

Conclusions Post-transplant management is individualised based on multiple factors such as clinical conditions e.g. renal/liver impairment and whether other agents such as ATG or steroids are being used.¹ The lack of documentation around the treatment decisions made it difficult to explain deviations from standards in this audit. Ciclosporin standards were not met completely but were most likely unfeasible due to a narrow target range and the time between first dose and level monitoring. There did not appear to be a clear association between standards not being met and episodes of rejection. It would be beneficial to repeat this as a larger, prospective audit using revised standards.

REFERENCES

1. Costanzo MR, Costanzo MR, Dipchand A, *et al.* The international society of heart and lung transplantation guidelines for the care of heart transplant recipients. *J Heart Lung Transplant* 2010;**29**:914–56.
2. Sandimmun Concentrate for Solution for Infusion 50 mg/ml - Summary of Product Characteristics (SmPC) - (eMC) [Internet]. [cited 2018 Sep 2]. Available from: <https://www.medicines.org.uk/emc/product/1036>

P56

WITHDRAWN AS AUTHOR REQUESTED IT IS NOT PUBLISHED

P57

CONTINUOUS DRUG DELIVERY IS SIGNIFICANTLY AFFECTED BY RELATIVE HEIGHT CHANGES BETWEEN PATIENT AND SYRINGE DRIVER

¹Aisha Zahid, ²Andrew Wignell*, ²Dusan Raffaj, ²Patrick Davies. ¹School of Medicine, University of Nottingham; ²Nottingham University Hospitals NHS Trust

10.1136/archdischild-2020-NPPG.65

Aims Syringe drivers are the principle method of giving continuous infusions of important drugs to patients. Many of these drugs are critical for the maintenance of normal physiology. Anecdotal evidence abounds of severe patient instability on movement of syringe drivers during infusion. Our objective was to define the variation in drug delivery seen in three different syringe drivers, with changes in relative height between the syringe driver and the end of the giving set.

Methods Three syringe drivers (Alaris CC (Becton Dickinson), Perfusor Space (B Braun), and Synamed µSP6000 (Arcomed)) were analysed for reliability of flow at 0.5, 1, 2, and 5 ml/hr. A small air bubble was introduced into the giving set, and the progression of this was documented before and after a vertical movement of the syringe driver by 25 or 50 cm upwards or downwards relative to the delivery port.

Results For all pumps, delivery was interrupted on movement of the pumps downwards, and a bolus was given with movement of the pump upwards. Delivery halted at lower pump speeds for longer than higher pump speeds. The maximum delivery interruption was 11.8 minutes. Boluses given on moving the pump up were calculated as the equivalent number of minutes needed to deliver the bolus volume at steady state. The maximum bolus given was equivalent to 15.8 minutes of delivery. We were unable to eliminate the effects seen by very slow, steady movement of the pumps up or down. Static height differences made no difference to delivery.

Conclusions Syringe drivers should not be moved vertically in relation to the patient. Critical drug delivery is interrupted for up to 12 minutes with relative downward movements, and significant boluses of drugs are given with relative upward movements. As far as possible, elimination of relative height movements is advised, and extreme caution is necessary if any movements are unavoidable.

P58

MANAGING ACCESS TO 'OUT OF HOURS' MEDICATIONS IN A TERTIARY PAEDIATRIC HOSPITAL

Mary Worrall*, Elizabeth Devlin, Moninne Howlett. *Children's Health Ireland at Crumlin*

10.1136/archdischild-2020-NPPG.66

Aims Many UK and Irish hospitals provide a Monday to Friday pharmacy service; automated dispensing cabinets and hospital-wide information systems remain uncommon. Locating and accessing out of hours (OOH) medications can be a significant workload for nursing staff. In an Irish 230-bed tertiary paediatric hospital processes involve: nursing staff contacting other wards by telephone to source items; completion of an 'Out of Hours Requisition'; and either transferring stock between wards or contacting nursing administration staff (NAS) to access stock from the Pharmacy Department. A quality improvement project was undertaken to: measure current levels of OOH medications; identify areas for improvement; implement and assess impact of new processes.

Methods 'Out of Hours Requisition' data were entered into a custom-built database and analysed for the period January - December 2018. The findings were discussed with nursing staff and NAS. Improving processes for locating medications was identified as a key area for improvement. The 'Out of Hours Requisition' form was amended to provide clearer instructions for completion. Using data from clinical area stock lists, a searchable Medicines Locator Database was developed and made accessible to all staff in the pharmacy department, clinical areas and the NAS office in December 2018 enabling staff to remotely identify the location of all medications stocked in the hospital. Data for 'Out of Hours Requisitions' for the period January - May 2019 were collated, analysed and compared with data from the same time period in 2018 (January - May). Microsoft Excel[®] was used for data collection, analyses and development of the Medicines Locator Database.

Results A total of 1747 OOH medications were accessed by NAS from pharmacy in 2018, 746 during the period January - May 2018. Anti-microbial agents (36%) were most common, with requests originating from 16 clinical areas. Request from the paediatric intensive care units (36%) and the surgical/orthopaedic ward (36%) were most frequent. 515 medications were accessed in the first 5 months after the introduction of the Medicines Locator Database (January - May 2019). This represents a 35% reduction in the number of medications dispensed in the same time period in 2018. No changes to the types of medications were identified, but some differences in clinical areas were found.

Conclusion This significant reduction (35%) in numbers of medications accessed out of hours, and the corresponding reduction in workload for NAS, demonstrates the benefits of reviewing medication management processes. Further substantial time savings for nursing staff locating stock at ward level are likely. Readily-available technology can be successfully

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

Mary Worrall*, Anne Fitzpatrick. *Children's Health Ireland, Crumlin*

10.1136/archdischild-2020-NPPG.67

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.

REFERENCES

- Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use' (SANTE-2017-11668). https://www.ema.europa.eu/en/documents/scientific-guideline/annex-european-commission-guideline-excipients-labelling-package-leaflet-medicinal-products-human_en.pdf
- NPPG Neonatal and Paediatric Pharmacists Group Newsletter No 61 Autumn 2016. Excipients in medicines for children. <http://nppg.org.uk/wp-content/uploads/2017/04/NPPG-61.pdf>
- Questions and Answers on Ethanol in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use' (CPMP/463/00) https://www.ema.europa.eu/en/documents/scientific-guideline/questions-answers-ethanol-context-revision-guideline-excipients-label-package-leaflet-medicinal_en.pdf
- EMA. Guideline on pharmaceutical development of medicines for paediatric use. https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-pharmaceutical-development-medicines-paediatric-use_en.pdf

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

¹Fatima Yaqub*, ²Joanne Crook, ²John Fell. ¹Imperial College London; ²Chelsea and Westminster Hospitals NHS Trust, London

10.1136/archdischild-2020-NPPG.68

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.