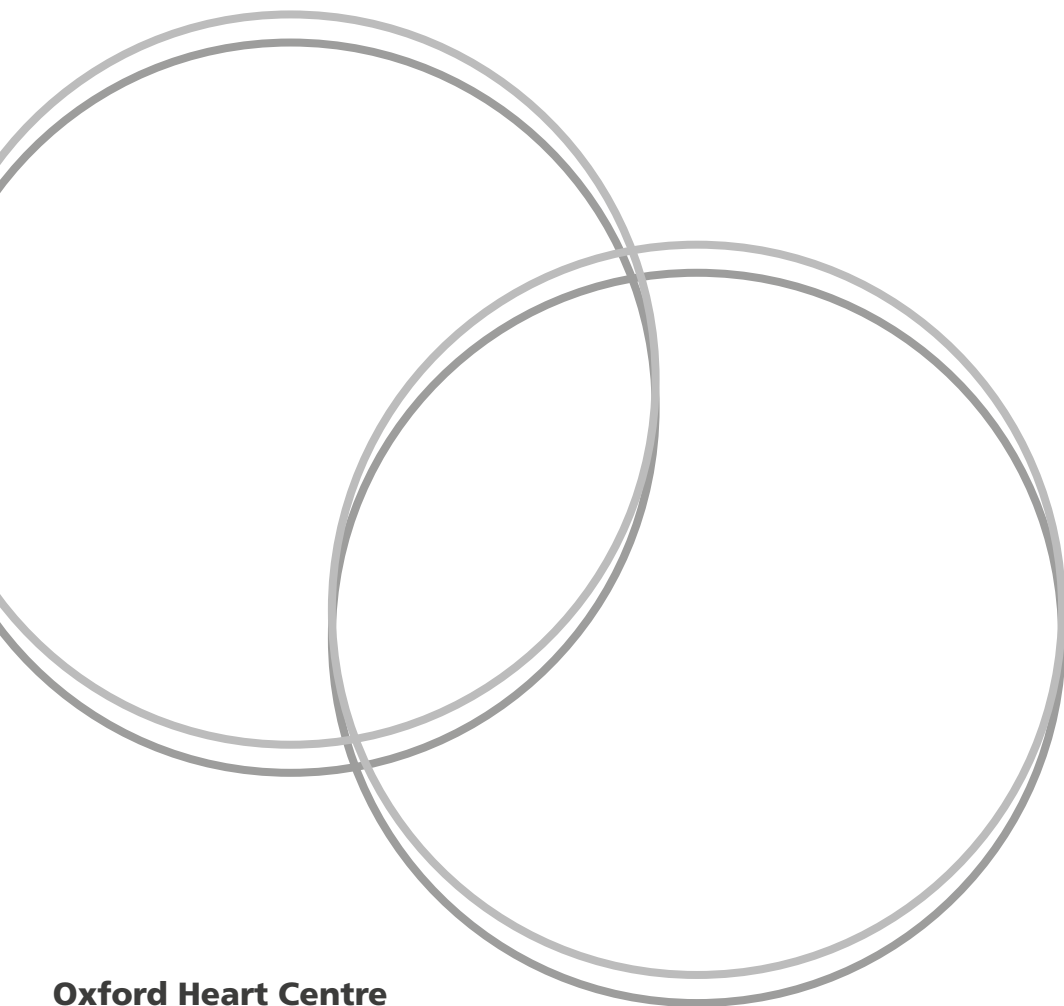




Oxford University Hospitals
NHS Foundation Trust

Transcatheter Aortic Valve Implantation (TAVI)

Information for patients



Oxford Heart Centre

What is TAVI?

You have been diagnosed with a condition called aortic stenosis – a narrowing of the aortic valve of the heart. Your cardiologist has decided you may benefit from treatment to replace the valve. However, due to your overall medical condition you are at higher risk of complications from conventional surgery to replace the valve.

You are being considered for a newer type of treatment where a catheter (plastic tube) is inserted into the heart via a small incision and a new valve implanted inside the old valve. The medical name for this procedure is Transcatheter Aortic Valve Implantation, or TAVI.

Patients being considered for treatment of aortic stenosis require careful and thorough assessment to ensure the best possible treatment is provided.

It is important to understand that not all patients referred for consideration of a TAVI procedure by another cardiologist or cardiac surgeon will be able to have the procedure. Reasons for this may include:

- Your own valve being either too large or too small for a Transcatheter valve to safely fit inside.
- Technical reasons why the procedure cannot be performed at an acceptable level of risk.
- Additional medical problems likely to either significantly increase the risk of the procedure or significantly reduce the likely chance of the procedure improving symptoms and quality of life.

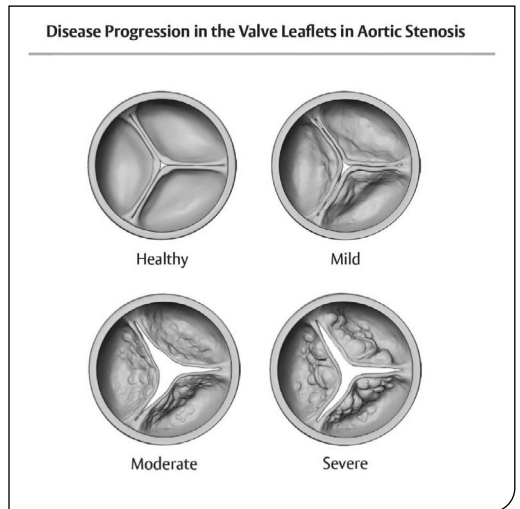
What is aortic stenosis?

The heart contains four valves, which make sure blood flows in the correct direction out of the pumping chambers. The aortic valve is an outlet valve on the left side of the heart which opens to allow blood to flow out of the heart and around the body.

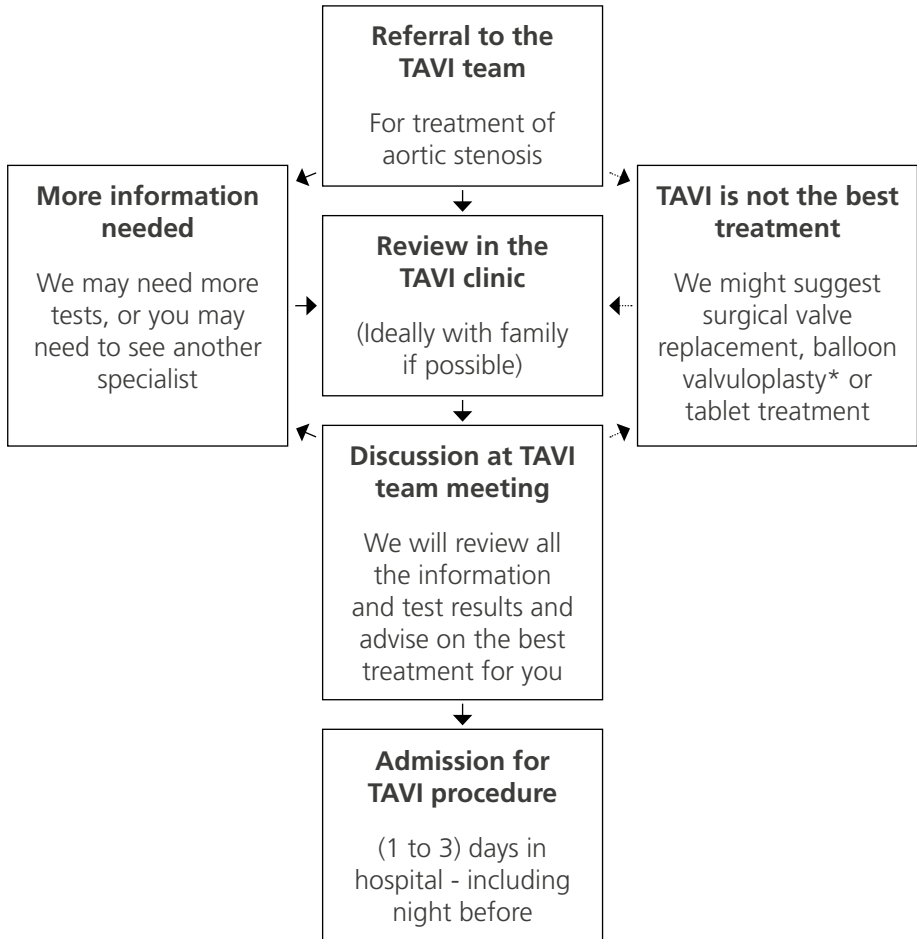
Aortic stenosis describes a narrowed valve which opens less easily, and it is harder for the heart to push blood out and around the body.

Aortic stenosis is usually caused by 'wear and tear' of the valve, and less commonly due to the valve being abnormal at birth, or other conditions.

The extra work placed on the heart can cause breathlessness, fluid retention, chest pain, dizzy spells or blackouts. There may be other reasons for these symptoms too.



Typical pathway for a patient referred to the TAVI team



*Balloon valvuloplasty is stretching of the aortic valve with a balloon. The effect is only short term.

It usually takes between 2 to 6 weeks from being seen in the TAVI clinic to a decision on treatment being made. If TAVI is recommended then typically this would be performed after a further 4 to 12 weeks, unless urgent.

What type of valve is used for a TAVI?

The TAVI valve is made of inert biological material from a pig or cow mounted on a metal stent (mesh frame) which is then squashed down to a small size. There are a variety of valves available, and the team will select which one will suit you best.

How is a TAVI valve inserted?

The procedure is usually carried out under sedation, but rarely it may need a general anaesthetic. The planned route will be discussed, and you will be told what to expect.

The compressed valve is inserted via a catheter (plastic tube) into the heart.

A tube is inserted via small incision into a large blood vessel at the top of the groin (the femoral artery) which leads up to the heart. This is known as Transfemoral approach.

If it is not safe to go through the groin, we may consider the following approach:

Transaxillary – a cut is made in the upper chest to access the artery that goes to the arm (axillary or subclavian). The catheter is passed into the heart.

The exact procedure used depends upon the size of your femoral arteries and whether there is any significant 'furring up' (calcification) of the femoral artery or the main blood vessel of the body (aorta). Most procedures are through the leg arteries as this is the safest approach. The other option may carry increased risks, and this will be explained to you.

What happens if I might be suitable for a TAVI procedure?

The first step for many patients is to be referred for review in the TAVI clinic where they will be seen by one of our consultants. The purpose of this clinic is to assess the following:

1. Is aortic stenosis the main problem?
2. Is aortic stenosis the cause of symptoms?
3. Is it appropriate to consider treatment including TAVI?
4. What investigations are needed next?
5. Is any treatment to the valve required urgently?

It is important to know that at this point it may be clear to the Consultant that TAVI is not suitable for you and if that is the case the reasons will be explained.

What happens after the TAVI clinic?

If further tests are needed, then these may be as a day case or via a short admission to the cardiology ward. A date for these investigations will be posted out to you. Typically this will be around 2 to 6 weeks after the clinic visit.

Some patients require additional clinic visits to monitor progress or seek additional information from other specialists involved in your care.

What happens during the assessment phase?

Further tests may include:

Routine blood tests, if not recently done

- Kidney and liver function.
- Haemoglobin to exclude anaemia.
- Blood clotting.

An ECG

- Recording of the heart electrical activity.

An echocardiogram

- An ultrasound examination of the heart.
- This is usually performed in clinic by either placing the ultrasound probe on the chest wall or occasionally passing a small probe into the oesophagus (gullet) under sedation - this usually takes between 10 to 30 minutes.

A coronary angiogram

- This is a procedure under local anaesthetic where a small plastic tube is inserted into the wrist artery or femoral artery at the top of the groin and passed to the heart under X-ray guidance.
- A special dye is injected to show up areas of the heart including the coronary arteries, aorta and the femoral artery.
- The procedure takes 30 minutes and at the end the tube is removed, and the artery gently pressed until the small hole has sealed.

CT angiogram

- An X-ray scan of the blood vessels.
- A special dye is injected into a vein in the arm and followed through the arteries including the aorta and the femoral arteries.

Discussion with a surgeon

- Surgical aortic valve replacement may be the preferred treatment option for aortic stenosis in some cases and these patients will need to be reviewed by a surgeon.

It is very important to have good dental hygiene to minimize the risk of infection of a heart valve – We advise for you to have a recent dental checkup before treatment is arranged.

What if I have already had some of these tests before?

Often routine tests such as a coronary angiogram or echocardiogram have already been performed. To avoid unnecessary duplication of tests we will obtain the results of these and decide if a repeat assessment is needed.

If you only need one or two further tests to complete your assessment this might be arranged via a single visit to our day case ward if you have appropriate transport and care on discharge, already available.

What happens after the tests?

The TAVI team meets weekly (every Thursday) to review all cases in detail. The team consists of a wide range of professionals involved in your care. All the results from the tests are reviewed and discussed. The team then decides what the best treatment option is and this may include:

1. Surgical aortic valve replacement.
2. Transcatheter aortic valve implantation.
3. Medical treatment with medications only.
4. Additional investigations.
5. A temporary stretch of the valve with a balloon (Balloon Aortic Valvuloplasty).

Additional investigations might include a special CT scan to evaluate the aorta and other arteries in more detail, or an MRI scan of the heart to assess the heart muscle function, or a stress echo where the heart is assessed at rest and after simulated exercise using drug stimulation. Detailed assessment of lung function is also often needed for patients with respiratory problems. The team might suggest that you need to see another specialist if there are specific concerns, as sometimes the scans can identify abnormal results that need further investigations.

Once the team have decided on the best option a letter will be sent to you and your GP (and any other doctors involved in your care) explaining the decision and what happens next.

We are a large University teaching hospital, and we are actively involved in clinical research studies. We hope that these studies will help us to improve the treatment of patients. You may be invited to participate in research and be contacted by a member of our research team. If you have any concerns or questions, please do not hesitate to contact us.

What happens during a TAVI procedure?

You will be admitted to the Cardiology department where a doctor will go through the benefits and risks and ask you to sign a consent form.

For patients up to the age of 56 years, please advise a member of staff prior to the procedure, if there is any possibility of pregnancy.

The procedure involves the use of ionising radiation (X-rays).

The benefit of the procedure outweighs the risk.

The procedure is performed in a cardiac catheterisation laboratory. You will have been in one if you have had an angiogram test. This is like an operating theatre with an X-ray machine. Immediately before the procedure you will have some local anaesthetic in your wrist and a cannula (a small tube) will be inserted into an artery to allow close monitoring of your blood pressure. The aim will be to remove all these the following day or sooner, depending on your progress.

The TAVI procedure will be performed using fluoroscopy (X-rays) and echocardiography (ultrasound of the heart) to allow the doctors to see your arteries and valve. The aim of these procedures is to avoid prolonged, deep anaesthesia and open-heart surgery which require a longer recovery period. The procedure normally takes between 60 and 90 minutes.

If you are having the transfemoral approach

The procedure is performed by a team of Cardiologists through a small puncture in your femoral artery at the top of the leg.

A vascular surgeon who has specific expertise in this type of procedure will be available should problems arise.

The procedure is designed to improve your heart function, without requiring removal of your own narrowed aortic valve. Before implantation, the narrowed aortic valve may need to be stretched open by inflating a balloon on the catheter (this is called balloon aortic valvuloplasty). The replacement valve will be carefully crimped (compressed) and mounted onto a delivery catheter, using a specially designed device. It will then be inserted into the femoral artery in your leg and delivered to the heart. The replacement valve will then be expanded to fit across your own aortic valve, holding it open permanently.

The puncture sites in your groins are closed using special stitches. **To allow access to your heart, you might have punctures to both sides of the groin.** Sutures (if placed) are removed before you are discharged from hospital.

As the valve is implanted, we may need to speed up your heart rate with the use of a temporary pacing wire – this wire is put in through a vein in your groin or arm and passed through the vein to the heart. An electrical impulse will then be passed through the wire in order to speed your heart rate up for a few seconds only – this reduces the blood pressure and motion of the heart, making the procedure easier. Once the new valve is in place, the pacing is stopped, and your heart rate will return to normal. The pacing wire is then removed.

In some circumstances the TAVI valve can affect the electrical wiring system within the heart and a permanent pacemaker is required - this may be performed immediately after the TAVI procedure or as a separate procedure before discharge.

What happens after a TAVI procedure?

As the procedure is performed under sedation you will recover in the theatre recovery suite for 2 hours, and you will be closely monitored by the nursing team. The Doctor will review you before returning to the cardiology ward. You will be connected to either a fixed bedside monitor, or a portable heart monitor (telemetry) to constantly monitor your heart rate and rhythm. You will need to stay on bed rest for at least 4 hours post procedure. If there is no bleeding to the groin site, you will be able to mobilise in the evening. You can eat and drink on return to the ward. **Your expected hospital stay will be 1 night post procedure, depending on your progress. It is important that you have someone at home or close by to assist you for the first few days, and you make your own arrangements for this to be in place before you come into hospital.**

Anonymous information relating to your TAVI procedure will be submitted to the National Outcomes Registry for monitoring and quality assurance purposes.

Your doctor will likely ask you to take aspirin or clopidogrel (blood thinning tablets) following the procedure lifelong to prevent blood clotting around the valve. If you are already taking a medication that reduces the risk of blood clot (DOAC, warfarin or Aspirin), you would be asked to continue taking the tablets.

Visiting times

Open visiting 8am to 8pm two visitors per patient per day.

Cardiology Ward telephone numbers:

01865 572 955 / 01865 572 671 / 01865 572 676

Free Wi-Fi is available throughout the hospital.

The ward area also has free use of a cordless phone.

What are the potential benefits of valve implantation?

Treatment with the new valve should improve your symptoms. It will give you a more normal aortic valve performance and improve your overall heart function. We would hope this will increase your life expectancy and improve your quality of life.

What are the potential risks of the procedure?

Implanting a TAVI valve is a major procedure and has a significant risk. We have performed over two thousand and four hundred of these procedures and we will do everything we can to minimize these risks. However complex procedures like TAVI are never completely predictable and it is important that you and your family understand this procedure. The risks include:

- Risk of death during the procedure approximately:
2 % (1 in 50 people might die during the procedure).
- Risk of heart attack or stroke:
3% (1 in 33 people might have a stroke or heart attack during the procedure).
- Risk of requiring a permanent pacemaker:
10% (1 in 10 people might need a pacemaker as part of the procedure).
- Damage to groin arteries or bleeding or infection:
5% (1 in 20 people may need additional procedures to repair the artery).
- Risk of a tear or breakage occurring in the main artery leading out from the heart which may be fatal (aortic root rupture):
1% (this might happen in up to 1 in 100 cases).
- Risk of post operative delirium resulting in prolonged hospital stay or recovery.

If there are any specific additional risks in your case these will be discussed with you.

A TAVI will only be recommended if your doctors feel this risk is lower than conventional aortic valve replacement surgery.

What are the risks of not having the procedure?

A TAVI is recommended if aortic stenosis is causing significant symptoms as without any treatment these will usually continue to worsen and heart function starts to deteriorate, requiring more medication and monitoring.

What can I do to improve my health before a TAVI procedure?

- Stop smoking.
- Controlling your weight.
- Visit your dentist.

If possible, visit your dentist to make sure your teeth and gums are as healthy as possible to reduce the risk of infection.

- Visit your GP.

If you have any on-going medical problems such as diabetes, asthma, bronchitis, thyroid problems or high blood pressure (hypertension), you should ask your GP if you need a check-up.

If you become unwell when you are due to come into hospital, please contact 01865 226 166 between 8am to 5pm Monday to Friday. If we don't answer, leave a message and we will get back to you.

Recovering from a TAVI procedure

When you have had your TAVI, you will need someone to collect you from hospital and we suggest that they stay with you for the first few days after discharge. This is not for nursing care but so that if you feel unwell you have someone to help you. If you live alone, please consider whether you could ask a family member or friend to stay with you so that you could call them if you felt unwell, or whether you could stay with them. Everyone is different so recovery times can vary. As soon as you are walking comfortably around the home you can carry out light housework such as washing up, dusting, laundry, small amounts of ironing (while sitting down) and light weeding in the garden. None of these activities should make you feel extremely breathless – if they do you are working too hard and need to slow down.

Will I need to do any specific exercises?

Walking is the best form of exercise you can take following a TAVI and it is essential for your recovery. You may find that the amount you can manage varies from day to day. You may feel a little 'washed out' and tired and need to rest in the afternoon. For the first one or two weeks after your surgery it is best to exercise little and often. Begin by walking around the house and taking short walks outside. You may feel slightly out of breath on walking at first, which should improve as your fitness level increases.

You may find this difficult if you have mobility problems, so just do what you can manage as it is important to be as active as possible. You may be able to manage much more than this eventually if you do not have other medical problems that might limit you. Always wait at least one hour after eating before you exercise and plan your exercise into your day to avoid taking on too much and tiring yourself out. Take things slowly and rest if you need to.

You should avoid strenuous activity for four weeks. This includes heavy lifting e.g., shopping, suitcases, or pushing and pulling e.g. cutting grass, heavy gardening and using the vacuum.

If you experience any of the following symptoms, please contact NHS 111 or 999 immediately

- Chest pain.
- Loss of consciousness/collapse.
- Rapid increasing shortness of breath.
- Confusion/change in character/drowsiness (Delirium).
- Slurred speech, facial droop, limb weakness.
- Any signs of infection (a red or inflamed wound, temperature, fever).

Travelling after your procedure

The DVLA advises that you do not drive for four weeks after your procedure. You do not need to inform the DVLA about your procedure, but we do advise you to tell your insurance company in order to avoid problems with any claims you may make in the future. If you have problems with your insurance the British Heart Foundation (BHF) can help you out. You can contact them on 0800 023 4567 or visit the Financial Ombudsman service website. If you hold a commercial license, you will need to inform the DVLA who will advise you further. Provided you have had no complications, you will be able to fly:

- One week after your TAVI unless instructed otherwise.

Despite this, if you are planning a holiday, it may be better if you wait at least six weeks before travelling, as it is unlikely that you will get the best out of your break before then. If you wish to fly within three months of your procedure, check with your doctor and the airline as each has its own procedure. Also, remember to ensure that you have valid travel insurance – you can contact the British Heart Foundation for advice.

After leaving hospital

Although it is less invasive than having open heart surgery, having a TAVI is a significant event and as well as affecting your physical health, it can affect you emotionally. This is a normal part of recovery, and these feelings will pass. Some people who have had a TAVI have reported the following symptoms or problems after the procedure. Some are caused by the procedure itself and others by the sedation. The symptoms are usually temporary and settle over the first few days or weeks after the procedure.

- **Blurred vision /dots in front of eyes:** This occurs because of the surgery. It is recommended that you do not have an eye test within the first three months after your surgery to allow this to settle.
- **Muffled hearing /heightened awareness of heartbeat:** You may be particularly aware of this when you are lying on your side at night. Again, this is perfectly normal, but can cause concern. Try a different sleeping pattern to see if this helps.
- **Constipation:** This can occur because of inactivity. You can ask us for a laxative to help this. Please tell your nurse if your bowels have not opened before you go home.
- **Loss of concentration /memory problems:** Many people find they are unable to concentrate on things like reading a book or newspaper. Be patient with yourself – as you recover your concentration levels will return to normal.
- **Ankle and leg swelling in both limbs:** This can occur during the first few weeks after your procedure. It will settle down, but you should speak to your GP if it does not start to improve. If you notice swelling in just one leg, see your GP.

How should I care for my wound?

Your wounds should be healed by the time you leave hospital, If a stitch has been placed in the skin after the procedure this will be removed before discharge. It is normal for your groin to be tender for a few days and sometimes can be tender for several weeks. It is also normal for a bruise to develop. You can shower when you get home but avoid rubbing the wound site. Do not have a bath or use creams or soap directly onto the groin site for up to a week after the procedure to avoid irritation and reduce the likelihood of infection.

However, if you notice any of the following, please contact your GP:

- A hard tender lump under the skin around the area of incision (although a pea-sized lump is normal).
- Any increase in pain, swelling, redness and /or discharge at the site.
- A cold foot on the same side as the angiogram.
- A raised temperature /fever.

If your groin starts to bleed you should apply pressure to the area keeping your leg as straight as possible (lying down if you can).

If the bleeding does not stop after 10 minutes, dial 999. If the bleeding stops within 10 minutes keep your leg as still as possible for the following hour. If bleeding re-starts, go to your Emergency Department but **do not drive yourself there.**

Will I be in pain?

It is very unusual to be in pain following this procedure. You can take paracetamol if required. If you are having chest pain you should seek medical attention immediately. Call 111 or 999

Dental Treatment

A dose of antibiotics is recommended before any dental procedures (except a routine check-up) following TAVI lifelong. It is important to inform your dentist that you have had a TAVI procedure.

Please ask your dentist to contact us if further advice is required. Your dentist can find the current and up to date guidelines online on the European Society of Cardiology Guidelines for Aortic Valve Disease.

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 six weeks if you are feeling well and have no problem with the wound. You do not need to wait for your out-patient appointment.

Will I have a follow-up appointment?

It is crucial that you return to the John Radcliffe in 3 to 6 months' time post procedure for an echocardiogram. We will assess the valve's performance to ensure it is seated well and there is no leak around the outside. You will receive notification of this appointment by post. If you do not receive your appointment letter within three months of leaving the hospital, please contact the TAVI coordinator via 01865 226 166 during normal working hours.

Who can I contact with my queries?

Type of query	Who to contact
General queries regarding TAVI	01865 226 166 or oxford.tavi@ouh.nhs.uk
To contact Personal Assistants of: 1) Professor Adrian Banning 2) Dr Jim Newton 3) Professor Rajesh Kharbanda 4) Dr Sam Dawkins 5) Dr Tom Cahill	Secretary to AB and JN 01865 228 934 Natalie Brechin PA to RK and TC 01865 220 325 Natalie.Brechin@ouh.nhs.uk Natalie Wren PA to SD 01865 226 567 Natalie.wren@ouh.nhs.uk
Awaiting news of appointment dates for investigations or admission for TAVI.	Samantha White TAVI Team Co-ordinator 01865 226 166
Health related questions whilst awaiting admission for investigations or TAVI or post discharge.	Kate Winn TAVI Specialist Nurse 01865 221 490 oxford.tavi@ouh.nhs.uk

Notes

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Further information

If you would like an interpreter, please speak to the department where you are being seen.

Please also tell them if you would like this information in another format, such as:

- Easy Read
- large print
- braille
- audio
- electronic
- another language.

We have tried to make the information in this leaflet meet your needs. If it does not meet your individual needs or situation, please speak to your healthcare team. They are happy to help.

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Oxford University Hospitals NHS Foundation Trust
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