Highlights from this issue

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SURFACTANT TREATMENT VIA LARYNGEAL MASK AIRWAY

The growing enthusiasm for less invasive surfactant administration (LISA) techniques is enabling more and more infants to be treated for RDS without the need for mechanical ventilation. As trials of LISA have shown improved outcomes in infants at high risk, it is difficult to know what the required evidence will be to influence practice in lower risk infants or with the use of further variants of LISA. Supraglottic airway devices offer another approach to LISA. This has the added appeal of avoiding direct laryngoscopy, which many understandably consider still to be quite invasive. Callum Roberts and colleagues present a narrative review of the evidence to date regarding use of supraglottic airway devices in this way. Trials so far have included just over 350 infants with encouraging reductions in the need for mechanical ventilation. A present limitation is that currently available devices are too large for the smallest infants so that current evidence is largely limited to infants weighing more than 1 kg. Natalie Smee and colleagues report a series of 60 infants weighing ≥1200 g treated using a laryngeal mask airway in 2 Scottish neonatal units. All the infants had sustained supplemental oxygen requirements on CPAP before treatment. Device application and surfactant administration was successful in all cases and later intubation for further treatment was required in 10 infants. If you are in any doubt about the potential of this technique, have a look at their video of the procedure in the supplementary material and it will certainly get you interested. ***See pages F336 and F342***

CONSENT AND THE CONTINUING EVOLUTION OF RESEARCH ETHICS

Two research articles and an editorial continue a theme from the March issue relating to the use of different consent models to enable greater research participation for newborn infants and their families. Samantha Sloss and colleagues studied the opinions of parents who were asked for deferred consent after their newborn infant had been enrolled in one or other of six delivery room intervention and support trials. Deferred consent had been given in 97% of cases. Structured interviews were conducted and 100 out of 108 families approached agreed to participate. Bereaved families were not approached for participation. In 16 cases the infant had been enrolled in two studies with deferred consent and in 5 cases three studies. Some of the infants had also been enrolled in studies with prospective consent so that the mean number of studies each infant had been enrolled in altogether was three and the maximum 7. The parents were satisfied with the consent process in 89% of families when deferred consent had been used and 92% of families when prospective consent was used. Most parents felt that they would have given the same answer if approached prospectively. Among the seven who thought that they would have declined if approached prospectively the main reasons related to being too stressed to process the information at the time. Most parents did not think that prospective consent was preferable. The detailed results are of interest to all but members of ethics advisory committees in particular might benefit from seeing the scale of involvement in research that families are happy with where this is a normal part of care and their openness to deferred consent for some studies.

Jenny McLeish and colleagues studied the experiences of parents and health professionals in relation to the use of an opt-out approach to consent for enrolment in a randomised trial of withholding feeds in relation to blood transfusion. Parents were given information about the trial. There was no consent form. The health professional explained that all eligible babies were in the trial unless parents opted out, and they could opt out at any time by telling any member of staff. Semi-structured interviews were conducted with parents and health professions and there was thematic analysis. The health professionals tended to operationalise the process as opt-in consent without a consent form. Most parents did not comment on the absence of a consent form. Parents found the principle of opt-out consent acceptable as it did not compromise their right to consent.

Neena Modi discusses the continuing evolution of research ethics and proposes that for comparative effectiveness studies of accepted treatments randomisation should become the standard of care, supported by opt-out as the default consent process, that research guidance should do more to put across the balance of benefits to risks of research participation and non participation, and that the clinical professions and their organisations should do more to normalise research participation in preference to allocation by clinician bias through the widespread imposition of expert opinion based guidance. ***See pages F258, F244 and F230***

HEART RATE DURING TRANSITION WITH DELAYED CORD CLAMPING

Peder Aleksander Bjorland and colleagues used dry ECG electrodes to record heart rate from 5 s after birth to 5 min in healthy term born infants who had delayed cord clamping. The use of ECG gave information more quickly than previous studies using SPO_2 monitors to determine heart rate. Heart rates below 100 beats per minute were very infrequent – the third centile heart rate crossed 100 beats per minute 34 s after birth. These observations further emphasise the likely negative impact of immediate cord clamping on transitional physiology. Previous centile charts constructed from data gathered after immediate cord clamping had around 50% of infants with heart rate <100 beats per minute at 1 min after birth and this must mainly have been a reflection of the effects of cord clamping prior to the onset of respiration. ***See page F311***

DIAZOXIDE AND NEC

Laura Prado and colleagues studied all infants who had been treated with diazoxide for hypoglycaemia in 2 Canadian neonatal units between 2012 and 2017. There were 55 infants who received the treatment. Gastrointestinal disturbance was observed in 33% and 7 (13%) of the infants were diagnosed with necrotising enterocolitis with radiological or ultrasonographic findings (pneumatosis, portal venous gas and pneumoperitoneum) in association with abnormal abdominal clinical signs. Medical treatment was sufficient in four infants, 1 infant was treated surgically and two infants died without becoming stable enough for surgery. The median postmenstrual age at diazoxide treatment in the infants who developed NEC was 36 weeks and the median postnatal age at treatment was 9 days. This report adds a further caution in the evaluation of risks and benefits of this treatment in the case of infants who have not yet reached term and whose duration of needing high glucose infusion rates to maintain normoglycaemia is not very prolonged. ***See page F306***