Method: Our NICU started a multi disciplinary local report committee.Procedures for analysing reports were made.In the analyses we looked at organisational factors, human errors and technical failures. Moreover we used 'why questions' and the 'barrier analysis'.

Implications for practice: Local reporting needs support by management.It is necessary that all disciplines are represented in the committee and that members are approachable and are ambassadors for incident reporting. Regular feedback and presenting results to management and medical and nursing staff, stimulates reporting. Work instructions after exchanging mother milk, a new feeding application form and ongoing attention for the administration of extra oxygen are examples which resulted in fewer incidents.

Conclusion: After three years incident reporting became more regular. The reports increased from 37 in 2006 to 138 in 2009.Meanwhile a number of procedures has been adapted and improved, as a result of which patient safety increased.

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SHORT TERM OUTCOMES WITH USE OF CHLORHEXIDINE GLUCONATE (CHG) AND POVIDONE-IODINE (PI) IN VLBWI WITH PERCUTANEOUSLY PLACED CENTRAL VENOUS CATHETERS

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Background and aims: CHG´s use as a skin antiseptic in neonates is limited because of concerns about systemic absorption and potential side-effects. No chlorhexidine-based antiseptic has been approved by the FDA for neonatal IV catheter placement. We compared the short-term risks of using CHG versus PI as an antiseptic for percutaneously placed central venous catheters (PPCVCs) in VLBWI.

Methods: The records of VLBWI admitted to the NICU at Miami Children's Hospital from 2004-8 were reviewed. Initially, PI was used. After a change in hospital guidelines, CHG replaced PI. Every 10 days the site was re-cleansed with the same antiseptic. Outcomes compared: BPD, NEC, IVH, PVL, ROP, failed hearing test (FHT), length of stay (LOS) and death in infants with lines placed during the first 30 days of life.

Results: PPCVCs were inserted in 187 infants (CHG=95, PI=92). Birthweight, gestational age, gender, total duration of PPCVCs and LOS were similar between CHG and PI groups. The mortality rates in CHG (12.8%) and PI (16.3%) were similar (p=0.54).

COMORBIDITIES: PI group (%), CHG group (%), p value

IVH grade 3-4	14.1	10.6	0.47
PVL	5.4	2.3	0.29
BPD	47	37	0.22
NEC, stages 2,3	6.5	6.4	0.96
ROP stage 3	2.2	2.1	0.89
FHT	21.8	25	0.68
	IODINE GROUP n=92	CHLORHEXIDINE GROUP n=95	p value

[Comorbidities (%)]

Conclusions: The use of CHG as an antiseptic for PPCVCs in VLBWI did not increase the risk of major adverse short-term outcomes and mortality when compared to the use of PI. Although this preliminary data is encouraging, prospective studies are needed to confirm its safety.

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UNLICENSED AND OFF-LABEL DRUG USE IN A NEONATAL UNIT IN FRANCE

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Aim: To determine the extent of unlicensed and off-label drugs prescribed in a neonatal unit at a University Hospital, Lyon, France. **Methods:** We conducted a prospective cohort study of newborns who were admitted to the neonatal unit in France during a 4 month-period (from January 1st to April 30th 2009). Using French primary reference source (Vidal 2009), all drug prescriptions were assessed to determine the extent of unlicensed or off-label use.

Results: A total of 65 newborns, 55 preterm and 10 full-terms were admitted to the neonatal ward and received 265 prescriptions. Fifty four percent (143/265) of prescribed drugs were licensed, 16.6% (44/265) were off-label for paediatric use, 21% (56/265) for age, 2.4% (6/265) for dosage and 6% (16/265) for route of administration. Unlicensed drug utilisation has not been detected. Seventy one percent (46/65) of infants received at least one off-label prescription.

Conclusion: Prescriptions of off-label drugs in neonatal unit is common. Clinical trials assessing the benefit and harms of off-label or unlicensed drugs frequently prescribed should improve the lack of trial-based data for children.

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PROSPECTIVE EVALUATION OF PROPYLENE GLYCOL TOLERANCE IN (PRE)TERM NEONATES: AN ACTIVE COMPARATOR APPROACH

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Introduction: Propylene glycol (PG) is a commonly used excipiens although accumulation can result in hyperosmolarity, renal toxicity and lactic acidosis. This is of concern in neonates given their limited metabolic capacity [1]. We therefore evaluated renal, metabolic and hepatic tolerance during PG exposure in neonates.

Methods: (pre)term neonates included in the PARANEO study (NCT00969176) received iv paracetamol PG (0.8 mg PG/mg paracetamol) for up to 48 h. Data on renal (diuresis, creatinaemia), metabolic (lactate, Anion Gap[AG]) and hepatic tolerance (AST, ALT, direct bilirubinaemia) were collected from 48 h before until 48 h after iv administration and compared with earlier reported observations on renal and hepatic tolerance during iv paracetamol (Perfalgan) exposure in neonates [2,3].

Results: Based on observations available in 40 neonates (median GA 36 wk, PNA 6 days, weight 2.5 kg) and following median PG exposure of 59 (15-238) mg/kg, progressive postnatal normalization of creatinaemia and diuresis, lactate, BE, AG and liver enzymes was observed while sodium remained stable.

Conclusions: Median PG exposure of 59 mg/kg over 48 h did not affect postnatal adaptation and renal and hepatic observations were similar to earlier observations on iv paracetamol tolerance in neonates. We therefore conclude that this level of PG exposure seems to be well tolerated, but further studies on PG disposition and clearance are needed.

[1] Wittaker et al. Arch Dis Child 2009;94:F236-40, [2] Allegaert et al. Acta Paediatr 2005;94:1273-9, [3] Allegaert et al. Paediatr Anaesth 2008;18:388-92.

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HYPOGLYCEMIC AGENTS SULFONYLUREAS CONSTRICT THE FETAL DUCTUS ARTERIOSUS IN THE RAT

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Background: Sulfonylureas (tolbutamide = Rastinon, glibenclamide = glyburide, glimepiride = Amaryl) inhibit K_{ATP} channels and induce release of insulin. In in-vitro studies, glibenclamide constricts the ductus arteriosus. Placental transport of sulfonylureas is variable; high with tolbutamide, and low with glibenclamide, respectively.

Purpose: To clarify the *in-vivo* ductus constrictive effects of various sulfonylureas.

Methods: Sulfonylureas were administered orogastrically to pregnant near-term (21FD) or pre-term (19FD) Wistar rats. Fetal ductus arteriosus was studied 2, 4, 8 and 24 hours later, with a rapid whole-body freezing method and measurement of the inner diameter of the ductus.

Results: Tolbutamide constricted the fetal ductus dose-dependently. With clinical dose (10 and 30 mg/kg), the near-term fetal ductus constricted moderately, and the ductal diameter decreased to 0.8 and 0.5 compared to the control four hours later. With a large dose (100 mg/kg), the fetal ductus constricted severely, and the diameter decreased to 0.2 compared to the control four hours later. Tolbutamide constricted the pre-term ductus comparatively less. Glimepiride with a large dose of 10 mg/kg constricted the near-term fetal ductus