the paracetamol level continued to rise in 11 courses and remained static above 25 mg/L in two courses.

Conclusion Overall, 51% of the paracetamol levels were outside the target range, with 31% > 25 mg/L and 20% < 15 mg/L. Infants with levels of > 25 mg/L did not show clinical signs of toxicity or had significantly elevated plasma transaminase levels. The patient population was comparable to that in the study[2] where levels were all within the target range. Therefore, further work needs to be done to establish why our levels are higher than those in the published study[2] before we can decide to discontinue monitoring levels.

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P28 A MULTI-PARTNER APPROACH TO APPROVING AN INNOVATIVE TREATMENT

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Aim Batten Disease CLN2 is a life limiting metabolic condition. Intra-cerebro-ventricular enzyme-replacement therapy (ICV ERT) cerliponase alfa may halt or slow disease progress and is available to children and young people (CYP) on an NHS England (NHSE) Managed Access Agreement and is approved by National Institute of Clinical Excellence (NICE). ICV ERT does not halt retinal degeneration and CYP eventually lose vision.

Here we describe a multi-partner approach to approving use of overage from ICV ERT vials for intravitreal injection as an innovative treatment at a tertiary children's hospital.

Method The specialist team sought approval to use overage from ICV cerliponase vials intravitreally (into the eye) for the treatment of retinal disease in Batten Disease CLN2. The pathway to approval involved discussion with the following parties:

- Drug manufacturer
- Disease specific charitable organisation
- NHSE specialist commissioning (SSC),
- Trust executive management team,
- Trust legal team,
- Technical services team
- Drugs and Therapeutics Committee (DTC)
- Clinical Ethics Committee (CEC)
- Metabolic medicine and ophthalmology clinical teams
- Theatres
- Pharmacy: clinical teams, Governance and Quality Assurance

The following risk mitigation steps were agreed:

- Risk of clinical harm and risk of deterioration following termination of treatment was detailed in the written consent and discussed at CEC
- Indemnity for practicing clinical team was discussed and agreed with NHS Resolution
- Insurance protection to cover possible deterioration of patients' clinical condition
- Funding for NHS resources was secured by the charitable organisation to support the operational aspects of administering the innovative treatment.
- Equity of Access was established by clearly defined inclusion criteria approved by DTC
- Trust reputational risk mitigated through working partnership with family groups.
- Commissioning issues discussed at Clinical Quality Review Group (CQRG) and the Managed Access Oversight Committee (MOAC) meetings with representation from commissioners and other stakeholders (e.g. NICE).
- Repatriation to other centres discussed with NHSE SSC commissioners who were supportive of shared care.
- The clinical team aim to apply for further funding to NHSE/NIHR once safety and efficacy data is obtained following initial treatment.

A risk assessment was undertaken and a standard operating procedure (SOP) for the administration of intravitreal cerliponase treatment in theatres was written. The treatment was built within the Trust electronic prescribing system.

Outcome The innovative treatment was prepared, prescribed and administered safely to patients. All stakeholders were aware and operationally, administration went smoothly.

The clinical team had a trust approved framework to undertake their proposed innovative treatment and presented their results to the DTC following 12 months of treatment. Subsequently, approval for continuation of treatment for a further 12 months in 3 patients was obtained. Full clinical results will be published in a peer reviewed journal.

Conclusions Innovative treatments require considered approval from multiple stakeholders. Early discussion with DTC, CEC and the trust executive team to consider all factors such as liability, research, insurance etc. was helpful in providing a considered framework for challenging innovative treatment. Experience from this case study is being used to further improve local governance for the approval of innovative treatment pathways.

P29 INFANT POSTNATAL PROPHYLAXIS (PNP) FOLLOWING MATERNAL VIRAEMIA DURING BREASTFEEDING WITH HUMAN IMMUNODEFICIENCY VIRUS (HIV)

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Background Increasingly, women living with HIV in resource-rich settings are choosing to breastfeed, but experience in managing maternal viraemia during breastfeeding and transmission risks to the infant are limited. In low- to middle-income settings, the overall postnatal risk of HIV transmission via breast milk when women are treated with combination ART has been reported as 0.30 (95% CI 0.1–0.6) to 1.08% (95% CI 0.32–1.85) at 6 months.[1 2]

Method Case series from the Paediatric Virtual Clinic (PVC) including national and international referrals.

Results

Case 1:

Term infant, mother suppressed on tenofovir disoproxil/emtricitabine, darunavir/ritonavir. Received 4 weeks of zidovudine (AZT) after birth; maternal and infant viral load (VL) at