

## **HEALTH AND WELLBEING SCRUTINY COMMISSION**

**9 NOVEMBER 2016**

### **REPORT OF THE LEICESTER CITY CLINICAL COMMISSIONING GROUP**

#### **Review of prescribing of paracetamol, other over the counter medicines and Gluten Free Foods**

##### **Purpose of report**

1. To provide a more in-depth report of the Healthwatch engagement for these areas of prescribing and to summarise the conclusions and draft proposals considered by the CCGs across Leicester Leicestershire and Rutland in order to promote patients self care in minor illnesses and patients requiring gluten free diets.

##### **Policy Framework and Previous Decisions**

2. There are several cross-Leicester, Leicestershire and Rutland (LLR) committees that provide guidance on prescribing medicines for all prescribers, including GPs (pharmacists, nurses, dieticians and other healthcare professional can become a prescriber). Membership of the two main committees includes pharmacists, GPs, consultants, Public health consultants and patient representatives. The members of these groups are trained in critical appraisal and make decisions about medicines based on evidence and efficacy.
3. The LLR electronic Formulary provides prescribers, including GPs, with guidance on evidence based cost effective medicines for most conditions so as to provide consistency of care across the area. This includes formulary choice and information on where products should not be used because they are not cost effective or do not have evidence of efficacy.
4. Current prescribing of gluten free foods in Leicestershire is outlined in the LMSG guidance which reflects the recommendations of the Coeliac Society and the British Dietetic Society. However, around 40% of CCGs have moved away from this guidance and have either ceased prescribing altogether or reduced choice and unit price.

##### **Background**

5. Demand for NHS services and treatments is increasing, meaning the gap between demand and funding over the next 5 years amounts to £30 billion nationally.
6. To support the delivery of the local Sustainability Transformation Plan it is essential to review prescribing guidance to support the most cost effective allocation of NHS resources within the local healthcare systems.
7. It is essential that patients are treated in the most appropriate setting of care ranging from self-care to emergency care. This means doing things where they *should* happen rather than where they *could* happen.

8. CCGs have a responsibility to provide a reasonable level of care for all patients but must also work within the financial resources allocated to them. To address this, the LLR Medicines Optimisation Committee has considered whether certain treatments should not be prescribed for one or more of the following reasons:
  - a. Remedies for self-care are available to buy from community pharmacists where patients could use the community pharmacists as the first port of call for common ailments.
  - b. Food products are readily available to buy in supermarkets.
  - c. There is a lack of evidence of clinical effectiveness.
  - d. Non-NHS items such as anti-malaria treatments, travel vaccines.
  - e. Dental preparations - which should be prescribed by a dentist.
9. These considerations may lead to a change to what patients have been able to access historically, and it was proposed in the first instance to consider whether paracetamol and gluten free foods should remain available on prescription.
10. To understand the potential impact that this proposal would have on patients in Leicester, Leicestershire and Rutland, a survey in partnership with respective HealthWatch organisations was completed and was led by West Leicestershire CCG on behalf of all three CCGs.
11. The Survey was circulated by Healthwatch Leicestershire, as well as Healthwatch Rutland and Healthwatch Leicester City, and opened on the 17<sup>th</sup> June 2016 and closed on the 17<sup>th</sup> July 2016. The final report was available in late August and additional information requests were added to the report in September.
12. The survey was promoted to a broad range of audiences through media and press releases, targeted emails, website promotion, mailshots to specialist networks and cascading through GP practices by various stakeholders. In total 821 surveys were completed, with 2,355 qualitative comments offered. This has provided valuable insight into the opinions and concerns and what matters most to the population around prescribing of paracetamol and other over the counter (OTC) medicines and also gluten free foods to inform the CCGs with their decision making.
13. A breakdown shows that responses were received from across the LLR area:

Leicestershire (2CCGs)	558 (73%)
Leicester City( 1CCG)	126 (16%)
Rutland	46 (6%)
Out of area	35 (5%)
Did not answer	56

14. Healthwatch (HW) concluded that there were no distinct differences from respondents living in Leicester City, Leicestershire or Rutland.
15. It is acknowledged that there were fewer responses in the Leicester City area. However, it should be noted that the qualitative comments from the survey for each CCG were very similar in theme and that the amount of responses received is high when compared to many other engagement exercises.

## Summary of responses

### Paracetamol for self-limiting illnesses

16. The NHS spent approximately £1.5 million pounds on prescribing paracetamol to patients in Leicester, Leicestershire and Rutland in 2015/16. Some of the prescriptions were for people with conditions which could have got better on their own without paracetamol. This includes conditions such as sore throats and colds. In some cases paracetamol taken for these conditions can extend the length of the condition as it works against the immune system, affecting body temperature to fight infection.
17. The proposal tested through the Healthwatch engagement survey was that the three CCGs in LLR establish guidance to support prescribers, including GPs, in reducing prescribing paracetamol for patients with self-limiting conditions (such as a viral illness), and to encouraged patients to increase the level of self-care for self limiting illnesses.
18. The proposal and guidance would not include patients who currently require paracetamol as part of regular pain management treatment or for long term conditions.

### Feedback received

19. Respondents were asked *“Are you currently or have you ever been in receipt of paracetamol on prescription?”* Over a quarter of respondents (26% - 193) currently receive or have previously been in receipt of paracetamol on prescription. 74% (551) respondents have never received paracetamol on prescription. 76 respondents did not answer this question.
20. The overwhelming majority of respondents answered that they would be affected either “not at all” or “only a little” by the proposed change. 7% of respondents answered that buying paracetamol tablets or in liquid form would affect them a lot.
21. In total 171 qualitative responses were provided to the questions concerning paracetamol. The following themes regarding the impact on patients, or their concerns, emerged from these comments:
  - concerns regarding cost;
  - access to shops;
  - restrictions applying to the quantities which can be purchased at any one time meaning individuals are unable to buy products in quantities sufficient to meet their needs;
  - some respondents were concerned that they would be unable to buy paracetamol of the same quality and strength that they receive on prescription.
22. Other responses highlighted a need for clarification regarding the scope of any change, with those with long-term chronic pain or other long term conditions requiring paracetamol expressing concern that the change may impact on their treatment. N.B., this patient group is excluded from the proposals.

### Review of feedback and next steps

23. Based on this feedback the LLR CCGs reviewed the points raised by the survey. Actions arising from this include:

- Address the need to clarify who would be affected by any change. The original proposal did not include patients who need regular paracetamol 4-6 hourly as part of their chronic pain management; however many comments were received about this issue.
- Provide clarity regarding the fact that those taking higher strength medication containing paracetamol (such as co-codamol 30/500) and currently only available on prescription would not be included in the scope of any potential change.
- Look at relative costs of OTC preparations concerned whilst balancing what is reasonable use of NHS funds and also moving the self-care agenda forward in an equitable way across the entire population, while considering the impact on those with low and fixed incomes.
- Work with local community pharmacies to address concerns regarding the ability to access the quantities required, and to ensure that patients can readily purchase from their community pharmacy larger volumes (96) of paracetamol if necessary.
- Consider access issues, including the impact on those in rural or isolated communities and those who are housebound and who may not have easy access to shops and pharmacies.
- Work with local community pharmacies to stock value for money preparations.
- Ensure that there is a caveat for GPs to prescribe if clinically urgent and patient unable to access own supply, or buy in a timely fashion i.e. prescriber decision at point of consultation.
- Support GPs to apply a consistent approach to prescribing to ensure consistency across LLR but which also supports clinical judgement regarding exceptional individual circumstances.
- Self-care campaign to encourage public to take responsibility for self –care of minor ailments, including buying a recommended supply of medicines to keep in their medicines cabinet.
- Information to dispel myths regarding quality of OTC medicines and emphasising that OTC are of the same quality as those currently provided on prescription.
- Consider further communication with schools and nurseries regarding the requirements for administration of oral paracetamol to children, to address concerns raised via the survey that this would not happen without prescription.

### **Gluten Free (GF) foods**

24. Currently the NHS in Leicester, Leicestershire and Rutland provide £700,000 worth of gluten-free food on prescriptions each year. In 2014, the NHS bill for gluten-free foods provided on prescription nationally was £26.8 million. The majority of this was for bread and flour.
25. The proposal tested via the survey was that the three CCGs in LLR County and Rutland either completely or partially stop the prescribing of gluten free products.

### **Feedback received**

26. 762 patients responded to the survey on gluten free foods. The survey sought to understand whether respondents had an underlying medical condition where gluten free foods were particularly relevant.

What condition do respondents have?
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I have Coeliac Disease (CD)	458 (60%)
I have Dermatitis Herpetiformis (DH)	40 (5%)
I am the parent/ guardian of a child with CD	95 (12%)
I am the carer of an adult with CD	20 (3%)
I do not have CD or DH	210 (28%)

27. Nearly two thirds of respondents (64%) said they were currently in receipt of gluten free foods on prescription. The most common products prescribed were reported as follows:
- Bread (n=445);
  - Flour (n=334);
  - Pasta (n=328);
  - Pizza (n=150); and
  - Cereals (n=150).
28. The majority (60%) of this cohort of respondents said they would be affected a lot if gluten free foods were no longer made available to them on prescription, 15% would be affected a little and 25% not at all.
29. The survey sought to understand the nature of any impact on individuals, were gluten free products to be removed from prescription. The feedback provided identified the following key themes and issues:
- Gluten free food is more expensive than non-gluten free equivalents, and any change may disproportionately affect those on low or fixed incomes, particular where more than one member of the household requires a gluten free diet.
  - There is a perception that gluten free products provided on prescription are of better quality than those available in high street stores and supermarkets.
  - Labelling on gluten free products in supermarkets is inadequate.
  - Gluten free products on prescription contain additional nutritional additives.
  - Concerns regarding accessibility, including the impact on those in rural or isolated communities, and those who are housebound, and who may not have easy access to shops which stock gluten free foods.
  - Concerns that individuals would not be able to access products if they were not stocked by pharmacies.
  - A sense that for those with coeliac disease gluten free products are a form of treatment and should be prescribed.
30. The survey also invited views as to how the NHS could further support those with coeliac disease. Responses provided included:
- The provision of better dietary advice and support for newly diagnosed patients.
  - Medical check-ups with a specialist.
  - Availability of gluten free meals/ snacks in hospitals.
  - Improved availability of gluten free foods in local shops.
  - Only prescribe staple foods.
  - Pre-paid card system to buy gluten free foods from supermarkets and shops.

### **Review of feedback and next steps:**

31. In taking work forward to respond to these comments and develop recommendations regarding the future availability of gluten free products on prescription, the CCGs:

- Looked at the relative costs and accessibility of gluten free foods so that patients on low incomes are not unreasonably affected whilst balancing what is appropriate use of NHS funds.
- Considered suggestions made to improve management of coeliac disease that are within the control of CCGs.
- Considered the extent to which any changes made would apply (for example, would restrictions apply to all food stuffs or should we seek to maintain a limited range of gluten free products on prescription).
- Worked with other organisations who could improve dietary management of patients with Coeliac disease.
- Worked with dietitians and patient groups (such as the Coeliac Society) to understand how to make information and advice, including that on diet and access to alternative foods, more readily available to patients at the point of diagnosis and during on-going reviews.

### **Resource Implications**

32. As part of the development of recommendations regarding any changes to prescribing guidance the potential financial savings offered against the potential impact on patients will be considered.

### **Timetable for Decisions**

33. We are seeking to achieve a position statement across all the LLR CCGs by Mid November 2016.

### **Conclusions from engagement**

34. The survey and engagement process has provided valuable insight into the potential impact of the two proposals tested on individual patients and carers within the LLR area. In seeking to move forward and develop recommendations for consideration by each of the three CCGs we will act on the feedback, particularly that which has raised concerns of accessibility or affordability, where there may be a disproportionate effect on individuals on low or fixed incomes or those who live in certain locations. These considerations will be addressed via an Equalities Impact Assessment to ensure all effects are identified and mitigating actions agreed.

35. These considerations will support a balanced assessment of the impact of any change on individuals or specific patient groups as well as supporting on-going work to ensure an equitable allocation of resources to health services across LLR.

36. Draft proposals and guidance have been developed and support is being sought from stakeholder organisations. As with all prescribing guidance and formulary recommendations the decision to prescribe is the healthcare professional's decision.

### **Proposals and guidance for consideration following the engagement exercise.**

37. Neither proposal is a complete removal of access to paracetamol, OTC remedies or gluten free foods from prescription.

### **Paracetamol and other over the counter products**

38. Proposed guidance will include the following:

- Patients should purchase paracetamol for use in short term, self-limiting illnesses wherever possible.
- Patients who use large volumes of paracetamol 4-6 hourly for the management of chronic pain and long term conditions will continue to receive paracetamol on prescription.
- Paracetamol combination products (e.g. co-codamol) are not included.
- OTC medications with clinical evidence of clinical benefit are not included.
- OTC products with low clinical evidence of clinical benefit are included and prescribers will be advised not to prescribe on prescriptions. This includes antifungal nail paint, cold sore treatments (topical), cough and cold remedies, infantile colic, lutein and antioxidant vitamins, omega 3 fatty acids and other fish oils and rubefaciants. A formulary review for these has been completed and approved through formulary review processes.
- Dental preps recommended by dentists, such as fluoride tablets, toothpastes and mouthwashes, should be purchased OTC or prescribed by the dentist. It is inappropriate to ask a GP to take clinical responsibility for this prescribing.
- A prescriber has the final decision on prescribing and consideration will be allowed for low and fixed income patients in respect to this guidance
- A programme to promote and inform patients of how to care for themselves will be developed.

### **Gluten free food**

39. It is proposed to reduce of the number of units of gluten free Products that can be prescribed for patients with a diagnosis of Coeliac Disease and Dermatitis Herpetiformis to 8 units per month of bread and flour mix.

40. The following points have contributed to this proposal

- The 8 units is based on Coeliac UK recommendations for bread/ flour allowance. It is however reasonable that those who require a gluten free diet should purchase some gluten free foods themselves, e.g. pasta, pizza bases, cakes, breakfast cereals etc.
- Maintaining an allowance of bread and flour on prescription will help patients maintain a gluten free diet as it will subsidise the increased cost of gluten free food and mitigate for those patients who struggle to access supermarkets.
- The range of gluten free bread and flour mix which is suggested to be prescribed will be capped to the low-mid range value (current range of all is £1.30-£.70 per 400g loaf) and to manufacturers who do not charge excessive delivery charges (4 loaves with a delivery charge of £150). Consideration of those breads and flour mixes most frequently requested has been considered within this to provide a structured choice.
- Prescribing of pasta and pizza bases, cereals and crisp breads are not recommended as these foods are available from supermarkets at a similar cost to

their gluten containing equivalents and therefore the patient is not unfairly disadvantaged by having to purchase these foods.

- Prescribing is not recommended for items considered to be luxury foods, such as gluten free cakes and biscuits. This supports the national campaign for healthy eating.
- Usually, most people have reasonable access to supermarkets and so accessing foods is not a problem. For those who do struggle to access a supermarket that sells GF food, use of freezers, internet shopping, buying non-perishable items such as pasta and cereal in bulk, can be deployed by individuals or their carers to mitigate access problems.
- For the purposes of using health resources such as GP time appropriately, patients will be able to change the food items on prescription once every quarter. GP practices may wish to utilise repeat dispensing for this purpose.
- The pathway and provision for coeliac care is being reviewed to include accurate diagnosis and appropriate follow up and dietetic support for newly diagnosed and existing patients.
- Prescribers will be reminded that for the prescribing of gluten free to be permitted the patient must have a diagnosis confirmed by biopsy as per NICE guidance not just through a positive blood test.

#### **Officer to contact**

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