Patient information and consent to cleft lip repair (with or without nasal correction and/or vomerine flap)

Key messages for patients

- 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 596272 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.

All information we hold about your child is stored according to the Data Protection Act 1998.
Important things you need to know
Patient choice is an important part of your child’s 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 your child is having an anaesthetic, you will have the opportunity to discuss this with the anaesthetist.

We will only carry out the procedure on your consent form unless, in the opinion of the health professional responsible for your child’s care, a further procedure is needed in order to save your child’s life or prevent serious harm to his/her health.

About cleft lip repair (with or without nasal correction and/or vomerine flap)
Cleft lip repair involves bringing the edges of the mouth muscles and skin across the cleft to close the gap, and repairing these using stitches. This allows normal lip function in feeding and speech.

Occasionally it is necessary to perform extra procedures at the same time to get the best result for your baby. These may include nasal correction if there is asymmetry of the nose, which involves adjusting the position and holding it in place with buried stitches. Sometimes a splint may be placed inside the nose and stitched to hold the nose in its new position.

If the cleft goes through the lip to the inside of the mouth, we may have to perform a procedure alongside the lip repair called a vomerine flap. This involves moving the lining of the bone inside the mouth to close the floor of the nose and create an intact hard palate.

The alternative option is not to treat the cleft. This will mean the appearance and function will remain as it is. This can lead to difficulties as your child develops with their speech, feeding, appearance and position of the teeth.

Intended benefits
- Improve the function of the lip and mouth.
- Improve symmetry and normalise appearance.

Who will perform my 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.

Before your 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.
Patient Information

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

On the day of the procedure we will 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 they lose 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 explain to you the benefits and risks from a blood transfusion. Your doctor can also give you information about whether there are suitable alternatives to blood transfusion for your treatment. There is a patient information leaflet for blood transfusion available for you to read.

During the cleft lip repair (with or without nasal correction and/or vomerine flap)

The surgery usually takes two to three hours depending on the cleft, but your baby will be in the theatres for half a day. This includes the time for the anaesthetic and recovery time. The recovery team will contact you when your baby is awake.

After the cleft lip repair (with or without nasal correction and/or vomerine flap)

Once the surgery is completed your baby will usually be transferred to the recovery ward where they will be looked after by specially trained nurses, under the direction of the anaesthetist. Your baby may be given oxygen via a facemask, fluids via their drip and pain relief until they are comfortable enough to return to your ward. Once your baby is awake the nurse will contact you to come to the recovery ward.

There may be some bleeding from the mouth or nose and you may see some stitches and dried glue on the lip. This is normal after this type of surgery. Your baby will have a cannula (a very small, flexible tube which is placed into a vein) in an arm or leg to enable them to be given medication and fluids (drip) after 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). These are areas where your baby will be monitored more closely because of the nature of their operation or because of certain pre-existing health problems they 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 what to 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.

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**Eating and drinking.** Your baby can feed when they are fully awake. You may breastfeed or bottle feed your baby in the recovery room.

**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 their general health, how quickly they are recovering and your doctor’s opinion. If the cleft is small or if the surgery is in the morning and your baby is feeding well, you may be discharged the same day.

**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: hypertrophic (red and raised initially), keloid (raised beyond the original scar), stretched, and/or scar contracture (shortening).
- Risk of anaesthetic.

Specific risks associated with this operation:

- Asymmetry. We will aim to achieve symmetry of the lip as much as possible. However, it is common to have some asymmetry after the operation due to differences in the amount of skin, tissue and bone available in the cleft. Any major asymmetry may require revisional surgery at a later date.

- 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.

**Anaesthesia**

Anaesthesia means ‘loss of sensation’. There are three types of anaesthesia: general, regional and local. The type of anaesthesia chosen by your anaesthetist depends on the nature of your surgery as well as your health and fitness.

When you arrive in the theatre or anaesthetic room and before starting anaesthesia, the medical team will perform a check of 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. The anaesthetist will monitor the condition, administer the right amount of anaesthetic drugs, and watch the need for fluid or blood replacement.

**What will my baby feel like afterwards?**

Most people will feel fine after their operation. Some people 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 of these symptoms if they occur.

**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 you have 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 procedure taking place, but enables us to plan your 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 diagnosis and treatment; they will form part of your 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 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 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 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.

We are a smoke-free site: smoking will not be allowed anywhere on the hospital site. For advice and support in quitting, contact your GP or the free NHS stop smoking helpline on 0800 169 0 169.

Other formats:

If you would like this information in another language or audio, please contact Interpreting services on telephone: 01223 348043, or email: interpreting@addenbrookes.nhs.uk For Large Print information please contact the patient information team: patient.information@addenbrookes.nhs.uk.
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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 function and symmetry

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: painkillers will be provided to minimize pain after the surgery

Bleeding, haematoma, wound healing problem, need to return to theatre: to stop bleeding or if wound complications require further surgery to help wound healing

Swelling and bruising

Scar – hypertrophic, keloid, stretched, shortening, asymmetry

Risk of anaesthetics

Need for revisional surgery

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:
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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:

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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
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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.

☐ Yes ☐ No

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: D.D./M.M./Y.Y.Y.Y.
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: D.D./M.M./Y.Y.Y.Y.
Relationship to patient:

If the patient is unable to sign but has indicated his/her consent, a witness should sign below.
Signed (Witness): .................................................................. Date: D.D./M.M./Y.Y.Y.Y.
Name of witness (PRINT): .................................................................
Address: ..............................................................................
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D Confirmation of consent

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:

E 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:

F 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: .................................................................

Patient safety – at the heart of all we do

Addenbrooke’s Hospital | Rosie Hospital

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