PO-0929 "LOW DOSE" POSTNATAL CORTICOSTEROIDS FOR PRETERM INFANTS AT RISK OF SEVERE BPD – A MYTH?

[1]L Hughes, [1]L Leung, [2]C Pitan, [2]L Doyle, [2]C Kamlin. *[1]Department of Pharmacy, The Royal Women's Hospital, Parkville Melbourne, Australia; [2]Newborn Services, The Royal Women's Hospital, Parkville Melbourne, Australia*

10.1136/archdischild-2014-307384.1550

Background Prescribing postnatal corticosteroids (PCS) for ventilator dependent preterm infant remains controversial. PCS improve short term lung function but may increase the risk of disability in later life. The DART study[1] was designed to address this risk using a 10-day tapering protocol with a total dose of dexamethasone of 0.89 mg/kg. We aimed to audit practice and calculate the total dose of PCS at a single centre using the DART protocol.

Method Over a four year period patients were identified from an electronic database and hospital charts reviewed. Infants receiving peri-extubation steroids were excluded.

Results Forty six infants with mean (SD) gestational age 25.0 (1.3) weeks, birth weight 685 (192) g received PCS as per DART protocol at a median (range) age of 25(6–197) days. Ventilatory support at the start of treatment: 6 infants on CPAP, 24 conventional and 16 high frequency ventilation. Mean FiO_2 prior to PCS was 0.55 (0.22) with mean airway pressure of 10.9 (2.7) falling to 9.1 (2.3) cm H_2O after three days. Median duration of therapy was 20 (3–86)days, with a total dexamethasone dose of 1.44 (0.375–9.1) mg/kg. Glycosuria was common (67%), one infant developed NEC and there were seven deaths with a 93% rate of either death or BPD (oxygen dependency at 36 weeks).

Conclusions PCS prescribed beyond three weeks has minimal impact on reducing BPD despite the total dose of PCS often exceeding those used in published studies. Long term follow up of these patients is recommended.

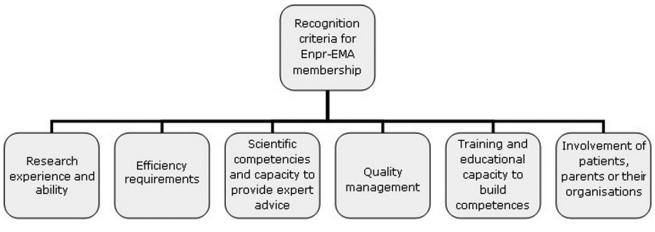
REFERENCE

1 Doyle *et al*. *Pediatrics* 2006;117:75–83

PO-0930 ENPR-EMA, A PLATFORM FOR DISSEMINATING GOOD PRACTICES ABOUT PAEDIATRIC MEDICINES RESEARCH ACROSS EUROPE AND WITH INTERNATIONAL PARTNERS

[1]B Pelle, [1]I Eichler, [2]M Turner. *[1]Paediatric Medicines, European Medicines Agency, London, UK; [2]Department of Women's and Children's Health, Institute of Translational Medicine University of Liverpool, Liverpool, UK*

10.1136/archdischild-2014-307384.1551



Abstract PO-0930 Figure 1 Set of six defined recognition criteria for Enpr-EMA membership

Abstract PO-0930 Table 1 List of active Enpr-EMA Working Groups

Working Group	Topic
3–5	How to establish communication between Enpr-EMA, networks and industry
(merged)	Sharing good practices within EnprEMA and with industry partners
4	Dialogue and interaction with Ethics Committees
6	A framework for networks to interact with industry and regulators when implementation/conduct of clinical trials agreed in PIPs is no longer possible
7	Neonatology
8	Paediatric Phamacovigilance
9	Strategies for funding and maintaining a paediatric research network
10	FP7 projects

Background and aims The European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA) was set up in accordance with Article 44 of the Paediatric Regulation[1]. Enpr-EMA is a network of research networks, investigators and centres with recognised expertise in performing clinical studies in the paediatric population with the mission of facilitating studies in order to increase the availability of medicinal products authorised for use in the paediatric population[2].

Methods To register with Enpr-EMA, networks must fulfil the requirements laid down by a set of six recognition criteria for quality of paediatric research (Figure 1). Enpr-EMA Working Groups have recently been established (Table 1) to address important issues.

Results There are currently 38 registered networks or centres[3] (Table 2). Past work includes supporting the development of 3 new networks; disseminating good practice relating to the involvement of children and young people in research. Ongoing work includes: sharing good practice within Enpr-EMA and Industry Partners; developing a check list of Ethics Committee submission documents; a roadmap to lobby the European Commission about the need to support medicines development in children; establishing a joint PDCO/Enpr-EMA Working Group on neonatology; initiating collaboration with paediatric networks in the USA.

Conclusions After successful implementation of Enpr-EMA as a platform for sharing good practices among paediatric clinical trials networks[4], Enpr-EMA is addressing some important hurdles to the development of medicines for children. Enpr-EMA invites paediatric centres/investigators to contribute to its work and/or become a member.

Acknowledgments Not applicable.

REFERENCES

1 Regulation (EC) No 1901/2006 of the European Parliament and the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation EEC No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004
2 Ruperto *et al*. A European network of paediatric research at the European Medicines Agency (Enpr-EMA). Arch Dis Child 2012;97(3):185–8
3 Enpr-EMA webpages: http://www.ema.europa.eu/ema/index.jsp?curl=pages/partners_and_networks/general/general_content_000303.jsp and mid=WC0b01ac05801df74a
4 5-year report to the European Commission. General report on experience acquired as a result of the application of the Paedi-atric Regulation, prepared by the European Medicines Agency with its Paediatric Committee: http://ec.europa.eu/health/files/paediatrics/2013_com443/paediatric_report-com (2013)443_en.pdf