Revisiting the role of consent in neonatal medicine: legal considerations and the need for empirical research

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It is acknowledged both by the law and by bioethicists that a competent person can exercise their right to self-determination and autonomy in making healthcare decisions, even if their healthcare provider thinks their decision unwise or unsafe.[1] Justice Cardozo's statement: "Every human being of adult years and sound mind has a right to determine what shall be done with his own body," still resonates as a fundamental paradigm for healthcare decision-making in competent adults.[2]

Consent to treatment renders a medical or surgical treatment lawful. Without it, the clinician might be open to either a criminal action of assault or to a civil action for the tort of battery or negligence. Consent should be considered more of a fluid process than an event. Consent does not and should not ever just equate with the signature of a patient or family member on a consent form. Though this may be an aspect of consent, we need to remember the three essential components:

1. legal competence
2. the ability to understand and retain relevant information
3. the ability to decide freely and without coercion.

The legal perspective with respect to consent and clinical negligence has also seen significant changes of which clinicians should be aware. Until recently, UK Courts had adopted the 'prudent professional' test in cases involving consent and alleged negligence. That is, if the information disclosed by the healthcare professional during the consent process aligned with the famous Bolam test whereby: "A medical professional is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art",[3] then there was no breach of the duty of care and the negligence claim was dismissed. However, in a landmark UK Supreme Court case[4] the Bolam test was rejected in favour of a test that asks what a 'reasonable person in the patient's position' would consider to be 'material' information. This, of course, is highly relevant to how we should be communicating with patients and their families.

How healthcare decisions are made where a patient is incompetent and not able to make an autonomous consensual decision is more complex. The landmark House of Lords' case of Gillick[5] determined that a child's right to consent is dependent upon competence, not age, with 'Gillick competence' being defined as having 'a sufficient understanding and intelligence to enable [the child] to understand fully what is proposed [and] sufficient discretion to enable him or her to make a wise choice in his or her own interests.'[5]

In newborn infants, competence cannot be established by virtue of age and stage of development. Gillick competence is not relevant. Therefore, healthcare decision-making is often predicated upon 'best interest' or welfare considerations as outlined in the Children's Act 1989, section 1.[1] How best interest considerations are determined is in itself complex and subject to a degree of professional variance of opinion but it is usual and accepted practice for the views of the family to be sought, ideally prior to treatment or intervention. There are rare and often complex instances where clinicians and families might disagree about proposed treatments however, and these will not be considered here.

A family's agreement to treatment allows the clinician 'approval to treat' through implied 'proxy' consent (assent). This practice is commonplace in neonatal medicine and is often complemented by a written record in the medical notes of the salient elements of the conversation held with the family. It is evident that the days of medical paternalism whereby 'doctor knows best' are resigned to history and the concept of collaborative decision-making with the family resonates strongly in child health, except where emergency treatment is required. In this latter case, the treating clinician is on firm legal and moral ground in treating an emergency and/or acting to ensure the newborn infant's welfare. There may be some instances of procedures or interventions where a clinician may feel compelled to seek formal written consent. This may be because of the complexity, risk or uncertainty of benefit associated with the intervention and may also provide evidence of communication in the event of medical litigation at a point in the future. However, available data indicate that approximately three-quarters of UK neonatal units have

no guidelines for obtaining consent and that there is substantial variation in practice in obtaining consent for different neonatal procedures.[6]

The British Association of Perinatal Medicine (BAPM) published guidance on neonatal procedures and the extent of consent required for different neonatal treatments and procedures in 2004[7] (**FIGURE 1**) however, it remains unclear whether this is robustly adhered to by professionals or how families of babies admitted to neonatal units feel about the guidance. Both of these are important considerations in helping better define how we should communicate with families in 2016. It is time to reflect on our long-held beliefs and practices in this area.

Are we sometimes guilty of sanctioning treatments and interventions by the families' very agreement to their baby being admitted to the neonatal unit? Do we use this implied consent to 'unlock' permission for further diagnostic and therapeutic tests? It might be argued that some of the proposed healthcare interventions are not in fact immediately urgent but rather urgent/semi-urgent and that this should enable a brief discussion of proposed healthcare interventions with the family. Do we, as clinicians, unwittingly elevate these urgent/semi-urgent healthcare interventions to emergency status in order to absolve ourselves of the requirement for an *a priori* discussion with the family about proposed healthcare interventions or the need for consent?

Given that 10% of all live births in the UK are admitted to neonatal units and that babies often move from one neonatal unit to another depending on their required level of care, it is important that the neonatal healthcare professional community re-visits how it seeks permission to treat babies admitted to neonatal units. A vital aspect of the care we provide relies upon effective communication and consistency in care and this should extend to the process of obtaining consent. The PARQ acronym (procedure, alternatives, risks, questions) is an exemplar of how clinicians might standardise how they explain a proposed treatment to the patient's family.[8]

In order to better understand professional and parental views on consent for procedures and interventions performed in neonatal units in the UK, with research ethics approval the first author is conducting a study entitled: An evaluation of the process of **co**nsent in **ne**onatal intensive care medicine from an ethical and legal perspective (The CoNe study). The study will employ quantitative and qualitative (thematic content analysis) methods to explore, via telephone interviews, clinician-clinician discordance and clinician-parent discordance for consent with respect to a number of commonly performed neonatal procedures.

Healthcare professionals interested in providing their views for this study are invited to email Dr Vimal Vasu (vimal.vasu@nhs.net) for further details.

Clinical photographs/video recordings
Screening of babies and/or their mothers in high risk situations with no prior knowledge of maternal status (eg suspected HIV or substance abuse)
Genetic testing
Gastrointestinal imaging involving contrast
MRI/CT scan
EEG with video recording
All surgical procedures
Percutaneous arterial lines
Chest drain insertion and replacement
Abdominal drainage for perforation or ascites
Irrigation following extravasation injury
Therapeutic lumbar or ventricular tap in the absence of a reservoir
Peritoneal dialysis
Bone marrow aspiration
Any biopsy
Exchange transfusion
Vitamin K for normal term babies
Nitric oxide for preterm babies
Immunisation
Treatment for retinopathy of prematurity
Use of donor breast milk

FIGURE 1 Procedures for which explicit written consent should be recorded in the patient's medical notes, according to BAPM (2004).[7]

References

1. **Re F** (Mental Patient: Sterilisation) 1990 2 A.C.1.
2. **Schloendorff v Society of New York Hospital** (1914) 211 N.Y. 125, 105 N.E. 92.
3. **Bolam v Friern Hospital Management Committee** (1957) 1 WLR 583.
4. **Montgomery v Lanarkshire Healthboard** (2015) UKSC 11.
5. **Gillick v West Norfolk and Wisbech AHA** (1986) 1 A.C. 112 HL.
6. **Shenoy S., Archdeacon C., Kotecha S., Elias Jones A.C.** Current practice for obtaining consent in UK Neonatal Units. *Bull Med Eth* 2003;17-19.
7. **BAPM.** *Consent for Common Neonatal Investigations, Interventions and Treatments*. 2014 [Online]. Available from: www.bapm.org/publications/documents/guidelines/procedures.pdf [accessed 12 July 2016].
8. **Sokol D.K.** Defending the sophisticated consent attack. *Br Med J* 2014;349:g6432.