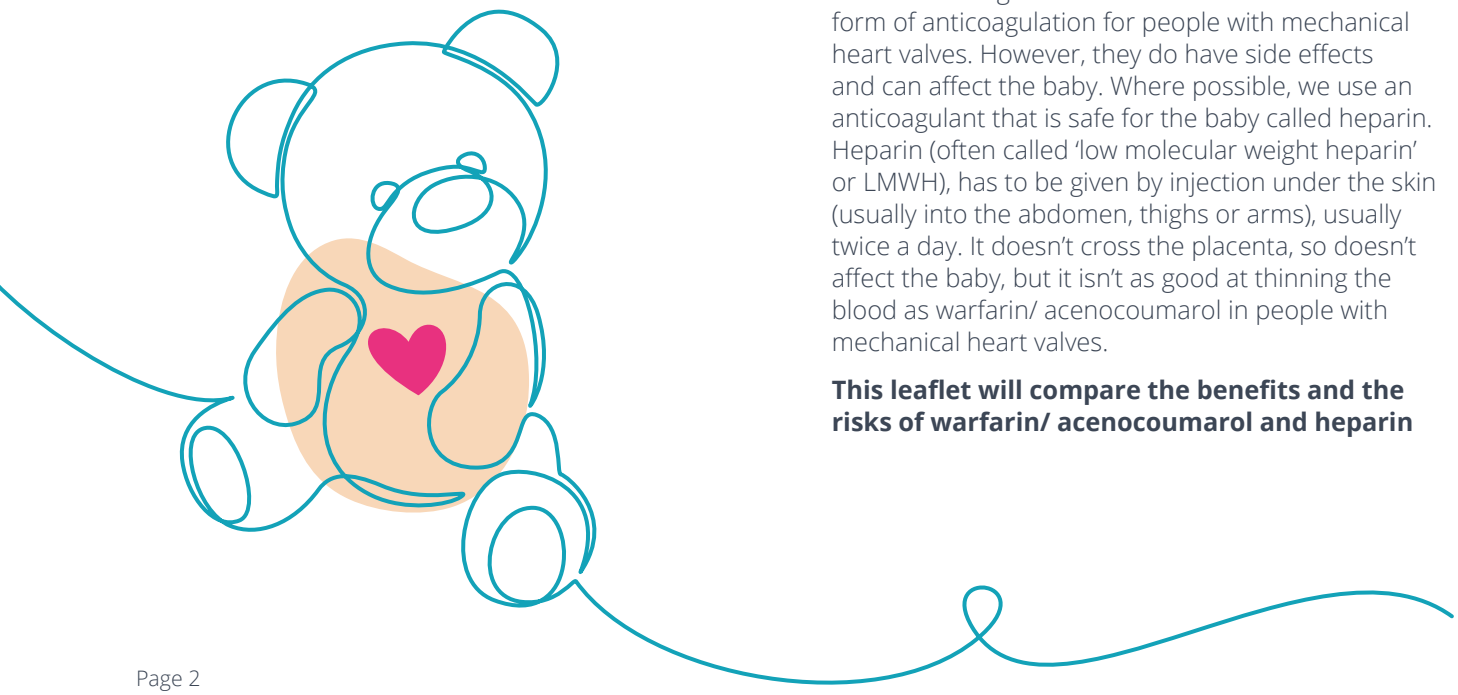
PATIENT
INFORMATION
LEAFLET

For people with mechanical/ metallic heart valves, who are considering pregnancy or are pregnant

Pregnancy in people with mechanical heart valves is high risk

This leaflet provides information on blood thinners, also known as anticoagulants, to people who have or are considering a mechanical/ metallic heart valve and are either pregnant or thinking about a pregnancy.



Anticoagulation and Mechanical Heart Valves

Patients with mechanical heart valves need anticoagulants, sometimes referred to as blood thinners. Without these, they may form a clot on their valve. If this happens, then this can be life-threatening and may also cause serious problems such as a stroke (a blockage of blood flow to the brain). Outside of pregnancy, vitamin-K antagonists, more commonly known as warfarin or acenocoumarol (Sinthrome) are used to prevent the formation of blood clots. Other blood thinners in tablet form, known as direct oral anticoagulants, do not provide sufficient protection for mechanical heart valves and can't be used.

Vitamin-K antagonists are considered to be the best form of anticoagulation for people with mechanical heart valves. However, they do have side effects and can affect the baby. Where possible, we use an anticoagulant that is safe for the baby called heparin. Heparin (often called 'low molecular weight heparin' or LMWH), has to be given by injection under the skin (usually into the abdomen, thighs or arms), usually twice a day. It doesn't cross the placenta, so doesn't affect the baby, but it isn't as good at thinning the blood as warfarin/ acenocoumarol in people with mechanical heart valves.

This leaflet will compare the benefits and the risks of warfarin/ acenocoumarol and heparin

Warfarin/ Acenocoumarol in Pregnancy

THE CHOICES AVAILABLE

While warfarin and acenocoumarol are very effective drugs in those with mechanical heart valves, they can occasionally cause problems in pregnancy. If taken in the early weeks of pregnancy (weeks 6 to 12), there is a small risk of facial development problems such as hairlip and/ or cleft palate, or other facial problems. If 100 women took warfarin or acenocoumarol, between 2 and 12 babies would be affected, see Table 1. Warfarin can also affect how the bones grow. The risk of miscarriage and stillbirth is also increased (*see table 1*).

Warfarin and acenocoumarol cross the placenta. The baby's blood is thinned too. Most of the time, this is not a problem, but occasionally (around 1-2% of the time) larger bleeds into the baby's brain may occur. Having good control of the level of anticoagulation (the INR) is important as this reduces the risk of bleeding problems.

Heparin, on the other hand, does not cross the placenta and so is less risky for the baby. The problem with heparin is that it is not as good at preventing blood clots. Blood tests (called "anti-Xa levels") will need to be done regularly (sometimes as much as a few times a week) to make sure that the level is right to prevent blood clots. Even with good levels, the risk of blood clots on the valve is still higher than with warfarin or acenocoumarol.

We understand that every mother's instinct is to put the baby before herself. You may prefer to use heparin rather than warfarin. It is important for you to understand the implications of this approach and the serious risks of a valve thrombosis for you and your baby. If it happens to you, you could have severe brain damage, lose limbs/ organs, or even die. You may be unable to care for your baby as a result.

For a summary of how the risks compare between the treatment options, please see Table 1.

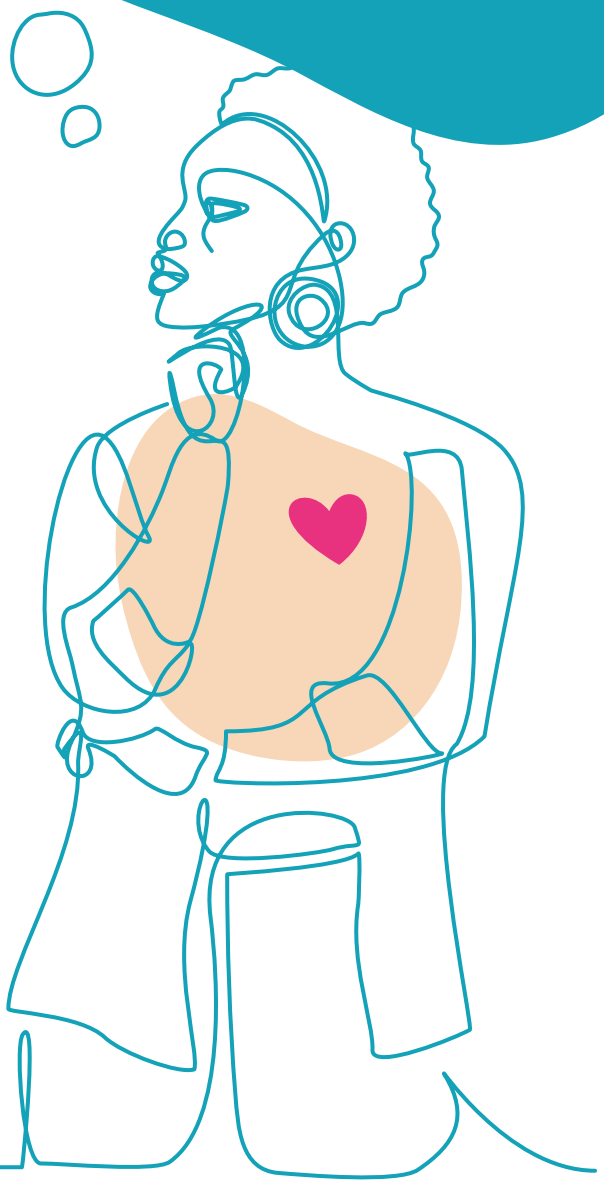
We recognise that this decision is very challenging. Some women will change their mind during the course of the pregnancy. Your healthcare team will support the decisions that are made, but it is important to talk about your worries and concerns with your pregnancy healthcare team as early as possible.

Helping you make your decision

When someone with a mechanical heart valve considers pregnancy, it is important they know and understand the risks and benefits of different treatment options. Ideally, you should talk to your medical team before pregnancy. They will review and discuss your individual risk and recommend a treatment programme for you.

The decision is personalised to you. These decisions are always made by a full team of obstetricians, cardiologists, haematologists, or obstetric physicians and most importantly, you and your family.

For women with a very high risk of thrombosis to their valve, surrogacy may be recommended as an alternative way to have the baby without the risk.



How we manage your anticoagulation

Weeks 1 to 36

Warfarin/ acenocoumarol:
If you decide to continue with warfarin/ acenocoumarol, a dedicated member(s) of the team will manage your dosing. Your INR will need more frequent testing than usual to ensure that the baby is exposed to as little risk as possible. This could be as often as several times per week. INR tests may be arranged locally to you or, in some cases you may be loaned a self-testing INR machine. Women on warfarin will often switch to heparin in the final stages of pregnancy, usually after 36 weeks, to avoid increased bleeding at the time of birth.

Heparin:
Those who choose to have heparin injections will need regular blood tests. These will often be every week, but may be even more frequent, to check the activity of the heparin on the clotting factors (this is called an 'anti-Xa level', or heparin assay). These blood tests usually need to be done at the hospital. At first this will often be weekly, but if results are stable may extend to every two weeks. The dose of heparin may change in response to the blood test results. Heparin will usually be given twice daily and due to changes to the body during pregnancy, the dose will usually be higher than the standard dose given outside of pregnancy.

Combination:
Most of the baby's development happens between 5-12 weeks of pregnancy. If warfarin is avoided at this critical time, it can prevent birth defects from happening. A switch from warfarin to heparin between 5-12 weeks of pregnancy may be recommended to lower the risk of birth defects. Aspirin may also be recommended to some women. Women on warfarin will often switch to heparin in the final stages of pregnancy, usually after 36 weeks, to avoid increased bleeding at the time of birth.

Week 37 to Delivery

An anticoagulation plan specifically for you will be made prior to delivery. As heparin is more straightforward to manage than warfarin/ acenocoumarol, women taking tablets will be converted to heparin after 36 weeks of pregnancy. Once labour starts, you should not take any further heparin. For women who will be induced, the last dose of heparin will be 24 hours before the planned induction of labour. If the labour is prolonged and a vaginal delivery, you may receive a low dose of heparin to protect your valve, this may have an impact on options for pain control such as an epidural. For those with the highest risk valves, sometimes it is recommended that they are on an infusion of heparin during delivery.

After Delivery

Following birth, it is safe to breastfeed while taking heparin, warfarin or acenocoumarol. The baby will need to have vitamin K, which is recommended to all newborn babies to prevent them having bleeding problems. This can be given as a drop into their mouth or as an injection.

You will be switched back to your warfarin/ acenocoumarol in the normal way with the help of your usual anticoagulation team and continue monitoring INRs as you were before pregnancy.

USEFUL INFORMATION

Other useful information is available at:

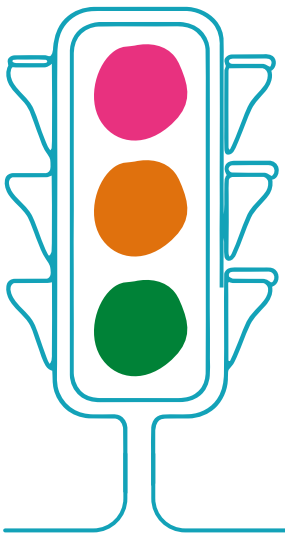
bumps
best use of medicine in pregnancy
(medicinesinpregnancy.org)

TABLE 1:

Comparing the risks of the different treatment options

	TREATMENT OPTION 1 **Warfarin/ Acenocoumarol:** Week 0-36 **LMWH:** Week 36+	TREATMENT OPTION 2 **LMWH:** Week 0-40 (throughout pregnancy)	TREATMENT OPTION 3 **LMWH:** Week 0-13 **Warfarin/ Acenocoumarol:** Week 14-36 **LMWH:** Week 36+
Risk of valve thrombotic complications	3%	9%	6%*
Risk of mother dying	1%	3%	2%
Overall risk to mother (death, valve thrombus or failure)	5%	16%	16%*
Fetal loss	33%	12%	23%
Fetal cleft palate/ bone deformity/ bleeding	2% - 12%¥	0%	1%

KEY FOR RISK RANKING IN EACH CATEGORY:



Highest

Intermediate

Lowest

These figures compare events between the different treatments and do not account for the background rates of abnormalities or pregnancy complications.

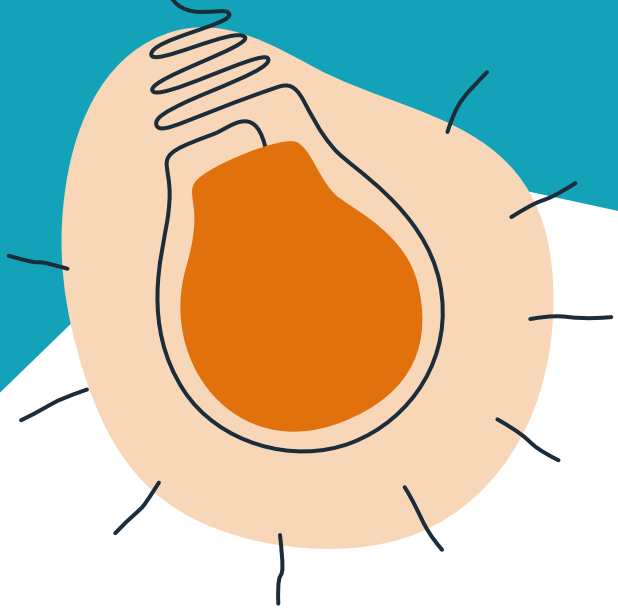
LMWH: Low Molecular Weight Heparin
e.g. enoxaparin, dalteparin or tinzaparin

*Half of all valve thromboses in pregnancy occur within the first trimester. When treatment option 3 is used, patients will be on LMWH during the first trimester. LMWH is known to be less effective than warfarin at preventing thrombosis during this higher risk time.

¥Some data suggest that warfarin doses less than 5mg/day are associated with less fetal risk. This data is inconclusive hence the wide range. The dose of warfarin is set based on the INR. Doses may need to exceed 5mg/day for some patients.

Data adapted from Lester et al.

Frequently Asked Questions



What should I do if I am planning a pregnancy?

Continue taking your warfarin as prescribed. Contact your anticoagulation team to arrange a pre-pregnancy counselling consultation to discuss the anticoagulation options and what a pregnancy would look like.

What should I do if I find out I am pregnant?

Continue taking your warfarin as prescribed. Contact your cardiology and anticoagulation team as soon as you find out you are pregnant to arrange a consultation with the obstetric /pregnancy cardiology team to manage your anticoagulation. You should have been given contact details at previous consultations. If you cannot find them, please contact your anticoagulation team or GP to ask them to refer you urgently.

What happens if I change my mind about my anticoagulation treatment during pregnancy?

If you are having doubts about your anticoagulation treatment, please contact your obstetric /pregnancy cardiology team to discuss further. Your treatment choice is yours to make and you will be supported whichever option you choose.

How will I know if there is a problem with my valve?

Symptoms of valve thrombosis include: tiredness, weakness, breathlessness and hearing muffled clicks from your valve. A common complication of valve thrombosis is a stroke. If you experience one sided weakness, facial droop, difficulty speaking or understanding others, you need to seek emergency medical attention. If you are admitted to your local hospital during the pregnancy, it is essential that your specialist obstetric/pregnancy cardiology team are informed immediately. We would encourage you to contact them directly as well to make 100% sure they're aware.

What should I do if I miss an injection?

The injections have a short duration of action and so the protection they offer will wear off quickly in the event of a missed dose.

Missed morning doses.
The most important thing is to take it as soon as you realise the dose was missed. Please contact your clinic for advice on dosing.

Missed evening doses.
If you realise before you go to sleep, take it there and then. If you realise the following day, there is nothing that can be done and start taking as prescribed that day.

What if I am unsure if I have taken the injection?
If you can't remember if you have had a dose, assume that you have and do not risk double dosing.

What should I do if I miss a dose of warfarin/ acenocoumarol?

If you realise you have missed a dose take it as soon as possible. If you are unsure do not risk double dosing. If you miss a dose please contact your clinic as they may want to amend your dose and you may need an INR sooner than scheduled.

TIPS FOR AVOIDING MISSED DOSES.

Remembering to take medicines as prescribed multiple times a day can be harder than it sounds. Simple things that can help prevent missed doses include:

- Setting reminders on your phone
- Linking taking your medication with other tasks you do every day e.g. brushing teeth, meals, bedtime routines etc
- Keeping spares in your handbag, car or work so that if you are away you have them to hand
- Keeping a log or diary

How often will I need to check my INR?

Due to changes in the body during pregnancy, INR control can be a bit more unpredictable. You may need to have your INR checked more frequently than you are used to. If your INR results are stable, you will be tested weekly. If your INR results are unstable you may need to test your INR two or three times a week, depending on the INR level and how out of range you are.

How often will I need to blood tests for heparin?

Particularly at the start, this may be as often as weekly depending on the test results and if dose changes are needed. Your clinic will inform you of how often you need to test.

What happens if I have a high INR?

Most of the time this will lead to a dose reduction or dose omission followed by an INR test. If the INR is very high it may be reversed with vitamin-K to reduce the risk of bleeding.

If I bleed what should I do?

Bleeding should be managed in the same way as outside of pregnancy. Minor bleeds such as self-limiting nose bleeds lasting less than 5 minutes do not require medical attention. Please make sure you notify your anticoagulation clinic if this happens at your next INR. Ongoing bleeding requires immediate medical attention. If you notice any vaginal bleeding please contact your obstetric team straight away.

Can I reduce my target INR to reduce the risk to the fetus with warfarin/ acenocoumarol?

The target INR is based on the thrombotic risk of the valve, which does not change during pregnancy. It is not recommended to reduce the target INR during pregnancy as this would lead to a higher risk of valve thrombosis.

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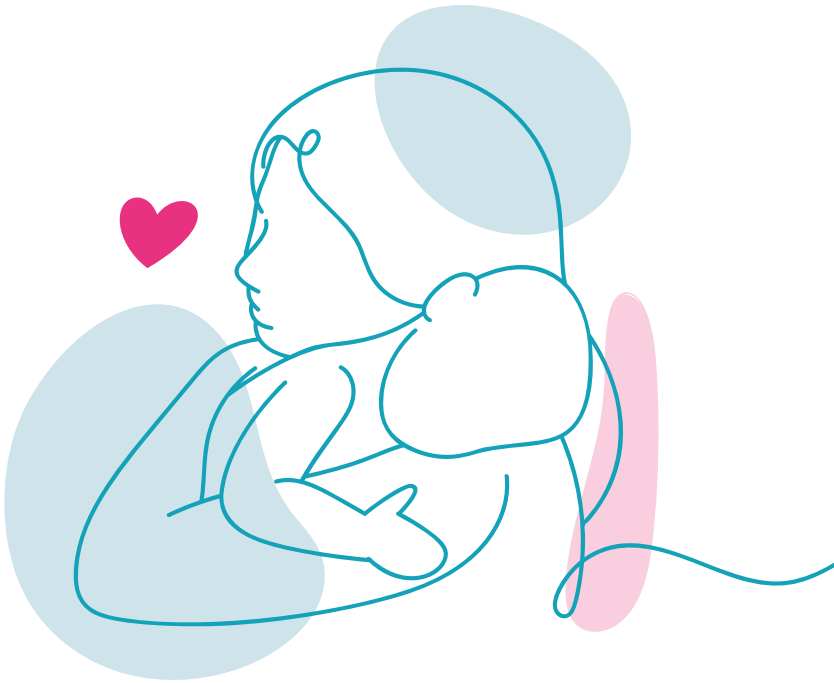

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September 2025