

**Genetics,
Carrier Testing,
Tests during Pregnancy
and for Newborn Babies**

genetics

genetics contents

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This booklet is not intended to replace genetic counselling by a specialist. It is designed to help you when you consult your General Practitioner (GP) or speak to the counsellors at your regional genetic centre (see pages 11-13).

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Introduction

People who have Cystic Fibrosis (CF) were born with it and, unless a cure for the condition is found, will have it for the rest of their lives. Cystic Fibrosis is inherited; it can't be caught after birth. This booklet is aimed at explaining the inheritance process and why some babies are born with Cystic Fibrosis.

During the past ten years, there have been exciting advances in our knowledge of Cystic Fibrosis. This booklet will explain:

- How CF is inherited.
- What is known about the CF gene.
- How carriers of the CF gene can be identified.
- How you might avoid having a child with Cystic Fibrosis.
- What we mean by gene therapy.



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What is Cystic Fibrosis?

Cystic Fibrosis is the UK's most common life-threatening inherited disease affecting around 7,500 children and adults.

People with CF produce very thick sticky mucus that clogs their lungs and digestive systems making it difficult to breathe and absorb food properly. Serious symptoms and complications of CF include infection and inflammation of the lungs, malnutrition, diabetes, liver problems and osteoporosis.

When CF was first recognised as a disease in the 1930s most babies with CF were only expected to live a few months; in the 1960s life expectancy had reached early teens. At present, over half those affected can expect to live beyond the age of 30 and with earlier diagnosis and modern treatment, life expectancy and quality of life will continue to improve.

People with Cystic Fibrosis face a daily regimen of treatment. This includes physiotherapy to help clear the mucus from the lungs, antibiotics to fight infection, and enzyme supplements with food to help digestion. Although new treatments are being developed, which will undoubtedly improve the quality and length of life for people with CF, the condition remains serious. There is no cure at present, but gene therapy to cure the lung disease is a realistic possibility within the foreseeable future.

Cystic Fibrosis is an inherited or genetic disease. This means that the condition occurs because of a faulty gene, in this case carried and passed on by **both** parents who do not themselves have Cystic Fibrosis. The condition is caused by a single faulty gene (called the Cystic Fibrosis Transmembrane Conductance Regulator - or CFTR gene). A person must inherit two copies of this faulty gene - one from each parent - to develop Cystic Fibrosis.

What are Genes?

Genes carry the blueprint for producing

What we look like - and how our bodies work - are controlled by our genes.

We all have different genes and that's why we are all different.

The word *genetic* simply means 'to do with genes'. And *genetic* research - the study of genes - is a branch of science that is helping us understand more and more about what happens inside our bodies and how we can inherit genetic characteristics from our parents. The section in the next column *Why is a baby born with CF?* - will help you understand more about why and how babies can be born with the inherited disease Cystic Fibrosis.

We all have thousands of genes. Genes carry the blueprint for producing proteins that allow our bodies to function properly. The gene for CF happens to be one of them. Our genes come in pairs, with one of each inherited from each parent. A person with CF has two faulty CF genes in each cell of the body while the parents each have one faulty gene and one that works normally. Parents of children with CF are therefore called "CF carriers". Since their healthy gene allows normal functioning, being a carrier does not mean they have Cystic Fibrosis.

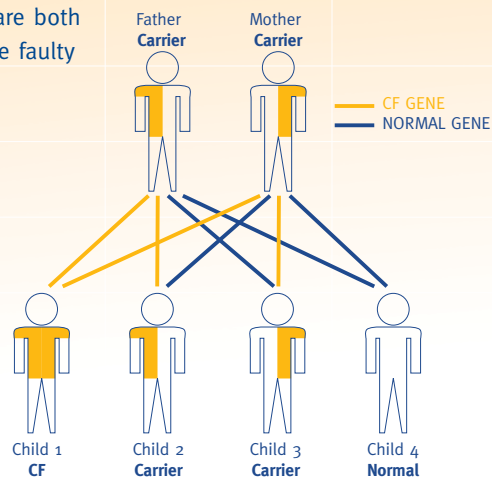
Why is a baby born with CF?

A baby is born with Cystic Fibrosis only if both its parents are carriers of the defective CF gene. Even then, though both parents each carries one faulty gene will not mean that the baby will be born with CF for certain. When both parents are carriers it is a matter of chance whether a particular sperm or a particular egg contains the faulty gene or a healthy one. When there is a faulty CF gene in both the sperm and the egg at conception the result is a baby who will have CF regardless of whether it is a boy or a girl.

The diagram shows the risk for each pregnancy for a couple who are both carriers of the faulty CF gene.

If both parents are carriers, a child has:

- A one in four chance of being born with CF.
- A two in four chance of being a carrier. This child will be perfectly healthy but may pass the faulty gene onto its own children.
- A one in four chance of being perfectly normal and having no faulty CF gene to pass on to future generations.



proteins that allow our bodies to function properly.



Two carrier parents might have several affected children, or only unaffected children - or, indeed, a mixture of both affected and unaffected children. It's only possible to calculate the chances; it's impossible to predict what will happen for any particular baby before conception.

If a couple already have a child with CF this doesn't change the risks in the next pregnancy. Each pregnancy has exactly the same chance (1 in 4) of resulting in a child with Cystic Fibrosis.

All this means that CF is a *genetic* disease. Most carriers of the defective gene have no idea that they're carriers, because they're usually completely healthy.

Occasionally carriers have been found to have some symptoms in common with CF, such as persistent chest infections or sterility in men due to blocked or absent sperm ducts. However, most carriers not only are perfectly healthy, they may have a health advantage (such as protection from diseases such as cholera) over non-carriers, which would explain why the faulty gene is so common.

Most people find out they are carriers when:

- a) they have a child with CF, or
- b) a close relative is affected and they're tested.

If only one parent has the faulty gene, there's no cause for concern. A baby must inherit a defective gene from both parents to be born with Cystic Fibrosis.

No-one is to blame for genetic diseases. We all have some genes that don't work properly, but we're not usually aware of it because there's also a normal gene that takes over.

QUICK FACTS

✦ In the UK, one person in 25 is a carrier and one in every 2,500 babies will have Cystic Fibrosis - that means that there's a baby born with CF nearly every day.

✦ The organs that are most severely affected are the lungs and the pancreas, resulting in breathing problems and poor digestion. Liver disease occurs in some people and diabetes is increasingly common in later life. Infertility is a particular problem in men with Cystic Fibrosis.

Screening

People can be tested to see whether they carry the CF Gene.

From 2002/3 all newborn babies in the UK will be tested to see whether they have Cystic Fibrosis. Adults can be tested to see whether they are carriers of the CF gene, and if their partner is also tested and also found to be a carrier, they can make informed choices about the implications of being parents.

Newborn screening

Until recently, only 20% of babies born in the UK were tested routinely for CF in the newborn period. The remaining 80% of babies were not tested and only diagnosed after the onset of chest, bowel or other symptoms and signs of Cystic Fibrosis. Often CF would go undiagnosed for months if not years.

The Government announced in 2001 that it would be introducing newborn screening for all babies carried out within the first week of life.

This is part of the “Guthrie test”, which involves taking a drop of blood from the heel of the baby that is tested for a number of different conditions. Most babies will get a clean bill of health, but for those few found to have CF, they will gain hugely from getting the proper treatment straight away and serious lung damage can be avoided or delayed.

What are your chances of being a carrier?

For most people in the UK, where there is no family history of Cystic Fibrosis, the chance of being a carrier is 1 in 25. If you have a child with CF, then both parents must be carriers (the only exception is when one parent has CF and their partner is a carrier).

For relatives of a person with CF the chance of being a carrier is higher than the general population. Tests are now available for relatives

and their partners to check whether or not they are carriers. These are available on the NHS from your Regional Genetics Centre listed on pages 11-13; talk to your GP about getting referred to your local Centre or contact them directly. It is up to each individual whether they wish to be tested or not.

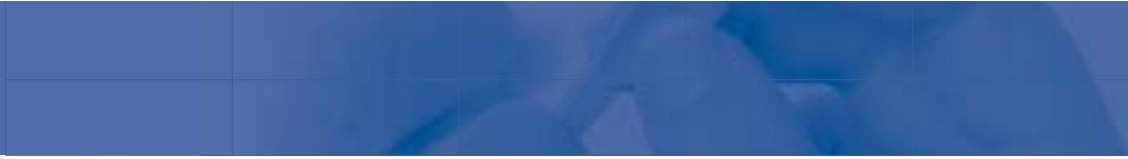
The table below outlines the chance of being a carrier if you are related to someone with Cystic Fibrosis:

Brother or sister	2 in 3
Aunt or uncle	1 in 2
First cousin	1 in 4
Second cousin	1 in 8
Third cousin	1 in 16

How are carrier tests performed?

Tests for checking whether someone is carrying the faulty CF gene are done usually using a simple blood or mouthwash test. With the mouthwash test you simply swill a weak sugar and salt solution around your mouth for 20 seconds. Cells





from this solution are then used for genetic testing. Most types of faulty CF genes (but not all) can be detected using this test.

Who should be offered carrier testing?

Relatives of those known to have CF have a higher chance of being a carrier and can be tested along with their partners at Regional Genetic Centres (see pages 11-13 for contact details). Whenever a carrier is detected, carrier tests are then made available to their relatives - hence the term "cascade" screening.

It is theoretically possible to test everybody to find out who are carriers, but unless you're related to someone with CF this test is not routinely available on the NHS. Because the CF gene is so common, it makes sense to test for its presence in the whole population, particularly amongst people who are thinking of having a baby. Carrying out CF testing would identify carrier couples before they have children. This would

allow them to avoid having children with CF, or to monitor the pregnancy with antenatal diagnosis (see page 11-13).

Several successful trials of population carrier screening have been carried out, although there isn't yet agreement about whether such general screening should be part of NHS care. At the moment, you're likely to encounter screening only when it's part of an extended research trial or if you're known to be at risk.

If you want to be tested, then you should contact the Genetics Centre for your region (listed at the end of this booklet). Different Centres may vary in their attitude to testing non-relatives of CF families and some Centres prefer you to be referred to them by your GP.

Since 1991 all pregnant women attending the Edinburgh antenatal clinics have been offered couple screening early in pregnancy. If the mother is found to be a CF carrier her partner is tested. If both are carriers, antenatal counselling

is given and they are offered antenatal diagnosis.

Cystic Fibrosis carrier testing is available privately and the CF Trust may be contacted for details.

SUMMARY

- It is possible to detect CF carriers in any family where there's already an affected child available for testing. This means that brothers and sisters of people with CF - and sometimes more distant relatives like aunts, uncles, nieces and nephews - can be tested.

- Current tests can detect up to 90% of CF carriers in the general population. However, a negative isn't absolutely definitive, even though the risk of being a carrier is reduced from about 1 in 25 to less than 1 in 200.

- From 2002/3 all newborn babies in the UK will soon be tested to see whether they have Cystic Fibrosis. This will allow them to receive proper treatment straight away.

Pregnancy

Carrier couples have many options to consider before unde

When both parents are carriers of the faulty CF gene they have a 1 in 4 chance of having a baby with CF *with every pregnancy* (see page 3 *Why is a baby born with CF*). While there have been great improvements in the length and quality of life for people with CF, it still remains a serious condition and carrier couples should think very seriously before undertaking a pregnancy.

There are a number of options open to couples: some opt for "taking a chance" and hope that the baby will not have CF and some choose not to have any (more) children. Many choose to have an antenatal test that will tell them whether the pregnancy will result in a baby being born with Cystic Fibrosis.

Recently, alternatives to antenatal testing are emerging that ensure that an embryo does not carry the faulty CF gene before it is implanted (see page 8 for an explanation about *pre-implantation genetic diagnosis*). Other options include artificial insemination using donor sperm, or egg donation fertilised with the father's sperm, which is then implanted in the mother's womb.

What is antenatal diagnosis?

This is a procedure that determines early on in the pregnancy whether or not a baby will have Cystic Fibrosis. If the baby is found to be unaffected, you'll be reassured to go ahead with the

pregnancy. If tests show that the unborn child does have CF, terminating the pregnancy is an option for you to consider. It's wise to have thought carefully about this before going ahead with an antenatal diagnosis test. The test is not generally recommended for those who find termination unacceptable, although some parents would prefer to know in order to be better prepared.

What does antenatal diagnosis involve?

The test is usually carried out between 10-15 weeks of pregnancy, although it can be performed a little later in some Centres - usually using chorionic villus sampling (CVS) sometimes known as chorionic villus biopsy (CVB). It involves staying in hospital for a few hours. A small sample of the placenta is removed and sent to the laboratory for analysis. The results are compared with those of the parents or any other child with CF in the family. If the tissue from the foetus has two faulty CF genes, then the child will

have CF. The test results take a few days to come through and the parents are told as quickly as possible. However, it must be kept in mind that there's a very small chance (1-2%) that a miscarriage might occur as a result of the procedure.

Occasionally, antenatal diagnosis is carried out later, between 15-18 weeks of pregnancy, using 'amniocentesis' to get a sample of cells from the foetus. Amniocentesis is an outpatient procedure and, although it's even less likely to cause miscarriage than chorionic villus biopsy (1 in 100), it's often avoided because most women think that if a termination is necessary it should be done as early as possible.

When should I see a genetic counsellor?

The CF Trust recommends that anyone considering antenatal screening should see a genetic counsellor before going through with the procedure. Genetic

ertaking a pregnancy.

counselling offers the opportunity to explore and discuss the options available as well as any other genetic aspects of Cystic Fibrosis. Genetic counselling is offered both before and during a pregnancy. If taken before a pregnancy, this allows a more cool headed appraisal of the options and decision making.

Most antenatal diagnosis so far has been carried out for couples who already have had one child with Cystic Fibrosis. These families have a clear idea of what it's like to have a child with CF and may have made up their own minds which option they would like to take.

As time goes on, more and more couples who are both carriers will be identified and will have no experience of the disease; it will be harder for them to decide what to do. Counselling will help anyone who wants to discuss the question of antenatal testing

and, whatever decision, people will be supported. A genetic counsellor will help guide people through the necessary procedures in the rapidly changing field of diagnosis but ultimately it is the parents' decision.

Pre-implantation genetic diagnosis

Another way for couples who are both carriers to have a baby known to be free of CF is by *pre-implantation genetic diagnosis*. The procedure involves *in vitro* fertilisation (IVF) similar to the technique used for infertile couples. Embryos are created in a "test tube" from the mother's eggs and the father's sperm. The embryos are then tested for CF and only embryos free of CF are implanted in the mother's womb.

This is not an easy option, nor is it freely available. It can be time-consuming and disruptive to the family routine as it usually requires travel to one of the few

Centres where it is available.

Centres offering pre-implantation genetic diagnosis are listed on page 13. The mother has to take fertility hormones to ripen a number of her eggs and these have to be collected through a fine tube passed into her lower abdomen. Generally two healthy embryos are put into the mother's womb. The chance of a successful pregnancy is 25%, and there is a higher risk of having twins.

There are only a few centres in the UK where pre-implantation genetic diagnosis is offered. It is also costly, at around £3,000 for each attempt and not all health authorities are prepared to pay for the treatment.

SUMMARY

- Always consult a specialist and a genetic counsellor before deciding for or against antenatal diagnosis. Ideally, you should consider this before pregnancy has started.

- Antenatal diagnosis is usually recommended for couples who are both carriers and have a 1 in 4 risk of having an affected child. For most of these couples, antenatal diagnosis is possible using a relatively simple test between 10 and 12 weeks of pregnancy.

- Lower risk pregnancies aren't usually tested for Cystic Fibrosis. Pregnant mothers who would like a test should discuss this with their GP or obstetrician.



The Cystic Fibrosis Gene Every one of us has

Every one of us has about 30,000 genes. In 1989 an international team of scientists identified the CF gene. They found that it makes a protein called CFTR (Cystic Fibrosis Transmembrane Conductance Regulator), which carries salt in and out of the cells that line the lungs and digestive system. In people with CF, the CFTR doesn't work properly. Usually, it gives out too much chloride (salt) and not enough water. This helps to explain why the secretions of the airways are sticky and become easily infected and why the sweat of a person with CF is excessively salty.

Are there different types of faulty CF genes?

There are many different ways in which genes can be faulty. Variations of a gene are called "mutations". Over 1,000 different mutations of the CF gene have been discovered, but most people in the UK have exactly the same gene defect. This common mutation is called $\Delta F508$ (pronounced delta F508) and 75% of people with CF in the UK carry two $\Delta F508$ genes. The vast majority (94%) of people with CF has this mutation as, at least, one of their faulty CF genes. While there are a large number of CF gene mutations, there are only 20 or so common ones.

Cystic Fibrosis carrier tests look for these more common mutations, and therefore picks up most, but not all, CF carriers. A negative test is not absolutely definite, although

the risk of being a carrier is markedly reduced.

Since two faulty CF genes are inherited, one from each parent, a child with CF may inherit the same mutation or different ones - dependant upon what mutation the parents are carrying. Does the type of mutation make a difference to the severity of the condition or to the type of symptoms that people with CF experience?

There is little difference between those who have two $\Delta F508$ genes or one $\Delta F508$ gene along with another faulty gene. In nearly all of these cases, the pancreas is unable to release the enzymes needed for proper digestion of food and they will have to take enzymes as pills with their food.

Only 5% of people with CF have sufficient pancreatic function to digest their food properly. These people usually have a rarer mutation for at

least one of their genes. One of the better known of these rarer genes is called R117H.

Different mutations make different faults in the CFTR protein. Some faults mean that CFTR isn't present at all, others result in CFTR being present, but either not working very well, or not enough of it is produced. The variations in the severity of symptoms experienced by people with CF can be partly explained by the types of their CF gene mutations.

Information about the many different mutations and their effects on the function of CFTR is important as it may lead to new treatments for CF tailor-made to help CFTR function better. These future treatments could be used on their own or in combination with gene therapy (see page 10 Gene therapy).

It is important to remember that CF genes are not the whole story. Other factors can

about 30,000 genes, a fault in one of them causes Cystic Fibrosis.

influence the outcome and quality of life of people with Cystic Fibrosis. These include getting both early treatment and the proper management advised at Specialist CF Centres. Genetic factors other than the CF gene itself can also play a role. These are called modifier genes and researchers are just beginning to identify them and discover their role in Cystic Fibrosis.

Gene therapy - what is it, and will it be a cure?

Many people - particularly those with a child who has CF - want to know whether research will lead to a cure.

Before the gene was identified, treatment was like a game of chance. Each symptom was treated as it appeared. There was no way of getting to the underlying cause of the disease. Now that the gene has been found, and the function of the CFTR protein is beginning to be understood, scientists are trying several new approaches.

One exciting prospect is gene therapy. This means getting

normal genes into the cells of patients who have only defective CF genes. It sounds simple and logical but there are many difficulties.

Discovering the best way to achieve this is an enormous undertaking and it must be said that progress won't be rapid. Gene therapy is such a novel form of treatment that we must proceed cautiously.

The first approaches are to try and get normal genes into the lungs of people with CF, because it's in the lungs that the most damage occurs.

Clinical trials have already shown that gene therapy works in principle, but for it to be an effective treatment many obstacles need to be overcome. While normal genes were taken up into the cells, they did not work very effectively nor for very long. Researchers are now focussing their efforts on developing new methods of more effectively delivering the genes into the cells where they are needed and enabling them to produce functioning CFTR. The results from early clinical trials are encouraging but there's a long way to go



and it will be some years yet before anything certain can be said.

The story of CF treatment must be put into perspective. Only a few years ago, the outlook for a baby born with CF was, to say the least, grim. Today, young adults with CF are living into their twenties, thirties and even forties - and these people are living active fulfilling lives.

The quality and length of life should be even greater as a result of the new genetics. The new research techniques, which have been and are currently, supported by the CF Trust, and applied so tentatively over ten years ago, are now bearing fruit.

Further advice is available from the Cystic Fibrosis Trust - full contact details are shown on the back cover of this booklet.

••••• **The future is an optimistic one.**

Regional Genetics Centres

Eastern

East Anglia Regional Genetics Service

Dept of Clinical Genetics
Box 134
Addenbrooke's Hospital
CAMBRIDGE CB2 2QQ
☎01223 216446

South West Thames Regional Genetics Service

Medical Genetics Unit
St George's Medical School
Cranmer Terrace
LONDON SW17 0RE
☎020 8725 5335

North West

Department of Clinical Genetics

Royal Manchester Children's Hospital
Hospital Road, Pendlebury
MANCHESTER M27 4HA
☎0161 727 2335

London

Guy's Hospital

Genetics Department
8th Floor Guy's Tower
Guy's Hospital,
LONDON SE1 9RT
☎020 7955 4648

Clinical Genetics Unit Institute of Child Health

30 Guilford Street
LONDON WC1N 1EH
☎020 7905 2177

North West Thames Regional Genetics Centre

The Kennedy Galton Centre
Northwick Park Hospital &
St Mark's NHS Trust
Watford Road
HARROW HA1 3UJ
☎020 8869 3180

Northern and Yorkshire

Institute of Human Genetics

International Centre for Life
Central Parkway
NEWCASTLE UPON TYNE
NE1 3BZ
☎0191 241 8721

Yorkshire Regional Genetics Service

Department of Clinical Genetics
Ashley Wing
St James's University
Hospital
LEEDS LS9 7TF
☎0113 206 5555

Merseyside and Cheshire Clinical Genetics Service

Royal Liverpool Children's Hospital
Alder Hey, Eaton Road
LIVERPOOL L12 2AP
☎0151 252 5238

Chester Regional Clinical Genetics Service

Moston Lodge
Countess of Chester
Hospital
Liverpool Road
CHESTER CH2 1UL
☎01244 364754

University Department of Medical Genetics and Regional Genetic Service

St Mary's Hospital
Hathersage Road
MANCHESTER M13 0JH
☎0161 276 6506



South East

Oxford Regional Genetics Service

The Churchill Hospital
Old Road
OXFORD OX3 7LJ
☎01865 226012

Wessex Clinical Genetics Service

Department of Clinical Genetics
Princess Anne Hospital
SOUTHAMPTON SO16 5YA
☎023 807 96166

South West

Peninsular Clinical Genetics Service

Dept of Clinical Genetics
Royal Devon & Exeter Hospital
Barrack Road
EXETER EX2 5DW
☎01392 403151

Clinical Genetics Service

Level B
St Michael's Hospital
Southwell Street
BRISTOL BS2 8EG
☎0117 928 5652

Trent

Dept of Clinical Genetics

The Leicester Royal Infirmary NHS Trust
LEICESTER
LE1 5WW
☎0116 258 5736

North Trent Clinical Genetics Service

Sheffield Children's Hospital
Western Bank
SHEFFIELD S10 2TH
☎0114 271 7025

Nottingham Clinical Genetics Service

2nd Floor H Block
City Hospital NHS Trust
Hucknall Road
NOTTINGHAM NG5 1PB
☎0115 962 7728

West Midlands

West Midlands Regional Genetics Centre

Birmingham Women's Hospital
Edgbaston
BIRMINGHAM B15 2TG
☎0121 627 2630

Northern Ireland

N Ireland Regional Genetics Service

Floor A
Belfast City Hospital
Lisburn Road
BELFAST BT9 7AB
☎02890 240503 Ext. 2364

Regional Genetics Centres continued overleaf



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Regional Genetics Centres - continued

Scotland

**North Scotland
Regional Genetics Service**
Medical School
Foresterhill
ABERDEEN AB9 2ZD
☎01224 552882

**Dundee - Department of
Human Genetics**
Pathology Department
Ninewells Hospital
DUNDEE DD1 9SY
☎01382 632035

**South East Scotland
Regional Genetics Centre**
Dept of Clinical Genetics
Western General Hospital
Crewe Road
EDINBURGH EH4 2XU
☎0131 651 1012

**West Scotland Regional
Genetics Service**
Institute of Medical
Genetics
Yorkhill Hospital
GLASGOW G3 8SJ
☎0141 201 0365

**Cytogenetics Laboratory
Pathology Dept**
Highland Acute Hospitals
NHS Trust
Raigmore Hospital
INVERNESS IV2 3UJ
☎01463 704000

Wales

**Medical Genetics Services
for Wales**
Institute of Medical
Genetics
University Hospital of
Wales
Heath Park
CARDIFF CF4 4XW
☎029 2074 4028

Pre-Implantation Genetic Diagnosis Clinics

**Guy's & St Thomas'
Hospital Centre for PGD**
4th Floor
Thomas Guy House
Guy's Hospital
St Thomas Street
LONDON
SE1 9RT
☎020 7955 4429

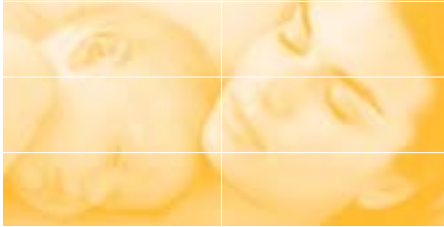
UCH
University College London
25 Grafton Way
LONDON
WC1E 6DB
☎020 7679 6077

Wolfson Family Clinic
Hammersmith Hospital
Du Cane Road
LONDON
W12 0HS
☎020 8383 8168

Leeds General Infirmary
Clarendon Wing
Belmont Grove
LEEDS
LS2 9NS
☎0113 392 6908

Notes

CF Trust Helpline
☎ 0845 859 1000
For information, advice and support (including the contents of this booklet).



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For further general information and literature published by the CF Trust, please contact:

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