Fisher's Exact Test showed an overall statistical significant relationship between polypharmacy and discrepancy rates ($p=0.05$). Only one source was used for MedRec in 32 (51%) of patients. In 2 (3%) of those patients that source were the patient's own medicines, not the parent/patient/carer.

Conclusion GP repeat lists on the SCR are not an accurate source in paediatric MedRec and should only be used to support another source. Discrepancy rates per patient were much higher compared to previous studies (86% vs 45%),^{2 3} and could have been overestimated as some GP surgeries do not add unlicensed medicines to the repeat section of the SCR. Only a small proportion of omitted medicines were unlicensed or off-label, suggesting licensing status on its own is not responsible for omissions.

A statistically significant relationship between polypharmacy and chance of discrepancy was found, but larger study numbers are needed. Local SOPs were not followed in a small number of patients (3% overall).

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05

TREATMENT OF INFANTILE BOTULISM WITH BOTULISM IMMUNE GLOBULIN (BABYBIG)

Nigel Gooding, Riaz Kayani, Lynne Whitehead. *Cambridge University Hospitals NHS Foundation Trust*

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Background A 7 month old male infant was admitted to their local hospital with poor feeding, reduced urine output, cough and respiratory distress. Worsening respiratory distress and apnoea required ventilation and transfer to a tertiary paediatric intensive care unit, with a presumed diagnosis of respiratory sepsis. Following 1 day of intensive care, intravenous sedation was discontinued with a view to extubation. After 48 hours sedation hold, the patient still had no spontaneous movements and unreactive pupils. Following further review, stool samples were sent to the Health Protection Agency (HPA) for botulism testing. Although initial tests (culture) were negative, a mouse bioassay test was subsequently reported as positive for botulism toxin. HPA and the California Public Health Department (CDPH) confirmed that treatment with botulism immune globulin (BabyBIG) was indicated. How does BabyBIG work: BabyBIG consists of human-derived anti-botulism-toxin antibodies and is approved in the U.S. for treatment of infant botulism types A and B. BabyBIG immediately neutralises circulating neurotoxin and allows motor nerve regeneration to begin. Complete recovery can take several months.^{1 2} Supply of BabyBIG: Diagnosis of botulism was made out of hours at a weekend, requiring BabyBIG to be obtained directly from CDPH. Pharmacy contacted the Medicines and Healthcare Regulatory Authority

(MHRA) on-call service to authorise UK importation of Baby BIG. Pharmacy worked closely with the clinical team and MHRA to ensure that relevant paperwork required by CDPH was completed. Cost of Baby BIG is \$43,000 USD and required the Trust Medical Director to authorise funding. CDPH authorised release of Baby BIG, which was received in the Trust 48 hours later. Administration of BabyBIG: Pharmacy prepared an IV monograph document to assist preparation and administration of BabyBIG, which is presented as 100 mg vials for reconstitution with 2 ml water for injection. BabyBIG is administered as a single dose of 50 mg/kg, infused at an initial rate of 25 mg/kg/hour for 15 minutes which, if tolerated, is increased to 50 mg/kg/hour for the remainder of the infusion. The infusion is administered via an 18 µm filter.

Patient outcome Within 24 hours of administration, there was some movement in the patient's upper limbs and some triggering of the ventilator. By day 12 post-administration pupils were more reactive and there were some antigravity movements. By Day 15 there were signs of facial movement and improved grip strength. A tracheostomy was performed to facilitate weaning from the ventilator. By Day 67 the infant was off the ventilator and on Day 93 was discharged to their local hospital.

Summary Pharmacy played a significant role, ensuring correct processes were followed for BabyBIG to be ordered out of hours, liaising with international partners, organising international transit, ensuring import documentation was available, providing important drug information to ensure the drug was prescribed and administered correctly, and answering parent's questions about the medication. In this case, BabyBIG provided a highly effective treatment for infant botulism.

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06

BRIDGING AN INFORMATION GAP: DEVELOPMENT OF DRUG SPECIFIC FACTSHEETS FOR CHILDREN AND YOUNG PEOPLE WITH CANCER

¹Anna Kinsella, ²J Delaney, Publications Committee, Paediatric Oncology Pharmacists Group, UK. ¹Leeds Teaching Hospitals Trust; ²Great Ormond Street Hospital; ³Children's Cancer and Leukaemia Group (CCLG)

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Aim Patient information leaflets (PILs) have been a legal requirement in the UK for all medicines for almost 20 years. However, as many of the drugs used in children with cancer are unlicensed or used outside the terms of their licence 'off-label', information provided by the manufacturer does not always tell parents/patients everything they need to know about the use of the medicine in children and young people. In 2014, a survey conducted by the Children's Cancer and Leukaemia Group (CCLG) revealed 92% of parents wanted more drug specific information. The aim of this piece of work was to address these information needs through the development of standardised drug specific factsheets for children and young people with cancer.

Methods Information was collated on the availability of paediatric drug specific PILs at primary treatment centres (PTC's)