

Abstract O-101 Table 1 Five more frequent painful procedures

Painful procedure	No. (%)
Nasal aspiration	11636 (28.4)
Heelstick	8995 (22.0)
Tracheal aspiration	8734 (21.3)
Tape removal	4080 (10.0)
Venipuncture	1152 (2.8)

studied over a 2-month period in all neonates admitted to the 16 NICUs in the Paris region.

Results For 589 neonates included, mean (SD) gestational age, birth weight, CRIB scores, and number of days of participation were 33.3 (4.5) wks, 1983 (943) gm, 1.5 (2.5), and 7.4 (4.5) days, respectively. 103239 procedures were performed in all neonates, 40927 were classified as painful and 62312 were stressful. The median (range) number of all procedures, painful procedures (PP) and stressful procedures (SP) per infant were, respectively, 124 (0–699), 44 (0–353), and 78 (0–406). Table 1 shows most frequent PP.

Analgesic therapy before PP varied widely among procedures. Analgesic therapy was given before 28.1% of PP. Continuous infusions of sedatives and/or analgesics were given during 38.8% of PP. Overall, 61.8% of PP were performed with an analgesic given before the procedures and/or while the neonate was

receiving continuous sedation/analgesia. Fig. shows factors associated with preprocedural analgesia use.

Conclusions There is an urgent need to reduce the number of procedures and the pain produced by routine NICU procedures in neonates. Analgesic therapy should be matched with the intensity and duration of acute pain caused by invasive procedures.

0-102 ANALYSES OF CURRENT UNLICENSED AND OFF-LABEL FOR AGE DRUG PRESCRIPTIONS AT A NEONATAL INTENSIVE CARE UNIT

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Background and aims Treatment of critically ill and preterm neonates includes the use of multiple drugs. Many drugs are unlicensed for children or used off-label. Recent changes of drug legislation by FDA and EMA should encourage more drug research in children. We aimed to study the current drugs used in a neonatal intensive care unit.

Methods All drug prescriptions at the level III NICU of Erasmus MC from January 2007 till June 2013 were retrieved from the patient data management system. The product license of each drug was used to judge the label for use in neonatal age.

Results A total of 4,054 neonates (2,240 males) with a median gestational age of 32+0 (range 23+6–42+2) weeks and a body-weight at admission of median 1.8 (range 0.36–5.4) kg, were included. Most frequently administered drugs were benzyl-penicillin, gentamycin, caffeine, morphine and surfactant. Of the 24,903 prescriptions, 7,948 (32%) were off-label for neonatal age, and 1,932 (8%) were unlicensed for children.

Conclusion The availability of adequately licensed drugs still shows important shortcomings. Almost all CNS drugs were off-label for neonatal age (93%) although few unlicensed for use in children (7%). On the other hand most antimicrobial drugs were on label (7%). We believe that drug research in neonates should have high priority to access safe and appropriate medicines.

Abstract O-101 Table 2 Logistic regression models factor association with the use of analgesia during 40927 painful procedures in neonates, adjusted for centres

	No. of Painful Procedures	Model for Specific Analgesia Prior to Procedure		Model for Some Form of Analgesia ^a	
		Odds Ratio (95% CI)	P-value	Odds Ratio (95% CI)	P-value
Sex					
Girl	17992	1 [Reference]		1 [Reference]	
Boy	22935	1.15 (1.09-1.22)	< .001	1.05 (1.00-1.10)	0.044
Gestational age, wk					
37-42	7187	1 [Reference]		1 [Reference]	
33-36	7285	1.35 (1.22-1.50)	< .001	0.79 (0.73-0.86)	< .001
30-32	8236	1.39 (1.25-1.54)	< .001	0.58 (0.53-0.63)	< .001
24-29	16219	1.37 (1.25-1.51)	< .001	0.59 (0.54-0.63)	< .001
Respiratory support ^b					
Spontaneous ventilation	5017	1 [Reference]		1 [Reference]	
Mechanical ventilation	24311	0.24 (0.22-0.26)	< .001	2.84 (2.63-3.08)	< .001
Noninvasive ventilation	11599	0.64 (0.59-0.70)	< .001	0.62 (0.58-0.67)	< .001
Parental presence					
No	36896	1 [Reference]		1 [Reference]	
Yes	4031	1.07 (0.97-1.17)	0.169	1.17 (1.09-1.27)	< .001
Category of procedure					
Tubes in natural cavities	21864	1 [Reference]		1 [Reference]	
Needle stick for vascular access	3008	31.47 (28.29-35.01)	< .001	11.52 (10.24-12.96)	< .001
Needle stick without vascular access	9766	12.48 (11.64-13.38)	< .001	4.83 (4.53-5.15)	< .001
Intubation	137	7.31 (5.00-10.89)	< .001	5.41 (3.62-8.09)	< .001
Surgical procedures and chest tube insertion	15	28.38 (9.05-88.38)	< .001	3.55 (0.67-18.92)	0.136
Other minor procedures	6137	3.66 (3.38-3.96)	< .001	1.80 (1.68-1.92)	< .001
Surgery during the study period					
No	38851	1 [Reference]		1 [Reference]	
Yes	2076	1.08 (0.93-1.24)	0.322	3.28 (2.80-3.83)	< .001
Day of procedure					
Day: 1 of admission	4988	1 [Reference]		1 [Reference]	
Day: 2 to 14 of admission	35939	1.51 (1.38-1.65)	< .001	2.25 (2.10-2.41)	< .001
Time of day					
Day time, 7 AM-6 PM	20897	1 [Reference]		1 [Reference]	
Night time, 7 PM-6 AM	20030	0.95 (0.90-1.00)	0.065	1.05 (1.00-1.10)	0.024
Continuous analgesia ^c					
No	24279	1 [Reference]		NA	
Yes	16648	0.62 (0.57-0.67)	< .001		
Clinical Risk Index for Babies (CRIB) score ^d	40927	0.98 (0.95-0.97)	< .001	1.13 (1.12-1.14)	< .001
Model area under the receiver operating characteristic curve		0.87 (0.87-0.88)*		0.78 (0.77-0.78)*	

Abbreviation: CI, confidence interval; NA, not applicable.

^a 'Some form of analgesia' refers to the use of specific analgesia, nonspecific concurrent continuous analgesia, or both.

^b During a procedure.

^c Infusion of non specific concurrent analgesia during procedure.

^d The Clinical Risk Index for Babies score is a measure of illness severity in neonates. It consists of 6 items collected in the first 12 hours after birth. It ranges from 0 to 23. Higher scores indicate higher clinical risk.

*Area with 95% CI (0.5, no predictive value; 1.0, perfect prediction)

Abstract O-102 Table 1

Classification of drugs	Patient days	Prescriptionsneonates	Off-label for	Unlicensed
Antimicrobial drugs	51,470	10,858	761 (7%)	143 (1%)
Central Nervous System drugs	37,796	5,100	4,720 (93%)	339 (7%)
Haemodynamic drugs	49,571	3,970	1,505 (38%)	1,375 (35%)
Respiratory drugs	43,596	3,434	608 (18%)	270 (8%)
Endocrinological drugs	4,215	243	162 (67%)	55 (23%)
Other drugs	8,369	1,293	190 (15%)	61 (5%)
Overall	195,004	24,903	7,948 (32%)	1,932 (8%)