

## **CoNe Study parent interview script (Version 1.0, 7/3/16)**

### **SCRIPT FOR PARENTAL TELEPHONE INTERVIEW FOR THE INTERVIEWER (Version 1.0 March 2016)**

**FAMILY NUMBER:**

**DATE:**

**TIME:**

Thank you for agreeing to participate in this research study. I anticipate that the interview will take 45-60 minutes in total. During the interview I will ask your view about a number of tests and procedures that occur on neonatal units and then ask you to indicate your views about consent for each procedure. It is likely that many of the tests or procedures will be unfamiliar to you and your baby may not have had many of them so I will explain what each test or procedure involves along with potential risks and benefits. In many cases, it is not easy for the doctor to provide a likelihood of either risks or benefits because sometimes there is no evidence to guide us on this information. If you require further clarification of what the procedure involves or are unsure of the terminology or wording used during the interview please ask and I will try to better explain the test or procedure. Along with your answers about what type of consent you feel doctors should obtain, I will also make written notes of the telephone interview, which will then be anonymised for the study analysis.

Consent is a process that provides permission for doctors to do tests and procedures. In adult patients who have capacity, a doctor providing treatment without the patient's consent is against the law. The situation with babies is different as they are unable to provide consent. Therefore, the parents usually provide consent on behalf of their baby and in the baby's best interests. Where treatment is an emergency, it is accepted that treatment can be given as the doctor is acting in the best interest of the baby. Around 10% of all babies born in the UK are admitted to neonatal units. Many of the tests and procedures are important and maybe urgent but only a few are actually required immediately and on an emergency basis. These test and procedures are often performed under the category of implied consent, which I will explain in a moment. So, the purpose of this study is to establish parent views on what tests and procedures require different levels of consent and compare this to professional views on the matter.

Before we start, I will explain the different types of consent that we are going to discuss today.

#### **Implied consent**

This is consent that is inferred from signs/actions or facts. For example, if a doctor examines a baby and tells the parents that the baby needs to be admitted to the neonatal unit for further observation and tests and the parents, through body language and through saying "okay" agree, this would be thought of as implied consent that further treatment on the neonatal unit (such as antibiotics and help with feeding) was agreed to.

#### **Explicit consent**

Explicit consent (sometimes referred to as express or direct consent) involves a discussion of the foreseeable risks and benefits of a test or procedure along with potential alternatives before the test or procedure is performed. It maybe verbal or maybe written.

#### **START OF QUESTIONNAIRE**

For each of the tests and procedures I discuss, I will mention the intended benefits and potential risks. You will then be free to comment and/or ask me any further questions about the procedure (which I will record) and you will then be asked to make a decision about whether the test/procedure should fall within the category of implied consent or explicit consent. If you chose explicit consent you will be asked whether this should be verbal or in a written form

Diagnostic test/Procedure	Implied consent	Explicit consent verbal	Explicit consent Written
<p>1. Peripheral intravenous cannulation</p> <p>A small thin tube is inserted into the baby's vein to give fluids or medications such as antibiotics.</p> <p>Benefits: treatment of underlying condition.</p> <p>Risks: pain, bleeding, infection, extravasation</p>			
<p>2. Peripheral arterial line insertion</p> <p>Involves insertion of a tube into an artery to monitor blood pressure and for withdrawing blood samples in babies requiring frequent blood tests.</p> <p>Benefits: BP monitoring/ blood sampling without causing pain.</p> <p>Risks: bleeding, infection, limb circulation problems, amputation</p>			
<p>3. Lumbar puncture</p> <p>Procedure done to diagnose meningitis (infection of brain lining). Involve a hollow needle inserted between the bones in the middle of the small of the back.</p> <p>Benefits: diagnosis of meningitis and appropriate treatment.</p> <p>Risks: infection, bleeding, pain</p>			
<p>4. Endotracheal intubation</p> <p>Procedure to help a baby breath when they are unable to do so adequately for themselves. Involves administration of medication for sedation and to relax muscle movement and passage of a tube into the airway.</p> <p>Benefits: stabilize breathing and treat baby's medical condition.</p> <p>Risks: unable to pass tube and problems with maintaining airway and breathing, trauma and bleeding.</p>			
<p>5. Central venous catheter insertion (longline)</p> <p>Insertion of a thin tube into a vein near the heart in order to safely administer certain medications and nutrition.</p> <p>Benefits: secure method for administering certain medications and nutrition.</p> <p>Risks: infection, bleeding, extravasation, rupture, malposition, tamponade</p>			
<p>6. Umbilical catheter insertion</p> <p>Involves insertion of a tube into the umbilical artery and/or vein. Access to the artery allows the monitoring of blood pressure and f blood sampling in babies requiring frequent blood tests. Access to the vein allows doctors to give certain medications and nutrition.</p> <p>Benefits of UAC: BP monitoring/ blood sampling without causing pain.</p> <p>Risks of UAC: bleeding, infection, limb circulation</p>			

<p>problems, amputation.</p> <p>Benefits of UVC: Secure access to circulation for resuscitation and medication administration.</p> <p>Risks of UVC: bleeding, infection, malposition, leaking, extravasation.</p>			
<p>7. Scalp vein insertion (cannula or long line)</p> <p>A small thin tube is inserted into a vein on babies scalp to give fluids or medications. This is usually done when no other veins can be easily found on the limbs.</p> <p>Benefits: treatment of underlying condition.</p> <p>Risks: pain, bleeding, infection, extravasation, malposition</p>			
<p>8. Surfactant administration</p> <p>A small amount of a liquid called surfactant is given by injection through a breathing tube to help the lungs work better in certain conditions.</p> <p>Benefits: improve lung condition and improve babies overall condition.</p> <p>Risks: tube obstruction, bleeding from lungs</p>			
<p>9. Intercostal drain insertion</p> <p>Insertion of a tube into the chest wall (with local anaesthetic and pain relief) to drain air that has accumulated outside of the lung (a pneumothorax) which can be life threatening.</p> <p>Benefits: treatment of the pneumothorax</p> <p>Risks. Bleeding, infection, bronchopleural fistula, increase risk of CLD in preterm infants</p>			
<p>10. Suprapubic aspiration of urine</p> <p>Needle inserted into lower abdomen and into bladder to obtain a sterile specimen of urine.</p> <p>Benefits: diagnosis of urine infection and appropriate treatment.</p> <p>Risks: bleeding, infection, bladder injury, bowel injury.</p>			
<p>11. Use of nitric oxide</p> <p>Sometimes when babies lungs are poorly they have high blood pressure levels in their lungs. This restricts how the heart can pump blood to the lungs and can mean that a baby remains blue. NO is used to treat this condition. It involves infusing a gas into the babies breathing circuit.</p> <p>Benefits: improvement in lung blood pressure.</p> <p>Risks: bleeding, methaemaglobinaemia.</p>			
<p>12. Blood transfusion</p>			

<p>Frequent blood sampling of babies on neonatal units means they can become anaemic (low Hb). Blood transfusion involves giving donated and matched blood through a vein over approx. 4 hours.</p> <p>Benefits; treatment of anaemia.</p> <p>Risks: extravasation, blood transfusion reaction, infection (low risk).</p>			
<p>13. Dilutional exchange transfusion</p> <p>Sometimes babies are born they can have too much haemoglobin in their blood. This can sometimes cause problems such as breathlessness, jaundice and low blood sugars. A dilutional exchange is sometimes performed to reduce the level of haemoglobin in the blood and make the baby better.</p> <p>Benefits: reducing the haemoglobin and this might reduce the risk of developmental problems later in childhood.</p> <p>Risks: bleeding, infection, low blood pressure, heart failure, blood chemistry problems (and associated problems)</p>			
<p>14. Double volume exchange transfusion</p> <p>Some babies who are severely jaundiced after birth require a procedure called a double volume exchange transfusion which involves insertion of central lines (UAC/UVC) and removal of around 80% of the blood of the baby and replacing it with fresh blood.</p> <p>Benefits: treatment of severe jaundice, which can cause brain injury such as cerebral palsy and hearing loss.</p> <p>Risks: bleeding, infection, low blood pressure, heart failure, blood chemistry problems (and associated problems)</p>			
<p>15. Pharmacological closure of a patent ductus arteriosus with indomethacin, ibuprofen or paracetamol</p> <p>Babies born prematurely can sometimes have a condition, which means that a channel called a duct that is useful during fetal life to bypass the lungs remains open. This can sometimes mean that after birth too much blood flows to the babies lungs and this can cause problems with a babies breathing. It is believed that closing the duct with medication can improve the baby's condition.</p> <p>Benefits: improve babies condition including how the lungs work</p> <p>Risks: problems with absorbing milk and other gut problems, renal failure, low platelets.</p>			
<p>16. Use of postnatal steroids to facilitate extubation from ventilator in preterm infants</p>			

<p>Some babies, especially those born extremely prematurely (e.g. &lt;28 weeks) have very poorly lungs. This means that they remain dependent on a machine called a ventilator to help support their breathing. In certain cases, doctors use steroids to improve the function of the baby's lungs.</p> <p>Benefits: being able to wean a baby from the ventilator and make progress</p> <p>Risks: short term- high blood pressure, high blood glucose, thickening of heart muscle (cardiomyopathy), risk of infection, thin bones. Long term- concerns about brain growth and development.</p>			
<p>17. Urine toxicology to screen for drugs of abuse</p> <p>Some babies have signs after birth that might suggest that the mother was using illicit drugs during pregnancy. Alternatively, it maybe known that a mum was taking illicit medications but the extent may not be clear. In these situations, a urine sample is sometimes taken to look for the presence or absence of illicit drugs.</p> <p>Benefits: enables doctors to understand the cause of the baby's problems and provide appropriate treatment. Child protection.</p> <p>Risks: None</p>			
<p>18. DNA CGH array or other specific genetic testing</p> <p>Sometimes when babies are born they are noted to have unique or unusual features that make doctors suspect they might have an underlying genetic condition. Sometimes a blood test can be sent to confirm or exclude this.</p> <p>Benefits; establishing diagnosis</p> <p>Risks: Period of uncertainty whilst awaiting result, finding something on the test that is not relevant to the health condition of the baby.</p>			
<p>19. Therapeutic hypothermia</p> <p>Babies who have been "stressed" around the time of birth can sometimes benefit from a period of being cooled to 33.5 degrees for 72 hours. In selected cases, this reduces the risk of developmental problems later in life.</p> <p>Benefits: reduce risk of death/developmental problems.</p> <p>Risks: distress from being cold, may need intubation, may need central lines</p>			
<p>20. Ventricular tap (for post haemorrhagic hydrocephalus)</p> <p>Some preterm babies develop bleeding in the brain. This can cause fluid filled channels called ventricles within the brain to swell up. This is a serious condition and can sometimes lead to increased pressure in the skull cavity. To help with this, doctors sometimes recommend that a needle be inserted into one of the fluid filled cavities to drain some of the excess fluid.</p>			

Benefits: potential to reduce swelling and pressure in brain cavity			
Risks: infection of the lining of the brain (meningitis)			

**CHIEF INVESTIGATOR NOTES ON INTERVIEW:**