Patient information and consent to open cavity mastoidectomy

Key messages for patients

- Please read your admission letter carefully. It is important to follow the instructions we give you about not eating or drinking or we may have to postpone or cancel your 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 when you are admitted for surgery. You will have an opportunity to ask any questions from the surgeon or anaesthetist when you are admitted. You may sign the consent form either before you come or when you are admitted.

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

- Laxatives and painkillers may be required after your hospital stay; please ensure you have appropriate supplies at home.

- Take your medications as normal on the day of the procedure unless you have been specifically told not to take a drug or drugs before or on the day by a member of your medical team. If you have diabetes please ask for specific individual advice to be given on your medication at your pre-operative assessment appointment.

- Please call the otology nurse practitioner on telephone number 01223 348672 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. 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.

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About open cavity mastoidectomy: How does the ear work?

The ear consists of the outer, middle and inner ear. The outer ear is covered by skin. The middle ear is covered by a mucus producing membrane. Sound travels through the outer ear and reaches the eardrum, causing it to vibrate. The vibration is transmitted through three tiny bones (ossicles) in the middle ear. The vibration then enters the inner ear where the nerve cells are. The nerve cells within the inner ear are stimulated to produce nerve signals. These nerve signals are carried to the brain, where they are interpreted as sound.

What is the mastoid bone?

The mastoid bone is the bony prominence that can be felt just behind the ear. It contains a number of air spaces, the largest of which is called the antrum. It connects with air space in the middle ear. Ear diseases in the middle ear can extend into the mastoid bone.

Why is open cavity mastoidectomy done?

Operations on the mastoid may be necessary when an ear infection within the middle ear extends into the mastoid. Most commonly this is a pocket of skin growing from the outer ear into the middle ear, known as cholesteatoma. This causes infection with discharge and some hearing loss. The pocket gets slowly larger, often over a period of many years, and causes gradual erosion of surrounding structures. Erosion of the ossicles can result in hearing loss. The only effective way to get rid of this pocket of skin is surgery.

You may change your mind about the operation at any time, and signing a consent form does not mean that you have to have the operation.

If you would like to have a second opinion about the treatment, you can ask your specialist. He or she will not mind arranging this for you. You may wish to ask your own GP to arrange a second opinion with another specialist.

Intended benefits

The chances of obtaining a dry, trouble free ear from this operation by experienced surgeons are over 80 percent. In some patients it is possible to improve the hearing as well. You should enquire from your surgeon the likelihood of success in your particular case.
If you have an operation in which the ear canal is preserved, it may be necessary to perform a second operation a year after the first to check there is no disease left behind.

Who will perform my procedure?
This procedure will be performed by a member of the Ear, Nose and Throat medical team with suitable experience.

Before your procedure
Most patients attend a pre-admission clinic, when you will meet a nurse practitioner. At this clinic, we will ask for details of your 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 at any time.

We will ask if you take any tablets or use any other types of medication either prescribed by a doctor or bought over the counter in a pharmacy. Please bring all your medications and any packaging (if available) with you. Please tell the ward staff about all of the medicines you use. If you wish to take your medication yourself (self-medicate), please ask your nurse. Pharmacists visit the wards regularly and can help with any medicine queries.

This procedure involves the use of general anaesthesia. We explain about the different types of anaesthesia or sedation we may use at the end of this leaflet. You will see an anaesthetist before your procedure.

Most people who have this type of procedure will need to stay in hospital for one night. Sometimes we can predict whether you will need to stay for longer than usual – your doctor will discuss this with you before you decide to have the procedure.

Hair removal before an operation
For most operations, you do not need to have the hair around the site of the operation removed. However, sometimes the healthcare team need to see or reach your skin and if this is necessary they will use an electric hair clipper with a single-use disposable head, on the day of the surgery. Please do not shave the hair yourself or use a razor to remove hair, as this can increase the risk of infection. Your healthcare team will be happy to discuss this with you.

During the procedure
Usually a general anaesthetic is used. There are several ways of doing this operation, depending on the extent of the ear disease. They have various names such as atticotomy, combined approach tympanoplasty and modified radical mastoidectomy and it takes between one and three hours. They involve a cut either above the ear opening or behind the ear.

The bone behind the ear is removed but the ear canal is usually preserved (combined approach tympanoplasty). Occasionally, it is necessary to remove the back of the ear canal to leave a cavity which allows easy inspection (modified radical mastoidectomy).
The mastoid cavity is closed up with cartilage. At the end of the operation, packing will be placed in your ear while it heals.

**Does it hurt?**

The ear may ache a little but this can be controlled with painkillers provided by the hospital.

**After the procedure**

Once your surgery is completed you will usually be transferred to the recovery ward where you will be looked after by specially trained nurses, under the direction of your anaesthetist. The nurses will monitor you closely until the effects of any general anaesthetic have adequately worn off and you are conscious. They will monitor your heart rate, blood pressure and oxygen levels too. You may be given oxygen via a facemask, fluids via your drip and appropriate pain relief until you are comfortable enough to return to your ward.

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.** After this procedure, you will be able to drink sips of water when you return to the ward. After a couple of hours, you will be able to try to eat a light meal.

**Getting about after the procedure.** We will help you to become mobile as soon as possible after the procedure. This helps improve your recovery and reduces the risk of certain complications. If you have any mobility problems, we can arrange nursing or physiotherapy help.

**Leaving hospital.** Generally most people who have had this operation will be able to leave hospital the day after the procedure, after the head bandage has been removed. There is sometimes some dizziness but this usually settles quickly.

**Resuming normal activities including work.** Usually you can resume light activities after 24 hours. Normal activities can be resumed after two weeks. Your doctor will advise you on how quickly you can resume normal and more vigorous activity. You may need to take one to two weeks off work.
Special measures after the procedure:

- There may be a small amount of discharge from the ear canal. This usually comes from the ear dressings.
- Some of the packing may fall out. If this occurs there is no cause for concern. It is sensible to trim the loose end of packing with scissors and leave the rest in place. The packing in the ear canal will be removed in the ear, nose and throat (ENT) department after two or three weeks.
- You should keep your ear dry. Plug the ear with a cotton wool ball coated with Vaseline when you are having a shower or washing your hair.
- Avoid straining/lifting anything heavy for the first few weeks after surgery.
- Only blow the nose gently.
- Avoid air travel for two months.
- If the ear becomes more painful or swollen then you should consult the ENT department or your General Practitioner.

We will give you further information about any special measures you need to take after the procedure. We will also give you information about things to watch out for that might be early signs of problems (eg infection).

Check-ups and results: A follow up appointment will be sent to you in the post once you are discharged. You will need to attend the ENT Department occasionally for the follow up of your ear for up to five years after the operation.

Significant, unavoidable or frequently occurring risks of this procedure

There are some risks that you must be aware of before giving consent to this treatment. These potential complications are rare. You should consult your surgeon about the likelihood of problems in your case.

Loss of hearing
In a small number of patients the hearing may be further impaired due to damage to the inner ear. If the disease has eroded into the inner ear, there may be total loss of hearing in that ear.

Dizziness
Dizziness is common for a few hours following mastoid surgery and may result in nausea and vomiting. On rare occasions, dizziness is prolonged.

Tinnitus
Sometimes the patient may notice noise in the ear, in particular if the hearing loss worsens.

Weakness of the face
The nerve that controls movement of the muscles in the face runs inside the ear and may be damaged during the operation, but this risk is rare. If it happens, the face may lose its movement on one side but it is usually temporary.
Taste disturbance
The taste nerve runs close to the eardrum and may occasionally be damaged. This can cause an abnormal taste on one side of the tongue. This is usually temporary but it can be permanent in one in ten patients.

Reaction to ear dressings
Occasionally the ear may develop an allergic reaction to the dressings in the ear canal. If this happens, the pinna (outer ear) may become swollen and red. You should consult your surgeon so that he can remove the dressing from your ear. The allergic reaction should settle down after a few days.

General risks associated with all major operations and from being hospitalised: eg bleeding, infection, blood clots.

Alternative procedures that are available
The only way to remove the infection completely is a mastoid operation. In patients who are unfit for surgery, the only alternative is the regular cleaning of the ear by a specialist and the use of antibiotic eardrops. This at best could only reduce the discharge.

If you have any further questions, please contact the Otology nurse practitioner on 01223 348672.

Information and support
Please contact the otology nurse practitioner on telephone number 01223 348672 if you have any further queries.

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. Sometimes different types of anaesthesia are used together.

Before your operation
Before your operation you will meet an anaesthetist who will discuss with you the most appropriate type of anaesthetic for your operation, and pain relief after your surgery. To inform this decision, he/she will need to know about:

- your general health, including previous and current health problems
- whether you or anyone in your family has had problems with anaesthetics
- any medicines or drugs you use
- whether you smoke
- whether you have had any abnormal reactions to any drugs or have any other allergies
- your teeth, whether you wear dentures, or have caps or crowns.
Your anaesthetist may need to listen to your heart and lungs, ask you to open your mouth and move your neck and will review your test results.

**Pre-medication**
You may be prescribed a ‘premed’ prior to your operation. This is a drug or combination of drugs which may be used to make you sleepy and relaxed before surgery, provide pain relief, reduce the risk of you being sick, or have effects specific for the procedure that you are going to have or for any medical conditions that you may have. *Not all patients will be given a premed or will require one and the anaesthetist will often use drugs in the operating theatre to produce the same effects.*

**Moving to the operating room or theatre**
You will usually change into a gown before your operation and we will take you to the operating suite. When you arrive in the theatre or anaesthetic room and *before starting your anaesthesia, the medical team will perform a check of your name, personal details and confirm the operation you are expecting.*

Once that is complete, monitoring devices may be attached to you, such as a blood pressure cuff, heart monitor (ECG) and a monitor to check your oxygen levels (a pulse oximeter). An intravenous line (drip) may be inserted. If a regional anaesthetic is going to be performed, this may be performed at this stage. If you are to have a general anaesthetic, you may be asked to breathe oxygen through a face mask.

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 you are put into a state of unconsciousness and you will be unaware of anything during the time of your operation. Your anaesthetist achieves this by giving you a combination of drugs.

While you are unconscious and unaware your anaesthetist remains with you at all times. He or she monitors your condition and administers the right amount of anaesthetic drugs to maintain you at the correct level of unconsciousness for the period of the surgery. Your anaesthetist will be monitoring such factors as heart rate, blood pressure, heart rhythm, body temperature and breathing. He or she will also constantly watch your need for fluid or blood replacement.

**Regional anaesthesia**
Regional anaesthesia includes epidurals, spinals, caudals or local anaesthetic blocks of the nerves to the limbs or other areas of the body. Local anaesthetic is injected near to nerves, numbing the relevant area and possibly making the affected part of the body difficult or impossible to move for a period of time.
Regional anaesthesia may be performed as the sole anaesthetic for your operation, with or without sedation, or with a general anaesthetic. Regional anaesthesia may also be used to provide pain relief after your surgery for hours or even days. Your anaesthetist will discuss the procedure, benefits and risks with you and, if you are to have a general anaesthetic as well, whether the regional anaesthesia will be performed before you are given the general anaesthetic.

What will I feel like afterwards?

How you will feel will depend on the type of anaesthetic and operation you have had, how much pain relieving medicine you need and your general health. 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. You may have fewer of these effects after local or regional anaesthesia although when the effects of the anaesthesia wear off you may need pain relieving medicines.

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

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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

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  
As a leading teaching hospital we take great pride in our research and staff training. 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 bio-medical 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.

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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.

**Privacy & dignity**

Same sex bays and bathrooms are offered in all wards except critical care and theatre recovery areas where the use of high-tech equipment and/or specialist one to one care is required.

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**Other formats:**

If you would like this information in another language, large print or audio, please ask the department where you are being treated, to contact the patient information team: patient.information@addenbrookes.nhs.uk.

Please note: We do not currently hold many leaflets in other languages; written translation requests are funded and agreed by the department who has authored the leaflet.

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**Document history**

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Consultant or other responsible health professional

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)
   - Remove middle ear disease
   - Provide a dry and safe ear

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
   - Bleeding
   - Infection
   - Pain
   - Numbness of ear
   - Scar
   - Facial weakness
   - Altered taste
   - No hearing improvement
   - Reduced hearing
   - Loss of hearing
   - Tinnitus
   - Dizziness
   - Ear dressing reaction

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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If any extra procedures that might become necessary during the procedure such as:

☐ Blood transfusion  ☐ Other procedure (please state)

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.

☐ 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:

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. Medical Training
   I agree to the involvement of trainee medical and other students as part of their formal training.

   ☐ Yes  ☐ No
Consent Form

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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: __/__/_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: __/__/_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: __/__/_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. 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:

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 (Health professional): ........................................... Date: ....D. D. / .M. M. / . Y. Y. Y. Y.
Name (PRINT): ................................................................. Job title: .................................................................