Patient information and consent to cleft palate repair (with or without grommet insertion)

Key messages for patients and their parents/guardians

- Please read your child’s admission letter carefully. It is important to follow the instructions we give you about your child not eating or drinking or we may have to postpone or cancel the operation.

- Please read this information carefully, you and your health professional will sign it to document your consent.

- It is important that you bring the consent form with you to the pre-admission clinic and when your child is admitted for surgery. You will have an opportunity to ask any questions from the surgeon or anaesthetist when your child is admitted. You may sign the consent form either before you attend with your child or when your child is admitted.

- Please bring with you all of your child’s medications and their packaging (including inhalers, injections, creams, eye drops, patches, insulin and herbal remedies), a current repeat prescription from your GP, any cards about your child’s treatment and any information that you have been given relevant to your child’s care in hospital, such as X-rays or test results.

- Simple painkillers such as paracetamol and ibuprofen may be required after surgery. We suggest that you discuss this with your pharmacist and have a seven-day supply of these medications at home for your child to take as required according to the instructions.

- Ensure that your child takes his/her medications as normal on the day of the procedure unless you have been specifically told not to administer a drug or drugs before or on the day by a member of your child’s medical team. If your child has diabetes please ask for specific individual advice to be given on his/her medication at the pre-operative assessment appointment.

- Please call the Cleft Coordinator on telephone number 01223 349627. If you have any questions or concerns about this procedure or your appointment.

After the procedure we will file the consent form in your medical notes and you may take this information leaflet home with you.

Important things you need to know

Patient choice is an important part of your care. You have the right to change your mind at any time, even after you have given consent and the procedure has started (as long as it is safe and practical to do so). If you are having an anaesthetic you will have the opportunity to discuss this with the anaesthetist, unless the urgency of your treatment prevents this.

We will also only carry out the procedure on your consent form unless, in the opinion of the health professional responsible for your care, a further procedure is needed in order to save your life or prevent serious harm to your health. However, there may be procedures you do not wish us to carry out and these can be recorded on the consent form.

Cleft palate repair (with or without grommet insertion, Document ID: 101226, V1, July 2019)
We are unable to guarantee that a particular person will perform the procedure. However, the person undertaking the procedure will have the relevant experience.

All information we hold about you is stored according to the Data Protection Act 1998.

**About cleft palate repair**

In cleft palate, there is a gap in the roof of the mouth. This means that the muscles in the mouth do not work well for eating, swallowing and speaking. Palate repair surgery aims to bring these muscles into a better working position and close the gap.

The alternative option is not to treat the cleft palate and/or ear problems. This will mean that the function will remain as it is. This can lead to difficulties with speech, feeding and hearing as your child develops.

**Intended benefits**

- Improve palate function to help with eating and speaking.
- Improve hearing (if grommets are required).

**Who will perform the procedure?**

This procedure will be performed by a surgeon on the cleft team. We are unable to guarantee that a particular person will perform the procedure. However, the person undertaking the procedure will have the relevant experience. If a grommet is required, this will be performed by an Ear, Nose and Throat (ENT) surgeon during the same operation.

**Before the procedure**

Most patients attend a pre-admission clinic, when you will meet a cleft specialist nurse and the pre-admission team. We will ask for details of your baby's medical history and carry out any necessary clinical examinations and investigations. Please ask us any questions about the procedure, and feel free to discuss any concerns you might have. We will ask if your baby takes any medication, including any bought over the counter in a pharmacy. Please bring all medications and any packaging (if available) with you.

When you come to the ward for your procedure, please also tell staff there about all of the medicines your baby uses, so we can make sure all the information is current and correct. If you wish to give medication to your baby yourself (self-medicate), please ask your nurse. Pharmacists visit the wards regularly and can help with any medicine queries.

This procedure involves use of anaesthesia. Your child will see an anaesthetist before the procedure.

Most patients need to stay in hospital for one to two nights and we will discuss accommodation options for yourself whilst your child is in hospital.
On the day of the procedure, we will do go through this consent form with you and answer any further questions you may have. If there is any change to the order of surgery, we will advise on new fasting times.

During surgery, your baby may lose blood. Usually, the amount of blood lost is minimal and no replacement is required. However, if your child loses a considerable amount, your doctor may want to replace the loss with a blood transfusion as significant blood loss can cause your baby harm. Your doctor can give you information about whether there are suitable alternatives to blood transfusion for your child’s treatment. There is a patient information leaflet for blood transfusion available for you to read.

**During the cleft palate repair**

The surgery usually takes three to four hours depending on the cleft, but your baby will be in the theatres for half a day including time for administering the anaesthetics and recovery time. Sometimes, small cuts are made to the side of the palate to help close wider gaps, and these will heal very quickly.

We usually place a tube through the nose into the stomach (nasogastric tube) while your child is under anaesthetic. This is to enable us to give your child regular painkillers without having to wake him/her up. Your child may also require another, larger tube (nasopharyngeal airway) in the other nostril if he/she has obstructed breathing on waking up. This usually needs to stay in place for 48 hours when most of the swelling has subsided; however, some babies need the tube to stay in for a longer period of time.

**Grommet insertion**

Babies with cleft palate sometimes also have ear problems that can affect hearing. This can often be made better with grommets (small tubes placed into the ear drum that drain fluid from the ear). If your baby has been assessed to require grommets to help with his/her hearing, this will involve making a small slit in the ear drum, removing any fluid behind it and then placing a small drainage tube (grommet).

**After the cleft palate repair**

Once the surgery is completed your baby will usually be transferred to the recovery ward, where he/she will be looked after by specially trained nurses. Your baby may be given oxygen via a facemask, fluids via a drip and pain relief until he/she is comfortable enough to return to his/her ward. Once your baby is awake the nurse will contact you to come to the recovery.

There may be some bleeding from the mouth, nose or ear (if a grommet is put in), and you may see some stitches in the roof of the mouth. This is normal after this type of surgery.

After certain major operations your baby may be transferred to the intensive care unit (ICU/ITU), high dependency unit (HDU), intermediate dependency area (IDA) or fast track/overnight intensive recovery (OIR).
Patient Information

These are areas where your baby will be monitored more closely because of the nature of his/her operation or because of certain pre-existing health problems your child may have. If your surgeon or anaesthetist believes your baby should go to one of these areas after the operation, they will tell you and explain to you what you should expect. **If there is not a bed in the necessary unit on the day of your operation, your operation may be postponed as it is important that you have the correct level of care after major surgery.**

**Eating and drinking.** Your baby can eat pureed food or drink once he/she is fully awake. Your cleft nurse specialist and the team will advise and help.

**Leaving hospital.** Once your baby is feeding well and comfortable on simple painkiller medications we will send you home. This is usually one to two nights hospital stay. However, the actual time that your baby will stay in hospital will depend on his/her general health, how quickly he/she is recovering from the procedure and your doctor’s opinion.

**Significant, unavoidable or frequently occurring risks of this procedure**

General risks associated with all major operations:

- Infection.
- Pain (painkillers will be provided to minimise pain after the surgery).
- Bleeding.
- Haematoma (collection of blood under the skin).
- Problems with wound healing.
- Swelling and bruising.
- Scar, and/or scar contracture (shortening).
- Risk of anaesthetic.
- Need to return to theatre. This is uncommon, but may be needed if there is a lot of bleeding, or if problems develop with the wound that require additional surgery to help wound healing.

**Specific risks associated with this operation:**

- Fistula. If the wound does not heal, a hole can form in the palate. If this is small it may heal by itself. If the hole is large, this can cause air to escape from the mouth into the nose and affect speech, or cause liquid or solid to come out of the nose when eating. This may require surgery to close the hole.

- Velopharyngeal insufficiency (VPI). Despite the surgery and bringing the muscles to a better working position, the palate may not be long enough or may not move well. This can result in speech sounding nasal as air escapes through the nose. Our cleft specialist speech and languages therapists will monitor the speech as it develops. VPI may need correcting at a later stage when your child is older.
• Breathing problems. With palate repair and swelling, breathing can become difficult or result in snoring or obstructed breathing during sleep (obstructive sleep apnoea, OSA). This can be temporary or permanent. We may have to place a temporary breathing tube through the nose called a nasopharyngeal airway (NPA), which will be removed when the swelling settles and breathing is safe. This is uncommon.

• Permanent hearing problems. Very occasionally there can be a hole (tympanic membrane perforation) which affects one in every hundred or scarring (tympanosclerosis) in the ear drum.

Anaesthesia

Anaesthesia means ‘loss of sensation’. When your child arrives in the theatre or anaesthetic room and before starting anaesthesia, the medical team will perform a check of your baby's name, personal details and confirm the operation you are expecting. It is common practice nowadays to allow a parent into the anaesthetic room with children; as the child goes unconscious, the parent will be asked to leave.

General anaesthesia

During general anaesthesia your baby is put into a state of unconsciousness and will be unaware of anything during the operation. Your anaesthetist will monitor your child’s condition, any need for fluid or blood replacement, and administer the right amount of anaesthetic drugs.

How will my baby feel afterwards?

Most patients will feel fine after their operation. Some patients may feel dizzy, sick or have general aches and pains. Others may experience some blurred vision, drowsiness, a sore throat, headache or breathing difficulties. We will treat any symptoms as necessary.

What are the risks of anaesthesia?

In modern anaesthesia, serious problems are uncommon. Risks cannot be removed completely, but modern equipment, training and drugs have made it a much safer procedure in recent years. The risk to you as an individual will depend on whether you have any other illness, personal factors (such as smoking or being overweight) or surgery which is complicated, long or performed in an emergency.

Very common (1 in 10 people) and common side effects (1 in 100 people)

Feeling sick and vomiting after surgery
Sore throat
Dizziness, blurred vision
Headache
Bladder problems
Damage to lips or tongue (usually minor)
Itching
Aches, pains and backache
Pain during injection of drugs
Bruising and soreness
Confusion or memory loss

**Uncommon side effects and complications (1 in 1000 people)**
- Chest infection
- Muscle pains
- Slow breathing (depressed respiration)
- Damage to teeth
- An existing medical condition getting worse
- Awareness (becoming conscious during your operation)

**Rare (1 in 10,000 people) and very rare (1 in 100,000 people) complications**
- Damage to the eyes
- Heart attack or stroke
- Serious allergy to drugs
- Nerve damage
- Death
- Equipment failure

Deaths caused by anaesthesia are very rare. There are probably about five deaths for every million anaesthetics in the UK. For more information about anaesthesia, please visit the Royal College of Anaesthetists’ website: [www.rcoa.ac.uk](http://www.rcoa.ac.uk)

**Information about important questions on the consent form**

1. **Creutzfeldt Jakob Disease (‘CJD’)**
   We must take special measures with hospital instruments if there is a possibility that your child has been at risk of CJD or variant CJD disease. We therefore ask all patients undergoing any surgical procedure if they have been told that they are at increased risk of either of these forms of CJD. This helps prevent the spread of CJD to the wider public. A positive answer will not stop your child’s procedure taking place, but enables us to plan his/her operation to minimise any risk of transmission to other patients.

2. **Photography, Audio or Visual Recordings**
   We ask for your permission to use images and recordings for your child’s diagnosis and treatment; they will form part of your child’s medical record. We also ask for your permission to use these images for audit and in training medical and other healthcare staff and UK medical students; you do not have to agree and if you prefer not to, this will not affect the care and treatment we provide. We will ask for your separate written permission to use any images or recordings in publications or research.
3 Students in training

Training doctors and other health professionals is essential to the NHS. Your child’s treatment may provide an important opportunity for such training, where necessary under the careful supervision of a registered professional. You may, however, prefer not to take part in the formal training of medical and other students without this affecting your child’s care and treatment.

4 Use of Tissue

As a leading biomedical research centre and teaching hospital, we may be able to use tissue not needed for your child’s treatment or diagnosis to carry out research, for quality control or to train medical staff for the future. Any such research, or storage or disposal of tissue, will be carried out in accordance with ethical, legal and professional standards. In order to carry out such research we need your consent. Any research will only be carried out if it has received ethical approval from a Research Ethics Committee. You do not have to agree and if you prefer not to, this will not in any way affect the care and treatment we provide. The leaflet ‘Donating tissue or cells for research’ gives more detailed information. Please ask for a copy.

If you wish to withdraw your consent on the use of tissue (including blood) for research, please contact our Patient Advice and Liaison Service (PALS), on 01223 216756.
Cleft palate repair (with or without grommet insertion)

**A** Patient’s side  left  /  right  or  N/A

Consultant or other health professional responsible for your care

Name and job title: ........................................

☐ Any special needs of the patient (e.g. help with communication)? ........................................

Please use ‘Procedure completed’ stamp here on completion:

**B** Statement of health professional (details of treatment, risks and benefits)

1 I confirm I am a health professional with an **appropriate knowledge of the proposed procedure**, as specified in the hospital’s consent policy. I have explained the procedure to the patient. In particular, I have explained:

   a) the intended benefits of the procedure (please state)
      Improve palate function- eating and speech
      Improve hearing

   b) the possible risks involved. Addenbrooke’s always ensures any risks are minimised. However all procedures carry some risk and I have set out below any significant, unavoidable or frequently occurring risks including those specific to the patient
      Infection, pain, swelling and bruising, scar
      Bleeding, haematoma, need to return to theatre
      Wound healing problem- fistula,
      Risk of anaesthetics
      Velopharyngeal insufficiency, need for further treatment to improve speech and eating
      Breathing problem: obstructive sleep apnoea, snoring, need for nasopharyngeal airway
      Tympanic membrane perforation or tympanosclerosis (grommets)

   c) what the treatment or procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient:
Cleft palate repair (with or without grommet insertion)

d) any extra procedures that might become necessary during the procedure such as:
   □ Blood transfusion   □ Other procedure (please state)

2 The following information leaflet has been provided:
   Cleft palate repair (with or without grommet insertion)

   Version, reference and date:   Version 1, 101226, July 2019
   or   □ I have offered the patient information about the procedure but this has been declined.

3 This procedure will involve:
   □ General and/or regional anaesthesia   □ Local anaesthesia   □ Sedation   □ None

Signed (Health professional):   Date:   D D / M M / Y Y  Y Y

Name (PRINT):   Time (24hr):   H H : M M

Designation:   Contact/bleep no:

C Consent of patient / person with parental responsibility

I confirm that the risks, benefits and alternatives of this procedure have been discussed
with me and that my questions have been answered to my satisfaction and understanding.

Important: please read the patient information about this procedure and then put a
tick in the relevant boxes for the following questions:

1 Creutzfeldt Jakob disease (CJD)
   Have you ever been notified that you are at risk of CJD or variant CJD
   for public health purposes? If yes, please inform your health professional.
   □ Yes   □ No

2 Photography, Audio or Visual Recording
   a) I agree to the use of any of the above type of recordings for the purpose
      of diagnosis and treatment.
   □ Yes   □ No

   b) I agree to unidentified versions of any of the above recordings being used
      for audit and medical teaching in a healthcare setting.
   □ Yes   □ No

3 Students in training
   I agree to the involvement of medical and other students as part
   of their formal training.
   □ Yes   □ No
**Consent Form**

**Cleft palate repair (with or without grommet insertion)**

4 **Use of Tissue**
   a) I agree that tissue (including blood) not needed for my own diagnosis or treatment can be used and stored for ethically approved research which may include ethically approved genetic research.
   
   b) Where additional clinical information is needed for the purposes of ethically approved research, I agree that relevant sections of my medical record may be looked at by researchers or by relevant regulatory authorities. I give permission for these individuals to have access to my records.

☐ Yes ☐ No

I have listed below any procedures that I do not wish to be carried out without further discussion.

I have read and understood the Patient Information about this procedure and the above additional information. I agree to the procedure or treatment.

Signed (Patient): ____________________________ Date: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Name of patient (PRINT): ____________________________

If signing for a child or young person; delete if not applicable.

I confirm I am a person with parental responsibility for the patient named on this form.

Signed: ____________________________ Date: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Relationship to patient:

If the patient is unable to sign but has indicated his/her consent, a witness should sign below.

Signed (Witness): ____________________________ Date: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Name of witness (PRINT): ____________________________

Address: ____________________________

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Confirmation of consent
(Where the treatment/procedure has been discussed in advance)
On behalf of the team treating the patient, I have confirmed with the patient that she/he has no further questions and wishes the treatment/procedure to go ahead.

Signed (Health professional): ........................................... Date: ...D.D./M.M./Y.Y.Y.Y...

Name (PRINT): ........................................................................ Job title: ..............................................................

Please initial to confirm all sections have been completed: ..............................................................

Interpreter’s statement (if appropriate)
I have interpreted the information to the best of my ability, and in a way in which I believe the patient can understand:

Signed (Interpreter): ............................................................ Date: ...D.D./M.M./Y.Y.Y.Y...

Name (PRINT): ........................................................................

Or, please note the language line reference ID number:

Withdrawal of patient consent
☐ The patient has withdrawn consent (ask patient to sign and date here)

Signed (Patient): ................................................................. Date: ...D.D./M.M./Y.Y.Y.Y...

Signed (Health professional): ............................................... Date: ...D.D./M.M./Y.Y.Y.Y...

Name (PRINT): ........................................................................ Job title: ..............................................................