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Highlights from this issue

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THE IMPORTANCE OF VALIDATING TREATMENTS

The paramount importance of using treatments based on evidence is the focus of the Editorial by Wilkinson and colleagues. Their title mentions children rather than neonates, but though most of their examples are from neonatal or perinatal trials, their argument is relevant to the whole practice of medicine. It is therefore with some pleasure that I draw to your attention that we have 5 randomised controlled trials reported in this issue, four at full length and one as a short report: we are doing our bit to lessen uncertainty, and to validate treatments and practices. Of course, good evidence depends on good trials, and trials are only as good as their methods, so it is useful to have a paper that unpicks the issues that arise when we use the composite of death and disability to measure the outcomes of trials in neonatal care. Parekh and colleagues challenge us to consider the correct way to handle mortality when undertaking trial analysis for composite outcomes, and conclude that no single approach is best in all circumstances. *See pages F190 and F193*

THE EFFECT OF NOT VALIDATING TREATMENTS

The understandable desire to reduce variation in practice can have unintended consequences that are not necessarily beneficial. Mukherjee and colleagues have investigated the impact of the recent guidance from National Institute for Health and Care Excellence (NICE) on early onset neonatal sepsis and found that the result of applying the guidance was to generate more investigations and greater lengths of stay. These consequences are not trivial: even if there is a benefit, such as a reduction in infective deaths among term babies, much larger numbers of babies will be harmed by having invasive investigations (venepuncture and lumbar puncture, neither of which are harmless), and receiving penicillin and gentamicin without actually having invasive bacterial disease. The economic cost is principally the consequence of staying in hospital

longer, but at a time when maternity services are notoriously stretched this will result in unintended opportunity costs as well. Readers will look in vain for validation of the NICE guidance. The benefits and harms of the care package that the NHS is required to implement could have been tested in a large scale cluster randomised controlled trial, but as they were not they remain a 'known unknown'. *See page F248*

PARENTS PRESENT FOR ROUNDS: SHARED DECISION MAKING?

The UK Quality Standard from National Institute for Health and Care Excellence (NICE) on patient experience in adult services emphasises the notion of shared decision making (QS15, Standard 6, February 2012). This is largely derived from the ethical imperatives of autonomy and justice rather than from empirical evidence, and does not specifically address the context in which decision making takes place. Meanwhile, many neonatal services have routinely encouraged the presence of parents for ward rounds for years, justifying this practice both from an ethical point of view and from the positive experiences that parents report; consequently many decisions about neonatal care are, in effect, shared between clinicians and parents. But no one has tested the value of parental participation on rounds in a rigorous trial until the one reported in this edition by Abdel-Latif and colleagues. The result? A resounding win for parental presence. *See page F203*

WHAT TO DO WITH THE GASTRIC ASPIRATE

Some decisions in neonatal care are predominantly 'shared' between a junior doctor and the nurse looking after the baby and parents are rarely involved. Few of these are more common than deciding what to do with an aspirated gastric residual when feeds are being gradually introduced: put it back, or throw it away? Yet the decision, whichever way it goes, is usually either a guess or a response based on habit. It is never

based on 'evidence' because no evidence has existed. Salas and colleagues, in their randomised trial of re-feeding the gastric residuals, show that in general there is no effect on time to full feeding, and any reduction in time to full feeds may be confined to formula fed babies. Importantly, there did not appear to be any obvious harm from the practice, though readers will spot that a much larger trial would have been needed if any effect on rates of necrotising enterocolitis were to be detected. *See page F224*

IF YOU CAN'T INTERPRET IT, DON'T MEASURE IT

The history of neonatal care is littered with embarrassing episodes in which measurements that reflected normal physiology were mistaken for diagnoses of pathology, and 'treatment' was given as a result. One thinks of the normal fall of blood glucose immediately after the umbilical cord is cut, the delayed fall in calcium concentrations at 48–72 hours, and currently the unending debate about when to worry about blood pressure. In the future we will look back and be embarrassed about bilirubin. And right now we should be thinking about clotting. Pal and colleagues have undertaken an important review which reminds us that neonatal clotting measurements cannot be interpreted in the context of adult ranges; that clotting parameters outside the adult normal range have little relationship with haemorrhagic events and mostly do not need to be 'treated'; that the best evidence shows that administration of fresh frozen plasma does not improve clinical outcomes at any age; and that we do actually have high quality randomised controlled trial evidence that giving fresh frozen plasma, as an early strategy in babies under 32 weeks, has no effect on short term or long term outcomes. As one of the investigating team on the neonatal trial they cite (the others are all now retired or dead), it was good to see attention drawn to this little known but important work. *See page F270*