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Concerns about consent, the NICE guidelines regarding resuscitation and early cord clamping

The new rules for consent are going to have a major impact on how consent is obtained for all medical procedures, particularly in the fields of obstetrics and emergency neonatal care. The new rules have arisen from the UK's Supreme Court judgement in an obstetric case with an adverse neonatal outcome.¹ The ruling means that doctors must take 'reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment and of any reasonable alternative or variant treatments.' Sokol² advises doctors to make extra sure that the discussion is fully documented. Medical paternalism has been dealt a clear and crucial blow by the Supreme Court. No longer tested by a responsible body of medical opinion, the judgement now rests with 'a reasonable person in the patient's position.'

Neonatologists have a range of conditions in which consent needs to be specifically obtained and others where explicit consent is not usually required. Common procedures such as blood tests come under the latter umbrella, whereas screening and genetic testing and all surgical procedures need specific and written consent from the parents.

The new law on consent makes no mention of guidelines. It is not sufficient to simply tell patients, for example, that NICE (the National Institute for Health and Care Excellence) recommends a particular action and expect this to be ample information for informed consent. Indeed, it is rather more about a patient's knowledge of the material risks, and what a reasonable person would consider an appropriate action, knowing the various risks. Clinical practice, however, will still be guided by recommendations from the various institutions.

The Royal College of Obstetricians and Gynaecologists (RCOG) recommends that, where possible, women should be informed during the antenatal period about predictable problems that can occur in labour.³ Currently about 10% of babies are considered to require resuscitation and are moved to a resuscitation unit, although many need no more than stabilisation, stimulation and warmth once there. The need for resuscitation and the circumstances when this might be necessary can be explored in detail during the antenatal period with the parents so that a clear plan is in place in the event that the heart rate at birth is <60 beats/min and not increasing.

Cord clamping at birth

The risks and benefits of early cord clamping at birth have been debated for many years and until recently, early cord clamping was considered to be an essential element in active management of the third stage of labour to reduce the risk of post-partum haemorrhage and was thus routine practice. However, this changed with the updated NICE intrapartum care guideline in December 2014, which states that active management of the third stage involves a package of care including deferred cord clamping.⁴

The *Day by Day Pregnancy Book*⁵ explains that the umbilical cord will normally be clamped 2-3 minutes after birth as this boosts the newborn infant's oxygen and blood volume. *Your Pregnancy Week by Week*⁶ explains how the baby changes from placental respiration to lung respiration at birth, which involves circulatory changes in the heart and ends with closure of the placental circulation. Thus the expectation is that delayed cord clamping is normal practice, even though this is only now being widely adopted. Everyone knows that birth is a natural function and can often occur completely unassisted; even delayed cord clamping, defined by NICE as delayed by up to five minutes after birth, could be regarded as an intervention. As physiological mechanisms constrict the umbilical vessels soon after birth, clamping, whether immediate or delayed, could be considered an intervention in the circulation. Admittedly, cutting the cord makes care of the baby more convenient for healthcare professionals, and probably for the mother, and clamping ensures that there is no risk of bleeding from the severed cord.

Would a 'reasonable person' consent to early cord clamping?

NICE states that the cord should not be clamped sooner than one minute from the birth of the infant. One exception is the baby with a heart rate <60 beats/min that is not getting any faster.⁴ Clamping and cutting the cord allows the baby to be separated from the mother and moved to the remote resuscitation unit, but does the intervention of clamping the cord while there is still a functioning placental circulation present a material risk to the infant and is there any reasonable alternative or variant treatment? As far

as consent is concerned, neonatal bradycardia presents the clinician with a dilemma.

What will a reasonable person think about the intervention of clamping the cord if at birth the infant's heart rate is <60 beats/min and not getting faster? Over how long an interval should the heart rate be measured? With modern electronic equipment the real-time heart rate can be continuously calculated and displayed, but this is not available for at least one minute after birth. The recommendation is to obtain the heart rate by auscultation, as oximetry is ineffective for at least the first minute after birth. Auscultation can only provide an estimate without any real accuracy especially if counted over a period of only 15 seconds. The result depends on simultaneously counting the heart rate and observing a clock. An error of a few seconds or a few beats can result in a large error in this short time. How accurate can this be in determining whether or not the rate is increasing unless the rate of increase is quite marked?

Is the determination of an 'increasing' heart rate expected to be a qualitative judgement rather than a precise measurement? The guideline states that deferred cord clamping should be at least one minute. During this minute a decision has to be made about the health of the neonate based on the heart rate. If the heart rate is <60 beats/min and not increasing, the cord should be clamped; but how accurately can this be determined in practice? The heart rate would need to be determined twice within the first minute if the timing of cord clamping is to be affected. A recent study⁷ showed that by one minute 10% of healthy neonates, requiring no resuscitation, have a heart

rate of ≤ 38 beats/min and by two minutes, 10% have a heart rate of ≤ 54 beats/min. Both of these limits are under the critical 60 beats/min and represent an increase of only 16 beats over one minute, a difference that might be unreliable by auscultation in a noisy delivery room.

When the need for resuscitation is anticipated a neonatologist is likely to be present, but many infants who receive resuscitation have had no concerns during labour. Therefore, in many births the obstetrician or midwife must measure the heart rate. Is this really possible to do with any accuracy at a caesarean section or assisted vaginal delivery?

Once the cord is clamped, NICE recommends that breathing and tone are then taken into account before resuscitation is commenced.⁴ Would a reasonable person consider it advisable to clamp the cord *before* a definitive decision has been made to initiate resuscitation of the neonate, knowing that clamping the cord will result in a loss of blood volume and oxygen supply? Or if they knew that it has been proposed that with a long delay between umbilical cord clamping and lung aeration, the infant will be exposed to a hypoxic episode superimposed on top of a period of severely restricted cardiac function, the combined effects of which are potentially catastrophic and could lead to a severe hypoxic/ischaemic event.⁸

Might a reasonable person consider that their newborn infant's heart rate of 59 beats/min is still within the normal range and that cutting off the supply of oxygen and blood volume is not justified?

The NICE guideline advises that separation of mother and baby should be minimised, taking into account the clinical circumstances.⁴ It also advises that if a

newborn infant requires basic resuscitation, and here the guideline is clearly referring to positive pressure ventilation, this should be commenced with air. Might a reasonable person not expect that the necessary clinical skills are available so that ventilation could be commenced at the side of the mother without clamping the cord or separating the baby from its mother, as recommended by the World Health Organization, the U.S. Agency for International Development (USAID) and the Maternal and Child Health Integrated Program (MCHIP)?⁹

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