

Prescribing of Gluten Free foods in Greater Nottingham

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Report on the withdrawal of Gluten Free food products from prescribing on 1st December 2018 to September 2019

Executive Summary

Following the recommendation from the Joint Commissioning Committee to stop the prescribing of Gluten Free (GF) food products for all patients in Greater Nottingham in September 2018 an evaluatory piece has been conducted to review and to assess impact this may have had on our patient population in the nine months following cessation of prescribing of GF foods.

This report details that we will continue to recommend no prescribing of GF products and that we will continue to monitor the impact as well as ensuring good referral pathways for patients once they are diagnosed. Stakeholders have recognised that stopping prescribing of GF products has occurred alongside effective communication, opportunities for education and pathways to Dietetic support for patients with Coeliac Disease. This includes the opportunity for annual review with the GP or Dietitian and group education when diagnosis occurs, which has better outcome for patients given that there is no evidence that providing GF products assures that the patient will follow a totally GF diet.

Education is most important to achieve behaviour change, so therefore at the forefront is the need for all food labels to be read, so patients understand the contents of their food. As 'free from' ranges continue to increase and expand in supermarket outlets, costs are coming down and choice is increased, therefore patients are making informed choices as awareness of food and its link to health outcomes rises.

Aim

To neutrally evaluate the impact following the decision to withdraw GF prescribing in December 2018. It was not anticipated that there would be a need to overturn the decision to withdraw GF products from prescribing; the CCG has looked at notable changes following the implementation of the decision in December 2018.

Background

Coeliac disease (CD) is an autoimmune condition associated with chronic inflammation of the small intestine, which can lead to malabsorption of nutrients, triggered by the protein gluten. If someone with coeliac disease is exposed to gluten (found in wheat, barley and rye) they may experience a range of symptoms and adverse effects. The symptoms from and consequences of not following gluten free (GF) diets may be mild or very severe and can include:

- Abdominal pain, diarrhoea, nausea, bloating, vomiting
- Weight loss in adults or failure to grow at the expected rate in children

- Malnutrition, iron, vitamin B12 and folic acid deficiencies
- Tiredness, headaches
- Skin rash, mouth ulcers, tooth enamel problems
- Osteoporosis, ulcerative jejunitis
- Malignancy (intestinal lymphoma)

The disease affects approximately 1 in 100 people in the UK where women are two to three times more likely to develop CD than men. There were approximately 850 patients across Greater Nottingham prescribed a GF product.

People with conditions such as Type 1 Diabetes, autoimmune thyroid disease, Down's syndrome and Turner syndrome are at a higher risk than the general population of having coeliac disease. First-degree relatives of a person with coeliac disease also have an increased likelihood of having the condition. It can be diagnosed at any age.

Symptoms are controlled by excluding foods that contain gluten from the diet. There are no medicines available to treat the condition and it cannot be cured. People with confirmed CD must give up eating all sources of gluten for life.

Over twenty to thirty years ago only a small range of GF foods, if any, were available to purchase and they were relatively expensive. To enable people to manage their disease, these foods were made available on prescription. However in recent years the range of GF foods has considerably expanded and become widely available via supermarkets at a more competitive price. However, gluten is not essential for a healthy diet and there are other foods that can provide carbohydrates e.g. potato and rice.

In 2017 the Department of Health (DH) recently conducted a national consultation on the availability of Gluten Free (GF) foods on prescription in primary care.

The options considered were:

- Option 1: Make no changes to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004.

Under this option all types of GF foods would continue to be prescribed in primary care at National Health Service (NHS) expense.

- Option 2: To add all GF foods to Schedule 1 of the above regulations to end the prescribing of GF foods in primary care.

Under this option no GF foods would be available on prescription in primary care.

- Option 3: To only allow the prescribing of certain GF foods (e.g. bread and flour) in primary care, by amending Schedule 1 of the above regulations.

Under this option only certain GF foods would be available on prescription in primary care.

The outcome from the national consultation was published on 1st February 2018 and the Government decided to restrict gluten-free prescribing to bread and mixes only. The majority of respondents to the consultation preferred this option.

The consultation response stated that:

“It is for CCGs to decide how they commission local services to best meet the needs of their populations”.

This statement signalled that the outcome of the consultation does not affect the statutory authority that a CCG has to determine the availability of GF foods in their local area. Greater Nottingham Clinical Commissioning Partnership decided to undertake a public consultation to support decision making about prescribing of gluten free foods for their population and following this decided to recommend stopping the prescribing of all GF foods.

Discussion

It is hard to quantify statistically what impact on health outcomes has been felt on the Greater Nottingham patient community in the short time since GF prescribing was stopped. Qualitative approaches were discussed to consider the impact on patient health outcomes. We noted from prescribing data (Appendix 1.1) that in general, people in older age groups were in receipt of prescriptions for GF foods, compared to those in younger age groups. This could indicate the need for ongoing education and information on food labelling as options in supermarkets increase for GF produce. Many people are reported through modern media and conversations in appointments to be self-diagnosing the need for gluten free diet, which also underlines the need for education in this area to inform the wider public.

Patient Experience information

The Greater Nottingham Patient Experience team fed back reporting of complaints that showed fifteen initial complaints in the initial two months following December 2018, but that this decreased month by month until April 2019, where no complaints were received. No complaints have since been received from April to September 2019 at the time of writing. It appears the decision has been accepted and patients have adjusted to purchasing their own GF products.

We considered gaining further information through a survey or through posting of letters, to survey people in our catchment who have CD to assess impact. However this would be time consuming, costly and is a loaded exercise, as those who are likely to reply are the ones who will be more likely to complain. We therefore recommended, after discussing with Senior Pharmacists, not to go down this route, but to continue keeping contact with Patient Experience and other stakeholders, such as secondary care dietitians, to monitor comments. This will continue into 2020.

Financial

Prescription expenditure on GF foods (April to June 2018)

Nottingham City CCG	£26,377
Nottingham North and East CCG	£5,786
Nottingham West CCG	£3,154
Rushcliffe CCG	£3,815

Using this data to calculate a full year effect produced an anticipated expenditure of £156,528 per

annum on GF foods.

Prescribing data and finance for the Medicines Management team to date shows that GF prescribing expenditure has reduced to very small amounts.

This has led to significant savings, as shown by ePACT2 data from the prescribing budget. The anticipated financial saving of £150,000 will be achieved.

Pathway, Primary and Secondary Care

We discussed with secondary care dietitians how we can better support patients once they are informed of their diagnosis and given the specialist dietary advice.

Discussion with the acute teams at Nottingham University Hospitals (NUH), informed us that patients are supported by gastroenterologist teams following diagnosis. These patients are offered group and one to one dietary advice as part of this. The effect of withdrawing prescriptions could lead to patients having more choice, if they are confident in reading of food labels and understanding nutritional requirements. Resource is provided in this area by NUH, however for patients who miss out on this we can recommend Coeliac UK, who for £2 per month support patients with information and a help line.

Main issues identified by our research shows that in reality, education forms the basis of best future treatment in our view. Putting in foundations so that patients needing to follow a GF diet are taught from the outset how to read food labels and understand identification of gluten containing foods is paramount. Over and above this, to understand natural alternatives to gluten in their diet, particularly to meet carbohydrate needs.

Wider Health promotion impression

There is an ongoing school of thought around public health and holistic living, promoting lifestyle advice to patients around a range of parameters. Medicines Management is focussing on ways to improve nutritional quality and this includes lifestyle advice where appropriate. For example, patients with CD ought to receive advice around avoidance of processed gluten containing foods, general food labelling and how to go about eating a healthy balanced diet. Our Dietetic opinion is the decision to remove gluten free prescribing will have a positive wider impact on health and wellbeing of families overall when combined with education. There is no evidence that provision of GF bread and flour means the patient will consume a GF diet. We want to see patients actively reading labels to note of any gluten containing foods when making choices. People can be given dietary advice to choose naturally gluten free sources of carbohydrate e.g. rice instead of pasta, as first line advice. All supermarkets now have 'Free from' ranges that offer good value choices for families including budget stores Lidl and Aldi. Many foods are naturally GF to meet carbohydrate, protein and fat requirements.

Summary of findings

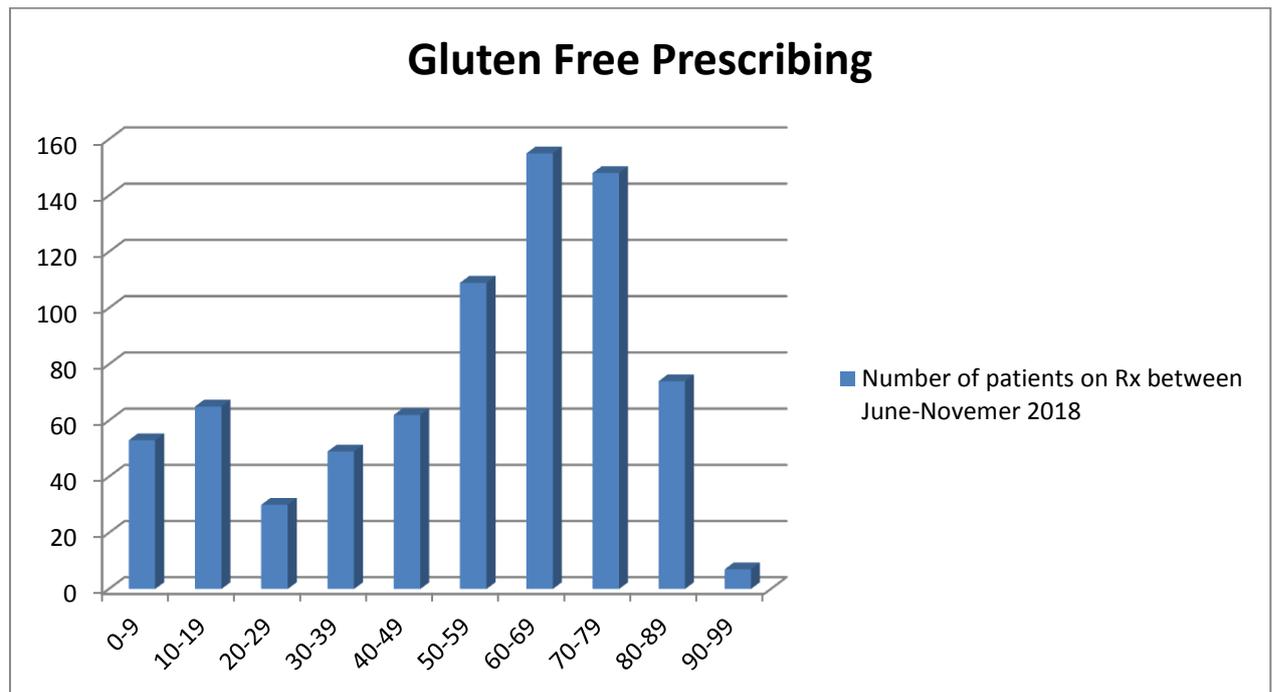
- Mid Nottinghamshire CCGs had already stopped GF prescribing. Greater Nottingham recognise the importance of consistency in care across Nottinghamshire
- Equity in relation to other conditions e.g. diabetic foods are not provided on prescription
- The clinical risk for patients with coeliac disease/ dermatitis herpetiformis not following a GF diet was noted but providing prescriptions does not mitigate this
- It is possible to have a healthy balanced diet without having gluten containing foods or gluten free alternatives.
- Gluten free foods are more widely available and whilst still more expensive have reduced in cost
- Patients to see GP in the case of a new diagnosis and access support offered including group education with a Dietitian and one to one appointment
- Patients already diagnosed to attend their annual review appointment with GP and can be referred to a Dietitian for specialist support if needed
- First Line Dietary Advice will be updated. It has been recommended that we use the NHS Choices Gluten Free Living advice (see Appendix 1.2). A one page summary of this will be posted on CCG websites as well as an attached PDF showing the full advice as well as a link to the NUH GI team.
- We will signpost to Coeliac UK, membership £2 per month and related resources. Coeliac UK are the leading charity in CD and also offer concessionary rates of £1 per month, which gives members support in a number of ways including resources, a helpline they can ring, the Food and Drink directory as well as recipes for GF eating.

Appendix 1.1 Figures for Greater Nottingham CCGs, Gluten Free prescribing

752 patients in total, dispensed between June and Nov 2018.

Raw data:

10 Years Age Band	BNF - Hierarchy	Identified Patient Count [1 of 2]
0-9	Gluten Free	53
10-19	Gluten Free	65
20-29	Gluten Free	30
30-39	Gluten Free	49
40-49	Gluten Free	62
50-59	Gluten Free	109
60-69	Gluten Free	155
70-79	Gluten Free	148
80-89	Gluten Free	74
90-99	Gluten Free	7



Appendix 1.2 Gluten Free Living – Advice for patients

Source: NHS Choices June 2019. Further information available from Coeliac UK

Coeliac disease is usually treated by simply excluding foods that contain gluten from your diet.

This prevents damage to the lining of your intestines (gut) and the associated symptoms, such as diarrhoea and stomach pain. If you have coeliac disease, you must give up all sources of gluten for life. Your symptoms will return if you eat foods containing gluten, and it will cause long-term damage to your health.

This may sound daunting, but your GP can give you help and advice about ways to manage your diet. Your symptoms should improve considerably within weeks of starting a gluten-free diet. However, it may take up to two years for your digestive system to heal completely.

Your GP will offer you an annual review during which your height and weight will be measured and your symptoms reviewed. They'll also ask you about your diet and assess whether you need any further help or specialist nutritional advice.

A gluten-free diet

When you're first diagnosed with coeliac disease, you'll be referred to a dietitian to help you adjust to your new diet without gluten. They can also ensure your diet is balanced and contains all the nutrients you need. If you have coeliac disease, you'll no longer be able to eat foods that contain barley, rye or wheat, including farina, graham flour, semolina, durum, cous cous and spelt.

Even if you only consume a small amount of gluten, such as a spoonful of pasta, you may have very unpleasant intestinal symptoms. If you keep consuming gluten regularly, you'll also be at greater risk of developing osteoporosis and cancer in later life.

As a protein, gluten isn't essential to your diet and can be replaced by other foods. Many gluten-free alternatives are widely available in supermarkets and health food shops, including pasta, pizza bases and bread. Many basic foods – such as meat, vegetables, cheese, potatoes and rice – are naturally free from gluten so you can still include them in your diet. Your dietitian can help you identify which foods are safe to eat and which aren't. If you're unsure, use the lists below as a general guide.

Foods containing gluten (unsafe to eat)

If you have coeliac disease, don't eat the following foods, unless they're labelled as gluten-free versions:

- bread
- pasta
- cereals
- biscuits or crackers
- cakes and pastries
- pies
- gravies and sauces

It's important to always check the labels of the foods you buy. Many foods – particularly those that are processed – contain gluten in additives, such as malt flavouring and modified food starch.

Gluten may also be found in some non-food products, including lipstick, postage stamps and some types of medication. Cross-contamination can occur if gluten-free foods and foods that contain gluten are prepared together or served with the same utensils.

Gluten-free foods (safe to eat)

If you have coeliac disease, you can eat the following foods, which naturally don't contain gluten:

- most dairy products, such as cheese, butter and milk
- fruit and vegetables
- meat and fish (although not breaded or battered)
- potatoes
- rice and rice noodles
- gluten-free flours, including rice, corn, soy and potato

By law, food labelled as gluten free can contain no more than 20 parts per million (ppm) of gluten. For most people with coeliac disease, these trace amounts of gluten won't cause a problem. However, a small number of people are unable to tolerate even trace amounts of gluten and need to have a diet completely free from cereals.

The Coeliac UK website has more about the law on gluten-free, as well as information and advice about a gluten-free diet and lifestyle.

Oats

Oats don't contain gluten, but many people with coeliac disease avoid eating them because they can become contaminated with other cereals that contain gluten. There's also some evidence to suggest that a very small number of people may still be sensitive to products that are gluten-free and don't contain contaminated oats. This is because oats contain a protein called avenin, which is suitable for the majority of people with coeliac disease, but may trigger symptoms in a few cases. If, after discussing this with your healthcare professional, you want to include oats in your diet, check the oats are pure and that there's no possibility contamination could have occurred.

You should avoid eating oats until your gluten-free diet has taken full effect and your symptoms have been resolved. Once you're symptom free, gradually reintroduce oats into your diet. If you develop symptoms again, stop eating oats.

Advice on feeding your baby

Don't introduce gluten into your baby's diet before they're six months old. Breast milk is naturally gluten free as are all infant milk formulas. If you have coeliac disease, Coeliac UK recommends foods containing gluten are introduced gradually when a child is six months old. This should be carefully monitored. The Coeliac UK website provides support for parents.

Other treatments

As well as eliminating foods that contain gluten from your diet, a number of other treatments are available for coeliac disease. These are described below.

Vaccinations

In some people, coeliac disease can cause the spleen to work less effectively, making you more vulnerable to infection.

You may therefore need to have extra vaccinations, including:

- flu (influenza) jab
- Hib/MenC vaccine, which protects against sepsis (blood poisoning), pneumonia and meningitis (an infection of the lining of the brain)
- pneumococcal vaccine, which protects against infections caused by the *Streptococcus pneumoniae* bacterium

However, if your spleen is unaffected by coeliac disease, these vaccinations aren't usually necessary.

Supplements

As well as cutting gluten out of your diet, your GP or dietitian may also recommend you take vitamin and mineral supplements, at least for the first six months after your diagnosis.

This will ensure you get all the nutrients you need while your digestive system repairs itself. Taking supplements can also help correct any deficiencies, such as anaemia (a lack of iron in the blood).

Dermatitis herpetiformis

If you have dermatitis herpetiformis (an itchy rash that can be caused by gluten intolerance), cutting gluten out of your diet should clear it up. However, it can sometimes take longer for a gluten-free diet to clear the rash than it does to control your other symptoms, such as diarrhoea and stomach pain.

If this is the case, you may be prescribed medication to speed up the healing time of the rash. It's likely that this will be a medicine called Dapsone, which is usually taken orally (in tablet form) twice a day. Dapsone can cause side effects, such as headaches and depression, so you'll always be prescribed the lowest effective dose.

You may need to take medication for up to two years to control dermatitis herpetiformis. After this time, you should have been following a gluten-free diet long enough for the rash to be controlled without the need for medication.

Refractory coeliac disease

Refractory coeliac disease is a rarer type of coeliac disease where the symptoms continue, even after switching to a gluten-free diet. The reasons for this are unclear. It's estimated that around one in every 140 people with coeliac disease will develop the refractory form of the condition. If refractory coeliac disease is suspected, it's likely you'll be referred for a series of tests to make sure your symptoms aren't being caused by another condition.

If no other cause can be found and the diagnosis is confirmed, you'll be referred to a specialist. Treatment options include steroid medication (corticosteroids), such as prednisolone, which help block the harmful effects of the immune system.