LUPUS
A Guide to Pregnancy

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THE NAOMI TATE MEMORIAL FUND

Naomi Tamara Natasha Tate was a young woman aged 26 who sadly died in 2009, she had lupus.

Naomi’s family, Pete, Paula and Nathan Perry set up ‘The Naomi Tate Memorial Fund’, now part of LUPUS UK, to assist in raising awareness of lupus, especially in pregnancy.

It was always intended that the fund would raise money exclusively for LUPUS UK.

We are very proud to be able to fund this LUPUS UK publication.
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LUPUS UK acknowledges with gratitude the assistance of Professor Caroline Gordon, Consultant Rheumatologist (Sandwell and West Birmingham Hospitals NHS Trust) and Dr Mary Gayed, Consultant Rheumatologist (Heart of England NHS Foundation Trust) in writing this booklet.
Lupus is a disease that is about six to nine times more common in women than men. It most commonly presents during the reproductive/childbearing years, but can develop at any point in life.

In the past women with SLE were discouraged from pregnancy due to the concern regarding the effects of the disease on the mother and the baby. However over the last 10-20 years, medical practice has changed and in many cases pregnancy is possible with close supervision. The advice will be tailored according to individual cases. This leaflet will explain what will need to be taken into consideration before, during and after pregnancy if applicable.
Before Pregnancy

It is important that pregnancy is planned for when SLE has been inactive for a minimum of six months on stable therapy. Conceiving while SLE is active will increase the risk of disease flares during pregnancy and increase the risk of complications for both mother and baby. Prior to pregnancy SLE patients should be screened and treated for kidney involvement, high blood pressure and any serious heart or lung problems.

As with all women planning pregnancy a healthy diet and appropriate exercise are recommended. Smoking, illicit drug use and drinking alcohol are discouraged. All women planning pregnancy are advised to use folic acid (0.4mg) for three months prior to pregnancy and during the first 12 weeks of pregnancy to reduce the risk of neural tube defects.

Drug Therapy

Another important reason to plan pregnancy is to ensure that drug therapy is appropriate prior to conception and during pregnancy. Methotrexate, mycophenolate mofetil and cyclophosphamide need to be stopped, and changed to an alternative (such as hydroxychloroquine and/or azathioprine) prior to conception, about three months before trying for a baby (see table 1 in appendix).

New biological agents such as rituximab should be stopped six months before pregnancy as there is so little data available. ACE inhibitors (blood pressure medication) should be stopped when a pregnancy is confirmed by a pregnancy test. There is a specific washout procedure that will need to be undertaken, if a woman is exposed to leflunomide during pregnancy.

Warfarin will need to be changed to subcutaneous heparin and aspirin when pregnancy is confirmed. Warfarin can cause congenital abnormalities and should be changed to subcutaneous heparin, which is safe in pregnancy, at the earliest possible opportunity. Treatment for high blood pressure needs to be reviewed and some drugs have to be changed (eg. lisinopril).

Calcium and vitamin D3 are encouraged before and during pregnancy to improve outcomes for both mother and baby. Bisphosphonates should be stopped 3-6 months before pregnancy.

We recommend that women should discuss all their drug therapy with the consultant supervising their care prior to pregnancy.
**Blood tests**

Prior to conception it is important to be aware if the mother has certain lupus antibodies, which may alter management during pregnancy (see table 2 in appendix).

It is important to know if the mother has anti-Ro and anti-La antibodies, as in approximately 1% of women with these antibodies they can cross the placenta and cause *congenital heart block*. If these antibodies are present they can only cross the placenta AFTER about 16 weeks and weekly foetal heart monitoring will be undertaken by a midwife/doctor from 16 weeks onwards. A few babies will die in utero due to congenital heart block and the related cardiac complications. The majority who are born do well. However approximately 30% will require a pacemaker during the first month of life, 30% in the first year and the remainder will require a pacemaker by the age of 10 to 12 years.

It is important to know if you have *anti-phospholipid syndrome* or *antibodies*, as this may increase the risk of blood clots (thrombosis) during pregnancy. In addition the presence of these antibodies can increase the risk of pregnancy complications such as *pre-eclampsia*, *intra-uterine growth restriction (IUGR)*, *premature delivery* or *still birth*. Treatment in pregnancy will depend on the mother’s past medical history.
In Vitro Fertilisation (IVF)

IVF is one of several techniques available to help people with fertility problems have a baby. Fertility in lupus patients has been reported to be the same as the general population. Some studies have shown that fertility can be reduced in patients with lupus due to the disease itself and treatments such as cyclophosphamide. Fertility was also reduced in SLE patients in these studies because they were older than healthy controls.

During IVF, an egg is removed from a woman's ovaries and fertilised with sperm in a laboratory. The fertilised egg, called an embryo, is then returned to the woman's womb to grow and develop. It can be carried out using your eggs and your partner’s sperm, or eggs and/or sperm from donors.

Although IVF can be successful in lupus patients, there are risks associated with it, and it is important that you seek advice from your doctor before undergoing the treatment. Ovarian stimulation, which is usually required to allow an egg to be removed from the woman’s ovary, can be associated with complications such as lupus flare and blood clots. The risks of infertility treatment are increased in patients with anti-phospholipid syndrome and lupus, as anticoagulation requires very careful management. As with pregnancy it is important that the lupus disease should not be active for at least six months prior to attempting ovarian stimulation, to ensure the best possible outcome for mother and child.
Effects of Lupus on Pregnancy

Risk of Flare during Pregnancy
Recent studies have suggested that the risk of flares during and after pregnancy, due to hormonal changes is approximately 25%, but most of these will be mild to moderate, affecting skin and joints predominately rather than kidneys. The flare risk is slightly higher in pregnant SLE patients compared to non-pregnant lupus patients. The risk varies according to patients’ background and how flares are defined. A higher risk of flares is seen in women with a flare within six months prior to conception, active kidney disease (lupus nephritis), previously very active disease, and if SLE therapy has been stopped.

Why are Flares Important?
It is important to promptly identify and treat flares during pregnancy as they can cause complications to both mother and baby. Complications include a possible increase in risk of pre-eclampsia in mothers, a three-fold increase in prematurity (<37 weeks) and IUGR (poor growth of the baby) resulting in still birth if there has been high SLE activity in early pregnancy.

Identifying Lupus Flares
It is essential to differentiate between lupus activity and pregnancy complications, as this will determine what treatment is given. SLE patients should be reviewed regularly by both their physician and obstetrician.

Renal disease (lupus nephritis) is present in approximately a third of UK lupus patients and can deteriorate during pregnancy, particularly if it has been active prior to pregnancy. It is important not to mistake active renal disease for pre-eclampsia which can co-exist. For doctors to diagnose lupus nephritis it is essential that the urine is examined for cells and/or casts as well as increasing proteinuria, which will normally rise before blood pressure. If cells are present, infection of the urine must be excluded. Conversely in pre-eclampsia the blood pressure will usually rise before the onset of proteinuria.

To assist with diagnosing a renal flare, there will often be other features of active disease in the patient and a change in the blood tests; rising anti-double stranded DNA antibodies and/or low complement. Pre-eclampsia will be more likely if associated with the features of HELLP syndrome (Haemolysis Elevated Liver enzymes Low Platelets).

If new clinical features are due to a lupus flare then women should be treated with steroids and immunosuppression, but if due to pre-eclampsia then steroids may make the blood pressure worse. The ultimate treatment for pre-eclampsia is
delivery of the foetus, but anti-hypertensives (treatment for high blood pressure) may be used in the first instance.

In pregnant lupus patients who develop neurological symptoms such as headache, seizures (epileptic fits), drowsiness, transient ischaemic attack (TIA) or stroke, a full assessment should be made, as there are multiple potential causes. These symptoms may be due to active lupus, thrombosis (blood clots), eclampsia or other pregnancy complications. This highlights the importance of screening for the presence of anti-phospholipid antibodies prior to pregnancy.

Some common changes due to pregnancy can be mistaken for lupus flare. All pregnant women can develop knee swelling (effusions) or carpal tunnel syndrome during pregnancy, but if there is a lupus flare your physician will detect synovitis (inflammation of joint lining). Pregnant women can develop redness (erythema) of palms and face, which is important to differentiate from a raised lupus rash.

**Clinical Assessment**

As outlined above, if the mother develops any clinical features that may be due to a lupus flare, she should arrange for a medical review. This should include a full history and medical examination. The urine must be tested and sent to the laboratory to identify protein, cells and casts.

**Serological Assessment**

Routine blood count, immunology, biochemistry for kidney and liver function blood tests should be taken. In the presence of a flare there may be evidence of leucopoenia (low white cells). Unreliable features during pregnancy include low platelets and anaemia, as these can occur as part of pregnancy.

A flare is suggested if there is a drop in complement (C3/C4). Complement normally increases by approximately 10-30% in pregnancy, so even remaining low in the normal range can be considered abnormal in the later phases of pregnancy and any fall at all of 25% or more should be an indicator of active disease during pregnancy.

Rising anti-double-stranded DNA antibodies in the 60% of SLE patients who make them, also indicates active disease.

Measuring ESR (erythrocyte sedimentation rate) is an unreliable test in pregnancy, as it rises non-specifically in all patients.
Treatment of Flares

Lupus patients who develop active disease during pregnancy can start low dose prednisolone or increase their current prednisolone dose. Prednisolone is largely inactivated by an enzyme in the placenta (after birth) and very little reaches the baby. However prednisolone, particularly at high doses (20mg/day or more), can be associated with an increased risk of hypertension, pre-eclampsia, diabetes, infection, osteoporosis and premature delivery. So patients will need close monitoring by their physician and obstetrician.

A number of studies have demonstrated the safety of prednisolone, hydroxychloroquine and azathioprine in pregnancy. Evidence suggests that the outcome for mother and baby is much better if the mother’s disease is prevented from flaring by continuing these drugs or starting them if the disease flares during pregnancy rather than by stopping the drugs, which was past medical practice.

Hypertension

In approximately 25% of lupus pregnancies, hypertension is present. It is important to ensure blood pressure is adequately treated by appropriate drugs for pregnancy (eg. nifedipine and labetalol), to reduce the risk of any complications. These include intra-uterine growth restriction (IUGR) and a higher rate of caesarean sections.

Pre-eclampsia

The risk of pre-eclampsia is higher in lupus patients with anti-phospholipid syndrome. It is essential to exclude lupus nephritis by ensuring there are no other clinical features of active lupus, no cells in the urine and that the immunology tests for lupus are normal.

Pre-eclampsia usually presents after 20 weeks of pregnancy in up to 30% of pregnancies. The risk is increased if: first pregnancy, previous pre-eclampsia, twins/multiple pregnancy, steroids (especially ≥20mg prednisolone), previous kidney disease and/or high blood pressure and a history of anti-phospholipid syndrome (with blood clots in the mother).
Effects of Lupus on Baby

IUGR

*Intrauterine growth restriction (IUGR)* refers to the poor growth of a baby while in the mother’s womb during pregnancy. Specifically, it means the developing baby weighs less than 90% of other babies at the same gestational age. The risk of IUGR is increased compared to the general population. In lupus pregnancies the risk is increased in women with *anti-phospholipid antibodies*, active lupus at conception and high blood pressure during pregnancy. IUGR increases the risk of *premature delivery*.

Prematurity

*Premature delivery* is more common in women with lupus and is defined as delivery before 37 weeks gestation. It occurs in 40-50% of SLE pregnancies.

The risk factors for premature delivery include active disease, kidney involvement, hypertension, *pre-eclampsia* and high dose steroids (prednisolone≥20mg).

The delivery may be spontaneous or more often induced, due to concerns regarding foetal growth (IUGR), reduced liquor (amniotic fluid around the foetus), foetal distress or rupture of membranes.

Once the baby is mature enough to be delivered and survive in a neonatal ward, it is often advised to have an induced birth or caesarean to deliver the baby before it dies in utero, if there are concerns.

*Premature delivery* may be necessary if the mother develops *pre-eclampsia*. Alternatively a *premature delivery* may be arranged if the mother develops a severe disease *flare* that requires treatment with an immunosuppressant that may not be safe for the baby such as cyclophosphamide.

There are numerous consequences of premature delivery for the foetus. The most serious are breathing problems; mothers will normally be given a course of special corticosteroids (eg dexamethasone which can cross the placenta), to promote foetal lung development. Other possible complications include infection, liver problems (jaundice), feeding difficulties, developmental delays or neonatal death (within 4 weeks of birth).

Foetal Loss

Foetal loss includes spontaneous abortion under 10 weeks, miscarriages between 10 to 19 weeks and still births from 20 weeks onwards.
There is an increased rate of foetal loss and miscarriages in lupus patients. The risk is higher in those with a previous history of foetal loss (especially >10 weeks), anti-phospholipid syndrome, active disease before or during pregnancy, kidney disease, high blood pressure and pre-eclampsia.

**Delivery**

In SLE patients a vaginal delivery should be possible, with pregnancy planning and joint care. A caesarean is normally reserved for emergencies, women who have previously had a caesarean who do not want the trial of vaginal delivery, and women with severe hip disease.

However to reduce the risk of still birth in women with active disease and/or anti-phospholipid syndrome, induction is usually planned at 38-39 weeks.
Pregnancy Related Complications in the Mother

Thrombosis
The most important complication is thrombosis (blood clots), especially if the mother has *anti-phospholipid antibodies*. All pregnant women, especially those with lupus and/or anti-phospholipid antibodies are at risk of thrombosis. *Anti-phospholipid syndrome* is characterised by recurrent venous or arterial thrombosis and recurrent miscarriages. It may also be associated with *premature delivery, pre-eclampsia, and stillbirth*. Patients with confirmed *anti-phospholipid syndrome* are likely to require treatment with both aspirin and subcutaneous heparin throughout pregnancy. Patients with recurrent miscarriages in the first trimester may be treated with aspirin. In some centres aspirin may be used in women with SLE without *anti-phospholipid antibodies* to prevent thrombosis and *pre-eclampsia*.

Gestational Diabetes
The risk of *gestational diabetes* (diabetes in pregnancy) is increased in women who have used steroids, especially in those on 10mg/day of prednisolone or greater during pregnancy. There is also an increased risk in women with a family history of diabetes and those from Asian backgrounds. Many units will arrange a glucose (sugar) tolerance test, to assess how the body handles glucose, to look for impaired glucose tolerance in the second half of pregnancy.

Osteoporotic Fractures
There is an increased risk of osteoporotic fractures in lupus patients who are on both steroids and subcutaneous heparin. They are often treated with calcium and vitamin D3 during pregnancy. Fortunately the risk is small, except for women on very high dose steroids and/or have had many courses of subcutaneous heparin.

Dyspepsia
Dyspepsia is a common symptom in pregnancy and can be worsened by aspirin and steroids. Antacids such as gaviscon in combination with ranitidine can be used to treat this.
Complications Affecting the Baby

Congenital Abnormalities
Major abnormalities, with the exception of congenital heart block, occur no more frequently in children born to mothers with lupus than in the general population (about 2%), as long as they are taking approved drugs such as prednisolone, hydroxychloroquine and azathioprine.

Major abnormalities have been documented in some babies exposed to methotrexate, mycophenolate and cyclophosphamide. So these drugs should be avoided in pregnancy.

Congenital Complete Heart Block
The most common congenital abnormality that can be linked to lupus is congenital heart block. This occurs in about 1% of pregnancies in women with anti-Ro or anti-La antibodies. This occurs due to the transmission of anti-Ro and/or anti-La antibodies across the placenta (afterbirth), usually between 16 and 32 weeks of pregnancy. The antibodies cannot cross the placenta before 16 weeks. Complete heart block is usually detected by week 28, but can occur later including after birth.

Women who are known to have anti-Ro or anti-La antibodies should have foetal heart monitoring from 16 weeks onwards by their midwife or hospital unit. If a slow foetal heart rate is detected during monitoring, women should be referred for further tests, including foetal echocardiogram. If heart block is suspected then treatment with special steroids e.g. Dexamethasone, which can cross the placenta may be used, but there is little evidence that it will reverse established heart block although it may help other related heart problems.

All babies born to mothers with anti-Ro and/or La antibodies are advised to have an ECG (electrocardiogram) after birth, to assess for any possible electrical abnormalities.

The majority of babies will do well. However there are a few babies who will die before birth due to congenital heart block and related cardiac complications. In around 30% of cases a pacemaker will be required in the first month of life, another 30% in the first year of life and the remainder will require a pacemaker by the age of 10 to 12 years. If a mother with anti-Ro and/or La antibodies has a child with congenital heart block, there is about a 20% risk of a subsequent child being born with congenital heart block.
**Neonatal Lupus**

The neonatal lupus syndrome is due to the transmission of anti-Ro and/or La antibodies across the placenta from week 16. The syndrome may present as a transient rash, heart block (discussed on page 10), liver abnormalities or low platelets.

Neonatal rash normally presents after delivery in the babies of women who have anti-Ro and/or La antibodies that are exposed to sunlight or UV light (for example to treat jaundice). The rash may persist a few weeks or months until the mother’s autoantibodies are cleared from the foetal circulation. If a mother has had a baby with a neonatal rash, the risk of a neonatal rash in the subsequent pregnancy is about 10% and the risk of congenital heart block is about 20%.

Low platelets in the baby are rare but most common in babies born to mothers with *anti-phospholipid antibodies* or a history of *immune mediated thrombocytopenia (ITP)*.
After Pregnancy

Flares
There is a risk of flares in the postpartum period, even if the disease has been stable before and during pregnancy. It is important to seek medical attention if you experience symptoms of a lupus flare, so your drugs can be appropriately managed.

Blood Clots
All women will have an increased risk of blood clots during and after pregnancy, this risk is further increased in women with lupus (with or without anti-phospholipid antibodies). It is essential to keep as active as possible and remain on any recommended blood thinning medication (heparin or warfarin). If you experience any symptoms of a blood clot such as a painful swollen calf or breathlessness with chest pain, you must seek urgent medical attention.

Breast Feeding
Breast feeding has multiple benefits to both mother and baby (see table 3 in appendix). It is safe to breastfeed whilst taking prednisolone, hydroxychloroquine and heparin or warfarin. It is increasingly accepted that it is safe to breast feed whilst taking azathioprine as there are only low levels of the active form of the drug in breast milk.

Contraception
Barrier methods or progesterone-only contraception are recommended. These include the oral progesterone-only (mini-pill) pill, intra-muscular progesterone injections or implant. The Mirena coil is also suitable for lupus patients.

Many women with lupus are advised to avoid oestrogen containing contraception, due to the increased risk of thrombosis (especially in those with anti-phospholipid antibodies) and the possibility of flares.
Conclusion

With careful planning, most women can go on to have successful pregnancies. It is important to make sure that the lupus has been inactive for at least six months and that drug therapy is appropriate prior to conception and during pregnancy. It is important to differentiate between active disease and other changes throughout pregnancy to ensure appropriate investigations and treatment are initiated. In conclusion, women with SLE require close monitoring before, during and after pregnancy to ensure the best possible outcomes for both mother and baby.
### Table 1 Drugs to stop before and after conception

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<thead>
<tr>
<th>Drug</th>
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<tr>
<td>Methotrexate</td>
<td>Stop 3 months prior to conception</td>
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<tr>
<td>Cyclophosphamide</td>
<td>Stop 3 months prior to conception</td>
</tr>
<tr>
<td>Leflunomide</td>
<td>Stop 2 years before conception or cholestyramine washout</td>
</tr>
<tr>
<td>Mycophenolate</td>
<td>Stop at least 6 weeks prior to conception</td>
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<tr>
<td>Reason</td>
<td>Drug</td>
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<tr>
<td>Painkillers</td>
<td>Paracetamol</td>
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<td></td>
<td>Codeine</td>
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<td></td>
<td>Pethidine</td>
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<td>Immunosuppression</td>
<td>Prednisolone</td>
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<td></td>
<td>Hydroxychloroquine</td>
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<td></td>
<td>Azathioprine</td>
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<tr>
<td>Bone Protection</td>
<td>Calcium &amp; Vitamin D3</td>
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<tr>
<td>Anticoagulation</td>
<td>Heparin</td>
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<td>(blood thinning treatment)</td>
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<td>Anti-hypertensives</td>
<td>Labetalol</td>
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<td>(treatment for high blood pressure)</td>
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<tr>
<td></td>
<td>Nifedipine</td>
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<td></td>
<td>Methyl-dopa</td>
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<td>Hydralazine</td>
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Table 3 benefits of breast Feeding

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<th>Reduced risk in Child</th>
<th>Reduced risk in Mother</th>
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<td>Asthma (young children)</td>
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<td>Obesity</td>
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<td>Type 1 and 2 diabetes</td>
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<td>Childhood Leukaemia</td>
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<td>Sudden infant death syndrome</td>
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Key Points

Before pregnancy occurs:
• Get disease activity under control (six months)
• Screen for kidney involvement (and treat)
• Exclude serious lung or heart problems
• Ensure normal blood pressure
• Explain all risks including autoantibodies and thrombosis (blood clots)
• Rationalise all drug therapy
• Plan for support in pregnancy and after

During pregnancy:
• Monitor disease activity, especially kidney
• Continue steroids, azathioprine, hydroxychloroquine
• Screen for pre-eclampsia and congenital heart block and foetal growth restriction
• Beware blood clots (thrombosis)

After pregnancy:
• Advice on breast-feeding and contraception
• Beware blood clots and lupus flare
**Glossary**

**Antiphospholipid Syndrome** - Recurrent blood clots in the presence of autoantibodies. To make a diagnosis lupus anticoagulant and/or Anti-cardiolipin IgG/IgM and/or anti-Beta 2 glycoprotein IgG/IgM must be present on two occasions at least 12 weeks apart.

**CHB** - Congenital complete heart block is disruption of the heart’s electrical system between the atria (upper part of the heart) and the ventricles (lower part of the heart), normally below 100 beats per minute.

**Conception** - Involves the fusion of an ovum with a sperm, leading to the development of a foetus.

**Flare** - Development of new or worsening features of lupus.

**Gestational diabetes** - Diabetes in pregnancy.

**HELLP** - Haemolysis Elevated Liver enzymes Low Platelets.

**Immune Mediated Thrombocytopenia** - Increased destruction of platelets by the body’s immune system.

**IUGR** - Intra-uterine Growth Restriction. Poor growth of a baby while in the mother’s womb during pregnancy, less than 90% weight of other babies same age.

**IVF** - In vitro fertilisation is one of several techniques available to help people with fertility problems have a baby.

**Lupus Nephritis** - Inflammation of the kidneys caused by lupus.

**Miscarriage** - A foetus that dies while in the uterus before the 20th week of pregnancy.

**Pre-eclampsia** - Defined as high blood pressure, combined with proteinuria (protein in the urine) and oedema (ankle swelling).

**Prematurity** - Live birth before the 37th week of pregnancy.

**Stillbirth** - A foetus that dies while in the uterus after the 20th week of pregnancy.
Publicity materials, leaflets, posters, a dvd for the newly diagnosed, media releases and more are always available from the charity’s National Office for better awareness about lupus in clinics, hospitals and public places.