Department of Health & Social Care

Equality Impact Assessment

Following the consultation 'Availability of Gluten Free Food on Prescription in Primary Care'

January 2018

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Department of Health & Social Care

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Executive summary

The Department of Health launched a public consultation to seek views on whether or not to make any changes to the availability of gluten free (GF) foods that can be prescribed in primary care.

Staple GF foods are available on prescription to patients diagnosed with gluten sensitivity enteropathies, and have been since the late 1960s when the availability of GF foods was limited. GF foods are now readily available in supermarkets and a wider range of naturally GF food types are now available, so the ability of patients to obtain these foods without a prescription has greatly increased.

Many Clinical Commissioning Groups (CCGs) now have limited types or units of GF foods available on prescription[1]. A number of CCGs provide only bread and flour; several have stopped prescribing all GF foods. CCGs were set up to ensure that their local populations receive the medicines and treatments they require, with locally managed resources. Differing approaches to the availability of GF foods is creating regional variations across England.

A public consultation was launched on 31st March 2017 and was open for submission of responses to 22nd June. The consultation sought views on three options:

- Option 1: Make no changes to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004.
- Option 2: To add all GF foods to Schedule 1 of the above regulations to end the prescribing of GF foods 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.

This report provides information about the equality issues and the analysis of the information that was provided in response to the consultation.

Changes to the prescribing of GF foods could save NHS resources and reduce the primary care prescription drugs bill by up to £22.7 million in year one following changes (based on Net Ingredient Cost (NIC) and dispensing fees).[2] .

Although we have not identified this in every section of this document, having weighed up the various impacts, we consider that the benefits of enabling this resource to be spent elsewhere outweighs the detriment that we have identified recognising that these detriments are potentially significant particularly in relation to Option 2.

[1] CCG websites and https://www.coeliac.org.uk/gluten-free-diet-and-lifestyle/prescriptions/prescription-policies/

[2] Prescription Cost Analysis (England) 2016

1. Introduction

1.1. The Department of Health's Shared Delivery Plan 2015 - 2020 contains the Department's objectives which includes "Improving efficiency and productivity of the health and care system". This project relates to this objective through ensuring that the Department helps the NHS make effective use of the drugs bill spending in primary care.

1.2. The Department of Health launched a public consultation to seek views on whether any changes should be made to prescribing legislation on GF foods. A range of options were set out in the consultation document, which included ending the prescribing of GF foods by adding them to Schedule 1 to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004, or by way of otherwise amending these Regulations. Schedule 1 is commonly known as the blacklist, and GPs are not permitted to prescribe products from this list at NHS expense.

1.3. Staple GF foods have been available on prescription to patients diagnosed with gluten sensitivity enteropathies since the late 1960s when the availability of GF foods was limited. GF foods are now more widely available in supermarkets, although stock can be variable, with a wider range of naturally GF food types available, meaning that the ability of patients to obtain these foods without a prescription has greatly increased.

1.4. Many CCGs have made changes to local prescribing formularies and have restricted or ended GF food[3]. This regional variation is leading to inequality of access. The prescribing position in CCGs in England (July 2017) is shown in Table 1.

Table 1 - CCG Prescribing Status

Prescribing Arrangements (July 2017)	Number of CCGs
Following Coeliac UK guidelines	78
Ended all GF foods on prescription (all patients)	25
No restrictions	4
Other restrictions; product type, quantities, or patient status	102

1.5. All people have to purchase food, including patients with a diagnosis of coeliac disease or dermatitis herpetiformis. These patients can obtain a range of staple GF foods on prescription to support adherence to a GF diet. Adherence to a GF diet is the only way to manage the condition and prevent further ill health related to coeliac disease.

1.6. The policy is not likely to impact on human rights as patients are not denied the foods that they need, naturally GF food and formulated GF food are available to purchase in

[3] https://www.coeliac.org.uk/gluten-free-diet-and-lifestyle/prescriptions/prescription-policies/

supermarkets and on-line. Patients who are diagnosed with coeliac disease will continue to be advised of the importance of adhering to a GF diet and information on how to do that. Patients are entitled to an annual review with their healthcare professional who can offer advice and guidance on maintaining a GF diet.

2. Statutory Duties

The Public Sector Equality Duty

2.1. The Department of Health is covered by the Equality Act 2010 and specifically by the Public Sector Equality Duty (PSED). The Duty covers the following protected characteristics: age, disability, gender reassignment, maternity, race (includes ethnic or national origins, colour or nationality), religion or belief (includes lack of belief), sex and sexual orientation.

2.2. There are three parts to the Duty, and public bodies must, in exercising their functions, have due regard to them all. They are the need to:

- eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act
- advance equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it
- foster good relations between persons who share a relevant protected characteristic and persons who do not share it.

2.3. Having due regard to the need to advance equality of opportunity between persons who share a relevant protected characteristic, and persons who do not share it, involves having due regard in particular to the need to:

i) remove or minimise disadvantages suffered by persons who share a relevant protected characteristic that are connected to that characteristic;

ii) take steps to meet the needs of persons who share a relevant protected characteristic that are different from the needs of persons who do not share it

iii) encourage persons who share a relevant protected characteristic to participate in public life or in any other activity in which participation by such persons is disproportionately low. The steps involved in meeting the needs of disabled people that are different from the needs of persons who are not disabled, include, in particular, steps to take account of disabled persons' disabilities.

2.4. Having due regard to the need to foster good relations between persons who share a relevant protected characteristic and persons who do not share it involves having due regard, in particular, to the need to:

a) tackle prejudice, and

b) promote understanding.

2.5 Officials have considered the implications for each of the three equality objectives in relation to the proposals for GF prescribing. Overall our view is that whilst there may be impacts, these are largely mitigated by the easier access to both formulated and naturally GF foods which are now more widely available in supermarkets and online, and to some extent, in food banks for people on low or no incomes. People can also manage their conditions by choosing naturally GF foods. Our judgement is that on balance the benefits of the proposals outweigh the identified impacts, in the light of the Department of Health's objective of helping the NHS make effective use of the drugs bill spending in primary care, as mentioned in relation to the Department of Health's Shared Delivery Plan 2015 - 2020 in paragraph 1.1 above.

Secretary of States duties under the National Health Service Act 2006

2.5. The National Health Service Act 2006 (NHSA) contains a number of overarching duties on the Secretary of State for Health which apply to every action undertaken in relation to the NHS and public health. The following duties appear to be engaged in relation to the proposals being analysed in this Equality Impact Assessment. These are -

a) the Duty to continue to promote a comprehensive health service in England (section 1)

b) the Duty as to improvement in quality of services (section 1A); and

c) the Duty as to reducing inequalities (section 1C).

Duty to continue the promotion in England of a comprehensive health service (section 1)

This Duty requires the Secretary of State to continue the promotion in England of a comprehensive health service designed to secure improvement -

a) in the physical and mental health of the people of England, and

b) in the prevention, diagnosis and treatment of physical and mental illness.

Duty as to improvement in quality of services (section 1A)

2.6. The Secretary of State must exercise the functions of the Secretary of State in relation to the health service with a view to securing the continuous improvement in the quality of services provided to individuals for or in connection with -

a) the prevention, diagnosis or treatment of illness, or

b) the protection or improvement of public health.

In relation to this Duty, and the section 1 Duty to continue to promote a comprehensive health service in England, our view is that the section 1A duty was never intended to mean entitlement to specific products. Within providing a comprehensive health service for people diagnosed with gluten sensitivity enteropathies, including coeliac disease, there is scope for deciding how much should be provided by the health service, and how much management of the condition is something that can be reasonably and fairly be left to the patient. In striking that balance, the Secretary of State can look at resource issues, and decide that overall some particular products may be withdrawn because of a reasonable analysis that the funds would be better spent elsewhere. Where products are not realistically available commercially there may be a requirement for the NHS to step in. Where products are readily available for the self-management for the conditions, it is reasonable to take the view that NHS resources are no longer required to ensure that patients can manage their conditions effectively. The release of funds from any GF food prescribing changes would be re-deployed into other parts of the health system. It would be at the discretion of each CCG to re-invest in other areas of health care in accordance with their local priorities.

Duty as to reducing inequalities (section 1C)

2.7. In exercising functions in relation to the health service, the Secretary of State must have regard to the need to reduce to reduce inequalities between the people of England with respect to the benefits that they can obtain from the health service.

2.8. It is important to emphasise that this duty is separate from the PSED duty, and is about a need to reduce inequalities that may or may not be based on protected characteristics.

Socio- economic impacts need therefore to be considered in terms of other socio-economic factors such as income, social deprivation and rural isolation. We have considered the various impacts of the GF proposals on various groups of people in this analysis. Socio-economic issues are dealt with in paragraphs 3.43 to 3.53.

2.9. A full impact assessment has been published alongside this document and this explores the health and other impacts and associated costs of each option. It includes information that was submitted as part of the public consultation. The key issues are summarised below.

Key equality issues that arose from the consultation responses

2.10. Families who are on low incomes are likely to feel a greater impact from any changes to the current system for the prescribing of GF foods as they may currently be eligible for exemptions from prescription charges. Some families may have multiple coeliac disease patients making an increased cost to their weekly food shopping bill likely, if GF prescribing was ended and they had to purchase GF foods.

2.11. Families or individuals on "no income", for example those who may be awaiting decisions on benefit entitlement, and who are exempt from prescription charges, may also be greater impacted. They may temporally rely on food banks for their food, where stocks of formulated GF food could be limited, which would mean that the patient/parent/carer would need to select foods that are naturally GF, such as meat, fish, rice, fruit and vegetables, as are available, to meet their dietary needs.

2.12. It is acknowledged that bread remains a staple part of many people's diet, including patients with coeliac disease. The impact of change to the availability of GF foods on prescription could be greater on those who are experiencing economic deprivation as formulated GF bread remains more expensive than its counterpart.

2.13. Although coeliac disease is not a disability, patients with limited mobility and the elderly may have problems obtaining non-prescription GF items, as they often rely on home deliveries of these items by their pharmacies. Though they can purchase GF foods on-line for home delivery by a supermarket or on-line retailer, many may not be able to quickly adapt to any changes to access formulated GF food.

2.14. People with additional autoimmune conditions could find themselves in a situation whereby their medication to treat that condition is provided on prescription, but their GF foods are not. This may impact on them visiting their GP regularly and risk detrimental ill health.

2.15. Respondents from the parent/carer group raised concerns about access to GF food for children and the elderly, as these groups were more likely to have their dietary choices and meals made for them. Elderly patients and younger children often rely on GF foods provided under prescriptions to supplement their dietary needs. Both these groups are eligible for exemption from prescription charges, meaning they would be impacted financially by changes to GF prescribing.

3. Evidence

3.1. The public consultation allowed interested stakeholders to submit information to highlight any issues with the three presented options.

3.2. As part of the pre-consultation work, a range of evidence was collated and reviewed from a variety of sources which included; journal articles, published reports, local CCG insights and changes, the National Institute for Health and Care Excellence (NICE) guidance[4] and Quality Standards[5].

3.3. As part of the responses to the consultation additional evidence was requested on a range of issues, including; the link between GF prescriptions and adherence to a GF diet, data on patient impact where changes had been made at CCG level and data to support the calculations on Quality Adjusted Life Years (QALY value). This information and revised calculations have been reflected in the updated Impact Assessment published alongside this document.

3.4. In response to the consultation stakeholders provided numerous additional references in relation to the above points. This included information where patients from protected groups could be more significantly affected by any changes, the availability and cost of GF foods, and the issues faced by those on low incomes. It was emphasised that those supermarkets which stocked GF food, that stock could be variable and not consistently available.

3.5. The issues of socio-economic disadvantage were also raised, as some patients found the cost of GF food would affect their adherence to a GF diet if they had to purchase their own GF food. Some respondents stated that availability in food banks was non-existent or sparse. The Trussell Trust provides a list of frequently included products in emergency food parcels which would likely contain tinned products such as meat/vegetables/fruit, cereals, rice, tea/coffee and biscuits. Some food banks may offer a delivery service for people in rural locations.[6] This service is variable and is dependent upon the food bank in the area. People requiring the services offered by a food bank would be referred by a relevant organisation such as Citizens Advice, Social Services and other welfare agencies.

3.6. Policy officials undertook a review of the information provided. This involved; accessing information contained in journal articles, reading and reviewing content, following web links and reviewing website content. These reports/papers/information sources were collated and scrutinised for relevance and factual information linking to the evidence which is also incorporated in the Impact Assessment, which additionally provides an overview of costs and calculations on health impacts for all options.

3.7. The numbers of coeliac patients is estimated to be 1% of the population.[7] The English population (mid 2016) was 55,268,100, so 1% of this figure gives an estimated

[4] https://www.nice.org.uk/guidance/ng20

[5] https://www.nice.org.uk/guidance/qs134

[6] https://www.truselltrust.org/get-help/emergency-food/

[7] https://www.nhs.uk/Conditions/Coeliac-disease/Pages/Introduction.aspx#Whos-affected

population with coeliac disease as 552,681. Coeliac UK estimate that only 24% of these patients have a diagnosis this gives an identified group of **132,643** coeliac diagnosed patients. This figure has been used to replicate percentages in English population to achieve an estimate of the coeliac population breakdown by; age, gender, ethnicity, disability, carers, low income, and those living in rural areas, this is detailed in Annex A.

Patient Choices and Adherence

3.8. Patients diagnosed with gluten sensitivity enteropathies, including coeliac disease, face a choice of whether to adhere to a gluten free diet. Where they are adherent, they face a reduced risk of complications. A patient presently faces the following choices:

- Adhere through purchasing naturally GF food
- Adhere through purchasing formulated GF food
- Adhere through obtaining formulated GF food provided through NHS prescription
- Not adhere

3.9. In practice, patients that adhere to a GF diet will do so through some combination of naturally GF food and formulated GF food both purchased privately and obtained through prescription. That is, through a combination of the three routes to adherence.

3.10. Under Option 2, patients would no longer be able to obtain formulated GF food through prescription. If they choose to adhere to a GF diet, they would need to do so by purchasing naturally GF food, or by purchasing formulated GF food. They would have fewer routes to adherence:

- Adhere through purchasing naturally GF food
- Adhere through purchasing formulated GF food
- Not adhere

3.11. Under Option 3, patients are able to obtain bread and mixes through prescription. Options for adherence are:

- Adhere through purchasing naturally GF food
- Adhere through purchasing formulated GF food
- Adhere through obtaining GF bread and mixes on prescription
- Not adhere

Prescribing Data

3.12. Data detailing the prescriptions for GF, and GF and Wheat Free (WF) foods dispensed by prescription items and the associated Net Ingredient Cost (NIC) (£) is shown in Table 2. It shows a breakdown of those prescriptions that attracted a dispensing fee at point of dispensing (charged) and those exempt from prescription charges by category, including those which had a pre-paid certificate. [8]

3.13. In 2016 **20%** of prescription items for GF and GF/WF food attracted a prescription fee at the point of dispensing, or were exempt due to having a pre-paid certificate (category F), whilst **80%** of GF and GF/WF items dispensed were exempt from charges

[8] Bespoke report provided by the NHS Business Services Authority for England in 2016

under all categories (with the exception of category F - pre paid certificates) as detailed in Table 2.

3.14. In relation to **all** prescription items prescribed in 2016; 89.4% were exempt from prescription charges, with 4.9% being exempt due to the patient having a pre-paid certificate, and 5% attracting a charge at the point of dispensing. The majority of exemptions for both GF, GF/WF and all prescription items were those prescriptions for patients aged 60 or over, that is 39.8% and 61% respectively.

Table 2 - Prescription Data for Gluten Free, and Gluten and Wheat Free Foods (2016)

Prescription Charge Status	Exemption Category	TOTAL ITEMS(%)	TOTAL NIC £ (%)
CHARGEABLE	Paid (at point of dispensing)	19,047(**1.29%**)	443,489(1.98%)
EXEMPT	**A - is under 16 years of age**	231,947(**15.72%**)	2,992,663(13.36%)
EXEMPT	**B - is 16,17 or 18 and in full time education**	38,581(**2.62%)**	585,926(2.62%)
EXEMPT	**C - is 60 years of age or over**	586,594(**29.76%**)	9,843,655(43.94%)
EXEMPT	D - has a valid maternity exemption certificate	15,140(1.03%)	191,818(0.86%)
EXEMPT	E - has a valid medical exemption certificate	137,603(9.33%)	1,950,699(8.71%)
EXEMPT	**F - has a valid prescription pre-payment certificate**	288,314(**19.54%)**	4,069,882(18.17%)
EXEMPT	G - has a valid War Pension exemption certificate	658(0.04%)	9,662(0.04%)
EXEMPT	H - gets Income Support or Employment & Support Allowance	59,680(4.05%)	864,585(3.86%)
EXEMPT	K - gets income-based Jobseeker's Allowance	9,058(0.61%)	139,155(0.62%)
EXEMPT	L - is named on a current HC2 charges certificate	7,268(0.49%)	106,469(0.48%)
EXEMPT	M - is entitled to, or named on, a valid NHS Tax Credit Exemption Certificate	46,891(3.18%)	671,202(3.00%)
EXEMPT	S - has a partner who gets Pension Credit guarantee credit (PCFC)	1,620(0.11%)	23,708(0.11%)
EXEMPT	X - was prescribed free-of-charge contraceptives	385(0.03%)	5,915(0.03%)
EXEMPT	Z - exemption cannot be determined	32,496(2.20%)	504,353(2.25%)
TOTALS		1,475,282.00	22,403,188.41

Disability

3.15. Coeliac disease is not defined as a disability under the Equality Act 2010 although it is a long term condition. It is an autoimmune disease which requires an adjustment to the diet to prevent symptoms. Some patients may have more than one autoimmune disease. People with certain conditions, including type 1 diabetes, autoimmune thyroid disease, Down's syndrome and Turner syndrome, have an increased risk of getting coeliac disease.[9]

3.16. If changes were made to GF prescribing then patients with additional autoimmune conditions could find themselves in a situation whereby their medication to treat that condition is provided on prescription, but their GF food requirements are not.

3.17. Some patients with an existing medical condition are exempt from prescription charges (see Table 2 - category E), this means that patients who receive GF and GF/WF food on prescription and are eligible for prescription exemptions due to having a "qualifying" medical condition, and hold a valid "medical exemption certificate".[10] This accounts for 9% of all GF and GF/WF prescription items.

3.18. A substantially higher proportion of individuals who live in families with disabled members live in poverty, compared to individuals who live in families where no one is disabled.[11] These patients may be impacted greater by any change to GF prescribing.

3.19. Option 1 - If no change was made to the current prescribing arrangements then patients would continue to access GF foods on prescription in accordance with their local CCG formularies. In the majority of CCGs GF foods continue to be available on prescription, which will meet the needs of the most vulnerable patients, including those with learning disabilities who may struggle to make informed choices when purchasing and preparing food. Patients with reduced mobility or those who have their prescriptions delivered will be able to continue to have staple GF delivered through pharmacies and any additional or luxury GF items required can be ordered through on-line retailers who offer home delivery.

3.20. Option 2 - If all GF prescriptions ceased then this would impact on the most vulnerable groups in society, meaning elderly and infirm patients could be adversely affected. These patient groups may have difficulty visiting a variety of supermarkets to find an adequate supply of GF foods, as stock can be variable. Patients with learning disabilities may struggle to make the correct food choices without appropriate guidance. Failure to follow a GF diet could lead to ill health for these patient groups. We have considered the GF proposals in the light of the combined impact on patients who are both disabled and elderly, and consider that any indirect discrimination that may result from the proposals will largely be mitigated by the greater availability of GF foods in supermarkets and online, and to a limited extent, in food banks for patients on low incomes. Patients will also be able to manage their condition by choosing naturally GF foods. To the extent that the proposals are likely to impact more on such patients, we

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[9] https://www.nhs.uk/Conditions/Coeliac-disease/Pages/Introduction.aspx#Whos-affected

[10] NHS (Charges for Drugs and Appliances) Regulations 2015

[11] https://www.gov.uk/government/publications/disability-facts-and-figures/disability-facts-and-figures

consider that any potential indirect discrimination is proportionate to the legitimate aim being pursued of helping the NHS make effective use of the drugs bill in primary care.

3.21. Option 3 - If a reduced list of staple GF products remained on prescription then all patients would have equal access to these. This means that patients who currently receive prescriptions for GF food would be able to get prescriptions for bread and mixes to support their continued adherence to a GF diet. Patients diagnosed in the future would also be able to access bread and mixes on prescriptions.

Sex

3.22. Coeliac disease affects approximately one in every 100 people, although it is thought that only 24% of these will have a clinical diagnosis[12]. Coeliac disease can affect both men and women, but NHS Choices states that reported cases of coeliac disease are two to three times higher in women than men.[13] This would mean that women could potentially be indirectly discriminated against should option 2 be pursued. We have considered the GF proposals in the light of this potential discrimination, and consider that any indirect discrimination that may result from the proposals will largely be mitigated by the greater availability of GF foods in supermarkets, and to a limited extent, in food banks for women on low incomes. To the extent that the proposals are likely to impact more on women than men we consider that any potential indirect discrimination is proportionate to the legitimate aim being pursued which is to assist the NHS make effective use of the drugs bill in primary care.

3.23. Option 1 from the consultation will not discriminate against men or women disproportionately as all patients regardless of gender would continue to access GF food on prescription. The national charity Coeliac UK recommend units of GF food based upon patients' age, sex and other factors e.g. pregnancy/breast feeding. Healthcare professionals can be guided by this and dieticians can provide tailored support to coeliac patients, providing advice based on their individual circumstances, and the recommended daily allowance (RDA) of calories, which differs for men and women.[14]

3.24. Life expectancy for males and females differs. Life expectancy for males is 79.2 years, and for females is 82.9 years[15] . This difference would impact the length of time GF prescriptions are required for patients of different genders, meaning the impact would, in the longer term, be greater on women than on men.

Race

3.25. Patients from all racial groups can be affected by coeliac disease. Estimates of patients reflecting the general population of England indicate that 87% are of "white ethnic origin".

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[12] Coeliac UK. https://www.coeliac.org.uk/coeliac-disease/about-coeliac-disease-and-dermatitis-herpetiformis/

[13] https://www.nhs.uk/Conditions/Coeliac-disease/Pages/Introduction.aspx#Whos-affected

[14] http://www.nhs.uk/Livewell/loseweight/Pages/understanding-calories.aspx

[15] https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/lifeexpectancies/bulletins/nationallifetablesunitedkingdom/2014to2016

3.26. No evidence has been found that patients from specific racial groups have higher rates of diagnosis of coeliac disease, meaning that any options from the policy will not discriminate against people from different racial backgrounds. Any changes will apply to all patients regardless of their race. It is possible that some racial groups rely more heavily on bread as part of their staple diet, whilst other groups have a preference for other staple foods which are naturally GF, for example, rice. This means that those patients in some ethnic groups could be disadvantaged if option 2 was introduced as they would need to purchase their own GF bread or source alternatives.

3.27. Patients from ethnic origins are more likely to be in lower income brackets[16], therefore option 2 would therefore potentially have a greater impact on these groups. This could be mitigated by patients adjusting their diets, or purchasing their own GF formulated foods. Patients on low incomes could access naturally GF food from food banks, as formulated GF food may not be widely available. This would enable them to adhere to a GF diet and minimise the risk of ill health.

3.28. Option 3 - If a reduced list of staple GF products remains on prescription then the list of available GF staple products will still offer a degree of patient choice to suit patients from different ethnic backgrounds e.g. different bread types.

Age

3.29. Coeliac disease can develop and be diagnosed at any age, and may develop after weaning onto cereals that contain gluten, in old age, or any time in between. Coeliac disease is most frequently diagnosed in people aged 40-60 years old[17]. Patients of all ages can access GF food on prescription, but exemption from prescription charges are available for the following age groups:

- Those under 16 years of age
- Those aged 16,17, and 18 and in full time education
- Those aged 60 and over.

3.30. The following table (Table 3) shows the distribution of age related exemptions for GF and GF/WF food prescriptions. It provides data by the number of prescription items, compared to all prescription items in England in 2016. The largest category of patients eligible for prescription exemptions are those aged 60 and over, this group is likely to be impacted most by any changes to prescribing policy. An age related prescription exemption, or a pre-paid certificate, entitles the patient to receive all prescription items without paying an individual prescription fee for all medicines and not just for GF foods.
Table 3 - Age Related Prescription Charge Exemptions

	PRESCRIPTION ITEMS (2016)

[16] http://www.poverty.org.uk/summary/uk.htm

[17] https://www.coeliac.org.uk/coeliac-disease/myths-about-coeliac-disease/

	GF, GF/WF Prescriptions[18]	All Prescriptions[19]
Charged - fee paid	1.3%	5.0%
Charged - pre-paid certs	19.5%	4.9%
Exempt age under 16, and 16, 17, 18 in full time education	18.3%	4.4%
Exempt age 60 and above	39.8%	61.0%
Exempt others	21.1%	24.7%

3.31. Option 1 - The policy will meet the needs of all age ranges as no age limits/exemptions would be in place nationally. Staple GF food would continue to be available on prescription and this would ensure that those who rely on prescriptions for their GF diet would continue to receive them. Coeliac UK recommends numbers of GF food units based on the patient's age. The difference in life expectancy for males (79.2 years) and females (82.9 years)[20] would impact the length of time GF prescriptions are required to support a lifelong GF diet in the management of coeliac disease.

3.32. Option 2 - All patients would have to pay for all their own formulated GF food requirements, or follow a diet that is naturally GF. Patients in the prescription age exemption categories would be impacted most as they would no longer be able to access (free of charge) GF foods on prescription and would have to purchase their own GF food, or follow a naturally GF diet.

3.32.1. As 18.3% of younger patients obtain free prescriptions, this group could be impacted by any change under options 2 or 3. This could result in an increased cost to the family shopping bill if they replaced the GF staples currently on prescription with formulated GF food that they would have to purchase, in part or in entirety.

3.32.2. The impact on those in the aged 60 and above category would be greater as they receive 39.8% of all prescription items for GF food. Having to purchase their own formulated GF food could lead to financial hardship as many patients in this age group are reliant on a pension as their main source of income. GF formulated food can be more expensive than their equivalents, for example bread which is regularly consumed as part of the British diet. To mitigate the increased costs they would

[18] NHS Business Services Authority (Bespoke report Sept 2017) for all GF and GF&WF prescriptions in 2016

[19] NHS Digital https://digital.nhs.uk/catalogue/PUB30014

[20] https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/lifeexpectancies/bulletins/nationallifetablesunitedkingdom/2014to2016

need to adjust their diets to include more naturally GF food. If they failed to adhere to a GF diet this could lead to ill health.

3.32.3. People who are elderly may additionally have issues with mobility, this could lead to them having difficulty accessing larger stores to source their GF food requirements. They may however, be able to access delivery services offered by larger supermarkets and/or pharmacies. Paragraphs 4.45 and 4.51 evaluate the impact on those with restricted mobility.

3.32.4. We have considered the greater impact of the GF proposals on this group which may potentially result in indirect discrimination against this group, particularly in relation to older women. We consider that any indirect discrimination that may result from the proposals will largely be mitigated by the greater availability of GF foods in supermarkets and online, and to a limited extent, in food banks for older people on low incomes. Patients will also be able to manage their condition by choosing naturally GF foods. To the extent that the proposals are likely to impact more on this group than on other groups, we consider that any potential indirect discrimination is proportionate to the legitimate aim being pursued, which is to assist the NHS to make effective use of the drugs bill in primary care.

3.32.5. Both groups (children and the elderly) often have their food choices and meal preparation undertaken by a parent or carer and may be reliant upon prescriptions to assist adherence. If children consume the same meals as other members of the household (e.g. a non-GF diet) this could impact on their growth, delay puberty and make them susceptible to other auto-immune conditions[21].

3.33. Option 3 - A limited range of staple GF foods would remain on prescription and changes would apply to all age groups. As stated above those in the prescription exemption categories related to age would experience a greater impact as they may have to supplement their diet with GF formulated food that they would have to purchase, if they required anything other than basic GF staple items that would remain on prescription.

Gender Reassignment (Including transgender)

3.34. Patients who have changed gender or who are transgender will not be affected any differently to other patients groups as any changes would apply to all patients regardless of their gender.

Sexual Orientation

3.35. Patients of differing sexual orientation will not be affected any differently to other patient groups as any changes would apply to all patients regardless of their sexual orientation.

Religion or Belief

3.36. Patients with religions or beliefs, or no religion will not be affected any differently to other patient groups as any changes would apply to all patients regardless of their religion, or religious beliefs.

[21] https://www.coeliac.org.uk/coeliac-disease/coeliac-disease-in-children/

Pregnancy and Maternity

3.37. Patients who are pregnant or new mothers who are breast feeding require additional calorie intake. They may need to obtain guidance on maintaining a healthy (GF) balanced diet to ensure they receive adequate nutrition. Patients in this group may also be affected by low incomes either before, during or after pregnancy. See paragraphs 3.43 to 3.47 below which deal with socio-economic disadvantage.

3.38. Option 1 - The policy will meet the needs of all patients as flexibility in the number of required units would be retained for those in this patient group.

3.39. Option 2 - The policy would mean that patients in this group are required to purchase any additional GF needed to supplement their calorie intake during this period of time. Those who are pregnant and on low incomes may be able to either access GF foods, or to obtain naturally GF foods in food banks

3.40. Option 3 - If a reduced list of staple GF products remained on prescription then all patients would have equal access to these. This means that patients who currently receive prescriptions for GF food would be able to get prescriptions for bread and mixes to support their continued adherence to a GF diet. Patients diagnosed in the future would also be able to access bread and mixes on prescriptions.

Carers

3.41. People who care for adults or children could be impacted by any changes as they are often responsible for food choices and meal preparation for the patient.

3.42. Option 1 - Carers will continue to be able to obtain GF foods on prescription to support the patient's adherence to a GF diet.

3.43. Option 2 - Carers will have to select GF food from supermarkets, although stock can be variable and inconsistent. Carers could also be affected by issues around low incomes, and mobility limitations - see paragraphs below which deals with these issues.

3.44. Option 3 - Carers will be able to access basic GF staple items on prescription but will have to source any additional GF formulated food, or naturally GF food for the patient.

Socio-economic disadvantage

3.45. Families who are on low incomes or families on no-incomes pending benefit decision outcomes, are likely to feel a greater impact from any changes as 80% of GF, GF/WF prescription items are exempt from prescription charges, and they more likely to be relying on food banks where stocks of formulated GF foods could be non-existent or limited. In the absence of formulated GF foods in food banks these patients would need to make an informed choice on eating naturally GF foods that are available via a food bank, or budget supermarket.

3.46. Those with limited transport options (e.g. non-car ownership) may struggle to access GF foods as they are not frequently stocked by smaller local retailers. The patient would have the option to obtain either naturally GF foods, or to utilise on-line ordering of formulated GF foods to mitigate the risk of ill health.

3.47. Option 1 - Patients from low income households will continue to be able to obtain GF foods on prescription to support their adherence to a GF diet.

3.48. Option 2 - Patients from lower income groups, or those with no incomes, may struggle to afford formulated GF food if this is no longer available on prescription, as GF

foods tend to be more expensive than its counterparts. This group of patients will continue to have access to naturally occurring GF food which everyone has to buy. If they are eligible to access food from a food bank, they could source their food from there, and if there was a limited/no supply of formulated GF food, they would need to make informed choices to select naturally occurring GF food. However there is a risk that these patients will no longer continue to adhere to a GF diet and risk ill health.

3.49. Option 3 - Patients would have access to a limited range of staple GF foods on prescription, and those from lower income households often rely on budget supermarkets, which may have a more limited, or non-existent range of GF formulated foods. The British Dietetic Association (BDA) state that the provision of GF foods on prescription reduces the financial burden of the patients purchasing GF formulated foods.

Families and Multiple Coeliac Households

3.50. First-degree relatives (parents, brothers, sisters and children) of people with coeliac disease are also at increased risk of developing the condition. In households where there is more than one coeliac patient, e.g. siblings, parent/child, changes to GF prescribing could have an impact on the family's food shopping bill.

3.51. Those families on low incomes or those without income may need to rely on food banks to obtain food. These may not contain formulated GF food, so the patient/parent or carer would need to make an informed choice to select naturally GF foods.

People living in rural areas

3.52. Patients living in rural areas who have limited transport options may also find it difficult to source formulated GF food locally as it is may not frequently be stocked by smaller/local retailers.

3.53. Option 1 - People living in rural areas will continue to be able to obtain GF foods on prescription to support their GF diet.

3.54. Option 2 - Some patients living in rural areas may not have immediate access to larger supermarkets that are more likely to stock GF food, additionally GF food is not often stocked by small/local shops. They could therefore be significantly more impacted by any changes to GF prescribing than those not living in rural areas, and may rely on home deliveries by pharmacies for GF prescriptions to a greater extent than those not living in rural areas. Wealthier people living in rural areas are more likely to have their own transport which would make it easier for them to visit larger supermarkets to obtain formulated GF food. A patient's mobility as they age may decline, as such this could leave them with fewer options to travel to obtain GF foods. Pharmacies located in villages may stock GF foods, or could order these to meet a patient's needs, however this is likely to be a more expensive option and would not meet the needs of patients in rural areas on low incomes. If changes were made to prescribing GF foods, then patients would need to adapt their diets to rely on naturally GF foods for their nutritional requirements, or place an order for delivery by a larger supermarket for formulated GF food. Some food banks do offer a delivery service to ensure that people who live in rural areas can access foods, and avoid difficult or expensive journeys.

3.55. Option 3 - Patients in rural areas would retain access to basic GF staple foods via prescription. Most have access to a local pharmacy who may also offer home deliveries for medicines and other prescription items.

Summary of Impacts

3.56. In summary, any change to the prescribing of GF food on NHS prescription would have an impact on some patients who share certain protected characteristics. The main impacts would be on the elderly, those with mobility problems, and patients on low incomes.

4. The Family Test

4.1. The family test was designed to complement the existing work of Departments to consider the three aims of the Public Sector Equality Duty.

4.2. Applying the family test when developing policy and complying with the PSED should lead to better overall outcomes for people. The test seeks to ensure that during the development of policy, particular attention is paid to its impact on supporting strong families and relationships:

- Couple relationships (including same sex couples) including marriage, civil partnership, co-habitation and couples not living together.
- Relationships in lone parent families, including relation between the parent and children with a non-resident parent, and with extended family.
- Parent and step-parent to child relationships.
- Relationship with foster children, and adopted children.
- Sibling relationships.
- Children's relationships with their grandparents.
- Relatives or friends looking after children unable to live with their parents.
- Extended families, particularly where they are playing a role in raising children or caring for older or disabled family members.

4.3. The five Family Test questions are:

- What kind of impact might the policy have on family formation?
- What kind of impact will the policy have on families going through key transitions such as becoming parents, getting married, fostering or adopting, bereavement, redundancy, new caring responsibilities or the onset of a long term condition?
- What impacts will the policy have on all family members' ability to play a full role in family life, including with respect to parenting and other caring responsibilities?
- How does the policy impact families before, during and after couple separation?
- How does the policy impact those families most at risk of deterioration of relationship quality and breakdown?

4.4. Respondents to the consultation suggested an adverse impact of any change on families where there is more than one coeliac patient. This could occur on the arrival of a new child through adoption, or birth. Additional expenditure on food may impact the family food shopping budget and risk non-adherence to a GF diet, which in turn may lead to ill health.

4.5. If formulated GF foods on prescription were restricted or ended, then an adverse impact on parents could develop if a child no longer adheres to a GF diet and becomes ill.

4.6. If option 2 is implemented there may be an increased burden on the elderly or carers as they may find it harder to source formulated GF food, and this could impact on families.

4.7. Information on patients having or developing an additional long term condition was provided during the consultation. This emphasised the importance of adherence to a GF diet and regular health checks.

5. Engagement and Involvement

5.1. This work was subject to the requirements of the cross-government Code of Practice on Consultation

5.2. Policy officials engaged stakeholders in gathering evidence. The following activities were undertaken.

5.2.1. Conducted searches on GF policies for English CCGs. This included telephone discussions with 18 different CCG representatives to source opinions on changes and challenges faced, and the reviewing of evaluation reports on changes made and patient impact by CCGs where available from outcomes of local consultations.

5.2.2. Discussions with representative from the Pharmaceutical Advisory Group (PAG).

5.2.3. Policy officials undertook a visit to the dietetics team in Rotherham hospital to meet dieticians who assessed patients on an individual basis. Demonstration of how the voucher scheme for foods operated and the importance placed on patient annual review.

5.2.4. Web based research on coeliac disease and its management. Websites included: Coeliac UK, British Dietetic Association (BDA), British Specialist Nutrition Association (BSNA), National Institute of Health and Care Excellence (NICE), NHS Business Services Authority (NHS BSA), NHS Digital and NHS Choices.

5.2.5. Sought and reviewed impact data on changes that have been made (where available).

5.2.6. Issued an e-mail to alert key stakeholders of the launch of the consultation (25 organisations, including GF manufacturers/suppliers).

5.2.7. Updated list of stakeholders following consultation responses.

5.2.8. Search on available literature including; journal articles, press releases, reports, CCG website reviews on proposed changes to GF prescribing.

5.2.9. Face to face meetings with Coeliac UK and then BSNA (along with representatives from 2 manufacturers (Juvela and Glutafin)).

5.2.10. A review of references provided by consultation respondents, including journal reports, press articles, websites and guidance.

5.3. The engagement activity was undertaken by policy officials and the statistics were reviewed by analysts from Medicines and Pharmacy Directorate within the Department of Health (DH).

- Engagement activities took place through face to face meetings, telephone discussions, e-mail exchanges and web based research.
- Outputs included; obtaining and reviewing local (CCG) prescribing policies, evaluation reports, prescribing data, bespoke reports and verbal updates with Coeliac UK and BSNA.
- By alerting key stakeholders to the consultation launch they were able to update their websites with a link to the DH consultation enabling a wide audience to review and respond to the public consultation.

Annex A - Estimated Patient Numbers

The numbers of coeliac patients is estimated to be 1% of the population.[22] The English population (mid 2016) was 55,268,100, so 1% of this figure gives an estimated population with coeliac disease as 552,681. Coeliac UK estimate that only 24% of these patients have a diagnosis; this gives an identified group of 132,643 coeliac diagnosed patients. This figure has been used to replicate percentages, against the national splits, in the coeliac populations by; age, gender, ethnicity, disability, carers, those living in rural areas, and those on low incomes.

England Coeliac Population Estimates

England 2016	Numbers	Population Number in England with CD (1%)	% of English Population with CD	Number Diagnosed with CD(24%)	% of Total English Population
All population	55,268,100	552,681	1%	132,643	0.24%
Age Groups (Young)	10,445,671	104,457	19%	25,070	0.05%
Age Groups (Old)	9,948,258	99,483	18%	23,876	0.04%
Gender (Male)	27,247,173	272,472	49%	65,393	0.12%
Gender (Female)	28,020,927	280,209	51%	67,250	0.12%
Ethnicity (White)	48,138,515	481,385	87%	115,532	0.21%
Ethnicity (Non-white)	7,129,585	71,296	13%	17,111	0.03%
Disabled	6,411,100	64,111	12%	15,387	0.03%
Carers	6,500,000	65,000	12%	15,600	0.03%
Rural location	11,440,497	114,405	21%	27,457	0.05%
Low Incomes	12,158,982	121,590	22%	29,182	0.05%

[22] https://www.nhs.uk/Conditions/Coeliac-disease/Pages/Introduction.aspx#Whos-affected