



Queensland
Government

Cholangiogram (Percutaneous Transhepatic) with or without Biliary Drain/Stent Consent

Facility:

(Affix identification label here)

URN:

Family name:

Given name(s):

Address:

Date of birth:

Sex: ☐ M ☐ F ☐ I

A. Does the patient have capacity to provide consent?

Complete for ADULT patient only

☐ Yes → **GO TO section B**

☐ No → **COMPLETE section A**

You must adhere to the Advance Health Directive (AHD), or if there is no AHD, the consent obtained from a substitute decision-maker in the following order: Category 1. Tribunal-appointed guardian; 2. Enduring Power of Attorney; or 3. Statutory Health Attorney.

Name of substitute decision-maker:

Category of substitute decision-maker:

Complete for CHILD/YOUNG PERSON patient only

☐ Yes Although the patient is a child/young person, the patient may be capable of giving informed consent and having sufficient maturity, understanding and intelligence to enable them to fully understand the nature, consequences and risks of the proposed procedure and the consequences of non-treatment – 'Gillick competence' (*Gillick v West Norfolk and Wisbech Area Health Authority* [1986] AC 112)
→ **GO TO section B**

☐ No Parent/legal guardian/other person* with parental rights and responsibilities to provide consent and complete this form
→ **COMPLETE section A**

*Formal arrangements, such as parenting/custody orders, adoption, or other formally recognised carer/guardianship arrangements. Refer to the Queensland Health 'Guide to Informed Decision-making in Health Care' and local policy and procedures. Complete the source of decision-making authority as applicable below.

If applicable, source of decision-making authority (*tick one*):

☐ Court order → ☐ Court order verified

☐ Legal guardian → ☐ Documentation verified

☐ Other person → ☐ Documentation verified

Name of parent/legal guardian/other person:

Relationship to child/young person:

B. Is an interpreter required?

☐ Yes ☐ No

If yes, the interpreter has:

☐ provided a sight translation of the informed consent form in person

☐ translated the informed consent form over the telephone

It is acknowledged that a verbal translation is usually a summary of the text on the form, rather than word-by-word translation.

Name of interpreter:

Interpreter code:

Language:

C. Patient OR substitute decision-maker OR parent/legal guardian/other person confirms the following procedure(s)

I confirm that the referring doctor/clinician has explained that I have been referred for the following procedure:

Cholangiogram (percutaneous transhepatic): ☐ Yes ☐ No

Biliary drain: ☐ Yes ☐ No

Biliary stent: ☐ Yes ☐ No

Site/side of procedure:

Name of referring doctor/clinician:

D. Risks specific to the patient in having a cholangiogram (percutaneous transhepatic) with or without biliary drain/stent

(Doctor/clinician to document additional risks not included in the patient information sheet):

E. Risks specific to the patient in *not* having a cholangiogram (percutaneous transhepatic) with or without biliary drain/stent

(Doctor/clinician to document specific risks in not having a cholangiogram (percutaneous transhepatic) with or without biliary drain/stent):

F. Alternative procedure options

(Doctor/clinician to document alternative procedure not included in the patient information sheet):



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G. Information for the doctor/clinician

The information in this consent form is not intended to be a substitute for direct communication between the doctor/clinician and the patient *OR* substitute decision-maker *OR* parent/legal guardian/other person.

I have explained to the patient *OR* substitute decision-maker *OR* parent/legal guardian/other person the contents of this form and am of the opinion that the information has been understood.

Name of doctor/clinician:

Designation:

Signature:

Date:

H. Patient *OR* substitute decision-maker *OR* parent/legal guardian/other person consent

I acknowledge that the doctor/clinician has explained:

- the 'Cholangiogram (Percutaneous Transhepatic) with or without Biliary Drain/Stent' patient information sheet
- the medical condition and proposed treatment, including the possibility of additional treatment
- the specific risks and benefits of the procedure
- the prognosis, and risks of not having the procedure
- alternative procedure options
- that there is no guarantee the procedure will improve the medical condition
- that tissues/blood may be removed and used for diagnosis/management of the condition
- that if a life-threatening event occurs during the procedure:
 - an adult patient will be treated based on documented discussions (e.g. AHD or ARP [Acute Resuscitation Plan])
 - a child/young person's health care will be provided in accordance with good clinical practice and in the best interests of the patient
- that a doctor/clinician other than the consultant/specialist may assist with/conduct the clinically appropriate procedure; this may include a doctor/clinician undergoing further training under supervision
- that if the doctor/clinician wishes to record video, audio or images during the procedure where the recording is not required as part of the treatment (e.g. for training or research purposes), I will be asked to sign a separate consent form. If I choose not to consent, it will not adversely affect my access, outcome or rights to medical treatment in any way.

I was able to ask questions and raise concerns with the doctor/clinician.

I understand I have the right to change my mind regarding consent at any time, including after signing this form (*this should be in consultation with the doctor/clinician*).

I/substitute decision-maker/parent/legal guardian/other person have received the following consent and patient information sheet(s):

- ☐ 'Cholangiogram (Percutaneous Transhepatic) with or without Biliary Drain/Stent'
- ☐ 'About Your Anaesthetic' (*Adult patient only*)
- ☐ 'About Your Child's Anaesthetic' (*Child/young person patient only*)

On the basis of the above statements,

1) I/substitute decision-maker/parent/legal guardian/other person consent to having a cholangiogram (percutaneous transhepatic) with or without biliary drain/stent.

Name of patient/substitute decision-maker/parent/legal guardian/other person:

Signature:

Date:

If the patient is a child/young person:

- ☐ I am not aware of any legal or other reason that prevents me from providing unrestricted consent for this child/young person for this procedure (*not applicable if the child/young person is Gillick competent and signs this form*).

2) Student examination/procedure for professional training purposes:

For the purpose of undertaking training, a clinical student(s) may observe medical examination(s) or procedure(s) and may also, subject to patient *OR* substitute decision-maker *OR* parent/legal guardian/other person consent, assist with/conduct an examination or procedure on a patient while the patient is under anaesthetic.

I/substitute decision-maker/parent/legal guardian/other person consent to a clinical student(s) undergoing training to:

- observe examination(s)/procedure(s) ☐ Yes ☐ No
- assist with examination(s)/procedure(s) ☐ Yes ☐ No
- conduct examination(s)/procedure(s) ☐ Yes ☐ No

Cholangiogram (Percutaneous Transhepatic) with or without Biliary Drain/Stent

Adult and Child/Young Person | Informed consent: patient information

A copy of this patient information sheet should be given to the patient or substitute decision-maker or parent/legal guardian/other person of a child or young person to read carefully and allow time to ask any questions about the procedure. The consent form and patient information sheet should be included in the patient's medical record.

In this information sheet, the word 'you' means the patient unless a substitute decision-maker, parent, legal guardian or other person is providing consent on behalf of the patient, in which case the word 'you' means the substitute decision-maker, parent, legal guardian or other person when used in the context of the person providing consent to the procedure.



1. What is a cholangiogram (percutaneous transhepatic) with or without biliary drain/stent and how will it help me?

A **cholangiogram** is an x-ray procedure that can help to diagnose a blockage of the bile duct. Bile ducts are small tubes that carry bile from the liver to the gallbladder and small intestine. Iodinated contrast (also known as x-ray dye) is injected and x-ray images taken. The cholangiogram can provide a map of the ducts that can be used when planning further treatment.

Depending on your condition you may also require a biliary drain or stent to be inserted.

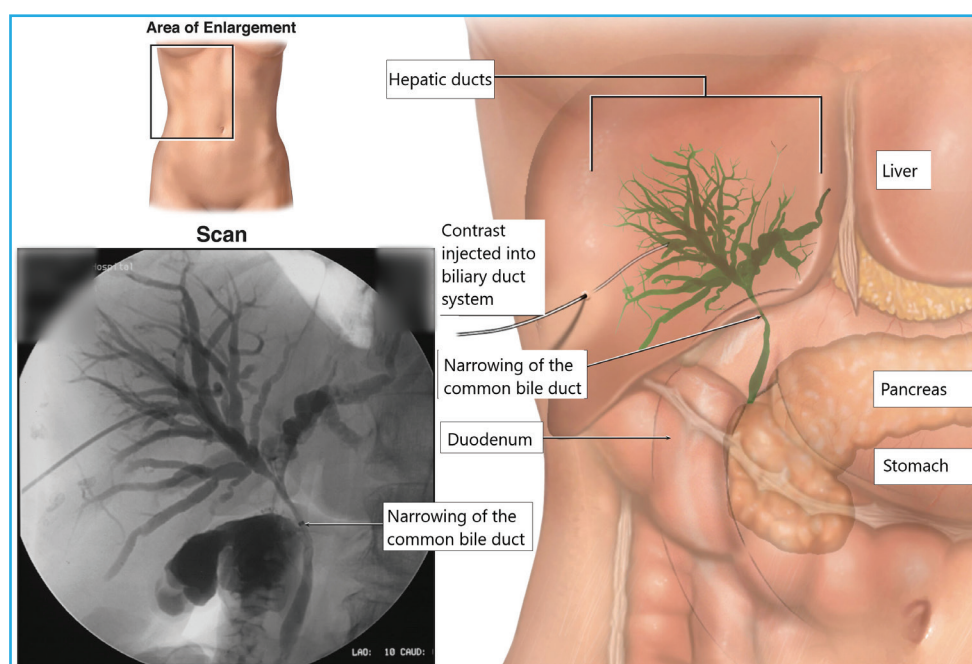


Image: Percutaneous transhepatic cholangiogram (adapted). Illustration Copyright © 2019 Nucleus Medical Media, All rights reserved. www.nucleusmedicalmedia.com

A **biliary drain** is a small flexible catheter (tube) that is inserted through the abdomen into the liver, and the bile ducts, to drain away your bile, this may relieve the pressure within the duct and any associated symptoms if there is a blockage. If a drain is recommended/required, the doctor/clinician will discuss how long you will need the drain.

A **biliary stent** is used instead of surgery to deal with a narrowed or blocked bile duct. It is an internal drainage tube placed in your bile duct to stop or to temporarily relieve an obstruction causing a blockage. This stent usually stays in for life.

The insertion of a biliary drain and/or a stent is done as an extra step to the cholangiogram procedure. This procedure is performed in the Medical Imaging department with guidance from imaging machines, such as ultrasound and x-ray.

Preparing for the procedure

The Medical Imaging department will give instructions on how to prepare for the procedure. It is important to follow the instructions that are given to you. Your procedure might be delayed if you don't follow all of the preparation steps.

Medical imaging staff will notify you beforehand if you are required to stop taking any blood thinning medicine. List or bring all your prescribed medicines, those medicines you buy over the counter, herbal remedies and supplements to show the doctor/clinician what you are taking.

This procedure will require the use of a local anaesthetic and possibly a mild sedation. If you received sedation and are being discharged on the same day, you cannot drive and you must have someone available to escort you home.

Do not drink alcohol, smoke, vape or take recreational drugs for at least 24 hours before the procedure as these may alter the effects of the sedation anaesthetic.

Please tell the doctor/clinician if you:

- are breastfeeding or pregnant, or suspect that you may be pregnant
- have a drug or medication dependence.

On the day of the procedure

- Nothing to eat or drink ('nil by mouth'): you will be told when to have your last meal and drink. Do NOT eat (including lollies), drink or chew gum after this time otherwise your procedure may be delayed or cancelled. This is to make sure your stomach is empty so that if you vomit, there will be nothing to go into your lungs.
- If you take medicines, most should be continued before a procedure and taken at the usual time, even on the day of the procedure, with a sip of water. There are some important exceptions:
 - your doctor/clinician will provide specific instructions about your medicines

- take to the hospital all your prescribed medicines, those medicines you buy over the counter, herbal remedies and supplements. This may include and is not limited to blood thinning medicines, the contraceptive pill, antidepressants and/or medicines for treating diabetes (e.g. insulin).
- If you feel unwell, telephone the Medical Imaging department for advice.
- Tell your doctor/clinician if you have:
 - health problems (e.g. diabetes, high blood pressure, infectious diseases, serious illnesses), including if undergoing regular treatment
 - had previous problems and/or known family problems with anaesthesia
 - false teeth, caps, loose teeth or other dental problems
 - allergies/intolerances of any type and their side effects.
- You will be required to change into a hospital gown and remove some of your jewellery.

Sedation

Sedation is the use of medicines that help make you feel relaxed and drowsy for your procedure. You may remember some or little about what has happened. You may still be aware of your surroundings and should be able to follow simple instructions, such as holding your breath when instructed by the doctor/clinician.

If a patient is unable to co-operate under sedation (for example a child or young person) a general anaesthetic may be required.

If you are booked for an anaesthetic or sedation, please read the information sheet *About Your Anaesthetic (for adults)* or *About Your Child's Anaesthetic (for child/young person)*. If you do not have one of these information sheets, please ask for one.

For a parent/legal guardian/other person of a patient having a cholangiogram (percutaneous transhepatic) with or without biliary drain/stent

To prepare the patient for this procedure and to ease their concerns, tell them what they can expect to happen during the procedure. This information sheet will assist you with this.

We welcome your help and support in preparing the patient for the procedure and in explaining why it's so important to lie still.

At the discretion of the procedure staff:

- a parent/adult (unless pregnant) may be invited into the procedure room to support the patient
- if the patient is having a general anaesthetic you may be able to see them off to sleep. Once they are asleep you will be asked to leave the procedure room and wait in the waiting area.

Other children are not allowed into the procedure room, and they must be supervised at all times by another parent/adult.

During the procedure

An intravenous (I.V.) cannula is a small plastic tube that will be inserted into a vein usually in your hand or arm. This is for medication or fluids required during the procedure, including sedation.

Routine observations, for example your blood pressure and heart rate, will be taken before the start of the procedure.

The skin around the procedure area will be cleaned and a sterile drape will be applied to cover your body. The doctor/clinician will use local anaesthetic to numb the skin and then make a small cut where the needle enters.

Using ultrasound as a guide the radiologist (doctor) will insert a needle through the skin into your liver and into the bile duct.

You must remain as still as possible. At times, you may be asked to hold your breath.

Once the needle is in the bile duct, the cholangiogram will be performed by injecting iodinated contrast into your bile ducts and taking x-ray images.

If required, a biliary stent may be inserted. This is done through the same cut in the skin and by sliding the stent over a wire that has passed through the narrowing in the bile duct.

If required, a biliary drain may be inserted into the bile duct. It will be connected to an external drainage bag to collect your bile.

The biliary drain may be sutured (stitched) to help keep it in place and a dressing applied.

The recovery time varies from 2 to 6 hours depending on the procedure and the anaesthetic used.

If the I.V. cannula is no longer required, it will be removed.



2. What are the risks?

In recommending the procedure, the doctor/clinician believes that the benefits to you from having the procedure exceed the risks involved. There are risks and possible complications associated with the procedure which can occur with all patients – these are set out below. There may also be additional risks and possible complications specific to your condition and circumstances which the doctor/clinician will discuss with you. If you have any further concerns, please ensure that you raise them with the doctor/clinician prior to giving consent to the procedure.

Common risks and complications

- minor pain, bruising and/or infection from the I.V. cannula
- bruising is more common if you have been taking blood thinning medicines, such as warfarin, aspirin, clopidogrel (Plavix), Iscover, Coplavix), prasugrel (Effient), dipyridamole (Persantin or Asasantin), ticagrelor (Brilinta), apixaban (Eliquis), dabigatran (Pradaxa), rivaroxaban (Xarelto) or complementary/alternative medicines, such as fish oil and turmeric
- pain or discomfort at the insertion site

- (*biliary drain only*) the catheter may become kinked or blocked. Sometimes it needs to be moved or replaced
- failure of local anaesthetic which may require a further injection of anaesthetic or a different method of anaesthesia.

Uncommon risks and complications

- infection, requiring antibiotics and further treatment
- damage to surrounding structures such as blood vessels, organs and muscles requiring further treatment
- excessive bleeding. This may require other procedures and/or corrective surgery
- an allergy to injected medications or contrast, requiring further treatment
- bile leak, this may require further treatment
- the procedure may not be possible due to medical and/or technical reasons.

Rare risks and complications

- skin burns or damage from exposure to x-rays
- seizures and/or cardiac arrest due to local anaesthetic toxicity
- death because of this procedure is very rare.

If general anaesthetic or sedation is given, extra risks include:

- faintness or dizziness, especially when you start to move
- fall in blood pressure
- nausea and vomiting
- weakness
- heart and lung problems, such as heart attack or pneumonia
- stroke resulting in brain damage.

Risks of radiation

The risks of radiation exposure from this procedure need to be compared to the risks of your condition not being treated. Exposure to radiation may cause a slight increase in the risk of cancer to you over your lifetime. However, the potential risk is small compared to the expected benefit of this procedure¹.

What are the risks of not having a cholangiogram (percutaneous transhepatic) with or without biliary drain/stent?

There may be adverse consequences for your health if you choose not to have the proposed procedure. Please discuss these with the referring doctor/clinician.

If you choose not to have the procedure, you will not be required to sign a consent form.

If you have signed a consent form, you have the right to change your mind at any time prior to the procedure. Please contact the doctor/clinician to discuss.



3. Are there alternatives?

Making the decision to have a procedure requires you to understand the options available. Please discuss any alternative procedure options with your doctor/clinician before signing the consent form.



4. What should I expect after the procedure?

Your healthcare team will talk to you about what to expect after your procedure and upon discharge from hospital.

You will be given a Patient Implant Card (PIC) for your records with the specific details of any implanted devices used. This information may be helpful for safety for any future Magnetic Resonance Imaging (MRI) scans.

If you had sedation, this will affect your judgement for about 24 hours. For your own safety:

- Do NOT drive any type of car, bike or other vehicle.
- Do NOT operate machinery including cooking equipment.
- Do NOT make important decisions or sign a legal document.
- Do NOT drink alcohol, smoke, vape or take recreational drugs. They may react with the anaesthetic medications.



5. Who will be performing the procedure?

Doctors, radiographers, nuclear medicine technologists, sonographers, nurses, and medical imaging assistants make up the medical imaging team. All or some of these professionals may be involved in your journey.

A doctor/clinician other than the consultant/specialist may assist with/conduct the clinically appropriate procedure. This could include a doctor/clinician undergoing further training, however all trainees are supervised according to relevant professional guidelines.

If you have any concerns about which doctor/clinician will be performing the procedure, please discuss this with the doctor/clinician.

For the purpose of undertaking professional training in this teaching hospital, a clinical student(s) may observe medical examination(s) or procedure(s) and may also, subject to your consent, assist with/conduct an examination or procedure on you while you are under anaesthetic.

You are under no obligation to consent to an examination(s) or a procedure(s) being undertaken by a clinical student(s) for training purposes. If you choose not to consent, it will not adversely affect your access, outcome or rights to medical treatment in any way.

For more information on student care, please visit www.health.qld.gov.au/consent/students.



6. Where can I find support or more information?

Hospital care: before, during and after is available on the Queensland Health website www.qld.gov.au/health/services/hospital-care/before-after where you can read about your healthcare rights.

You can also see a list of blood thinning medications at www.health.qld.gov.au/consent/bloodthinner.

Further information about informed consent can be found on the Informed Consent website www.health.qld.gov.au/consent. Additional statewide consent forms and patient information sheets are also available here.

Staff are available to support patients' cultural and spiritual needs. If you would like cultural or spiritual support, please discuss this with your doctor/clinician.

Queensland Health recognises that Aboriginal and Torres Strait Islander patients will experience the best clinical care when their culture is included during shared decision-making.



7. Questions

Please ask the doctor/clinician if you do not understand any aspect of this patient information sheet or if you have any questions about your proposed procedure.

If you have further questions prior to your appointment, please contact the Medical Imaging department via the main switchboard of the facility where your procedure is booked.



8. Contact us

In an emergency, call Triple Zero (000).

If it is not an emergency, but you have concerns, contact 13 HEALTH (13 43 25 84), 24 hours a day, 7 days a week.

References:

1. Australian Radiation Protection and Nuclear Safety Agency (ARPANSA). Ionising radiation in our everyday environment, 2021. Available from www.arpansa.gov.au