

ethanol and benzalkonium chloride. Opportunities for product substitution were defined as EOI-containing formulations for which an EOI-free product was reported in the survey with identical active pharmaceutical ingredient (API), galenic form and strength.

Results Of 31 invited European countries 20 with 115 NICUs responded. A total of 564 trade names (TN) with 53 APIs were used in more than 10% of units. EOI containing formulations (n = 151) were used for 31 APIs, found overall in 363 TNs. Compared to parenteral forms (50/199; 25%), enteral (83/130; 64%) and topical TNs (18/34; 53%) contained EOI more frequently (OR; 95% CI 5.3; 3.3–8.5 and 3.4; 1.6–7.1, respectively). An EOI free substitution was available for 31/50 parenteral (63%), 17/83 enteral (21%) and 3/18 topical (17%) TNs. Overall, 51/151 (34%) TNs with EOI could be replaced; substitution was possible in 92/151 (61%) of cases if the requirement for identical API strength was ignored.

Conclusions EOI-free formulations available on the European market could be used to reduce the number of TNs with EOI by at least a third.

0-099 THE IMPACT OF BREASTFEEDING ON THE INCIDENCE AND SEVERITY OF NEONATAL ABSTINENCE SYNDROME

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Background and aims In light of the current epidemic in the abuse of opioids, a major increase in neonates with neonatal abstinence syndrome (NAS) is likely. Incorporation of breastfeeding as a first pillar of treatment of NAS seems appropriate. We aimed to quantify the impact of breastfeeding on the incidence and severity of NAS.

Methods Pooling of published NAS cohorts, with specific emphasis on the impact of breastfeeding on the incidence (yes/no opioid administration) and duration (duration opioids, duration hospitalisation) of NAS.

Results Three studies [1–3] were retrieved and resulted in a pooled dataset of 400 neonates (218 breastfed, 54.5%). There is a significant reduction in NAS (54 vs 77%, number needed to treat 5–6). The same trends are observed when the duration of opioid treatment (difference -18 to -23 days) or the length of hospital stay (difference -4 to -10 days) are considered.

Conclusions Breastfeeding is associated with a clinical significant reduction on both the incidence and the duration of NAS in opioid exposure newborns. Incorporation of breastfeeding as a first pillar of treatment for relieving the NAS symptoms seems to be a very natural, and effective way of addressing this.

REFERENCES

Abdel-Latif ME *et al.* Pediatrics 2006
Wachman EM *et al.* JAMA 2013
Welle-Strand GK *et al.* Acta Paediatr 2013

0-100 RELATIONSHIP BETWEEN ADVERSE DRUG REACTIONS AND OFF-LABEL/UNLICENSED DRUG USE IN HOSPITALISED CHILDREN. EREMI STUDY

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Background and aim To date few studies have shown a significant association between the off-label drug use and adverse drug reactions.

(ADRs). The main aims of this study are to evaluate the relationship between adverse drug reactions and unlicensed or off-label drugs prospectively in hospitalised children and to provide more information on prescribing practice, the amplitude, nature and consequences of unlicensed or off-label drug use in paediatric inpatients.

Methods In this ongoing multi-centre prospective study, the French summaries of product characteristics in Theriaque (*a prescription products guide*) are being used as a primary reference source for determining paediatric drug labelling. Detection of ADRs is carried out by health care professionals and research groups using a trigger tool and patients' electronic health records. The causality between suspected ADRs and medication is evaluated using the Naranjo and the French methods of imputability.

Preliminary results for a 6 month period: 40% of the 73 detected ADRs were estimated as severe. 1498 patients have been included.

Conclusions This is the first large multi-centre prospective study in France that evaluates the relationship between adverse drug reactions and unlicensed or off-label drugs in hospitalised children. This study will help to identify the risk factors that could be used to adjust preventive actions in children care, guide future research in the field and increase the awareness of physicians in detecting and declaring ADRs. This study is funded by l'ANSM (French national agency of drug security).

0-101 NUMBER OF PROCEDURES AND ANALGESIC THERAPY IN NEONATES ADMITTED TO NICUS: EPIPPAIN 2 STUDY

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Background Neonates admitted to NICUs are frequently subjected to invasive procedures, often with sub-optimal analgesic treatment.

Objective To determine the number of invasive procedures and analgesic practices in NICUs.

Methods Invasive procedures and corresponding analgesic therapies on days 1–14 of NICU admission were prospectively