Patient Information

Patient information and consent to laparoscopic cholecystectomy

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 one of the hepatobiliary (HPB) specialist nurses on telephone number 01223 256147 if you have any questions or concerns about this procedure.

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 Laparoscopic cholecystectomy, CF142, V7, January 2017
About laparoscopic cholecystectomy

This is an operation to remove the gall bladder using key-hole surgical techniques. The gall bladder is being removed because it is giving you pain due to gallstones. These small stones form in the gall bladder and can cause a range of problems including pain, jaundice, infection and pancreatitis. Gallstones are very common but do not always cause symptoms. Gallstones that are not causing trouble can usually be left alone.

Your liver has many functions, one of which is to produce a substance called bile. This green liquid drains from the liver to the intestine via the bile duct. The gall bladder is a small reservoir attached to the side of the bile duct. The small amount of bile produced while we are not eating can be stored and concentrated here between meals. When we eat particularly fatty foods, the liver makes more bile and the gall bladder also contracts and empties this extra stored bile into the bile duct. It then travels to the intestine to mix with the food. Bile has many functions, one of which is to allow us to absorb fat. The gall bladder sits just under the liver, which is in the right upper part of the abdomen, just under the ribs.

We can manage without the gall bladder. Very rarely, patients notice that their bowels are a little looser than before the operation. You will be able to eat a normal diet after your operation, assuming that there is nothing else wrong with you.

Intended benefits

Removing the gallstone will prevent the pain that you are getting from gallstones.

Who will perform my procedure?

This procedure will be performed by a team of surgeons who have the appropriate experience.

Before your procedure

Most patients attend an outpatient clinic, when you will meet a senior member of the surgical staff who will explain all the options to you in detail. If you have been recently discharged from the hospital you may not need to be seen again in the clinic. Most patients would also attend a pre-admission clinic, where you will meet a member of pre-assessment nursing staff. 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 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 be able to go home a few hours after the operation. 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.

During surgery, you may lose blood. If you lose a considerable amount of blood your doctor may want to replace the loss with a blood transfusion as significant blood loss can cause you harm. The blood transfusion can involve giving you other blood components such as plasma and platelets which are necessary for blood clotting. Your doctor will only give you a transfusion of blood or blood components during surgery, or recommend for you to have a transfusion after surgery, if you need it.

Compared to other everyday risks the likelihood of getting a serious side effect from a transfusion of blood or blood component is very low. 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 procedure**

Four small holes (about 1cm long each) are made in the abdominal wall (tummy). Through these, special long instruments are used to free up the gall bladder with its stones from underneath the liver and it is completely removed. This is all visualised on a TV screen by a miniature camera inserted through one of the four key-holes. During the procedure a small tube will usually be inserted into the bile duct allowing the surgeon to take an x-ray. This is to make sure of the anatomy and also to exclude the presence of any bile duct stones which would require additional treatment.

A soft plastic drainage tube (a drain) is occasionally placed in the abdomen via one of the small holes to allow fluid to drain away from the operation site for the first few hours after the operation.

**How is this different from the traditional operation for gall bladder problems?**

The actual operation is the same. The only thing that differs is the way in which we Laparoscopic cholecystectomy, CF142, V7, January 2017
get to the gall bladder to remove it. Traditionally, we make a small cut underneath the ribs (10-15 cm long). This takes longer to heal than the four little holes of key-hole surgery and the recovery is slower.

Is there a guarantee that this operation can be carried out using key-hole surgery?

No, there is no guarantee that the operation can be completed by key-hole surgery. If there is some technical difficulty with removing the gall bladder then a traditional cut would be needed to remove it. The time in hospital would be a little longer (two to three days) and the recovery at home would be between six to eight weeks. The risk of having to convert to open surgery is small, about one to three per cent.

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.

After certain major operations you 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 you will be monitored much more closely because of the nature of your operation or because of certain pre-existing health problems that you may have. If your surgeon or anaesthetist believes you should go to one of these areas after your 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.** You can eat and drink normally as soon as you are fully awake following the operation.

- **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. When you wake up from the anaesthetic, we will encourage you to move, sit up and get out of bed, do some deep breathing exercises, cough and be generally active. If you have any mobility problems, we can arrange nursing or physiotherapy help.

- **Leaving hospital.** Most people who have had this type of procedure under general anaesthetic will be able to go home a few hours following surgery. The actual time that you stay in hospital will depend on your general health,
how quickly you recover from the procedure and your doctor's opinion.

**Resuming normal activities including work.** It will then take 7 to 14 days to recover at home and most people are back to their normal activities within two to four weeks.

**Special measures after the procedure.** Sometimes, people feel sick after an operation, especially after a general anaesthetic, and might vomit. If you feel sick, please tell a nurse and you will be offered medicine to make you more comfortable.

Immediately after the operation there is some discomfort from the small cuts in the skin of the tummy but this is well controlled with simple pain-killers. All the wounds are closed with special dissolving stitches placed under the skin so that no stitches need to be removed.

We will give you more detailed 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 (for example infection).

**Check-ups and results.** Before you leave hospital, we will give you a date to return to clinic for the results of your surgery. At this time, we can check your progress and discuss any further treatment that may be recommended.

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

As with all operations there are small risks. These are assessed on an individual basis depending upon a patient’s fitness and this should be discussed with your specialist prior to surgery. However, overall this is a very safe operation.

There is a 1 in 400 risk of an injury to the bile duct, which will need further procedures or operations to repair the damage.

There is a small risk of bleeding, infection and hernia formation following this procedure.

Peripheral nerve injury due to prolonged immobilisation.

In the event of a stone or stones being found in the bile duct (4% risk), further procedures will be required.

There is a 1 to 3% risk of the key-hole operation being converted to an open traditional gallbladder operation and the chances of this happening are higher in complex cases and in those patients who have had previous surgery.

Like any other operation, complications such as infection, bleeding, chest infections, Laparoscopic cholecystectomy, CF142, V7, January 2017
adhesions, hernia, deep vein thrombosis (DVT) and pulmonary embolus (PE) can occur.

In the longer term, there is 15-20% incidence of persistence of pain or discomfort following the removal of the gall bladder. This is more likely to happen if there was any uncertainty regarding the gall bladder being the actual cause of the pain prior to the operation. If your symptoms persists after two to three months after surgery please contact your GP.

**Alternative procedures that are available**

Unfortunately there is no non-surgical alternative; the only successful treatment is to remove the gall bladder and gallstones completely. The results of this operation are very good and most patients can then return to eating a normal diet.

**Information and support**

We might give you some additional patient information before or after the procedure, for example leaflets that explain what to do after the procedure and what problems to look out for. If you have any questions or anxieties, please feel free to ask a member of the surgical team. They would be pleased to answer any queries you might have including the more detailed technical aspects of this procedure.

If you have further questions please contact one of the HPB specialist nurses, on 01223 256147. Outside normal working hours, please contact ward C7 on 01223 217300 and ask to speak to the nurse in charge.

**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.

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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.

**Local anaesthesia**

In local anaesthesia the local anaesthetic drug is injected into the skin and tissues at the site of the operation. The area of numbness will be restricted. Some sensation of pressure may be present, but there should be no pain. Local anaesthesia is used for minor operations such as stitching a cut, but may also be injected around the surgical site to help with pain relief. Usually a local anaesthetic will be given by the doctor doing the operation.

**Sedation**

Sedation is the use of small amounts of anaesthetic or similar drugs to produce a ‘sleepy-like’ state. Sedation may be used as well as a local or regional anaesthetic. The anaesthesia prevents you from feeling pain and the sedation makes you drowsy. Sedation also makes you physically and mentally relaxed during an investigation or procedure which may be unpleasant or painful (such as an endoscopy) but where your co-operation is needed. You may remember a little about what happened but often you will remember nothing. Sedation may be used by other professionals as well as anaesthetists.

**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
- 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
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. 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.

We are now 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, 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.
Removing the gallstone will prevent the pain that you are getting from gallstones.

Full details are set out in the information leaflet and include:

- bleeding
- infections
- Injury to bowel, bile duct and blood vessels
- bile leak
- hernia from port sites
- clot in legs (DVT: deep vein thrombosis)
- clot in lungs (PE: pulmonary embolus)
- peripheral nerve injury due to prolonged immobilisation

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:
Consent Form

Laparoscopic cholecystectomy

d) 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:

Laparoscopic cholecystectomy

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or ☐ I have offered the patient information about the procedure but this has been declined.

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:

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

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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.

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.

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: ...........................................

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: ..............................................

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: ..............................................

Signed (Health professional): ........................................ Date: .............................................

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

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