Case Based Review of Gastroenterology Patients
Terms of Reference
Version 4 FINAL (28 11 15)

Background

Following concerns raised GOSH commissioned an external review of the gastroenterology service. This was conducted by the RCPCH in June 2015. Based on verbal concerns raised with them, the review panel highlighted a potential issue concerning the care of patients in the service who either a) have a diagnosis of eosinophilic colitis, or b) do not have one of the below specified diagnoses, but where they have undergone significant investigations, interventions or treatment.
This second cohort of patients is those who **DO NOT** have a diagnosis of:

- Inflammatory Bowel Disease
- Short Gut Syndrome
- Pseudo-obstruction
- Coeliac Disease

Or: who are **NOT** being assessed as part of the highly specialised services for Intestinal failure or severe infantile enteropathy

These patients may include those with constipation, or on dietary exclusion or other therapeutic interventions.

The existence and diagnosis of EGID (in particular colitis) is controversial. Although there is literature on the condition, there is also controversy about its true incidence, definitive diagnosis and effective treatment
As a highly specialised organisation, we recognise that all specialties constantly innovate in treatments, and are driven to do so to ensure the best care for our patients. However, we also have an obligation to ensure that innovations and treatment pathways are evaluated, are evidence based and do not result in harm to our patients.
An external review of these patient cohorts is therefore being commissioned. Should any concerns be identified, further actions will be taken to ensure that these are addressed in all relevant children under the care of Great Ormond Street Hospital. Concerns may be raised by the panel as a whole, or by individual panel members to Drs Cale or Diwakar.

Panel

The review panel consists of a number of paediatric gastroenterologists and allergists (See list at end of document). All panel members are acting in a professional capacity, and not representing their organisation nor any other body with which they are associated. All patient and other matters discussed as part of the investigation are confidential.
Should any panel member feel that they do not have sufficient/relevant expertise either for a specific case or the whole review process then they must bring this to the attention of the Chair and Dr Cale/Diwakar. If necessary, additional sub-specialty expertise will be sought from within or outside the UK (see list below).

Perceived or potential conflicts of interest and bias must be declared by panel members, and will be recorded and held by the company secretary (Dr Ferrant). Indemnity for the investigation lies with Great Ormond Street Hospital. Panel members are advised to notify their medical director/CEO that they are participating in the review.
The panel will be asked to provide a clinical opinion, based on the information provided to them by GOSH. The panel will not be expected to provide a detailed report for each patient, rather an overall assessment. The panel may wish to highlight where the treating physician should be asked for clarification of certain points of care, or where additional information is required before an assessment can be made. The panel may wish to flag cases where they feel a more in depth review would be helpful.
The panel may request review of histopathology or other investigations by an independent expert. This expert will be selected by Drs Cale/Diwakar.
The panel will be considered chorate if at least 3 panel members are in attendance. If there is a disagreement between panel members regarding a case when all panel members are not present, the case must be put to the full panel. This may be done virtually.

Methodology

1. **Selection of Patient cohorts:**
    a. EC (up to 40 patients to be reviewed):
        i. All patients with Eosinophilic Colitis will be identified from diagnostic coding or other locally held patient lists and the electronic document management system which stores patient correspondence etc.
        ii. Patients for review will be selected from this list who have received any of the following interventions:
            1. Exclusion or elimination diet
            2. Presence of gastrostomy or use of NG/J tube
            3. steroids
            4. Other immunosuppressants (eg MMF, azathioprine) or monoclonal antibody treatments
    b. "Other Diagnosis"(Up to 40 patients to be reviewed)
        i. 200 consecutive patients referred into gastroenterology in 2014 will be reviewed by a clinically qualified project team member.
        ii. Patients will be identified from this cohort who meet the criteria for this cohort as defined above.
        iii. A further 100 patients will be reviewed until sufficient patients have been identified, if necessary working backwards to 2013 and beyond
        iv. The selection process will endeavour to ensure that patients are a representative spread of the categories, and also are not an exclusively historical cohort.

c. The panel will have no role in patient selection, this will be done by GOSH led by Drs Cale and Diwakar
d. Cases highlighted to Dr Diwakar as part of the review will be included in the list of potential patients to be reviewed. Before their inclusion consideration will be given to whether they meet the above criteria, and in particular ensuring that they do not produce a historical or other bias to the cohort.
e. The list of patient names will be available to the GOSH gastroenterology consultants once it is complete.

2. Initial Review

a. A sample of 5 patients was reviewed by the panel at an initial day long meeting (17 11 15).
b. Case notes were reviewed and histological information (reports) provided.
c. For each patient consideration will be given to the criteria below
d. Review methodology and selection criteria did not need to be adjusted as a results of that meeting

3. For each patient reviewed the panel will be asked to consider the following (based on the case notes and other information provided to them):

a. Basis of diagnosis
    i. Clinical
        1. History (parentally reported or directly observed)
        2. Examination
    ii. Histology
    iii. Endoscopic findings
    iv. Other eg motility studies
b. Treatments used, dosages, duration and any observed side effects
c. Response to treatment
    i. Clinical (parentally reported or directly observed)
    ii. Histological (or other investigation)
d. Side effects of treatment (lifestyle impact if information available as well as physical)

4 For each Individual Patient and the Cohort as a whole the panel will be asked to consider (based on the case notes and other information provided to them)

a. What criteria are used for diagnosis at GOSH: is this in line with national/international guidelines or accepted practice
b. What are the criteria for initiating treatment (s)
c. When treatments are used:
    i. Is efficacy monitored.

ii. What side effects are caused

d. Is there evidence of over/under diagnosis
e. Is there evidence of over/under treatment
f. Is there evidence of harm (physical/emotional)

The panel should consider for each response the strength of the evidence.

Outputs

1. An assessment from the external review team as to whether any harm has been caused to this cohort of patients
    a. Patient proformas should be completed for each patient and given to Dr Cale/Diwakar where there are specific concerns
    b. An overall report should be produced at the conclusion of the review

2. If, at any point, the panel is concerned that there is significant harm then this must be discussed with Dr Cale or Dr Diwakar immediately. They will then determine appropriate further actions.

3. An assessment from the external review team as to whether further review of all patients with specific diagnoses (or subsets thereof) should be reviewed. Dr Diwakar and Dr Cale will determine the Terms of Reference of further review of patients.

4. Information obtained from the review will be used to support the development of a guideline for the diagnosis and treatment of these children including key decision and review points

5. Information obtained from the review will be used to review the complex patient MDT and determine if/how/when these patients are reviewed/re-reviewed in that meeting.