (Project Manager)

Coeliac UK (CUK):
Norma McGough (Director of Policy, Research and Campaigns)
Lisa Bainbridge (Head of Campaigns)
Heidi Urwin (Research Manager)
David Sanders (Chair of CUK Health Advisory Council)

**Reference Group**
University of East Anglia (UEA); David Wright
Pharmacy services negotiating committee (PSNC); Alastair Buxton
Pharmacy Voice (PV); Rob Darracott
Royal Pharmaceutical Society (RPS); Heidi Wright
Tillotts Pharma Ltd (TPL); Will McCully
Appendix 2: Process flow

Early Detection of Coeliac Disease Using Community Pharmacy

COMMUNITY PHARMACY

Enquiring about or purchasing OTC medication for IBS and/or anaemias
STUDY SHEET 1

Briefly introduce the Study being conducted by this Pharmacy
STUDY SHEET 2
INFORMATION LEAFLET
PHARMOUTCOMES

Has a prescription about or purchasing OTC medication for IBS and/or anaemias
STUDY SHEET 1

Record the reason on decline form.
DECLINE REASON FORM

NO due to lack of time OR picking up medication for another person

NO due to lack of time OR picking up medication for another person

Confirm they meet the inclusion criteria?
STUDY SHEET 2

NO

NO

CONFIRMATION LEAFLET
PHARMOUTCOMES

PHARMACY PROCESS FLOW

Thank you for your time.
We are running this free service until September so if you have more time on another occasion you may like to participate then?
Please pass this information on to the person you’re picking up medication for - they’re welcome to call in to the pharmacy at any time.
In the meantime - please do take away a leaflet on coeliac disease.
Coeliac UK has a website: www.coeliac.org.uk which provides information and support.
The linked site: www.isitcoeliacdisease.org.uk allows anyone to complete an online assessment test.*

Unfortunately, we’re not able to test you under the guidelines of the Study. This is simply due to the strict criteria as part of the test.*
(Provide an explanation of reasons for exclusion if possible)
(Refer to leaflets & websites as above)

Thank you for your time.
We are running this free service until September so if you have more time on another occasion you may like to participate then?
Please pass this information on to the person you’re picking up medication for - they’re welcome to call in to the pharmacy at any time.
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(Refer to leaflets & websites as above)
**Early Detection of Coeliac Disease Using Community Pharmacy**

**PHARMACY PROCESS FLOW**

1. **Conduct the Point of Care Test (POCT)**
   - **SIMTOMAX® KITS**
2. **Fill in Section 2 of Questionnaire - direct into PHARMOUTCOMES**
   - **STUDY QUESTIONNAIRE PHARMOUTCOMES**
3. **Check the results of the POCT?**
   - **NEGATIVE**
   - **POSITIVE**
4. **Ask the participant to fill in Customer Experience Questionnaire anonymously and post in feedback post box**
   - **CUSTOMER EXPERIENCE FORM FEEDBACK POST BOX**
5. **Data entry of Customer Experience forms into PharmOutcomes**
   - **CUSTOMER EXPERIENCE FORMS PHARMOUTCOMES**

**PHARMACIST:**

"The POCT has come back as negative. This means that you're highly unlikely to be at risk of being identified with coeliac disease. We are providing you with this letter as a confirmation of your results. It explains the test that you took, the results and any next steps."

**STUDY POCT NEGATIVE LETTER**

"Thank you for your time. Please do take away a leaflet on coeliac disease.
Coeliac UK has a website: [www.coeliac.org.uk](http://www.coeliac.org.uk) for more information and support. There is also a linked site: [www.isitcoeliacdisease.org.uk](http://www.isitcoeliacdisease.org.uk) where anyone can take an online assessment test.

We are running this free service until September for anyone that would like to be tested."

**STUDY POCT POSITIVE LETTER**

"The POCT has come back as positive. This means that you are at risk of being identified with coeliac disease. Please do not worry as this test means you will be better informed if you decide to follow up with your GP. We provide you with this letter, which you can keep and can take with you to discuss with your Doctor. It explains the test that you took, the results and possible next steps."

"Thank you for your time. Please do take away a leaflet on coeliac disease.
Coeliac UK has a website: [www.coeliac.org.uk](http://www.coeliac.org.uk) for more information and support. There is also a linked site: [www.isitcoeliacdisease.org.uk](http://www.isitcoeliacdisease.org.uk) where anyone can take an online assessment test.

We are running this free service until September for anyone that would like to be tested."
Appendix 3: Study Information

Community pharmacy and recognition of coeliac disease
This pharmacy is involved in a project to increase awareness and early recognition of coeliac disease in people who are taking medications for IBS and/or anaemia.

Coeliac disease is an autoimmune condition caused by an abnormal response to gluten, a protein found in wheat, barley and rye, cereals found in many foods such as bread, pasta and breakfast cereals. It is estimated that 1 in 100 people have coeliac disease but only 24% of them are diagnosed, meaning there is almost half a million people in the UK who have coeliac disease but don’t yet know it.

The symptoms of coeliac disease are similar to the symptoms of many gastrointestinal problems and are often missed and treated as irritable bowel syndrome (IBS). Undiagnosed and untreated coeliac disease can cause nutritional deficiencies and anaemia is common.

Pharmacy teams are in a good position to identify people, who may be at risk of developing coeliac disease from their prescribed or over the counter (OTC) medication.

Testing for coeliac disease - For customers identified as being at risk of coeliac disease we are offering a rapid finger prick test to see if you may be at risk of having coeliac disease - the test is quick and painless. A member of the pharmacy team will talk to you about the point of care test (POCT) called Simtomax® and answer any questions or concerns you may have. The service is offered free of charge due to the support of Coeliac UK and Tillotts Pharma Ltd who are providing the Simtomax® test kits.

What does Simtomax® do?
Sptomax® determines if you have specific antibodies in your blood. These antibodies are produced in response to eating gluten in people with coeliac disease. It is important that you have not changed to a gluten-free diet before taking the test as this may lead to inaccurate test results.

What will you have to do?
You will be asked to give a few drops of your blood which a member of the pharmacy team will take by pricking your finger.

Whilst the test is working you will also be asked to complete a brief questionnaire about any symptoms you may have. All information will be anonymous, no personal identifiable information will be collected and used within the Project.

When do I get the results?
You will not have to wait long – the results of your test are available in 10 minutes

What happens next?
A member of the pharmacy team will give you a letter with your results and will discuss them with you:

- If the test is negative, there are no antibodies, it is unlikely you have coeliac disease. However if you have ongoing symptoms you should tell your doctor who may wish to carry out other tests.
- If the test is positive - you will be advised to visit your GP who can arrange for additional tests to help confirm your diagnosis for coeliac disease. The Simtomax® test on its own does not confirm a diagnosis for coeliac disease and it is important you keep eating foods containing gluten until your diagnosis is confirmed, which requires an endoscopy and biopsy.
- You will be asked to provide anonymous feedback of your experience of the service provided to you within the pharmacy. This is helpful for us to understand whether the service should be extended to other areas.

An audit of this service is funded by the charity Coeliac UK in collaboration with the National Association of Primary Care (NAPC).
Appendix 4: Coeliac UK Awareness Leaflet

Here is the good news. Coeliac disease can be treated. However, early detection is crucial.

**Appendix 4:** Coeliac UK Awareness Leaflet

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**WHAT'S THE TREATMENT?**

There is good news. Coeliac disease can be treated. Glutens free diets can control the digestive problems related to the condition. Many patients are able to lead full and healthy lives on a gluten-free diet. If you think you may have coeliac disease, you should be referred to your GP for advice on a gluten-free diet and treatment.

**WHAT NEXT?**

If you think you may have coeliac disease, you should be referred to your GP for advice on a gluten-free diet and treatment.

**IS IT COELIAC DISEASE?**

Coeliac disease is a lifelong autoimmune condition where the body's immune system reacts to gluten, a protein found in wheat, barley and rye. The body's reaction to gluten causes damage to the lining of the small intestine, the place where food and nutrients are absorbed.

**WHAT IS COELIAC DISEASE?**

Coeliac disease is a lifelong autoimmune condition where the body's immune system reacts to gluten, a protein found in wheat, barley and rye. The body's reaction to gluten causes damage to the lining of the small intestine, the place where food and nutrients are absorbed.

**WHAT ARE THE SYMPTOMS AND WHO IS MOST AT RISK?**

Coeliac disease causes a range of symptoms that can affect different people in different ways. People with undiagnosed and untreated coeliac disease can have a wide range of symptoms. The symptoms may vary in severity and can be mild or severe. The symptoms may develop gradually over time or occur suddenly.

**HOW DO I GO ABOUT GETTING DIAGNOSED?**

Coeliac disease is diagnosed by a specialist scientist with expertise in the condition. The specialist scientist will usually ask you a series of questions about your symptoms and medical history. The specialist scientist may also ask you to take a blood test to check for coeliac disease. The specialist scientist may also ask you to take a biopsy of your small intestine to check for damage to the lining of the small intestine. A biopsy of the small intestine is usually performed under general anaesthetic.

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Coeliac disease has a range of symptoms that can affect different people in different ways. People with undiagnosed and untreated coeliac disease can have a wide range of symptoms. The symptoms may vary in severity and can be mild or severe. The symptoms may develop gradually over time or occur suddenly. The symptoms may include:

- **Frequent bouts of diarrhoea or loose stools**
- Nausea, feeling sick and vomiting
- Stomach pain and cramping
- Lots of gas and bloating
- Feeling tired all the time, ongoing fatigue
- Anaemia (you would be told if you're anaemic following a blood test)
- Intestine damaged by coeliac disease
Appendix 5: Coeliac POCT Test Results – Positive and Negative

Testing for Coeliac Disease POCT Results Letter

POSITIVE

You have undergone a test for coeliac disease today and found to have a positive result. The Simtomax® test looks specifically for antibodies (small proteins produced by your immune system) to Deamidated Gliadin Peptides (DGP). DGP is produced in patients with coeliac disease. Your test indicates that you have antibodies (IgA or IgG) to DGP. DGP is one of the latest screening markers used for coeliac disease.

The test is highly accurate at detecting antibodies that a person with coeliac disease produces in response to eating gluten. Occasionally positive results are found in people who do not have coeliac disease. When this occurs it is known as a “false positive” result and may happen in a small percentage of tests undertaken.

You have reported that you have / do not have* symptoms associated with coeliac disease and that you have / do not have other conditions associated with coeliac disease (*delete and list as applicable):

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You have / do not have* a first degree relative diagnosed with coeliac disease (*delete as applicable)

Given you have been found to have antibodies to DGP, it is recommended that you see your General Practitioner (GP) and provide him/her with the report below. Your GP may perform additional blood tests and may suggest that you need an endoscopy with biopsy, to confirm the diagnosis. In the meantime you should not make any changes to your diet, but continue on a normal diet until you have a confirmed diagnosis.

Report

The Simtomax® test looks at both IgA and IgG to DGP – these were POSITIVE

In addition the results showed:

No IgA deficiency  [ ] IgA deficiency  [ ]

For reference, further information about the service provided to you today is available on the Coeliac UK and NAPC websites (insert URLs).

[Add pharmacy stamp and date]
Early Detection of Coeliac Disease Using Community Pharmacy
Final Report

Testing for Coeliac Disease POCT Results Letter

NEGATIVE

You have undergone a test for coeliac disease today and found to have a negative result. The Simtomax® test looks specifically for antibodies (small proteins produced by your immune system) to Deamidated Gliadin Peptide (DGP). DGP is produced in patients with coeliac disease in response to eating gluten. Your test indicates that you did not have antibodies (IgA or IgG) to DGP.

Providing you have been eating an adequate gluten containing diet (as confirmed with a member of the pharmacy team) the test is accurate (~95%) for ruling out coeliac disease. However, in a small number of cases, the test can provide a negative result despite you actually having coeliac disease. This is known as a “false negative”. If your symptoms are troublesome you may wish to follow up with your General Practitioner (GP) and provide him/her with the report below. This may help your GP to determine the cause of your symptoms quicker by helping rule out coeliac disease as the cause of your symptoms. Should your GP continue to have a high index of suspicion that your symptoms are related to coeliac disease he or she may perform additional screening blood tests.

Report

The Simtomax® test looks at both IgA and IgG to DGP – these were NEGATIVE

In addition the results showed:

- No IgA deficiency
- IgA deficiency

For reference, further information about the service provided to you today is available on the Coeliac UK and NAPC websites (insert URLs).

[Add pharmacy stamp and date]
Appendix 6: POCT Operating Procedure

Simtomax® operating procedure

1. Before performing the test check the expiry date of the test device to ensure it is still in date.
2. Use alcohol gel/foam to sanitise hands prior to commencing the test.
3. Put on gloves and remove the test device from the packaging, but do not open the lid of the device.
4. Wipe the patient’s fingertip with the alcohol swab provided and then allow the finger to dry before using the lancet.
5. Remove the cap from the lancet and press it against the patient’s fingertip to discharge the lancet and prick the finger.
6. Gently massage the finger in the direction of the fingertip in order to produce a droplet of blood.
7. Hold the pipette horizontally and touch the blood sample with the tip of the pipette. Repeat this action until the blood reaches the fill line (Fig 1). This corresponds to the volume of blood required to run the test. Do not squeeze the bulb of the pipette; the blood is drawn up by capillary action.

8. Deposit all of the blood into the sample window of the test device (marked 1) by squeezing the bulb of the pipette and then allow 30 seconds for the blood to soak into the device (fig.2).

9. Provide the patient with the plaster provided with the test kit.
10. Open the test device and immediately add 5 drops of buffer solution into the circular port (marked 2; fig 3). Do not allow the buffer solution to come in contact with the skin or eyes.
11. Allow the test to run on a flat surface for 10 minutes with the lid of the device open.
12. After 10 minutes read the results of the test (fig. 4). The control line (CT) must be present otherwise the test is invalid.

![Figure 3](image)

**Figure 3.**

13. Record the test result (coeliac and IgA status) on the form provided and counsel the patient as appropriate.

14. Once the test is completed, place the lancet, test device and micro pipette into an appropriate sharps container and place the gloves and alcohol swab into an appropriate clinical waste bag.