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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Please note that the medical terminology in italics is defined in the glossary on page 16
Lupus a Guide to Pregnancy

Introduction

Lupus is a disease which is at least ten 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 concern regarding the effects of the disease on the mother and the baby. However, over the last 10-15 years, medical practice has changed, and in many cases pregnancy is possible with close supervision, and advice will be tailored according to individual cases. This booklet 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 when SLE has been inactive for a minimum of six months on stable therapy. Conceiving while SLE disease is active will increase the risk of disease flares during pregnancy and also 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. Drugs such as methotrexate, mycophenolate mofetil, and cyclophosphamide will need to be stopped, and changed to an alternative prior to conception such as hydroxychloroquine and/or azathioprine. (see table 1- page 12)

New biological agents such as rituximab should be stopped preferably 12 months before pregnancy as there is so little data available. Another example are ACE inhibitors which should be stopped prior to pregnancy, or at the latest 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 if continued for more than six weeks after conception. Subcutaneous heparin is not usually recommended for long term treatment before pregnancy, but is safe in pregnancy. Other changes that may need to be made include swapping proton pump inhibitors, such as lansoprazole to ranitidine which has more safety data in pregnancy.

Calcium and vitamin D3 are encouraged before and during pregnancy to improve outcomes for both mother and baby. Bisphosphonates should be stopped well before pregnancy (ideally two years or more) as there is a small risk of causing congenital abnormalities.

We recommend that women should consult the Consultant supervising their care to discuss all their drug therapy prior to pregnancy. (see table 2- page 13)
Blood tests

Prior to conception it is important to be aware if the mother has certain antibodies, which may alter management during pregnancy, for example anti-Ro and anti-La antibodies. In approximately 1% of cases these 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 the mother has anti-phospholipid syndrome or antibodies, as this will increase the risk of blood clots (thrombosis) during pregnancy. In addition, the presence of antibodies can increase the risk of pregnancy complications such as pre-eclampsia, IUGR premature delivery or stillbirth. Treatment in pregnancy will depend on the mothers past medical history.
During pregnancy

Risk of flare during pregnancy
The risk of flares during and after pregnancy, due to hormonal changes is estimated to be approximately 50%, 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 controls. 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 6 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 pre-eclampsia in mothers and a threefold increase in prematurity (<37 weeks), IUGR (poor growth of the baby) resulting in stillbirth 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 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. In patients with lupus nephritis proteinuria will normally rise before blood pressure, whereas in pre-eclampsia blood pressure will rise before proteinuria. 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 complements. 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 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 of pregnancy can be mistaken for lupus flare. All pregnant women can develop knee swelling (effusions) or carpel tunnel syndrome during pregnancy, but if there is a lupus flare the 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 which 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 leucopenia (low white cells). Unreliable features during pregnancy include low platelets and anaemia, as these can occur as part of a normal pregnancy.

A flare can be confirmed if there is a simultaneous drop in complement (C3/C4). Complement normally increases by 10-50% 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 (afterbirth) and very little reaches the baby. However prednisolone, at high doses, 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 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 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 antibodies. It is essential to exclude lupus nephritis to ensure 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 presents after 20 weeks in approximately 35% of pregnancies. The risk is increased if it is a first pregnancy, there has been 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 which requires treatment with an immunosuppressant that may not be safe for 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 corticosteroids (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 stillbirths 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), *antiphospholipid antibody 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 stillbirth in women with active disease and/or *antiphospholipid antibody 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 antiphospholipid antibodies. All pregnant women, especially those with lupus and/or antiphospholipid antibodies are at risk of thrombosis. Antiphospholipid antibody 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 antiphospholipid antibody 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 antiphospholipid antibodies to prevent thrombosis and pre-eclampsia.

**Gestational diabetes**

Gestational diabetes 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. 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 those who 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.

Although there is little available data, there have been major abnormalities documented in babies exposed to methotrexate, mycophenolate and cyclophosphamide.

Congenital complete heart block

The most common congenital abnormality that can be linked to lupus is congenital heart block. This occurs in 1% of pregnancies in women with anti-Ro or anti-La antibodies due to the transmission of 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 such as steroids e.g. dexamethasone, which can cross the placenta may be used.

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 above), liver abnormalities or low platelets.

Neonatal rash normally presents after delivery in the babies of women who are anti-Ro and/or La antibodies who are exposed to sunlight or UV light (for example to treat jaundice). The rash may persist for a few weeks or months until the mothers 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 a subsequent pregnancy is about 10% and the risk of congenital heart block is about 20%.

Low platelets are rare, but most common in babies born to mothers with antiphospholipid 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 the mother experiences symptoms of a lupus flare, so their drugs can be appropriately managed.

**Blood clots (thrombosis)**
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 antiphospholipid antibodies. It is essential to keep as active as possible and remain on any recommended blood thinning medication (heparin or warfarin).

If a mother experiences any symptoms of a blood clot such as a painful swollen calf or breathlessness with chest pain, they must seek urgent medical attention.

**Breastfeeding**
Breastfeeding has multiple benefits to both mother and baby (see table 3). It is safe to breastfeed whilst taking prednisolone, hydroxychloroquine and heparin or warfarin. Most centres will advise that it is safe to breastfeed whilst taking azathioprine as there are only low levels of the active metabolite in breast milk.

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

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 in a stable relationship.
Conclusion

With careful planning, most women can 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 pregnancy changes throughout pregnancy to ensure appropriate investigations and treatment are initiated. In conclusion, pregnant women with SLE require close monitoring before, during and after pregnancy to ensure the best possible outcomes for both mother and baby.

Appendix

Table 1 Drugs to stop before and after conception

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<tr>
<th>Drug</th>
<th>Recommendations</th>
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<td>Methotrexate</td>
<td>Stop three months prior to conception</td>
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<tr>
<td>Cyclophosphamide</td>
<td>Stop three months prior to conception</td>
</tr>
<tr>
<td>Leflunomide</td>
<td>Stop two years before conception</td>
</tr>
<tr>
<td>Mycophenolate</td>
<td>Stop three months prior to conception</td>
</tr>
<tr>
<td>Bisphosphonates</td>
<td>Stop two years before pregnancy</td>
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### Table 2: Drugs that can be used in pregnancy under the supervision of a doctor

<table>
<thead>
<tr>
<th>Reason</th>
<th>Drug</th>
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<tr>
<td><strong>Pain Killer</strong></td>
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<tr>
<td></td>
<td>Paracetamol</td>
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<td></td>
<td>Codeine (avoid in labour)</td>
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<tr>
<td></td>
<td>Pethidine</td>
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<tr>
<td><strong>Immunosuppression</strong></td>
<td>Prednisolone</td>
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<tr>
<td></td>
<td>Hydroxychloroquine</td>
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<tr>
<td></td>
<td>Azathioprine</td>
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<tr>
<td><strong>Bone Protection</strong></td>
<td>Calcium &amp; vitamin D3</td>
</tr>
<tr>
<td><strong>Anticoagulation</strong></td>
<td>Heparin (avoid Warfarin after six weeks)</td>
</tr>
<tr>
<td>(Blood thinning treatment)</td>
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<tr>
<td><strong>Anti-hypertensives</strong></td>
<td>Labetalol</td>
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<tr>
<td>(Treatment high blood pressure)</td>
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<tr>
<td></td>
<td>Nifedipine</td>
</tr>
<tr>
<td></td>
<td>Methyl-dopa</td>
</tr>
<tr>
<td></td>
<td>Hydralazine</td>
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<tr>
<td></td>
<td>Avoid diuretics</td>
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<tr>
<td></td>
<td><strong>NOT</strong> ACE inhibitors e.g. Lisinopril</td>
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### Table 3 benefits of breastfeeding

<table>
<thead>
<tr>
<th>Reduced risk in child</th>
<th>Reduced risk in mother</th>
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<tr>
<td>Infection</td>
<td>Type 2 diabetes</td>
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<tr>
<td>Atopic Dermatitis</td>
<td>Breast cancer</td>
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<tr>
<td>Asthma (young children)</td>
<td>Ovarian cancer</td>
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<td>Obesity</td>
<td>Postpartum depression</td>
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<td>Type 1 and 2 diabetes</td>
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<td>Childhood Leukaemia</td>
<td></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 during pregnancy and after delivery

During pregnancy:

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

After pregnancy:

- Advice on breastfeeding and contraception
- Beware blood clots and lupus flare
Glossary

Antiphospholipid (antibody) syndrome - recurrent blood clots in the presence of autoantibodies. To make a diagnosis of 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

Flare - development of new or worsening features of lupus

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% other babies same age

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 - is 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.