NHS

Royal Papworth Hospital

NHS Foundation Trust

Percutaneous mitral valve repair

A patient's guide and consent form

Compassion
Excellence
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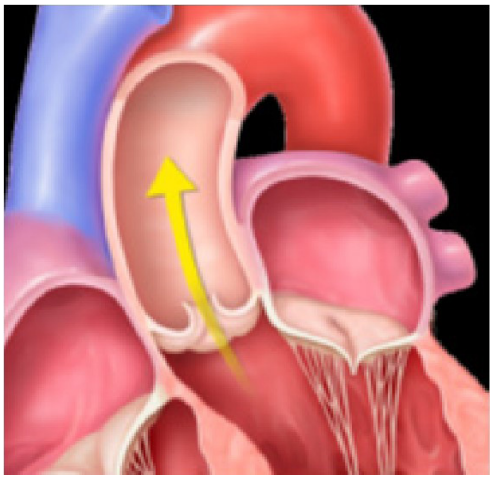
How your heart works

Your heart beats thousands of times per day, pumping dozens of gallons of blood each hour. It pumps blood through your lungs to replenish it with oxygen, and then pumps the oxygen-rich blood back out to the rest of your body.

The heart has four chambers; the upper two chambers are called atria (each one is an atrium), and the lower two are called ventricles. There are four valves that function as the doorways between these chambers (see figure below). Each valve is made of thin but strong flaps of tissue called leaflets. The valves open in one direction to let blood pass from one chamber to the next, closing quickly between heartbeats so blood does not flow backward.

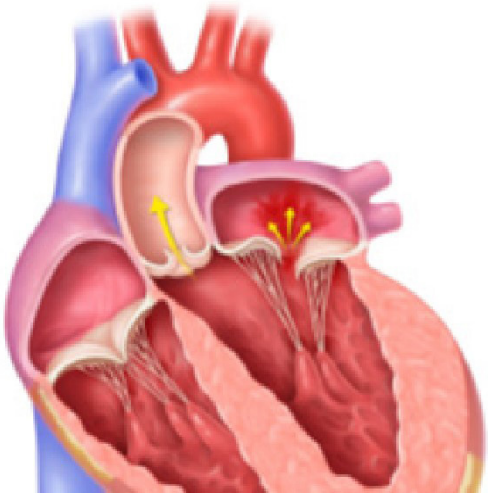


Normally functioning mitral valve

The mitral valve and mitral regurgitation

The mitral valve is one of the four heart valves that control the flow of blood in and out of the heart. The mitral valve separates the upper left heart chamber (left atrium) from the lower left heart chamber (left ventricle). The mitral valve has two flaps, called leaflets. The leaflets open to let blood flow into the left ventricle, and close to stop blood flowing backwards to the left atrium. Mitral regurgitation is a leaking mitral valve. The leaflets do not meet in the middle, so the heart pump (left ventricle) must work harder, and the chambers of the heart may enlarge.

Until recently, leaking mitral valves were repaired with open heart surgery. Open heart surgery requires a general anaesthetic and involves opening up the breastbone (sternum) or making an incision between the ribs, diverting the flow of blood away from the heart, and then replacing/repairing the mitral valve by opening up the heart from the outside.



Improperly functioning mitral valve allowing blood to flow back into the left atrium (mitral regurgitation)

What is a percutaneous mitral valve leaflet edge repair?

A mitral clip device (i.e. clip) is a device that can be used to repair a leaking mitral valve and relieve symptoms of mitral regurgitation and heart failure.

A clip procedure is also carried out under a general anaesthetic but is a less invasive way to repair the mitral valve. This involves repairing the mitral valve through the skin via the groin, using a thin flexible tube, called a catheter. It does not involve open-heart surgery or cutting the breastbone.

The implanted clip holds the leaflets together in a specific area of the valve, with holes (orifices) on either side for the blood to flow in.

Mitral clip device next to five pence

Benefits of a clip procedure

Even with the best medical treatment, mitral regurgitation usually gets worse over time, leading to signs and symptoms of heart failure such as breathlessness, fatigue and swollen ankles or legs (fluid overload). This procedure should reduce your mitral regurgitation, so improving the symptoms of heart failure and reducing shortness of breath.

Risks of a clip procedure

As with any treatment, there are risks associated with clip therapy. Your doctor will discuss how the risks of clip therapy compare with other options that may be available.

The risks of a percutaneous mitral valve leaflet edge repair (clip) procedure include:

- Stroke - 1%
- Death - 1%. This can be due to your underlying heart problem or due to complications of the procedure
- Bleeding - 5%. Bleeding from the puncture site/s after the procedure. This is managed with manual pressure and/or a pressure device. Bleeding usually resolves within a few hours
- Collection of blood around the heart requiring drainage - 1%. The blood may need draining using a small tube inserted below the breastbone, or with an operation
- Abnormal heart rhythm - 5%. This is treated with drugs or sometimes with an electric shock to the heart
- Damage to the blood vessel requiring surgical repair - 1%. A damage to the blood vessel that is used to insert the catheter that requires repair through surgery
- Kidney injury. After the procedure, there is a risk of damage to the kidneys, due to the changes in blood pressure and the drugs given to you. The kidneys may recover in a few days, but you may need to have your kidney function monitored for an extended period of time
- Collection of fluid in the lungs (pulmonary oedema). This may occur during the procedure and may mean that we need to keep you asleep for a longer period of time afterwards. You may need admission to the intensive care unit for support with your breathing
- Damage to teeth, throat or oesophagus. During the procedure, the doctor will put a flexible tube (a probe) down your throat into your swallowing tube (oesophagus). This is a transoesophageal echo (TOE), which enables the doctor to obtain the required visual guidance to perform the procedure. Around 0.01% have complications from TOE

Before a decision can be made regarding your suitability for a clip procedure, you will need some, or all, the following tests:

- Physical examination
- Blood tests. We will need some up-to-date blood test results
- Electrocardiogram (ECG). This enables us to look at your heart rate and rhythm

- Echocardiogram (echo). An echocardiogram uses sound waves (ultrasound) to build up a moving picture of your heart and shows the structure and function of your heart valves and heart chambers. An echocardiogram takes around 20 minutes

- Transoesophageal echo (TOE). A TOE is another way of carrying out an echo and allows your doctor to look more closely at your heart. A flexible tube (probe) is passed down your throat, to send sound waves to your heart, and collect echoes that bounce back. A TOE takes approximately 20–30 minutes

- Coronary angiogram. A coronary angiogram uses a series of X-rays to allow doctors to look at the coronary arteries. The coronary arteries are the main arteries that supply your heart muscle. A thin plastic tube (catheter) is guided through an artery in your wrist or groin, to your heart. Then a special dye is injected through the catheter, so your arteries clearly show. A coronary angiogram takes about 30 minutes

- Computed tomography (CT) scans. A CT scan is an X-ray that produces three-dimensional images of your body. A radiographer will give you an injection containing a special dye so that your blood vessels and heart show clearly on the scan. A CT scan can also be used to look at the arteries that supply your heart muscle (coronary arteries) – a test called a CT coronary angiogram. A CT scan can also be used to look at the blood vessels in your legs that will be used for the clip procedure

If a clip procedure is right for you, a letter will be sent to you telling you when your procedure will be, and which ward you will stay on. About one to two weeks before the date of your hospital admission, you will have a pre-admission appointment. This is carried out by coming to the hospital or by telephone. A nurse will call you to discuss your medical history and to find out what medication you are taking. You will be advised which medications you need to stop, and when, before your procedure. Oral anticoagulation will be discontinued two to five days prior to the procedure. Where indicated bridging with low molecular weight heparin will be commenced upon stopping of oral anticoagulation.

You will be able to ask any questions about the procedure during this call. You will come into hospital on the day before your procedure.

If you feel unwell before your clip procedure, telephone the heart valve specialist nurse on **01223 638411**.

The general anaesthetic

The procedure is carried out under a general anaesthetic administered by an anaesthetist. There are several members of the anaesthetic team whom you will meet when you come for the procedure. These include an operating department practitioner (ODP) who will assist the anaesthetist and a junior anaesthetic doctor or an anaesthetic associate (AA), who work under the close supervision of the consultant anaesthetist.

The general anaesthetic commonly involves insertion of a cannula into a vein often in your hand or arm through which the anaesthetic is administered. We use standard monitoring of your heart, blood pressure and oxygen levels. We will need to insert another monitoring line called an arterial line into an artery usually in your arm. This may be done before you go off to sleep. Oxygen is given for you to breathe through a clear plastic mask before going off to sleep and will be given to you afterwards until you are fully awake again.

You will be asleep for as long as the procedure itself takes with the addition of some time before and after. You may feel sleepy for a little while afterwards.

You should be offered an opportunity to attend the anaesthetic pre-assessment clinic prior to the day of your procedure. Here you will meet a senior anaesthetist and will have a chance to ask questions about the

anaesthetic for your procedure.

Please let this anaesthetist know if you have had prior problems with anaesthetics or have a family history of serious problems with anaesthetic agents, such as a rare condition called malignant hyperpyrexia or an allergy to an anaesthetic agent.

You will typically meet the anaesthetist who will be looking after you during your procedure at the time that you come for it. If you have been admitted to hospital for this procedure as an emergency then there will not be an opportunity to see you in the clinic beforehand and an anaesthetist will come to see you on the ward.

Risks of a general anaesthetic

There are a number of common and a few rare risks associated with a general anaesthetic which are important to know about.

Common risks (1 in 10) include:

- Bruising or bleeding around the site of the cannula or arterial line
- A dry mouth or lips
- A sore throat
- Shivering
- Itching
- Nausea and vomiting
- Difficulty passing urine, which may require a catheter to be inserted into your bladder. This is more likely if the procedure takes a long time or if you have experienced this type of problem before
- Temporary memory loss (mainly in over 60 year-olds)

All of these common risks are temporary and should settle down soon afterwards.

Less common risks (1 in 100 – 1 in 3,000) include:

- Infection of a cannula or arterial line
- Corneal abrasion (1 in 2,800). We will protect your eyes whilst you are asleep, however occasionally patients may suffer an accidental scratch to the eye called a corneal abrasion. This can cause pain and blurred vision for a few days, but usually heals without long term consequences. More serious damage to the eyes resulting in permanent loss of vision is very rare
- Hoarse voice
- Vocal cord damage is also possible after an anaesthetic. This is because we will need to use a tube that passes between the vocal cords.
- Dental damage. Please let us know if you have any loose teeth or fragile dental work.
- Peripheral nerve damage that is permanent.

Uncommon risks (1 in 10,000 – 1 in 20,000):

- Aspiration of gastric contents into the lung
- Allergy to an anaesthetic drug
- Awareness (1 in 20,000)

The risk of death or brain damage resulting from a general anaesthetic is extremely rare and is less likely than the risk of death from any procedure to repair or replace the mitral valve.

Please note that these anaesthetic risks are also present during an operation to repair the mitral valve using open cardiac surgery.

The decision to opt for the less invasive clip procedure alters the risks associated with the procedure itself but not the risks from the

anaesthetic. There may be some risks in addition to these which your anaesthetist may discuss with you if they think they are relevant for you.

The reason we tell you about these potential complications is so that you can tell us if you think you may be at higher risk for getting one of these complications than another person. It is also so that you can make an informed decision about whether or not to go ahead with the procedure.

To put the uncommon risks into context it is often helpful to consider the many risks in our day to day lives that we do not even consider, for example for most people it is probably riskier to travel in a car than it is to have a general anaesthetic.

What to bring to hospital?

Please bring with you:

- All your current medications.
- Your completed hospital forms.
- A dressing gown.
- Comfortable clothes, such as shirts that button up, loose blooses or tops, tracksuit bottoms, trousers or skirts, and well-fitting slippers, trainers or shoes.
- A bag with your toiletries.

Before your clip procedure

Hygiene

Hygiene is very important both before and after your procedure. Have a shower the night before your admission and the morning of your clip procedure. We will send you an antiseptic body wash to use the night before admission and you will be given some on the ward for your shower in the morning. Pay special attention to washing under skin folds such as under the breasts, the groin and genital area.

Do not shave or remove hair from your chest, arms, legs or groin before your clip procedure. If needed, shaving will be done in hospital just before your procedure.

Food and drink

Do not eat anything after midnight on the day of your clip procedure. You may continue to drink water until six am.

Medication

Continue to take your medicines as usual, unless your specialist valve nurse or cardiologist has asked you not to do so.

If you take any of the following medications: Gliclazide, Glibenclamide, Glimepiride, Glipizide, Tolbutamide, Canagliflozin, Dapagliflozin, Empagliflozin, Ertugliflozin, Dulaglutide, Exenatide, Liraglutide, Lixisenatide, Xultophy, please seek advice from the pharmacist in pre-admission about when to stop them, or call the heart valve helpline on **01223 638411**.

In hospital - before the clip procedure

When you arrive at Royal Papworth Hospital, go to the main reception where the receptionist will direct you to your ward.

When you get to the ward, a nurse will show you your bed. Male and female patients may share the same ward but have individual bedrooms with en-suite.

Informed consent for the procedure will be taken by the consultant responsible for the procedure on the ward. Dry clip of the groins will occur, and you will shower. Please ensure dentures and jewellery are removed. After showering you will need to change into a hospital gown and disposable pants. The ward nurse/healthcare assistant will apply VTE stockings.

Please affix patient label or complete details below.

Full name:

Hospital number:

NHS number:

DOB:

PIC 213: patient agreement to PI 213 - percutaneous mitral valve repair

Intended procedure/surgery

Statement of health professional

(To be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy). I have explained the procedure to the patient. In particular I have explained:

The intended benefits:

As detailed on page 3 of this booklet

Significant, unavoidable or frequently occurring risks:

As detailed on page 3 of this booklet

Any extra procedures, which may become necessary during the procedure

- ☐ Blood transfusion
- ☐ Other procedure - please specify below:

……

……

……

I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

This procedure will involve:

- ☐ General anaesthesia
- ☐ Local anaesthesia and sedation

Consultant/performer

Signed: ……

Date: ……

Name (PRINT): ……

Job title: ……

Contact details:

(If patient wishes to discuss options later.)

Statement of patient

Please read the patient information and this form carefully.

If your treatment has been planned in advance, you should already have your own copy of leaflet 213 which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now.

If you have any further questions, do ask - we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

- **I understand** what the procedure is and I know why it is being done, including the risks and benefits.
- **I agree** to the procedure or course of treatment described on this form and have read this information leaflet on percutaneous mitral valve repair (PI 213) and had the opportunity to ask questions.
- **I agree** to the use of photography for the purpose of diagnosis and treatment and I agree to photographs being used for medical teaching and education.

Please affix patient label or complete details below.

Full name:

Hospital number:

NHS number:

DOB:

NHS
Royal Papworth Hospital
NHS Foundation Trust

- **I understand** that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.
- **I understand** that any tissue removed as part of the procedure or treatment may be used for diagnosis, stored or disposed of as appropriate and in a manner regulated by appropriate, ethical, legal and professional standards.
- **I understand** that any procedure in addition to those described on this form will be carried out only if necessary to save my life or to prevent serious harm to my health.
- I have listed below any procedures **which I do not wish to be carried out** without further discussion:

……

……

……

I have been told in the past by Public Health that I am at increased risk of CJD (Creutzfeldt-Jakob disease) or vCJD (variant Creutzfeldt-Jakob disease).

☐ Yes *(Health professional to refer to Trust CJD procedure DN92.)*

☐ No

Patient

Patient signature: ……

Date: ……

Name (PRINT): ……

Statement of interpreter (where appropriate).
I have interpreted the information above to the patient to the best of my ability and in a way which I believe they can understand.

Signed: ……

Date: ……

Name (PRINT): ……

Confirmation of consent

(To be completed by a health professional when the patient is admitted for the procedure, if the patient has signed the form in advance).

On behalf of the team treating the patient, I have confirmed with the patient that they have no further questions and wish the procedure to go ahead.

Signed: ……

Date: ……

Name (PRINT): ……

Job title: ……

Important notes (tick if applicable).

☐ Patient has advance decision to refuse treatment (e.g. Jehovah's Witness form)

☐ Patient has withdrawn consent (ask patient to sign/date here)

Patient signature: ……

Date: ……

Name (PRINT): ……

Top copy to be filed in medical notes, carbon copy to be retained in booklet for patient.

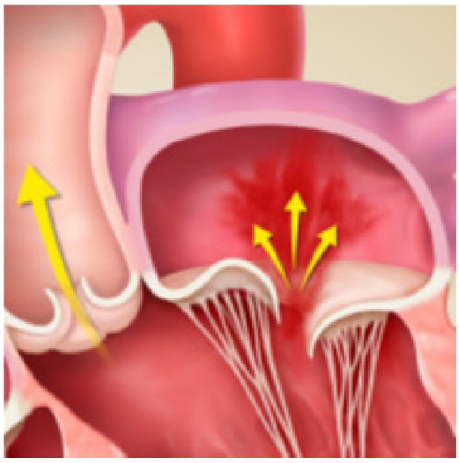
Clip procedure

You will have your clip procedure in the cardiac catheterisation laboratory (cath lab). Before you are taken to the cath lab, you will be asked to change into a hospital gown and will have a cannula (a small plastic tube) inserted into a vein in one of your arms so we can give medication to you. When you arrive at the cath lab, staff will check your identification and which procedure you are having. The anaesthetist will then put you to sleep. A ventilator (artificial breathing machine) will help you breathe during the procedure. Machines will also be used to monitor your heart rate, blood pressure and oxygen levels.

Inserting the clip

The doctor will give you an injection of local anaesthetic (a type of medication) which will numb the area around your groin and will then make a small (one centimeter) cut, to insert a tube (catheter) into a vein (**Fig.1**). The tube allows the doctor to reach your heart and insert the clip (**Fig. 2**). The tube is also a safe way for doctors to give you drugs during your procedure. The doctor guides the tube through the vein to your mitral valve (**Fig. 3**). The doctor then guides the clip through the tube to the valve (**Fig. 4**). Once in place, the clip is opened and closed until it is in the best position. X-rays or fluoroscopy (similar to a small X-ray film of your heart) will be used to fit the clip onto the valve correctly.

The clip procedure usually takes between two and three hours.



Before procedure

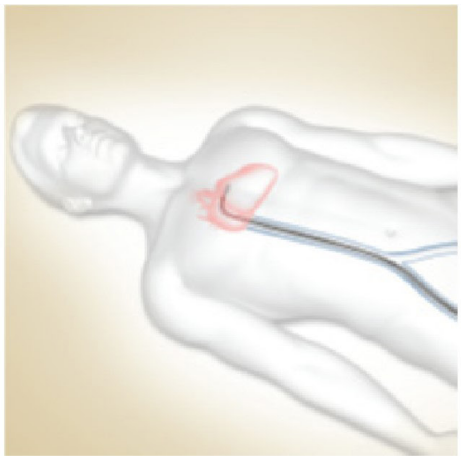


Fig. 1

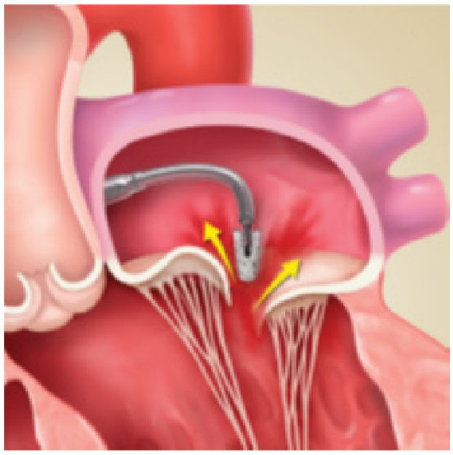


Fig. 2

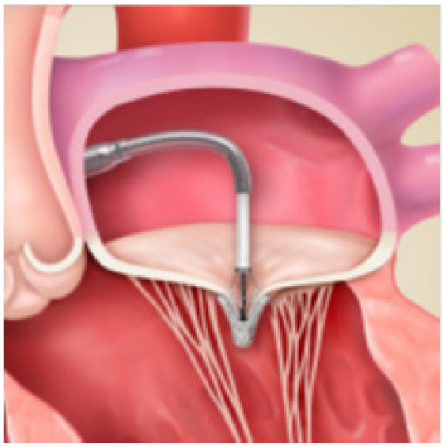


Fig. 3

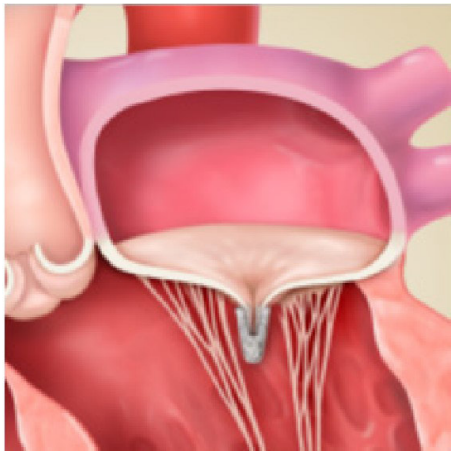


Fig. 4

Following your procedure

You will go from the X-ray department to the recovery area for up to a couple of hours where you will be extubated and closely monitored. Following this you will return either to the ward or the high dependency unit. A heart monitor will continue to measure your heart rate and rhythm, and you may have some intravenous fluids (directly into a vein in your hand) to keep you hydrated. You may also need intravenous drugs to support your heart for a short time after the procedure.

Your doctor will explain if you need drugs and how they work. On the ward a bedside swallow evaluation will be performed by an appropriately trained nurse and you will be allowed to commence oral intake when safe to do so. Anticoagulation (if discontinued) will be resumed when safe to do so and at the instructions of the responsible consultant/ operators. Routine medications will be resumed.

You may feel tired from the anaesthetic, but early ambulation will be encouraged, ideally within 6 to 12 hours of the procedure.

The valve team will confirm discharge planning with you and your family so that post-discharge care plans are in place. The anticipated date of discharge will be one to two days post-procedure if clinically appropriate.

Recovery at home

The following are only general guidelines as everyone's recovery is slightly different. It is advisable that you have someone to care for you for the first week after discharge. Please speak to your nurse or doctor as soon as possible if you think this will be a problem.

Activity

You should avoid strenuous activity for a few weeks. This includes heavy lifting (e.g. shopping, suitcases) or pushing and pulling (e.g. cutting grass, vacuum cleaning). You may feel a little 'washed out' and tired and need to rest in the afternoon. However, it is important for your recovery to have a short walk every day. This can be gradually increased. You do not have to avoid climbing stairs or walking up inclines, but you may have to start off at a slower pace. You may feel slightly out of breath on walking, which should improve as your fitness level increases.

There can be some fluid retention as a result of the surgery; you may notice some swelling of your ankles. If this swelling travel further than your ankles, please get reviewed by your GP.

Your wounds should be healing by the time you leave hospital, if they still require a dressing, we will organise a district or practice nurse to continue this. If your wound becomes red or inflamed, please get your GP or practice nurse to check it.

You may have bruising to your groin(s) which is not uncommon and may take several weeks to resolve.

You may have a hard lump under the skin due to a collection of blood (haematoma). Please consult your GP if this becomes painful or grows bigger.

Driving

You are not allowed by DVLA to drive for four weeks after your procedure. If you have a LGV or PCV licence you will need to undergo an exercise test before getting your licence back.

Work

If you were working before your procedure there is no reason why you cannot return to this after a period of recovery up to two weeks.

Cardiac rehabilitation

You will be invited to attend cardiac rehabilitation about six weeks after your procedure. This is a programme of graduated exercise and general health discussions. If you

live outside the area you may be referred to your local hospital. Patients who attend generally feel more confident about coping with everyday life. It will also help to increase your fitness level.

Follow-up care

On discharge you will be given a letter for your GP explaining what you have had done and a list of your medications. The valve nurse specialist will phone you a week after discharge to check on your progress. If you have any concerns you can call the cardiac support nurse line **01223 638100** (Monday to Friday 08:30 - 18:00). We would like to hear sooner rather than later about any potential problems.

You will be invited to attend an outpatient follow up appointment with the nurse specialist approximately six weeks after your procedure. During this visit you will have an ECG and a clinical assessment. Patients will be reviewed in the structural heart disease/ specialist valve clinic by a consultant cardiologist in the structural heart disease team at six months post-procedure. This appointment will include a clinical assessment, a 12-lead ECG and transthoracic echocardiography.

Patients will then return to routine annual follow-up at their referring cardiology centre or at Royal Papworth Hospital (where appropriate).

If you need further information please contact the heart valve specialist nurse on **01223 638411**.

Recommended summary plan for emergency care and treatment (ReSPECT)

What is ReSPECT?

ReSPECT stands for 'recommended summary plan for emergency care and treatment'. It is a process that helps people to think about what treatment is suitable in an emergency, should they be unable to make decisions at the time.

Why is it important?

We know that, when people are very unwell, they are often unable to think clearly about what treatment they may or may not want because their brain and body are overwhelmed by the illness. It is also normal for people to feel anxious about what is happening when they are sick and in hospital, and this can also make it difficult to think clearly. This is why we think it is a good idea, where possible, for decisions about medical treatment to be made in advance – before there is an emergency situation or crisis.

How does it work?

The ReSPECT process is designed to help conversations between you and your healthcare professionals: they need to make sure you understand your health problems and which treatments may or may not benefit you. You need to make sure the healthcare professionals understand what matters most to you and whether there is anything you are particularly worried about or would want to avoid.

This conversation is used to complete a ReSPECT form that records a person's health problems, their preferences and which medical treatments may or may not be suggested. The original form should stay with the patient, though it is extremely helpful to have a record of the content of the form on their electronic patient record.

A ReSPECT form is not a legally binding document and can be changed or withdrawn at any point.

The ReSPECT form is often used to indicate treatments that someone may not want and/or treatments that their healthcare professionals consider would no longer be of benefit to them. If people are getting worse from progressive conditions, it may be helpful to consider in advance about things such as whether they would wish to go back into hospital and, if in hospital, what sort of treatments might or might not be helpful for them.

This often incudes a decision on whether or not they should have attempted cardiopulmonary resuscitation (CPR) if their heart was to stop.

Who is it for/is this relevant for me?

This process has increasing relevance for people who have complex health needs, people who may be nearing the end of their lives and those who are at risk of sudden deterioration or cardiac arrest.

However, many people come to Royal Papworth to have major procedures or surgery with the intention of curing a progressive disease or with the intention of substantially prolonging their life and, if that is you, you may wonder how a ReSPECT discussion applies to you and others like you.

One of the key things to understand about the ReSPECT process is that it can be used simply to document a person's wishes and priorities, without setting any limitations on what treatment they should have. This is important because all the procedures and operations we do here come with the risk of complications.

In the unlikely event that things do not go as planned, it is really helpful to have some idea about a person's preferences and about their fears, worries and hopes.

Once again, the document is not legally binding, but it can help those looking after you to know what you might want if you weren't able to say for yourself.

Resources used to produce this leaflet:

Transcatheter Mitral Valve Repair with MitraClip® Therapy - what you and your family should know about this minimally invasive procedure. (Abott. 2014)

Having a Mitraclip Procedure.
Royal Brompton and Harefield NHS Foundation Trust. (October 2019)

Percutaneous mitral valve leaflet repair for mitral regurgitation. Interventional procedures guidance [IPG649] Published date: 29 May 2019

Royal Papworth Hospital NHS Foundation Trust.
Integrated care pathway for percutaneous mitral valve repair.

Royal College of Anaesthetists
rcoa.ac.uk/patientinfo/risks

Royal Papworth Hospital NHS Foundation Trust

A member of Cambridge University Health Partners

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royalpapworth.nhs.uk

01223 638000

Large print copies and alternative language versions of this leaflet can be made available on request.

View a digital version of this leaflet by scanning the QR code.

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