employed to improve processes in the absence of more sophisticated technological solutions. A staff survey is planned to evaluate awareness and usability of the database and identify further areas for improvement.

P59 ASSESSING MEDICINES FOR SAFE USE IN PAEDIATRICS

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Aim This service review aimed to reassess and upgrade the 'New Products Assessment Form' and to develop an assessment tool in line with European regulations governing paediatric medicines. Many medicinal products routinely used to treat the paediatric population have not been studied or authorised for paediatric use, which means there is widespread unlicensed and 'off-label' use of medicines. Medicines deemed safe in adult formulations may not be appropriate for paediatric patients. Medicines must therefore be carefully selected based on agreed criteria including, but not limited to: licensing, excipients, administration, labelling, similarity to other products, safety and handling.

Method A literature review was conducted. Guidance, information, and advice was sought from other healthcare institutions, and European guidelines and directives informing current practise around excipients in paediatric medicines. Pharmacy colleagues were consulted during the development of the tool, and an accessible assessment tool was completed for use in a tertiary paediatric hospital.[1–4]

Results This is the first comprehensive 'New Products Assessment Form' in the hospital which complies with the European Medicines Agency (EMA) directives governing excipients in paediatric medicines. The document highlights clearly potential issues and risks associated with product excipients, licensing status, warning label guidance and allows for recording of rationale for the selection of medicines. The 'New Products Assessment Form' is intended to highlight potential issues associated with excipients and their associated acceptable daily intake (ADI), but it will also highlight other risks associated with medicines used in paediatrics e.g. inadequate labelling, translation requirements for foreign products, sound-alike/look-alike products, safety and handling, and others.

Conclusion This revised assessment tool has been approved for use in the hospital pharmacy. It will be made available in hospital and community pharmacies on request. Use of the tool should be monitored and audited.

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P60 EFFICACY OF SWITCHING TO INFLIXIMAB BIOSIMILAR (REMSIMA®) IN PAEDIATRIC INFLAMMATORY BOWEL DISEASE (PIBD): A 2-YEAR RETROSPECTIVE EVALUATION

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Aim To evaluate patient outcomes 2 years post switching Infliximab therapy from Infliximab originator molecule Remicade® to biosimilar Remsima®.

Methods Patients with PIBD who experienced induction with Remicade® therapy, were <18 years old at last follow-up and were receiving active treatment with Remsima® 2 years post switching were selected to be included for evaluation. Outcome measures included monitoring disease activity and treatment failure at baseline (before switching) and at selected time points up to 2 years post-switch. Disease activity was assessed looking at a range of parameters: disease activity scores; trough infliximab levels; haematological markers (HGB, platelets, WBC); LFTs (bilirubin, ALT, ALP); inflammatory markers (ESR, CRP) and faecal calprotectin levels. Patients who failed therapy were assessed for adverse reactions and infliximab antibody formation. Data was analysed with the Cochran Q test, repeated measures ANOVA test and Friedman test; with post-hoc Bonferroni and Wilcoxon Signed-Ranks tests if appropriate.

Results Data was available for 18 patients after exclusion criteria were applied. There was a significant increase in trough infliximab levels by the end of the period from an average of 5 ug/L to 12 ug/L at 2 years. The average dose/kg increased over 2 years by 1.5 mg/kg. Disease activity markers showed no changes between time points except a decrease in ALP levels from baseline to 1 year, but values remained within normal ranges. Four patients were discontinued from Remsima® due to side effects or loss of efficacy. The average time to treatment failure on Remsima® was 38 months (~19/20 doses). Three out of four patients developed infliximab antibodies, 2 of these patients went on to suffer adverse reactions; 1 exhibited joint pain which settled weeks after each infusion and the other developed an immediate infusion reaction in the form of a rash with urticaria on the 3rd infusion of Remsima®.

Conclusion Infliximab biosimilars, such as Remsima®, were approved for use in PIBD by the EMA after studies in adult populations with rheumatic diseases.[1 2] Induction studies have shown efficacy in PIBD but data on switching is limited and short-term.[3 4] Our data shows no significant differences in clinical patient outcomes over a 2-year period in a cohort switched from Remicade® to Remsima®. In fact, a significant increase in trough infliximab levels in patients remaining on Remsima® suggests efficacy in producing therapeutic levels in PIBD patients. Increased levels may be explained by dose intensification used by the PIBD multi-disciplinary team (MDT), reflecting careful dose optimisation strategies used at this trust throughout the time period. Patients losing response were not unexpected and are likely not due to the biosimilar switch but rather due to the length of time the patients were on treatment. The small sample size and retrospective nature of this study mean larger cohort studies are required over prolonged time periods to confirm these findings. PIBD MDTs should continue to monitor patients for adverse reactions, particularly in those who develop infliximab antibodies.

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P61 PATIENT PERSPECTIVES ON SWITCHING TO AN INFLIXIMAB BIOSIMILAR IN PAEDIATRIC INFLAMMATORY BOWEL DISEASE (PIBD)

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Aim To establish patient perspectives on switching to an infliximab biosimilar, which will enable the PIBD team to improve patient experience during future biosimilar switches.

Methods Families of patients receiving treatment with an Infliximab biosimilar (Remsima®) 2 years after switching from the originator (Remicade®) were selected from the active patient database for telephone interview. One family who chose not to switch was also included for interview. A 5-question interview was prepared, which asked parents to rate their overall experience according to a satisfaction rating scale from 1–5. Parents were asked about their knowledge of reasons for switching, if they needed to look up additional information resources and, finally, ways to improve the switching process.

Results 18 patients were identified, 16 parents were available for interview. 13 parents gave overall positive feedback with satisfaction scores of 4 or 5 on the numerical satisfaction scale. 3 parents were dissatisfied with the switching process, giving scores of 0, 1 and 3. This resulted in an average satisfaction score of 4.1. The majority of satisfied parents had little knowledge of the switch, not remembering details and indicating the switch was best performed this way. Nonetheless, most recognised costs as the reason for switching. The majority of parents did not need to look up additional information resources, 2 parents named The Crohn's and Colitis Charity and Facebook support groups as useful resources. Two dissatisfied patients requested to switch back to Remicade® therapy due to side effects. The family of the patient who chose not to switch made this decision because Remsima® was not yet available in the United States, where they also received treatment.

Conclusion Biosimilar biologics continue to be approved by the EMA as originators come off patent. Efficacy of infliximab biosimilars in paediatric IBD patients is extrapolated from adult rheumatology data, with limited long term outcome data.[1] [2] Successful switches for NHS trusts lead to financial benefits; these savings allow for NHS investment to enable more patients to be treated.[3]Patient autonomy and, in paediatrics, parental views must be respected during this switching process. The majority of interviews with parents were positive, re-affirming the process of this switch. Parental perceptions of side effects attributed to Remicade® highlight the importance of discussing realistic outcomes of therapy with both the originator and biosimilar. When questioned, the parent who refused to switch explained that they did not have faith in the efficacy of the biosimilar and had major concerns of treatment failure. A fear of treatment failure may be described as a 'nocebo' effect [4] which hypothesises that negative attitudes incur less effective results. Increasing our awareness of patient perceptions on switching biosimilars and monitoring reasons for switch failure will better inform us going forward with future biologic switches.

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P62 CYCLOPHOSPHAMIDE AND MAINTENANCE MYCOPHENOLATE MOFETIL FOR THE TREATMENT OF ANTI-N-METHYL-D-ASPARTATE RECEPTOR (ANTI-NMDAR) ENCEPHALITIS IN A PAEDIATRIC PATIENT

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Background Anti-NMDAR encephalitis is one of the commonest known types of autoimmune encephalitis with an increasing recognition in the paediatric population.[1] [2] It is characterised by abnormal behavioural and cognitive symptoms, seizures and movement disorders where treatment failure or failure to treat can result in long term disabilities or mortality.[1]

A 4-year-old patient with a background of autism was admitted to the paediatric intensive care unit (PICU) due to encephalitis with convulsive status epilepticus where he remained intubated for 22 days and was later diagnosed with anti-NMDAR encephalitis. The patient had persistent abnormal choreoathetoid movements and intermittent seizures despite multiple anti-epileptics, two courses of corticosteroids, two courses of intravenous immunoglobulin, two cycles (10 sessions per cycle) of plasmapheresis and a course of weekly rituximab. Due to the lack of response from these initial pharmacological interventions, the use of cyclophosphamide and mycophenolate mofetil was considered. Cyclophosphamide and mycophenolate mofetil inhibits the proliferations of B- and T-lymphocytes[3] [4] which acts as the basis of its immunosuppressive actions. However, available evidence on the dosing and monitoring information in the paediatric population for this unlicensed indication is limited.

Pharmacy Contributions After discussion with the multi-disciplinary team (MDT) with extensive input from the paediatric neurologist, a literature search was conducted to determine an appropriate dosing regimen. As this was an off-label use, the paediatric neurologist and the attending consultant took clinical responsibility. Intravenous cyclophosphamide was started at 750 mg/m^2 once a month for three cycles and oral mycophenolate mofetil was started at 600 mg/m^2 twice a day as